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Editorial Note: In the print edition of the **Federal Register** Table of Contents for May 9, 2024, FR Doc. 2024-10162, was incorrectly listed under the Agricultural Marketing Service. The document should have been listed under the Commodity Credit Corporation.

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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Presidential Documents

Title 3—

The President

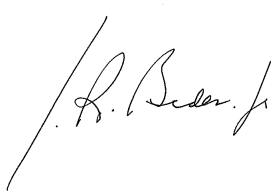
Memorandum of April 24, 2024

Delegation of Authority Under Section 614(a)(1) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 614(a)(1) of the FAA to determine whether it is important to the security interests of the United States to furnish up to $145 million in assistance to Ukraine without regard to any provision of law within the purview of section 614(a)(1) of the FAA.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, April 24, 2024

[FR Doc. 2024–10401
Filed 5–9–24; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Proclamation 10746 of May 2, 2024

Boundary Enlargement of the San Gabriel Mountains National Monument

By the President of the United States of America

A Proclamation

Through Proclamation 9194 of October 10, 2014, President Obama established the San Gabriel Mountains National Monument (monument) to protect the rich cultural history, striking geologic features, and vibrant ecological diversity contained within a portion of the Angeles National Forest. Situated in the mountains north of Los Angeles, the monument is a verdant oasis that contains abundant and distinctive flora and fauna; unique geology; and evidence of centuries of occupation and use by Tribal Nations and Indigenous peoples, Spanish missionaries and colonists, Mexican rancheros, and Euro-American settlers and prospectors. In addition to protecting these and other objects of historic and scientific interest, the monument's pristine natural lands and proximity to Los Angeles make it a unique place of rejuvenation and recreation for the people of the ever-changing urban and suburban communities of greater Los Angeles.

Expanding the monument to include the expanse of the Angeles National Forest that stretches south and west from the current boundary to the National Forest boundary near foothill communities of Los Angeles will protect additional objects of scientific and historic interest. This expansion area contains evidence of thousands of years of use and occupation by Indigenous peoples, as well as evidence of more recent human uses, including the ruins of grand recreation resorts and of a missile unit built during the Cold War. A diversity of animals, birds, reptiles, and other wildlife, including numerous threatened and endangered species, live among the unique geological and ecological features of the expansion area, including its unusual canyons, chaparral, and coastal sage scrub lands, and use the area to travel from the lowlands in the south to the soaring mountains in the north.

Since time immemorial, the rich landscape within the expansion area has sustained a mosaic of Indigenous peoples, including the people known as the Gabrielino, Kizh, or Tongva, and the Chumash Kitanemuk, Serrano, and Tataviam peoples. The displacement of these peoples from the area began between 1770 and 1816, when Spanish missionaries forcibly assimilated the region's Indigenous families into surrounding missions, and continued past California's admission into the Union. Today, their descendants are part of Tribal Nations and other Indigenous peoples in the region, some of whose members continue to use the area for ceremonial purposes, as well as for collecting traditional plants important for basketry, food, and medicine.

Evidence of many eras of human history can be found in the expansion area. Dozens of known sites shed light on the daily life and activities of Indigenous peoples, including seasonal habitation, plant and mineral resource collection, food processing, tool manufacturing, and transportation corridors. One known site contains a seasonal encampment where there is evidence of food processing and tool production use from 1150 to 1771, including midden, flaked lithics and tools, ground stones, and hearths and earth ovens. The area also contains evidence of use associated with permanent Indigenous villages that were located adjacent to the expansion area

at the base of the area's canyons, including the Tongva villages of Muuhonga and Tohuunga.

Other sites contain lithic materials, including fused shale and obsidian that came from areas far to the north. These materials provide evidence of the ancient Indigenous trade routes that crisscrossed the area, bringing small game, deer, acorns, sage, piñon nuts, yucca, elderberry, and manzanita berry, among other resources, south into the Los Angeles Basin, and asphaltum, shell and soapstone cooking vessels, beads, pipes, effigies, pendants, and comals north into the mountains.

Mining made its way to the San Gabriel Mountains in the 19th century, following the discovery of gold in Placerita Canyon in 1842. Visitors to the area today can still see evidence of this first gold rush, including the remains of a mine shaft and ore cart rails of the Dawn Mine and mill site, which remained in operation until 1954. The remains of the Tujunga Mining District, including the shafts of the Josephine Mine above Mill Creek, evidence a second minor gold rush in the late 1880s.

The expansion area also contains evidence of Euro-American settlers who looked to these lands to provide mineral resources, wood for fuel and construction, other building materials, and water. Near Little Tujunga Canyon, three well-preserved limekilns, eligible for inclusion in the National Register of Historic Places, were constructed around 1870 with local limestone and granite cobbles within a mortar matrix. Visitors to the area can also traverse trails first developed by Indigenous peoples and later modified by Euro-American settlers. For example, ranchero and later Mayor of Los Angeles Benjamin Davis Wilson, also known as Don Benito, using labor from Indigenous and Spanish workers, built the trail known today as the Mount Wilson Trail to transport timber to his rancho. The Gabrielino Trail, which the Congress designated as America's first National Recreation Trail in 1970, incorporates trails that another 19th century trail maker, Wilbur Sturtevant, developed possibly along established Indigenous routes.

The expansion area also contains evidence of highly popular recreational pursuits of the Great Hiking Era of the early 20th century, when throngs of hikers and outdoor enthusiasts went to the mountains of southern California. This evidence includes the remains of the Mount Lowe Electric Railway (Railway), which was opened in 1893 to transport passengers from foothill communities to three impressive mountain resorts. The Railway, which is listed in the National Register of Historic Places as a Historic District, was the only scenic mountain electric traction railway ever built in the United States and became a tourist destination because of its remarkable location and engineering audacity. It recorded an estimated three million visitors between 1893 and 1938.

Today's visitors who hike to Echo Mountain will see portions of the railroad bed and crossties, a platform, trestle foundations, and scattered remains of the powerhouse's massive cog-wheel or ''bullwheel'' used to pull the incline car up the mountain. Nearby, visitors can also observe the remains of a once grand resort served by the Railway, including a staircase and the foundation footprint of a 70-room hotel, the remains of a zoo, the foundation of an observatory and telescope pedestal, two large concrete water tanks, and rock retaining walls outlining the tennis courts and casino. Visitors can also see remnants of a three million candlepower searchlight installed on the mountain from the 1893 Columbia Exposition World's Fair, and a largely intact, original ''echophone'' used by visitors to hear the canyon's echoes. A trestle abutment of the Railway can also be found near the Mount Lowe Campground. Nearby, at the head of Grand Canyon, visitors can see the rear wall of another of the resorts served by the Railway, the 12-room Swiss-style Ye Alpine Tavern.

To the north and west of the Railway, ruins of hike-in camps include the foundation of Switzer's Camp, developed by Commodore Perry Switzer in the early 1880s. That camp hosted Henry Ford, Shirley Temple, and numerous other celebrities.

The southeastern portion of the expansion area contains 64 cabins that were once part of the Big Santa Anita Canyon Summer Home Tract. This development was established to respond to the burgeoning early 20th century desire to be closer to, and have second homes in, natural settings. The tract originally contained 88 cabins and 12 associated campgrounds. Eligible for inclusion in the National Register of Historic Places, the cabins epitomized the rustic architectural design style of the early 20th century, and are notable for the care taken in sensitively siting them into the rugged topography.

Above El Prieto Canyon, in the southern portion of the expansion area, is the homestead site of a former cabin built and lived in by Robert Owens. Owens was a formerly enslaved person who built a thriving wood and building supply business in and around the canyon, becoming the wealthiest African American in Los Angeles County in 1865.

The expansion area also includes the historic Big Tujunga Dam, completed in 1931, and Brown Mountain Dam, constructed by the United States Forest Service (Forest Service) in 1943. The Lincoln Avenue Water Company water system is also in the area, which was constructed in the 1880s and is eligible for inclusion in the National Register of Historic Places.

The Los Pinetos Nike Missile site, which is eligible for inclusion in the National Register of Historic Places, played a vital role in United States national defense during the Cold War era. This site, along with the Mount Gleason Nike Missile site, which was destroyed by a wildfire in 2009, is among the 300 Nike Missile sites constructed across the country from 1955 to 1958 that were intended to serve as the last line of defense against Soviet bomber planes. The Los Pinetos Nike Missile site is unusual because its launch, administrative, and battery control facilities are located within a single line of sight.

In addition to extensive historical resources, the expansion area reflects massive geologic forces over hundreds of millions of years that created an exceptional landscape, providing views deep into the ancient Earth. The steep and rugged San Gabriel Mountains are one of the fastest growing mountain ranges in the world. These mountains form a major part of the east-west trending Transverse Ranges of southern California, a portion of which is in the expansion area. They were formed from eons of geological movement during the Mesozoic and Cenozoic Eras when the geologic Farallon Plate and the North American Plate crashed together. Dragged as much as 50 degrees in some places by these powerful forces, the San Gabriel Mountains have an unusual east-west orientation, instead of the more typical north-south orientation.

Around Mount Lowe, the uplift of rare anorthosite complex rocks that are 1.2 billion years old, including anorthosite pluton, syenite, and mafic rocks, reveals the dramatic twisting that can occur as mountains are formed. Evidence of this geological process typically lies far below the surface, making the area a hotbed of geological study and a natural classroom for the public. Around Mendenhall Peak, the bands and swirls of 1.7 to 1.8 billion-year-old Mendenhall Gneiss, the region's oldest rocks, are exposed.

The expansion area also contains scientifically important paleontological resources, particularly invertebrate fossils such as oysters and gastropods, at sites including Gold Canyon near Little Tujunga Canyon.

The expansion area is composed of many distinct and diverse ecosystem zones that support rich biodiversity, including more than 500 native plants and fungi, as well as important habitat including riparian woodlands, montane hardwood and conifer forests, coastal sage scrub, alluvial sage scrub, and extensive chaparral. The area also provides important connectivity to enable species to move from the foothills of the south to the soaring mountains of the north.

Perennial streams, springs, and associated riparian areas, and numerous seasonal tributaries, all support wetland-dependent plant species such as the California muhly and the Sonoran maiden fern, the latter of which

is designated as rare by the State of California. These riparian areas also provide critical habitat for sensitive fish and amphibians, including the threatened Santa Ana speckled dace and the threatened Santa Ana sucker found in Big Tujunga Creek, and the endangered Arroyo Toad found in both the Arroyo Seco and Big Tujunga Creek. Habitats for the steelhead trout and the Arroyo chub, a State species of special concern, are also found in Arroyo Seco and Big Tujunga Creek.

A rich variety of rare plants can be found in the expansion area, including the San Gabriel manzanita, San Gabriel Mountains leather oak, San Gabriel Mountains sunflower, San Gabriel bedstraw, and San Gabriel Mountains dudleya, all of which are found only or primarily in the San Gabriel Mountains, and the California muhly, fragrant pitcher sage, Greata's aster, and Plummer's mariposa lily, found only in southern California. Other rare species include the Mount Gleason paintbrush, California satintail, and Chaparral yucca, which is part of an extraordinary, mutually beneficial partnership with the interdependent California yucca moth.

While extremely reduced from its overall historic range, pockets of alluvial scrub habitat, particularly around Big Tujunga Canyon, provide a home for the rare endemic Davidson's bushmallow. Southern California's bigcone Douglas-fir, which is well adapted to the region's natural wildfire regime, is present in strongholds around San Gabriel Peak, the Switzer Falls Trail, and south of Mount Wilson, providing important nesting and roosting habitat for the California spotted owl, which the United States Fish and Wildlife Service has proposed to list as endangered.

Coastal sage scrub, among the most threatened plant communities in California, occurs primarily at elevations below 2,500 feet south of Mount Wilson and along the north side of Big Tujunga Creek. This rare plant community includes California sagebrush, brittlebush, California buckwheat, and various types of sage. Coastal sage scrub, which can be found in Placerita Canyon, provides critical habitat for the threatened coastal California gnatcatcher.

Montane hardwood and conifer forests south of Big Tujunga Bridge and Mount Wilson are typified by live oak, bigleaf maple, California bay, incense cedar, Pacific madrone, Coulter pine, sugar pine, and California incense cedar, as well as understory species such as ceanothus, coffeeberry, gooseberry, and currants. These forests provide habitat for a wide variety of wildlife such as black bears, mule deer, various reptiles, birds, and butterflies, as well as fish and amphibians that rely on the cool water found there. Birds that can be found seasonally or year-round in the expansion area include the endangered California condor and Least Bell's vireo; the threatened western population of yellow-billed cuckoo; the Swainson's hawk, which is listed as threatened by the State of California; the Peregrine falcon; and the California-listed willow flycatcher. The southwestern pond turtle, which the United States Fish and Wildlife Service has proposed to list as threatened, is also found in the area, along with the two-striped garter snake and the Southern California legless lizard, which are designated as sensitive species by the Angeles National Forest. Many species of bats use the area's canyons and waters, including the pallid bat and big free-tailed bat, both California special status species, along with migrants and resident bats, such as the hoary bat, Yuma myotis, small-footed myotis, canyon bat, big brown bat, Mexican free-tailed bat, long-eared myotis, and California myotis.

In addition to these key habitats, the area also contains important migration corridors that connect vulnerable habitats throughout the greater region. A striking example in the northwest portion of the expansion area is Bear Divide, which funnels thousands of migratory birds through a narrow pass along the Pacific Flyway, the primary avian migration route on the West Coast that extends from Central America to the Arctic. Another important corridor is the Arroyo Seco-Hahamongna Corridor, which connects the south-central portion of the expansion area to other nearby natural areas outside the Angeles National Forest boundary.

Despite its proximity to urban Los Angeles, the expansion area includes secluded and largely undeveloped areas such as the 4,700-acre Arroyo Seco Inventoried Roadless Area, which is an iconic landscape feature.

Protecting the expansion area will preserve an important spiritual, cultural, prehistoric, and historic landscape; maintain a diverse array of natural and scientific resources; and help ensure that the objects of historic and scientific interest within the area endure for the benefit of all Americans. As described above, the expansion area contains numerous objects of historic and scientific interest in need of protection. In addition, it provides exceptional outdoor recreational opportunities, including hiking, hunting, fishing, biking, horseback riding, backpacking, scenic driving, and wildlife viewing, all of which are important to residents of and visitors to the Los Angeles region.

WHEREAS, section 320301 of title 54, United States Code (the ''Antiquities Act''), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which shall be confined to the smallest area compatible with the proper care and management of the objects to be protected; and

WHEREAS, I find that each of the objects identified above, and objects of the type identified above within the area described herein, are objects of historic or scientific interest in need of protection under section 320301 of title 54, United States Code, regardless of whether they are expressly identified as an object of historic or scientific interest in the text of this proclamation; and

WHEREAS, I find that there are threats to the objects identified in this proclamation, and in the absence of a reservation under the Antiquities Act, the objects identified in this proclamation are not adequately protected by applicable law or administrative designations, thus making a national monument designation and reservation necessary to protect the objects of historic and scientific interest identified above for current and future generations; and

WHEREAS, I find that the boundaries of the monument reserved by this proclamation represent the smallest area compatible with the proper care and management of the objects of scientific or historic interest identified above, as required by the Antiquities Act; and

WHEREAS, it is in the public interest to ensure the preservation, restoration, and protection of the objects of scientific and historic interest identified above;

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be part of the San Gabriel Mountains National Monument and, for the purpose of protecting those objects, reserve as part thereof all lands and interests in lands that are owned or controlled by the Federal Government within the boundaries described on the accompanying map, which is attached hereto and forms a part of this proclamation. The reserved Federal lands and interests in lands within the expansion area encompass approximately 105,919 acres. As a result of the distribution of the objects throughout the area, the boundaries described on the accompanying map are confined to the smallest area compatible with the proper care and management of the objects of historic or scientific interest identified above.

Nothing in this proclamation shall change the management of the areas protected under Proclamation 9194. The terms, conditions, and management direction provided by Proclamation 9194, including any term limiting the construction or effect of Proclamation 9194, are incorporated by reference

and shall apply to the area reserved by this proclamation except to the extent that they are inconsistent with a provision in this proclamation.

All Federal lands and interests in lands described on the accompanying map are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or other disposition under the public land laws or laws applicable to the Forest Service, other than by exchange that furthers the protective purposes of the monument; from location, entry, and patent under the mining laws; and from disposition under all laws relating to mineral and geothermal leasing.

This proclamation is subject to valid existing rights. If the Federal Government subsequently acquires any lands or interests in lands not currently owned or controlled by the Federal Government within the boundaries described on the accompanying map, such lands and interests in lands shall be reserved as a part of the monument, and objects of the type identified above that are situated upon those lands and interests in lands shall be part of the monument, upon acquisition of ownership or control by the Federal Government.

The Secretary of Agriculture (Secretary), through the Forest Service, shall manage the expansion area pursuant to applicable legal authorities and in accordance with the terms, conditions, and management direction provided by this proclamation and, as described above, those provided by Proclamation 9194.

The Secretary shall prepare, in consultation with the Secretary of the Interior, a management plan for the expansion area set forth in this proclamation, which shall include provisions for continuing outdoor recreational opportunities consistent with the proper care and management of the objects identified above, and shall promulgate such rules and regulations for the management of the expansion area as the Secretary shall deem appropriate. At the Secretary's discretion, such management plan may be included as a component of the existing management plan developed pursuant to Proclamation 9194. The Secretary shall provide for maximum public involvement in the development of the management plan, including consultation with Tribal Nations and meaningful engagement with Indigenous peoples that have cultural, traditional, or ancestral ties to the area, with community environmental, conservation, health, and justice organizations, and with State and local governments. To the maximum extent practicable, the Secretary shall carefully incorporate Indigenous Knowledge in the development and implementation of the management plan, work with Tribal Nations to appropriately protect that knowledge, and, to the extent practicable, explain any limitations on the Secretary's ability to protect such information from disclosure before it is shared with the Forest Service. The management plan shall provide for the protection and interpretation of the objects of scientific and historic interest identified above. The management plan shall also provide for continued public access to the area to the extent consistent with the protection of the objects identified above.

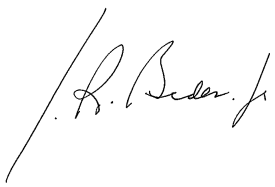
The Secretary, through the Forest Service, shall establish an advisory committee under chapter 10 of title 5, United States Code, to provide information and advice regarding the development of the management plan and management of the expansion area. The advisory committee shall consist of a fair and balanced representation of interested stakeholders, including State agencies and local governments; Tribal Nations and Indigenous peoples with cultural, traditional, or ancestral ties to the area; recreational users; conservation organizations; wildlife, hunting, and fishing organizations; the scientific community; business owners; and the general public in the region.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of the monument and not to locate or settle upon any of the lands thereof.

If any provision of this proclamation, including its application to a particular parcel of land, is held to be invalid, the remainder of this proclamation and its application to other parcels of land shall not be affected thereby.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of May, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-eighth.



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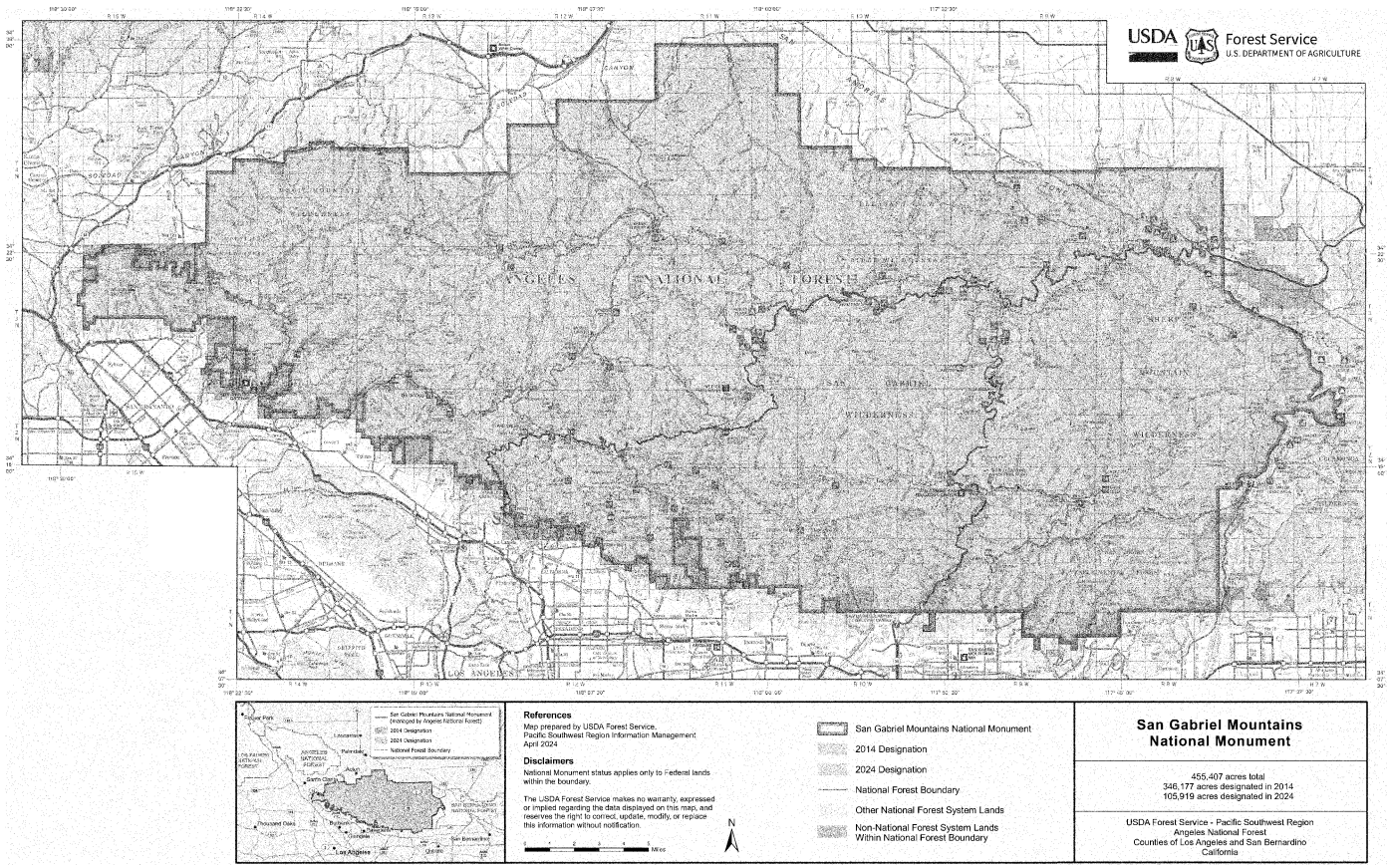

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Rules and Regulations

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Friday, May 10, 2024

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 734, 738, 740, and 758

[Docket No. 240506–0127]

RIN 0694–AJ65

Conforming and Clarifying Changes to the Export Administration Regulations (EAR)

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule makes conforming and clarifying changes to the Export Administration Regulations (EAR). These changes include making conforming changes to the EAR to ensure that destination names reflect the current destination names that are recognized by the United States Government, clarifying the removal of certain license requirements for exports, reexports, and transfers (in-country) to and within Australia and the United Kingdom, making a conforming change to reflect that Cyprus is no longer a Country Group D:5 country, and clarifying how Russia and the Russian Federation are referenced for consistency with the designation of Russia as a U.S. Arms Embargoed destinations.

DATES: This rule is effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: For questions on this rule, contact Philip Johnson at *RPD2@bis.doc.gov* or (202) 482–2440.

SUPPLEMENTARY INFORMATION:

I. Background

BIS is amending the EAR (15 CFR parts 730–774) by making conforming changes to the EAR to ensure that destination names reflect the current destination names that are recognized by the United States Government, by making conforming changes to ensure that the EAR reflects amendments and description of those amendments made pursuant to two recent rules, by making a conforming change to reflect that Cyprus is no longer a Country Group D:5 country, and by clarifying how Russia and the Russian Federation are referenced in the EAR to ensure consistency with the designation of Russia as a U.S. Arms Embargoed destination.

The four sets of changes this final rule makes are described in section II as follows:

A. Conforming changes to the Commerce Country Chart and Country Groups to ensure consistency with destinations names that are recognized by the United States Government;

B. Conforming changes to the Commerce Country Chart entries for Australia and the United Kingdom;

C. Conforming change to reflect Cyprus is no longer a Country Group D:5 country; *and*

D. Removing obsolete references to Russia and the Russian Federation in provisions that predate the country's addition to Country Group D:5.

II. Regulatory Changes

A. Conforming Changes to the Commerce Country Chart and Country Groups To Ensure Consistency With Destination Names That Are Recognized by the United States Government

This final rule in supplement no. 1 to part 738 (Commerce Country Chart) removes Swaziland from the Commerce Country Chart and replaces it, in alphabetical order, with Eswatini. On April 19, 2018, King Mswati III declared that the country be known as the Kingdom of Eswatini, rather than the Kingdom of Swaziland. BIS makes this change to conform to King Mswati III's declaration, as subsequently formally recognized by the State Department (*see https://www.state.gov/countries-areas/eswatini/*). This final rule also removes Macedonia (The Former Yugoslav Republic of) from the Commerce Country Chart and replaces it, in alphabetical order, with North Macedonia. BIS makes this change to the conform to the State Department's formal recognition of the new name in February 2019 (*see https://history.state.gov/countries/macedonia*). Lastly, this final rule removes Turkey from the Commerce Country Chart and replaces it, in alphabetical order, with Türkiye. BIS makes this change to conform to the State Department's recognition on January 9, 2023 of the new country's new name (*see https://www.state.gov/countries-areas/turkey/*). This rule revises only the names of the three countries; the information set forth in each of the three entries otherwise remains the same.

As a conforming change to the changes made to the Commerce Country Chart described above, this final rule removes Swaziland from Country Group B in supplement no. 1 to part 740, Country Groups), and replaces it (in alphabetical order) with Eswatini. Similarly, this rule removes Macedonia (the Former Yugoslav Republic of) from Country Group B and replaces it, in alphabetical order, with North Macedonia.

B. Conforming Changes to Commerce Country Chart Entries for Australia and the United Kingdom

This final rule also revises the Commerce Country Chart entries for Australia and the United Kingdom in supplement no. 1 to part 738 to align with the policy decisions and regulatory changes described and implemented in the August 19, 2024 interim final rule, ''Export Control Revisions for Australia, United Kingdom, United States (AUKUS) Enhanced Trilateral Security Partnership'' (89 FR 28594, published and effective on April 19, 2024) (April 19 IFR). Specifically, the April 19 IFR removed the license requirements for national security column 1 (NS1), regional stability column 1 (RS1), and missile technology column 1 (MT1) reasons for control for these two countries, as well as the footnote 3 designations for both of these countries, because the license requirements referenced in footnote 3 were no longer applicable.

This rule corrects inadvertent errors in which a subsequent interim final rule, ''Revisions of Firearms License Requirements'' (89 FR 34680, published on April 30, 2024, and effective on May 30, 2024) (April 30 IFR), erroneously included an ''X'' under the NS1, RS1, and MT1 reasons for control for Australia and the United Kingdom and also erroneously included the previously-applicable footnote 3 designation for these two countries. This final rule revises the entries for

Australia and the United Kingdom by removing the license requirement for NS1, RS1, and MT1, as well as the footnote 3 designation, for consistency with the intended regulatory changes described in the April 19 IFR.

The changes in this final rule described under this section II.B are limited to removing text (as described above) that inadvertently appeared in the two Commerce Country Chart entries. The April 30 IFR correctly removed the footnote 9 designation for Australia and the United Kingdom. The April 30 IFR addressed the license requirement described in footnote 9 for these two destinations by adding an ''X'' in the crime control column 2 (CC2) reason for control for these two countries.

C. Conforming Change to Reflect the Fact That Cyprus is No Longer a Country Group D:5 Country

The U.S. State Department recently amended § 126.1 of the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) to specify that Cyprus's status as a proscribed destination is suspended from October 1, 2023 through September 30, 2024 (see 88 FR 63016). Consistent with this change, Cyprus was effectively removed from Country Group D:5. As set forth in the Note to Country Group D:5 in supplement no. 1 to part 740 of the EAR, if there are any discrepancies between the list of D:5 countries and the countries identified by the Department of State as subject to a U.S. arms embargo, the State Department's list shall be controlling. To avoid confusion on the part of exporters, reexporters, and transferors, this final rule removes Cyprus from D:5. D:5 was the only ''X'' in the entry for Cyprus under Country Group D, so the entry is no longer needed.

D. Removing, for Clarity, References to Russia and the Russian Federation for Provisions That Also extend to Country Group D:5

The final rule, ''Implementation of Sanctions Against Russia Under the Export Administration Regulations (EAR)'' (87 FR 12226, published March 3, 2022, and effective February 24, 2022), included amendments to supplement no. 1 to part 740 (Country Groups) of the EAR consistent with the ITAR § 126.1. The March 3 final rule updated the Country Group designation for Russia in supplement no. 1 to part 740 to reflect its identification by the Department of State as a country subject to a United States arms embargo. As noted above, BIS harmonizes the arms embargo-related provisions in the EAR with the Directorate of Defense Trade Control's (DDTC's) regulation of arms embargoes in § 126.1 of the ITAR. Three sections of the EAR, which predated the March 18, 2021 (*see* 86 FR 14802) addition of Russia to § 126.1 under the ITAR, continued to separately identify Russia or the Russian Federation from Country Group D:5. These references are unnecessary due to the fact that Russia was subsequently added to Country Group D:5. Specifically, this final rule revises § 734.18(a)(5)(iv); § 740.9(a) introductory text (the fourth and seventh sentences) and paragraph (b)(5)(ii); and § 758.10, Note 1 to paragraph (b)(1), by removing references to Russia or the Russian Federation when the same sentence also refers to Country Group D:5. In the case of § 740.9(b)(5)(ii), the broader exclusion under paragraph (b)(5)(i) means the narrow exclusion under (b)(5)(ii) should not include Russia, which is subject to the broader exclusion as a Country Group D:5 country.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. ECRA, as amended, provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. BIS has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094. Pursuant to E.O. 12866, as amended by E.O. 14094, this final rule has not been determined to be a ''significant regulatory action.''

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves an information collection approved by OMB under control number 0694–0088, Simplified Network Application Processing System. BIS does not anticipate a change to the burden hours associated with this collection as a result of this rule. Information regarding the collection, including all supporting materials, can be accessed at *https://www.reginfo.gov/public/do/PRAMain.*

3. This rule does not contain policies with federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to Section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date. Additionally, this rule is exempt from the ordinary rulemaking requirements of the APA pursuant to 5 U.S.C. 553(a)(1) as a military or foreign affairs function of the United States Government.

5. Because neither the APA nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no Final Regulatory Flexibility Analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 738

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 758

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 734, 738, 740, and 758 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 734—SCOPE OF THE EXPORT ADMINISTRATION REGULATIONS

■ 1. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 2. Section 734.18(a)(5) is amended by revising paragraph (a)(5)(iv) to read as follows:

§ 734.18 Activities that are not exports, reexports, or transfers.

(a) * * *

(5) * * *

(iv) Not intentionally stored in a country listed in Country Group D:5 (*see* supplement no. 1 to part 740 of the EAR).

Note 1 to paragraph (a)(5)(iv): Data in-transit via the internet is not deemed to be stored.

* * * * *

PART 738—COMMERCE CONTROL LIST OVERVIEW AND THE COUNTRY CHART

■ 3. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. Supplement no. 1 to part 738 is amended by:

■ a. Revising the entry for ''Australia'';

■ b. Adding an entry for ''Eswatini'' in alphabetical order;

■ c. Removing the entries for ''Macedonia (The Former Yugoslav Republic of)'';

■ d. Adding an entry for ''North Macedonia'' in alphabetical order;

■ e. Removing the entry for ''Swaziland'';

■ f. Removing the entry for ''Turkey''; and

■ g. Adding an entry for ''Türkiye'' in alphabetical order.

■ h. Revising the entry for the ''United Kingdom'';

The additions and revisions read as follows:

Supplement No. 1 to Part 738—Commerce Country Chart

* * * * *

Countries	Chemical & biological weapons			Nuclear non-proliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
*		*			*		*		*		*			*		
Australia	X												X			
*		*			*		*		*		*			*		
Eswatini	X	X		X		X	X	X	X	X		X	X	X		
*		*			*		*		*		*			*		
North Macedonia	X	X		X		X	X	X	X	X		X	X	X		
*		*			*		*		*		*			*		
Türkiye	X					X		X	X				X			
*		*			*		*		*		*			*		
United Kingdom	X												X			
*		*			*		*		*		*			*		

* * * * *

PART 740—LICENSE EXCEPTIONS

■ 5. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 6. Section 740.9 is amended by:

■ a. Removing ''Russia,'' in the fourth and seventh sentences of paragraph (a) introductory text wherever it appears; and

■ b. Removing ''Russia,'' in paragraph (b)(5)(ii) wherever it appears.

■ 7. Supplement no. 1 to part 740 is amended by:

■ a. In the ''Country Group A'' and ''Country Group B'' tables, removing the entry for ''Turkey'' and adding an entry for ''Türkiye'' in alphabetical order;

■ b. In the ''Country Group B'' table:

■ i. Adding an entry for ''Eswatini'' in alphabetical order;

■ i. Removing the entry for ''Macedonia, The Former Yugoslav Republic of'', and adding an entry for ''North Macedonia'' in alphabetical order;

■ ii. Removing the entry for ''Swaziland''; and

■ c. In the ''Country Group D'' table, removing the entry for Cyprus.

The additions and revisions read as follows:

Supplement No. 1 to Part 740—Commerce Country Chart

COUNTRY GROUP A

Country	[A:1] Wassenaar participating states [1]	[A:2] Missile technology control regime [2]	[A:3] Australia group	[A:4] Nuclear suppliers group [3]	[A:5]	[A:6]
*	*	*	*	*	*	
Türkiye	X	X	X	X	X	
*	*	*	*	*	*	

* * * * * * *

[1] Country Group A:1 is a list of the Wassenaar Arrangement Participating States, except for Malta, Russia and Ukraine.

[2] Country Group A:2 is a list of the Missile Technology Control Regime countries, except for Russia.

[3] Country Group A:4 is a list of the Nuclear Suppliers Group countries, except for the People's Republic of China (PRC), Russia, and Belarus.

* * * * *

Country Group B—Countries

* * * * *

Eswatini

* * * * *

North Macedonia

* * * * *

Türkiye

* * * * *

PART 758—EXPORT CLEARANCE REQUIREMENTS AND AUTHORITIES

■ 8. The authority citation for 15 CFR part 758 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 9. Section 758.10 is amended by removing ''Russia,'' in Note 1 to paragraph (b)(1) wherever it appears.

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2024–10280 Filed 5–8–24; 11:15 am]

BILLING CODE 3510–33–P

PEACE CORPS

22 CFR Part 303

RIN 0420–AA31

Procedures for Disclosure of Information Under the Freedom of Information Act; Correction

AGENCY: The Peace Corps.

ACTION: Final rule; correction.

SUMMARY: The Peace Corps is correcting a final rule that appeared in the **Federal Register** on April 11, 2024. This final rule amends the regulations that the Peace Corps follows in processing requests under the Freedom of Information Act (FOIA) to comply with the FOIA Improvement Act of 2016. These amendments clarify and update procedures for requesting information from the Peace Corps and procedures that the Peace Corps follows in responding to requests from the public for information.

DATES: Effective May 13, 2024.

FOR FURTHER INFORMATION CONTACT: David van Hoogstraten, 202–692–2150, *policy@peacecorps.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2024–06800, appearing on page 25519 in the **Federal Register** on Thursday, April 11, 2024, the following corrections are made:

§§ 303.11 and 303.12 [Corrected]

■ 1. On page 25525, in the third column, in part 303, in amendment 12, the instruction ''Redesignate §§ 303.11 and 303.12 as §§ 303.13 and 303.14, respectively'' is corrected to read ''Redesignate §§ 303.11 and 303.12 as §§ 303.12 and 303.13, respectively.''

Dated: May 6, 2024.

James Olin,

FOIA and Privacy Officer.

[FR Doc. 2024–10181 Filed 5–9–24; 8:45 am]

BILLING CODE 6051–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 501

Reporting, Procedures and Penalties Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule; request for comments.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is issuing this interim final rule to amend the Reporting, Procedures and Penalties Regulations (the ''Regulations''), to require electronic filing of certain submissions to OFAC and to describe and modify certain reporting requirements related to blocked property and rejected transactions. In particular, the rule would require use of the electronic OFAC Reporting System for submission of reports related to blocked property and rejected transactions, remove the mail option for certain other types of OFAC submissions, describe reports OFAC may require from financial institutions for transactions that meet specified criteria, and add a reporting requirement for any blocked property that is unblocked or transferred. Additionally, OFAC is clarifying the scope of the reporting requirement for rejected transactions, in part to respond to comments received on the interim final rule OFAC published on June 21, 2019 to amend the Regulations. Further, OFAC is modifying the procedures for requests relating to property that is blocked in error and updating the Regulations with respect to the availability of information under the Freedom of Information Act (FOIA) for certain categories of records. OFAC is also clarifying that persons may submit a petition for administrative reconsideration to seek removal of a person or property from the List of Specially Designated Nationals and Blocked Persons or any other list of sanctioned persons maintained by OFAC. OFAC is also adding a description of reports OFAC may require financial institutions to provide about transactions that meet specified criteria to aid in the identification of blocked property. Finally, OFAC is making several technical and conforming edits. OFAC is soliciting public comments for 30 days on this interim final rule.

DATES: This interim final rule is effective August 8, 2024. Written comments may be submitted on or before June 10, 2024.

ADDRESSES: You may submit comments via the following methods, electronic is preferred:

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions on the website for submitting comments. Refer to Docket Number OFAC–2024–0002.

Mail: Office of Foreign Assets Control, U.S. Department of the Treasury, Treasury Annex/Freedman's Bank Building, 1500 Pennsylvania Avenue NW, Washington, DC 20220. Refer to Docket Number OFAC–2024–0002.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that appears at the end of this document. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Background

The Regulations (31 CFR part 501), originally issued August 25, 1997 (62 FR 45098), set forth standard reporting and recordkeeping requirements, license application procedures, and other procedures relevant to the economic sanctions programs administered by OFAC. As described further below, OFAC is providing updates within nine sections of the Regulations: §§ 501.602, 501.603, 501.604, 501.605, 501.801, 501.804, 501.805, 501.806, and 501.807.

Electronic Filing of Submissions

OFAC Reporting System for reports of blocked property and rejected transactions. This interim final rule would generally require filers to use the electronic OFAC Reporting System (ORS) for submission to OFAC of initial reports of blocked property and Annual Reports of Blocked Property pursuant to § 501.603(d) and reports of rejected transactions pursuant to § 501.604(d), beginning on August 8, 2024. Electronic submission of reports improves efficiencies in reporting and reviewing data, and thus reduces the overall burden on both filers and the U.S. government over the long term. Many filers currently use ORS, on a voluntary basis, to submit initial reports of blocked property, Annual Reports of Blocked Property, and reports of rejected transactions. OFAC encourages filers to become familiar with ORS and to submit reports using that system in advance of the August 8, 2024 deadline. If a submitter can provide evidence of unique and extraordinary circumstances that would not permit the electronic filing of reports, such as lack of access to the internet, the submitter may request to submit reports in an alternative manner by calling 202–622–2490. Such requests will be subject to a presumption of denial and granted only in writing.

Email Submission of Other Reports. OFAC is amending several sections of the Regulations to require electronic submissions and to remove options for mail submission. OFAC is amending § 501.603(d)(2) to require electronic submission of reports of unblocked or transferred blocked property, as required pursuant to revised § 501.603(b)(3)(i). OFAC will accept such reports of unblocked or transferred blocked property pursuant to revised § 501.603(b)(3)(i) via either email or ORS. OFAC is also amending § 501.605(a) of the Regulations to require submission of the documentation and notifications required therein by email, given the time sensitivity of these reports, and to remove the options for submission by facsimile or mail. Finally, OFAC is requiring email submission or removing the options for mail submission in the following sections of the Regulations: §§ 501.804, 501.805, 501.806, and 501.807. Electronic submission and use of OFAC's website will allow for more efficient receipt and processing of reports and requests from the public.

Reports of Unblocked or Transferred Blocked Property

OFAC is revising § 501.603(b)(3)(i) to require reports within 10 business days of when blocked property is unblocked or transferred, including pursuant to a valid order issued by a U.S. government agency or U.S. court, as set out in that paragraph. This amendment will enable OFAC to ascertain the current status of blocked and unblocked property. Reports need not be submitted for credits of interest payments that would not be transfers of blocked property or debits to blocked accounts for normal service charges, in each case as authorized pursuant to OFAC sanctions. As noted above, filers must submit reports pursuant to this section electronically, either via email to *OFACReport@treasury.gov* or via ORS. Additionally, in revised § 501.603(d)(1), OFAC is expanding the retention requirement previously in § 501.603(b)(2)(iii) for Annual Reports of Blocked Property to extend to initial reports of blocked property.

Reports of Rejected Transactions

OFAC is revising elements of § 501.604 in response to public comments received on the June 21, 2019, interim final rule (84 FR 29055), which expanded the scope of the reporting requirement for rejected transactions.

Clarifying the definition of ''transaction.'' Several commenters requested clarity on the scope and types of rejected transactions that need to be reported to OFAC by non-financial institutions. In response to these comments, OFAC is amending § 501.604(a) to clarify the scope of the term ''transaction'' for purposes of that section by specifying that the term includes transactions related to securities, checks, or foreign exchange, as well as sales or purchases of goods or services, thereby clarifying that securities, checks, foreign exchange, and goods and services are not in and of themselves transactions, when not provided as part of a transaction.

Confirmation of the scope of the term ''U.S. persons.'' OFAC received several comments that requested clarity about whether the term ''U.S. persons,'' as used in § 501.604, includes U.S. persons other than U.S. financial institutions. OFAC confirms that this reporting requirement applies to all U.S. persons, as identified in the relevant parts of this chapter (or in the case of part 515, persons subject to U.S. jurisdiction), not only U.S. financial institutions.

Clarifying information that must be reported for rejected transactions. Comments received by OFAC also noted that not all information required by OFAC may be readily available at the time a transaction is rejected, and, in many cases, it would be burdensome and sometimes impractical for filers to seek out additional information about transactions that they have already rejected. In light of these concerns, OFAC is amending § 501.604(b) to clarify that the information required therein must be reported only to the extent the information is available to the filer at the time the transactions was rejected.

Additional responses to public comments. Many comments received by OFAC anticipated that the interim final rule would cause a large increase in the volume of rejected transaction reports from non-financial institutions, which the comments suggest would be overly burdensome for businesses to submit as well as for OFAC to review. Since the publication of the interim final rule, however, OFAC has not received a large number of reports of rejected transactions from non-financial institutions as compared to the number of such reports from financial institutions. OFAC does not expect the volume of reported rejected transactions to be overly burdensome for businesses, particularly given that OFAC is providing additional clarity on the scope of rejected transaction reporting through this rule.

Some commenters expressed concerns about the ability to identify all rejected transactions and provide all requested information in a timely manner without significant costs, particularly if this information was not already being gathered in the course of rejecting a transaction. As noted above, OFAC is amending the Regulations to require reporting of only the information that is available to the filer at the time the transaction is rejected. OFAC notes that many businesses already have systems to identify rejected transactions related to OFAC sanctions, so it would be less burdensome for those specific businesses to report those rejected transactions to OFAC. However, OFAC recognizes that there may have been an up-front increase in burden and costs for other businesses, such as some non-financial institutions, that did not already have such a system to identify rejected transactions in place.

OFAC received a few comments questioning the utility to OFAC of receiving rejected transaction reports, particularly from U.S. non-financial institutions. OFAC continues to believe that these reports are valuable to OFAC in supporting its mission, including to identify attempts by sanctioned persons

to utilize both financial and non-financial institutions to evade sanctions or further illicit activity.

Compliance Release Requests for Property Blocked Due to Mistaken Identity or Other Similar Errors

OFAC is revising the procedures at § 501.806 for requesting release of funds blocked due to ''mistaken identity'' to extend to a broader category of any property blocked due to ''typographical or similar errors leading to blocking.'' OFAC is also narrowing the procedures so they are available only to the person that mistakenly blocked the property. In these cases, the person that mistakenly blocked the property may request a ''Compliance Release'' from OFAC's Compliance Division. Others may continue to request unblocking of property through license applications submitted to OFAC's Licensing Division.

Rules Regarding the Availability of Information

In §§ 501.603(e), 501.604(e), and 501.801(b)(6), OFAC is updating the rules governing the availability of information under FOIA for certain categories of information that are submitted to OFAC pursuant to the Regulations, to clarify that such information will generally be protected from disclosure if OFAC determines that an exemption or exclusion under FOIA applies or the disclosure is otherwise prohibited by law.

Procedures for Delisting

In § 501.807, OFAC is clarifying that persons may submit a petition for administrative reconsideration to seek removal of a person or property from the List of Specially Designated Nationals and Blocked Persons (SDN List) or any other list of sanctioned persons maintained by OFAC, and making a technical update to the contact information, including to require submission by email.

Instruction To Report Certain Transactions

OFAC is adding a note to § 501.602 to describe reports OFAC may require financial institutions to provide about accounts or transactions that meet specified criteria to aid in the identification of blocked property. If OFAC has reason to believe an account or transaction (or class of transactions) may involve the property or interests in property of a blocked person, OFAC may instruct the financial to report transactions that meet specified criteria and to notify OFAC prior to processing such transactions. Upon review, OFAC may determine that a reported transaction involves the property or interests in property of a blocked person and may take further action.

Other Technical and Conforming Changes

OFAC is updating the instructions in §§ 501.603(b)(2)–(3), 501.801(b)(2), and 501.806(d)(5) to request the relevant ORS identification numbers, when available, to support efficient processing of these reports. OFAC is making edits throughout §§ 501.603, 501.604, 501.801, and 501.805 to update the OFAC website links. OFAC is amending § 501.804(b) to add contact information for OFAC. OFAC is also amending §§ 501.603(a)(1) and 501.604 to make clear that the reporting requirements extend to persons subject to U.S. jurisdiction in the case of the Cuban Assets Control Regulations, 31 CFR part 515. Additionally, OFAC is amending § 501.805(a) and (b) to make clear that OFAC records required by FOIA shall be made available in accordance with the provisions of the Regulations in addition to referenced provisions of 31 CFR part 1. OFAC is also amending § 501.805(c) to add an OFAC website link to obtain forms and remove the mail, phone, and in person options.

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Public Participation

Because the amendment of the Regulations is a rule of agency procedure and involves a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the collections of information related to the Regulations have been previously approved by the Office of Management and Budget (OMB) under control number 1505–0164. This interim final rule modifies the requirements for certain of the collections of information under the Regulations, such as requiring use of electronic submission for certain reports and clarifying the scope of certain reporting requirements. Specifically, in §§ 501.603 and 501.604, the rule would mandate the use of electronic filing via ORS for initial reports of blocked property and reports of rejected transactions, as well as Annual Reports of Blocked Property, in order to improve efficiencies for both filers and the U.S. government. In addition, OFAC is revising § 501.603(b)(3)(i) to require reports not only when blocked property is unblocked, but also when it is transferred, such as pursuant to a valid order from a U.S. government agency or U.S. court, as further set out in that paragraph. In § 501.604, OFAC is clarifying the scope of rejected transactions and associated information that must be reported to reduce unnecessary burdens on filers. Additionally, the rule will amend § 501.605(a) of the Regulations to allow for only electronic submission of the documentation and notifications required therein, given the time sensitivity of these reports, and to remove the options for submission by facsimile or mail. The rule will also remove the options for mail submission or require email submission in the following sections of the Regulations: §§ 501.804, 501.805, 501.806, and 501.807. OFAC is making other technical and conforming edits in the rule to increase the presence of websites and use electronic reporting, such as in §§ 501.603, 501.604, and 501.801 to update the OFAC website links. Finally, OFAC is amending § 501.805(c) to add an OFAC website link to obtain forms.

These modifications to the collections of information under the Regulations have been submitted to OMB for review and approval under control number 1505–0164. Written comments and recommendations for the modified collection can be submitted by visiting *www.reginfo.gov/public/do/PRAMain.* Find this document by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. Comments are welcome and must be received by June 10, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The likely filers and record-keepers affected by these collections of information contained in 31 CFR part 501 are financial institutions, business organizations, nonprofit organizations, individuals, and legal representatives.

Since OFAC's last filing in June 2021, OFAC has reviewed the data on

reporting received and processed between April 4, 2022, and April 4, 2023, to estimate the reporting burden, as set forth below. Given the number and type of reports received and processed during this period, the overall burden of the recordkeeping requirement imposed by § 501.601 is estimated to increase, largely due to the imposition of a broad range of sanctions in response to Russia's unjustified and unprovoked invasion of Ukraine in February 2022, which has led to a large influx of related reporting.

Additionally, the new electronic reporting mandate for some reports may impose initial costs on businesses that do not already file such reports electronically. OFAC is taking into account this potential initial increase in burden and cost for some parts of the private sector in its updated Supporting Statement related to this regulatory amendment. However, in the long term, OFAC expects the use of electronic reporting via ORS to reduce the overall time, cost, and burden of reporting for filers. OFAC estimates that, during the first three months of 2023, less than 1% (estimated 0.03%) of reports for blocked property or rejected transactions were submitted to OFAC using non-electronic methods, while approximately 96% of reports were submitted electronically via ORS, and approximately 3% of reports were submitted electronically to OFAC via email. In its updated Supporting Statement related to this regulatory amendment, OFAC is taking into account a potential small initial increase in burden and cost for the small number of filers (an estimated 3%) who would need to transition from filing reports via traditional mail service or via email to the new ORS electronic system. Overall, OFAC estimates that there should be a minimal overall burden in mandating electronic submission via ORS because nearly all filers currently send reports to OFAC via ORS.

The total burden for this collection is estimated to be:

Estimated Number of Respondents: 136,784.

Frequency of Response: On occasion.

Estimated Total Number of Annual Responses: 136,784.

Estimated Time per Response: Varies by form from 15 minutes to 5 hours.

Estimated Total Annual Burden Hours: 44,220.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

List of Subjects in 31 CFR Part 501

Administrative practice and procedure, Banks, Banking, Exports, Foreign trade, Licensing and registration, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, OFAC amends 31 CFR part 501 as follows:

PART 501—REPORTING, PROCEDURES AND PENALTIES REGULATIONS

■ 1. The authority citation for part 501 continues to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2332d, 2339B; 19 U.S.C. 3901–3913; 21 U.S.C. 1901–1908; 22 U.S.C. 287c, 2370(a), 6009, 6032, 7205, 8501–8551; 31 U.S.C. 321(b); 50 U.S.C. 1701–1706, 4301–4341; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note).

■ 2. Amend § 501.602 by redesignating Note 1 to § 501.602 as Note 2 to § 501.602 and adding new Note 1 to § 501.602 to read as follows:

§ 501.602 Reports to be furnished on demand.

* * * * *

Note 1 to § 501.602. If OFAC has reason to believe an account or transaction (or class of transactions) may involve the property or interests in property of a blocked person, OFAC may issue an instruction to one or more financial institutions that: (1) provides information or criteria to aid in the identification of blocked property; and (2) requires the financial institution to report transactions that meet the specified criteria and notify OFAC prior to processing such transactions. Upon review, OFAC may determine that a reported transaction involves the property or interests in property of a blocked person and take further action.

* * * * *

■ 3. Amend § 501.603 by:
■ a. Revising the section heading;
■ b. Revising and republishing paragraph (a);
■ c. Redesignating paragraphs (b)(1)(ii)(G) and (H) as paragraphs (b)(1)(ii)(H) and (I), respectively, adding new paragraph (b)(1)(ii)(G), and revising newly redesignated paragraph (b)(1)(ii)(H);
■ d. In paragraph (b)(2)(ii)(F), remove the ''and'' at the end of the paragraph;
■ e. Revising (b)(2)(ii)(G);
■ f. Adding a new paragraph (b)(2)(ii)(H);
■ g. Removing paragraph (b)(2)(iii);
■ h. Revising the paragraph heading to paragraph (b)(3);
■ i. Revising paragraph (b)(3)(i);
■ j. In paragraph (b)(3)(ii)(A), add ''or transfer'' after ''unblocking'';
■ k. Revising paragraphs (b)(3)(ii)(F) and (b)(3)(ii)(G);
■ l. Adding Note 1 to paragraph (b)(3); and
■ m. Revising and republishing paragraphs (d) and (e).

The revisions, republications, and additions to read as follows:

§ 501.603 Reports of blocked, unblocked, or transferred blocked property.

(a) *Who must report*—(1) *Persons holding, unblocking, or transferring blocked property.* Any U.S. person (or person subject to U.S. jurisdiction in the case of part 515 of this chapter), including a financial institution, holding, unblocking, or transferring property blocked pursuant to this chapter shall submit the relevant reports described in this section to the Office of Foreign Assets Control (OFAC). This requirement applies to all U.S. persons (or persons subject to U.S. jurisdiction in the case of part 515 of this chapter), who have in their possession or control any property blocked pursuant to this chapter, including financial institutions that receive and block payments or transfers, or who have had in their possession or control such property that is unblocked or transferred, as set out in paragraph (b) of this section.

(2) *Primary responsibility to report.* A report may be filed on behalf of a person who holds, transfers, or releases blocked property by an attorney, agent, or other person. Primary responsibility for reporting, however, rests with the actual holder, transferrer, or releaser of the property, or the person exercising control over property located outside the United States, with the following exceptions: primary responsibility for reporting any trust assets rests with the trustee; and primary responsibility for reporting real property rests with any U.S. co-owner, legal representative, agent, or property manager in the United States. No person is excused from filing a report by reason of the fact that another person has submitted a report with regard to the same property, except upon actual knowledge of the report filed by such other person.

(3) *Financial institution.* For purposes of this section, the term ''financial institution'' includes a banking institution, domestic bank, United States depository institution, financial

institution, or U.S. financial institution, as those terms are defined in the applicable part of this chapter.

(b) * * *

(1) * * *

(ii) * * *

(G) Any action taken with respect to the property (*e.g.,* depositing the property into a new or existing blocked, interest-bearing account that is labeled as such and is established in the name of, or contains a means of clearly identifying the interest of, the person subject to blocking pursuant to the requirements of this chapter);

(H) The legal authority or authorities under which the property is blocked. This may include a reference to the sanctions program (current programs are on OFAC's website: *https://ofac.treasury.gov*), the applicable part of this chapter (*e.g.,* 31 CFR part 515, 31 CFR part 544), an Executive order (E.O.) (*e.g.,* E.O. 13224, E.O. 13599), or a statute (*e.g.,* Foreign Narcotics Kingpin Designation Act). (*Note:* For this purpose, the term ''SDN'' is generic and cannot be used to identify the legal authority for blocking property); and

(2) * * *

(ii) * * *

(G) The legal authority or authorities under which the property is blocked. This may include a reference to the sanctions program (current programs are listed here: *https://ofac.treasury.gov*), the applicable part of this chapter (*e.g.,* 31 CFR part 515, 31 CFR part 544), an Executive order (E.O.) (*e.g.,* E.O. 13224, E.O. 13599), or a statute (*e.g.,* Foreign Narcotics Kingpin Designation Act). (*Note:* For this purpose, the term ''SDN'' is generic and cannot be used to identify the legal authority for blocking property); and

(H) The relevant OFAC Reporting System identification numbers, when available.

(3) *Reports of blocked property that is unblocked or transferred*—(i) *When reports are due.* Reports shall be submitted to OFAC within 10 business days from the date blocked property is unblocked or transferred, except that if such reports are already required as a condition of a general or specific license, no additional report is required to be submitted under this section. For example, such reports must be filed when blocked property is unblocked or transferred pursuant to a valid order from a U.S. government agency or U.S. court, including pursuant to a valid judicial order issued pursuant to Section 201(a) of the Terrorism Risk Insurance Act (Pub. L. 107–297, 116 Stat. 2322, 28 U.S.C. 1610 note) or a valid order of forfeiture by any U.S. government agency or U.S. court. Reports do not need to be filed under this section for debits to blocked accounts for normal service charges authorized pursuant to OFAC sanctions.

(ii) * * *

(F) The legal authority or authorities under which the property was unblocked or transferred. This may include, for example, reference to a specific or general license under an applicable part of this chapter or an E.O.; and

(G) A copy of the original blocking report filed with OFAC pursuant to § 501.603(b)(1) and the OFAC Reporting System report identification numbers, when available.

Note 3 to paragraph (b)(3). The reporting requirement set forth in this paragraph (b)(3) applies in addition to the reporting requirement set forth in § 501.605 of this part, which requires litigants to notify OFAC of proceedings that may affect blocked property or retained funds.

* * * * *

(d) *How to report.* (1) Except as otherwise provided, all initial reports of blocked property required under § 501.603(b)(1) and the Annual Reports of Blocked Property required under § 501.603(b)(2) must be filed electronically through the OFAC Reporting System (ORS), available on OFAC's website, *https://ofac.treasury.gov/ofac-reporting-system.* While blocked funds may be maintained in omnibus accounts, the Annual Reports of Blocked Property must contain a disaggregated list showing each blocked asset contained within the omnibus account. A copy of reports submitted pursuant to this section shall be retained for the submitter's records. If a submitter can provide evidence of unique and extraordinary circumstances that would not allow the submitter to use ORS, such as lack of access to the internet, the submitter may request to submit reports in an alternative manner by calling 202/622–2490. Such requests will be subject to a presumption of denial and granted only in writing.

(2) All reports of unblocked or transferred blocked property required pursuant to § 501.603(b)(3) must be submitted electronically to OFAC via email at *OFACReport@treasury.gov,* with the number of this section in the subject line, or through ORS, available on OFAC's website, *https://ofac.treasury.gov/ofac-reporting-system.* If a submitter can provide evidence of unique and extraordinary circumstances that would not allow the submitter to report electronically, such as lack of access to the internet, the submitter may request to submit reports in an alternative manner by calling 202/622–2490. Such requests will be subject to a presumption of denial and granted only in writing.

(e) *Rules governing availability of information.* Information submitted to OFAC pursuant to this section will be protected from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the provisions of 31 CFR part 1 if OFAC reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or disclosure is prohibited by law. See 31 CFR 1.5 for additional provisions relating to confidential commercial information.

■ 4. Amend § 501.604 by:

■ a. Revising the section heading;

■ b. In paragraph (a)(1), add ''in the case of part 515 of this chapter'' after ''(or a person subject to U.S. jurisdiction'';

■ c. Revising and republishing paragraph (a)(3);

■ d. Revising paragraph (b) introductory text;

■ e. In paragraph (b)(6), remove ''*www.treasury.gov/resource-center/sanctions/SDN-List/Pages/program_tags.aspx*'' and add in its place ''*https://ofac.treasury.gov*''; and

■ f. Revising and republishing paragraphs (d) and (e).

The revisions and republications to read as follows:

§ 501.604 Reports of rejected transactions.

(a) * * *

(3) *Transaction.* The term transaction for purposes of this section includes wire transfers, trade finance, transactions related to securities, checks, or foreign exchange, and sales or purchases of goods or services.

(b) *Required information to be reported.* Reports of rejected transactions shall include the following information, to the extent the information is available to the person submitting the report at the time the transaction is rejected:

* * * * *

(d) *Where to report.* Reports under this section shall be submitted to OFAC through the OFAC Reporting System, available on OFAC's website, *https://ofac.treasury.gov/ofac-reporting-system.* If a submitter can provide evidence of unique and extraordinary circumstances that would not allow the submitter to use ORS, such as lack of access to the internet, the submitter may request to submit reports in an alternative manner by calling 202/622–2490. Such requests will be subject to a presumption of denial and granted only in writing.

(e) *Rules governing availability of information.* Information submitted to OFAC pursuant to this section will be

protected from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the provisions of 31 CFR part 1 if OFAC reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or disclosure is prohibited by law. See 31 CFR 1.5 for additional provisions relating to confidential commercial information.

■ 5. In § 501.605, revise and republish paragraph (a) to read as follows:

§ 501.605 Reports on litigation, arbitration, and dispute resolution proceedings.

(a) U.S. persons (or persons subject to U.S. jurisdiction in the case of part 515 of this chapter) participating in litigation, arbitration, or other binding alternative dispute resolution proceedings in the United States on behalf of or against persons whose property or interests in property are blocked or whose funds have been retained pursuant to § 596.504(b) of this chapter, or when the outcome of any proceeding may affect blocked property or retained funds, must:

(1) Provide notice of such proceedings upon their commencement or upon submission or receipt of documents bringing the proceedings within the terms of the introductory text to this paragraph (a);

(2) Submit copies of all pleadings, motions, memoranda, exhibits, stipulations, correspondence, and proposed orders or judgments (including any proposed final judgment or default judgment) submitted to the court or other adjudicatory body, and all orders, decisions, opinions, or memoranda issued by the court, to the Office of the Chief Counsel (Foreign Assets Control) at *OFACReport@treasury.gov* with the number of this section in the subject line, within 10 days of filing, submission, or issuance. This paragraph (a)(2) shall not apply to discovery requests or responses, documents filed under seal, or requests for procedural action not seeking action dispositive of the proceedings (such as requests for extension of time to file); and

(3) Report by email to the Office of the Chief Counsel (Foreign Assets Control), at *OFACReport@treasury.gov* with the number of this section in the subject line, the scheduling of any hearing or status conference in the proceedings whenever it appears that the court or other adjudicatory body may issue an order or judgment in the proceedings (including a final judgment or default judgment) or is considering or may decide any pending request dispositive of the merits of the proceedings or of any claim raised in the proceedings.

* * * * *

■ 6. Amend § 501.801 by:

■ a. In paragraph (a), revise the third sentence; ''

■ b. Revise paragraph (b)(2)(ii);

■ c. In paragraph (b)(5), remove ''by written correspondence'' and add in its place ''via the OFAC License Application Page at *https://ofac.treasury.gov/ofac-license-application-page*''; and

■ d. Revise paragraph (b)(6).

The revisions to read as follows:

§ 501.801 Licensing

(a) * * * General licenses are set forth in subpart E of each part contained in this chapter, made available on OFAC's website (*https://ofac.treasury.gov*), or published in the **Federal Register**.* * *

(b) * * *

(2) * * *

(ii) *Information to be supplied.* The applicant must supply all information specified by relevant instructions (available on OFAC's Reporting and License Application Forms page at *https://licensing.ofac.treas.gov*) or forms, and must fully disclose the names of all parties who are concerned with or interested in the proposed transaction. If the application is filed by an agent, the agent must disclose the name of his or her principal(s). Such documents as may be relevant shall be attached to each application as a part of such application, whether filed electronically or by mail, except that documents previously filed with OFAC may, where appropriate, be incorporated by reference in such application. For applications for the release of blocked funds, applicants are encouraged to include, when available, the OFAC Reporting System (ORS) transaction and submission identification numbers. Applicants may be required to furnish such further information as is deemed necessary to assist OFAC in making a determination. Any applicant or other party in interest desiring to present additional information may do so at any time before or after OFAC makes its decision with respect to the application. Any requests to make such an oral presentation must be submitted via the OFAC License Application Page at *https://ofac.treasury.gov/ofac-license-application-page* to the attention of the Licensing Division, referencing the relevant Case ID number and a ''Request for Oral Presentation.'' Such requests are rarely granted.

* * * * *

(6) *Rules governing availability of information.* Information submitted to OFAC pursuant to this section will be protected from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the provisions of 31 CFR part 1 if OFAC reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or disclosure is prohibited by law. See 31 CFR 1.5 for additional provisions relating to confidential commercial information.

■ 7. In § 501.804, revise paragraph (b) to read as follows:

§ 501.804 Rulemaking.

* * * * *

(b) Any interested person may petition the Office of Foreign Assets Control for the issuance, amendment, or repeal of any rule, including a general license, at *OFACReport@treasury.gov* with the number of this section in the subject line.

§ 501.805 [Amended]

■ 8. Amend § 501.805 by:

■ a. In paragraphs (a) and (b), after the phrase ''31 CFR part 1'' add the phrase '', as well as the provisions of this part'' in both places it appears;

■ b. In paragraph (c), remove the phrase ''in person or by writing to the Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW—Annex, Washington, DC 20220, or by calling 202/622–2480'' with the phrase ''on OFAC's website (*https://ofac.treasury.gov*).''; and

■ c. In paragraph (d)(2), remove the reference ''*http://www.treas.gov/ofac*'' and add in its place the reference ''*https://ofac.treasury.gov*''.

■ 9. Revise and republish § 501.806 to read as follows:

§ 501.806 Procedures for unblocking property believed to have been blocked and reported in error due to mistaken identity or typographical or similar errors.

When a party believes it has blocked property pursuant to the applicable regulations of this chapter due to mistaken identity or typographical or similar errors, such party may seek to have such property unblocked pursuant to the following administrative procedures:

(a) Any person who has blocked and reported to the Office of Foreign Assets Control (OFAC) property pursuant to § 501.603 may submit a request for authorization to release blocked property that was blocked in error due to mistaken identity or typographical or similar error.

(b) Requests to release such property must be sent via email to *OFACReport@treasury.gov* and include the phrase ''31 CFR 501.806—Request for a Compliance Release'' in the subject line of the email.

(c) A request to release property must include the name, address, telephone number, and email address of the person seeking the release of the property.

(d) A request to release property should include the following information, where known, concerning the blocked property:

(1) The name of the person that holds the blocked property or filed the initial report of blocked property;

(2) The actual value, or if unknown, estimated value, in U.S. dollars of the blocked property, as included in the initial report of blocked property;

(3) The date of the blocking included in the initial report of blocked property;

(4) A copy of a valid government-issued identification document, social security number or employer identification number for a person whose property is believed to have been blocked in error, when applicable;

(5) The OFAC Reporting System (ORS) identification numbers associated with the initial report of blocked property filed with OFAC, when available;

(6) A description of the property or underlying transaction; and

(7) A narrative description of the reasons why the applicant believes the property was blocked in error.

(e) Upon receipt of the materials required by paragraph (d) of this section, OFAC may request additional material, if available, from the applicant concerning the blocked property pursuant to § 501.602.

(f) Following review of all applicable submissions, OFAC will determine whether the property should be released. In the event that OFAC determines that the property should be released, it will direct the person to release the property to the appropriate party.

■ 10. Revise and republish § 501.807 to read as follows:

§ 501.807 Procedures governing delisting from the Specially Designated Nationals and Blocked Persons List or any other list of sanctioned persons or property maintained by the Office of Foreign Assets Control.

A person may submit a petition for administrative reconsideration pursuant to the procedures outlined below in order to seek removal of a person or property (*e.g.,* a vessel) from the List of Specially Designated Nationals and Blocked Persons (SDN List) or any other list or identification of sanctioned persons or property maintained by the Office of Foreign Assets Control (OFAC):

(a) A person blocked under the provisions of any part of this chapter, including a specially designated national, specially designated terrorist, specially designated narcotics trafficker, or a person otherwise subject to sanctions pursuant to the provisions of any part of this chapter (each, a ''sanctioned person''), or a person owning a majority interest in property (*e.g.,* a vessel) that is blocked or otherwise subject to sanctions may submit arguments or evidence that the person believes establishes that insufficient basis exists for the sanction or that the circumstances resulting in the sanction no longer apply. The sanctioned person also may propose remedial steps on the person's part, such as corporate reorganization, resignation of persons from positions in a blocked entity, or similar steps, which the person believes would negate the basis for the sanction. A person owning a majority interest in property (*e.g.,* a vessel) that is blocked or otherwise subject to sanctions may propose the sale of the vessel, with the proceeds to be placed into a blocked interest-bearing account after deducting the costs incurred while the vessel was blocked and the costs of the sale. This submission must be made via email to *OFAC.Reconsideration@treasury.gov.*

(b) For purposes of reconsideration petitions relating to persons or property sanctioned by OFAC:

(1) The information submitted by the person seeking removal of a person or property from the SDN List or any other list or identification of sanctioned persons or property maintained by OFAC will be reviewed by OFAC, which may request clarifying, corroborating, or other additional information.

(2) A person seeking removal of a person or property from the SDN List or any other list or identification of sanctioned persons or property maintained by OFAC may request a meeting with OFAC; however, such meetings are not required, and the office may, at its discretion, decline to conduct such meetings prior to completing a review pursuant to this section.

(3) After OFAC has conducted a review of the request for reconsideration, it will provide a written decision to the person seeking the removal of a person or property from the SDN List or any other list or identification of sanctioned persons or property maintained by OFAC.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–10033 Filed 5–8–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 45

[Docket ID: DoD–2023–OS–0065]

RIN 0790–AL70

Medical Malpractice Claims by Members of the Uniformed Services

AGENCY: Department of Defense (DoD) Office of General Counsel, DoD.

ACTION: Final rule.

SUMMARY: The DoD is finalizing amendments to apply offsets for payments made by the U.S. Government for medical malpractice claims to potential economic damages only and not to total potential damages. Under this rule total potential damages will no longer be reduced by offsetting most of the compensation otherwise provided or expected to be provided by DoD or the Department of Veterans Affairs (VA) for the same harm that is the subject of the medical malpractice claim. Instead, only economic damages will be reduced by offsetting most of the compensation otherwise provided or expected to be provided by DoD or the VA for the same harm that is the subject of the medical malpractice claim. This rule also clarifies future lost earnings may be awarded until the time DoD determines that the claimant is, or is expected to be, medically rehabilitated and able to resume employment; in cases of permanent incapacitation, until expiration of the claimant's work-life expectancy; or, in cases of death, until the expiration of the claimant's work-life expectancy, after deducting for the claimant's personal consumption.

DATES: This final rule is effective May 10, 2024.

FOR FURTHER INFORMATION CONTACT: Melissa D. Walters, (703) 681–6027.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2733a of title 10, United States Code, allows members of the uniformed services or their authorized representatives to file claims, and the Secretary of Defense to pay such claims, for personal injury or death caused by a DoD health care provider in a covered

military medical treatment facility, as defined in that section. DoD published an interim final rule to establish uniform standards and procedures for adjudicating these claims on June 17, 2021 (86 FR 32194) and a final rule on August 26, 2022 (87 FR 52446). Proposed amendments to this regulation were published in the **Federal Register** on October 20, 2023 (88 FR 72412), that proposed to apply offsets for payments made by the U.S. Government to economic damages only and clarify when future lost earnings may be awarded. Comments were accepted for 60 days until December 19, 2023. DoD is making no changes to the regulatory text based on the comments received.

II. Discussion of Comments and Changes

A total of 24 comments were posted on the regulatory docket. Summaries of the comments and the Department's responses are as follows.

General

Two comments from individual members of the public reflected general support for the proposed changes. One of these commenters stated that the proposed changes would benefit Service members and reduce the financial burdens on them and their families following injury or death.

One comment was too general to be actionable. The commenter generally sought to have a fair, efficient, and consistent system without making any suggestions for changes to the proposed rule.

The Department received a number of comments that were outside of the scope of the proposed rule and therefore did not result in changes to the proposed rule. Several comments expressed concerns about the quality of care provided by DoD or the VA and included personal narratives from Service members, their family members, or others on Service members' behalf about specific medical care the Service members received from DoD and VA medical providers. One comment sought to have 32 CFR part 45 extended to all patients of DoD's military health system and not just members of the uniformed services. Another commenter sought to have the doctrine in *Feres* v. *United States,* a 1950 Supreme Court decision, overturned to allow Service members to bring lawsuits in Federal court. An individual submitted comments seeking a change related to the definition of ''DoD health care provider'' in 32 CFR part 45. An additional comment beyond the scope of the regulation recommended that Service members receive copies of their DD Form 2807–1, ''Report of Medical History,'' and their DD Form 2807–2, ''Accessions Medical History Report,'' in addition to their DD Form 214, ''Certificate of Uniformed Service.'' One comment suggested that Service members be educated about the claims process. Finally, one individual generally expressed concerns about the claims process, including a belief that settlements under the process were unfair and lacked transparency.

Section 45.9 Calculation of Damages: Economic Damages

Comment: A State legislator supported the portions of the proposed rule clarifying when future lost wages may be awarded.

Response: This comment did not recommend any changes to § 45.9 and no changes were made to this section.

Section 45.10 Calculation of Damages: Non-Economic Damages

Comment: One individual commented that the rule change may provide additional compensation for non-economic harms, although noted that compensation could never make a malpractice victim or survivor whole. A number of comments, including comments from Members of Congress, a local elected official, a State legislator, and individuals sought elimination of the cap on non-economic damages.

Response: DoD did not make any changes as a result of these comments. Section 2733a(g)(2)(B) of title 10, U.S.C., requires DoD to adjudicate claims, including calculating damages, based on uniform national standards consistent with generally accepted standards used in a majority of States in adjudicating claims under the Federal Tort Claims Act (FTCA), 28 U.S.C. 2671 *et seq.,* without regard to the place where the Service member received medical care. This standard in 10 U.S.C. 2733a(g)(2)(B) is a different standard from the FTCA. Under the FTCA, 28 U.S.C. 2672 and 1346(b)(1), the law applied is the law of the place where the medical care was provided. A majority of States, 28, have caps on non-economic damages applicable in medical malpractice claims and therefore DoD has retained the cap on non-economic damages.

DoD administratively removed a description of ''physical disfigurement'' that used outdated terminology and is unnecessary for purposes of claims adjudication.

Section 45.11 Calculation of Damages: Offsets for DoD and VA Compensation

Comment: One commenter, a city elected official, was supportive of eliminating offsets from non-economic damages. A State legislator indicated support for the changes that would allow more Service members to receive compensation for non-economic damages than under the current regulation. A number of comments, including from Members of Congress, a State legislator, and individuals, sought to eliminate offsets from the portion of potential malpractice damage awards for economic damages in addition to the portion for non-economic damages. Some comments incorrectly seemed to suggest that ''offsets'' meant that the Service member's DoD and VA compensation would be reduced. Some comments also seemed to suggest, inaccurately, that the Department is offsetting an amount equal to all VA compensation for all line of duty injuries, not just offsetting the amount of compensation received for those additional injuries caused by malpractice.

Response: Federal law provides a comprehensive system of compensation for military members and their families in cases of death or disability incurred in military service. This system applies to all causes of death or disability incurred in service, whether due to combat injuries, training mishaps, motor vehicle accidents, naturally occurring illnesses, household events, with limited exceptions (*e.g.,* when the member is absent without leave or the injury is due to the member's intentional misconduct or willful negligence). This compensation system also applies to injuries incurred in service caused by medical malpractice.

Offsets from economic damages account for the fact that compensation has already been paid or will be paid by the Government for economic injuries caused by the malpractice. In other words, the claimant has already received, is receiving, or will be receiving compensation from the U.S. Government on account of his or her economic losses. For example, VA disability ratings ''represent as far as can practically be determined the average impairment in earning capacity'' resulting from service-related injuries. (*See* 38 CFR 4.1) DoD is required by 10 U.S.C. 2733a(g)(2)(B) to apply the law in the majority of states when adjudicating Service member medical malpractice claims. Offsetting economic damages for compensation already paid by the United States is consistent with general tort law principles that states would apply.

The fact that offsets are made from potential medical malpractice damages awards does not change a Service member's entitlement to the DoD or VA

compensation. The same amount of DoD or VA compensation is still paid to a claimant even if the claimant receives an award of medical malpractice damages. What happens with offsets is that the applicable amount of DoD or VA compensation is subtracted from the medical malpractice damages award that otherwise would be payable.

Additionally, offsets are made only for the amount of compensation received from the DoD or VA that is related to the medical conditions caused by the malpractice. The amount of compensation for medical conditions unrelated to the malpractice is not offset. For example, if a Service member receives VA disability compensation both for a combat injury to her hand and for an injury to her knee caused by malpractice, only the amount of compensation for the knee injury would be used as an offset from the proposed damages award.

DoD did not make changes to this section.

III. Effective Date

Pursuant to 5 U.S.C. 553(d), DoD has decided not to delay the effective date of this rule and to make it effective immediately. The final rule relieves a restriction on the amount of non-economic damages claimants may receive. Moreover, there is good cause not to delay the effectiveness of this rule. The amendments apply to claims received by DoD on or after the date this final rule is published in the **Federal Register** and to claims pending before DoD on that date. An immediate effective date allows more timely adjudication of those claims currently pending which would be impacted by the final rule and more timely payments to those claimants. Further, delaying the effective date would result in no benefit to claimants because the final rule imposes no burdens on them and therefore they do not need time to prepare for compliance with the final rule.

IV. Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review,'' as Amended by Executive Order 14094, ''Modernizing Regulatory Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 (as amended by Executive Order 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distribution of impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be a significant regulatory action under paragraph 3(f) of the amended Executive Order 12866. Accordingly, it has been reviewed by the Office of Management and Budget as required by these Executive orders.

Congressional Review Act (5 U.S.C. 804(2))

This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601 et seq)

The General Counsel of the Department of Defense certified that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require a regulatory flexibility analysis.

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require non-Federal spending in any one year of $100 million in 1995 dollars, updated annually for inflation. This final rule does not mandate any requirements for State, local, or tribal governments, nor affect private sector costs.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that this final rule does not impose new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This final rule does not have a substantial effect on State and local governments.

Executive Order 13175, ''Consultation and Coordination With Indian Tribal Governments''

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or affects the distribution of power and responsibilities between the Federal Government and Indian tribes. This final rule will not have a substantial effect on Indian tribal governments.

V. Impact of this Regulation

a. Summary

The amendments adjust and update certain portions of the regulation related to calculation of damages. Currently, DoD offsets from both economic and noneconomic damages compensation made by DoD and VA on account of the injuries from malpractice. The amendments apply offsets to economic damages only. Under the current rule, a claimant who has little or no economic damages would be unable to recover any damages if the compensation that the claimant already receives or will receive from DoD and VA for the injuries from malpractice exceeds the total amount of potential economic and non-economic damages. Under the amendment, these claimants will be able to recover non-economic damages because the amount of the DoD and VA compensation will no longer be used to offset the non-economic damages.

The amendments also include two changes that were made to better describe the applicable principles used when adjudicating claims to make the rule clearer for claimants. First, language was added to address medical rehabilitation as it relates to future lost earnings by explicitly stating the principle that future lost earnings do not continue beyond the point when DoD determines that the claimant is, or is expected to be, medically rehabilitated and able to resume employment. Second, because 10 U.S.C. 2733a(b)(5) prevents recovery for claims that are allowed to be settled and paid under any other provision of law, language was added to explicitly state that an injury or condition does not result in lost earnings for purposes of this regulation if the lost earnings stem from disability discrimination, since disability discrimination is compensable under other provisions of law. These principles, if applicable to the facts of a claim, already would have been applied in adjudicating those claims. Therefore, these changes will have no meaningful economic impact.

b. Affected Population

At the end of Fiscal Year 2022, there were approximately 1,410,000 Active Duty Service members, and 440,000 Reserve and National Guard members eligible for DoD healthcare benefits. These uniformed Service members will be able to file claims with DoD alleging malpractice from care at DoD military medical treatment facilities as defined in 10 U.S.C. 2733a.

c. Costs

DoD does not estimate that any additional claims will be filed as a result of the amendments to the regulation. Since the enactment of 10 U.S.C. 2733a, individuals who believe they have been subjected to malpractice have filed claims involving injuries ranging from minor injuries to death, regardless of the potential application of offsets.

d. Transfers

Regardless of the number of claims in which malpractice occurred, the only claims in which damages will be awarded are those which exceed the offsets for any payment to be made. The amendments solely impact non-economic damages. No amendments are being made that impact offsets from economic damages.

Similar to malpractice claims under the FTCA, claims payable under this regulation could include a wide range of non-economic damages depending on their facts. A claim involving minor pain and temporary injuries would result in a lower non-economic damages award than a claim involving significant, continuing pain and/or debilitating injury. Initially, non-economic damages were capped at $500,000. This cap was raised to $600,000 in August 2022 and again to $750,000 in October 2023.

Based on claims adjudicated under this part in 2021 and 2022, four claims were adjudicated in which offsets were applied. In two of these claims, the economic damages alone were larger than the offsets so the payouts would not have been impacted had the amendments been in effect. Only for the remaining two claims would the outcome have been different had the amendments been in effect. In one claim, an additional $200,000 would have been paid to the claimant if offsets had not been made from non-economic damages. In the other claim, an additional $100,000 would have been paid to the claimant if offsets had not been made from non-economic damages.

Claims in 2021 and 2022 may not necessarily be representative of claims in future years. Claims were accepted beginning January 1, 2020, but could only begin to be adjudicated beginning on July 17, 2021, when the interim final rule at 86 FR 32194 became effective. The first claims adjudicated under this new process were claims that did not require a decision on the merits of whether malpractice occurred, such as claims that were denied because the alleged malpractice fell outside the statute of limitations in 10 U.S.C. 2733a(b)(4). Just as with claim resolution processes involving non-Service member claims, more complex claims, which tend to involve higher amounts of damages, require time for review. Since Service members' claims have only been able to be adjudicated since July 17, 2021, more complex claims may still be under adjudication, and the two claims that would have had a different outcome in 2021 and 2022 may not be representative of the number of claims that would be impacted going forward.

Taking the limited information DoD has into account, DoD estimates that the amendments to the regulation will affect two claims per year. The average of the additional non-economic damages at issue in the two claims which would have been impacted if this regulation had been in effect was $150,000. Assuming $150,000 additional would be paid in two claims, the estimated total additional transfers from the Government to claimants therefore would be $300,000. Of this, the first $100,000 of each of the two claims would be paid by DoD, with the remainder to be paid by the Treasury.

There could be significant variation in the number of claims that would be impacted by the amendments to the regulation from year to year. In some years, there could be no claims affected by the amendments, so there would be zero additional transfers from the Government to claimants. In other years, there could be more claims impacted by the amendments and/or claims involving different amounts of non-economic damages than the $150,000 estimate. For example, assuming that in another year there were four claims in which non-economic damages would be paid and assuming the non-economic damages in these four claims would be paid at the cap of $750,000, this would lead to transfers of $3 million from the Government to claimants.

e. Benefits

The amendments to the regulation will allow some Service members to receive compensation for non-economic damages that they would not have been able to receive under the current regulation. The amendments afford some Service members additional compensation in light of the non-economic harms they have experienced as a result of malpractice.

List of Subjects in 32 CFR Part 45

Claims, Malpractice, Medical, Uniformed services.

Accordingly, the Department of Defense amends 32 CFR part 45 to read as follows:

PART 45—MEDICAL MALPRACTICE CLAIMS BY MEMBERS OF THE UNIFORMED SERVICES

■ 1. The authority for part 45 continues to read as follows:

Authority: 10 U.S.C. 2733a.

■ 2. Amend § 45.1 by revising paragraph (b) to read as follows:

§ 45.1 Purpose of this part.

* * * * *

(b) *Relationship to military and veterans' compensation programs.* Federal law provides a comprehensive system of compensation for military members and their families in cases of death or disability incurred in military service. This system applies to all causes of death or disability incurred in service, whether due to combat injuries, training mishaps, motor vehicle accidents, naturally occurring illnesses, or household events, with limited exceptions (*e.g.,* when the member is absent without leave or the injury is due to the member's intentional misconduct or willful negligence). This comprehensive compensation system applies to cases of personal injury or death caused by medical malpractice incurred in service as it does to all other causes. This part provides for the possibility of separate compensation in certain cases of medical malpractice but in no other type of case. A medical malpractice claim under this part will have no effect on any other compensation the member or the member's family is entitled to under the comprehensive compensation system applicable to all members. However, if the U.S. Government makes a payment for harm caused by malpractice, this payment reduces the potential damages under this part as provided in § 45.11.

* * * * *

■ 3. Amend § 45.9 by revising paragraph (b)(4) and adding paragraph (d) to read as follows:

§ 45.9 Calculation of damages: economic damages.

* * * * *

(b) * * *

(4) For future lost earnings:

(i) Until DoD determines that the claimant is, or is expected to be, medically rehabilitated and able to resume employment;

(ii) In cases of permanent incapacitation, until expiration of the claimant's work-life expectancy; or

(iii) In cases of death, until the expiration of the claimant's work-life expectancy, after deducting for the claimant's personal consumption.

(iv) Future lost earnings must be substantiated by appropriate documentation and claimants have an obligation to mitigate damages.

(v) In addition, loss of retirement benefits is compensable and similarly discounted after appropriate deductions. Estimates for future lost earnings and retirement benefits must be discounted to present value.

* * * * *

(d) *Disability discrimination.* An injury or condition does not result in lost earnings for purposes of, and is not compensable under, this part if the lost earnings stem from disability discrimination, which may be settled and paid under other provisions of law.

■ 4. Amend § 45.10 by revising paragraphs (a) through (c) to read as follows:

§ 45.10 Calculation of damages: non-economic damages.

(a) *In general.* Non-economic damages are one component of a potential damages award. The claimant has the burden of proof on the amount of non-economic damages by a preponderance of evidence. DoD may request an interview of or statement from the claimant or other person with primary knowledge of the claimant. DoD may also require medical statements documenting the claimant's condition and, in cases of disfigurement, photographs documenting the claimant's condition.

(b) *Elements of non-economic damages.* Non-economic damages include pain and suffering; physical discomfort; mental and emotional trauma or distress; loss of enjoyment of life; physical disfigurement; and the inability to perform daily activities that one performed prior to injury, such as recreational activities. Such damages are compensable as part of non-economic damages.

(c) *Cap on non-economic damages.* In any claim under this part, total non-economic damages may not exceed a cap amount published by DoD via a **Federal Register** notice. DoD will periodically publish updates to this cap amount via **Federal Register** notices, consistent with changes in prevailing amounts in the majority of the States with non-economic damages caps.

* * * * *

■ 5. Amend § 45.11 by:
■ a. Revising paragraph (a);
■ b. Redesignating paragraphs (c) and (d) as paragraphs (d) and (c), respectively;
■ c. Revising the first sentence in the newly redesignated paragraph (c);
■ d. Adding a sentence to the end of the newly redesignated paragraph (d);
■ e. Revising paragraph (e); and
■ f. Removing paragraphs (f) and (g).

The revisions and addition read as follows:

§ 45.11 Calculation of damages: offsets for DoD and VA Government compensation.

(a) *In general.* Total potential economic damages calculated under this part are reduced by offsetting most of the compensation otherwise provided or expected to be provided by DoD or VA for the same harm that is the subject of the medical malpractice claim. DoD has the burden to establish the applicability and amount of any offsets.

* * * * *

(c) * * * In determining offsets under this section from economic damages, DoD will use the present value of future payments and benefits. * * *

(d) * * * Claimants must provide information not available to DoD, but requested by DoD, for the purpose of determining offsets.

(e) *Benefits and payments that may be considered as potential offsets.* The general rule is that potential damages calculated under this part may be offset only by DoD or VA payments and benefits that are primarily funded by Government appropriations. Potential damages calculated under this part are not offset by U.S. Government payments and benefits that are substantially funded by the military member. The following examples are provided for illustrative purposes only, are not all-inclusive, and are subject to adjustment as appropriate.

(1) The following DoD and VA payments and benefits are primarily funded from Government appropriations and will be offset:

(i) Disability retired pay in the case of retirement due to the disability caused by the alleged medical malpractice;

(ii) Disability severance pay in the case of non-retirement disability separation caused by the alleged medical malpractice.

(iii) Incapacitation pay.

(iv) Involuntary and voluntary separation pays and incentives.

(v) Death gratuity.

(vi) Housing allowance continuation.

(vii) Survivor Benefit Plan.

(viii) VA disability compensation, to include Special Monthly Compensation, attributable to the disability resulting from the malpractice.

(ix) VA Dependency and Indemnity Compensation, attributable to the disability resulting from the malpractice.

(x) Special Survivor Indemnity Allowance.

(xi) Special Compensation for Assistance with Activities of Daily Living.

(xii) Program of Comprehensive Assistance for Family Caregivers.

(xiii) Fry Scholarship.

(xiv) TRICARE coverage, including TRICARE-for-Life, for a disability retiree, family, or survivors. Future TRICARE coverage is part of the Government's compensation package for a disability retiree or survivor.

(2) The following U.S. Government payments and benefits are substantially funded by the military members or are otherwise generally not eligible for consideration as potential offsets:

(i) Servicemembers Group Life Insurance.

(ii) Traumatic Servicemembers Group Life Insurance.

(iii) Social Security disability benefits.

(iv) Social Security survivor benefits.

(v) Prior Government contributions to a Thrift Savings Plan.

(vi) Commissary, exchange, and morale, welfare, and recreation facility access.

(vii) Value of legal assistance and other services provided by DoD.

(viii) Medical care provided while in active service or in an active status prior to death, retirement, or separation.

Dated: May 6, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10130 Filed 5–9–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2024–0177]

RIN 1625–AA08

Special Local Regulation; Red River, Shreveport, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local

regulation (SLR) for certain navigable waters of the Red River. This action is necessary to provide for the safety of life on these navigable waters near Shreveport, Louisiana, during high-speed powerboat races from May 24, 2024 through May 26, 2024. This rulemaking prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port Sector Lower Mississippi River or a designated representative.

DATES: This rule is effective from 6 a.m. on May 24, 2024 through 6 p.m. on May 26, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email MSTC Lindsey Swindle, Waterways Management, U.S. Coast Guard; telephone 571–610–4197, email *Lindsey.M.Swindle@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On December 8, 2023, an organization notified the Coast Guard that it will be conducting high-speed powerboat races from 6 a.m. through 6 p.m. each day from May 24, 2024, through May 26, 2024. The races will take place between mile marker 228.1 and mile marker 228.8 on the Red River, Shreveport, LA, and involve approximately 55 powerboats ranging from 14 to 18 feet in length. No spectator craft will be allowed in the regulated area. The Captain of the Port Sector Lower Mississippi River (COTP) has determined that potential hazards associated with the high-speed powerboat race would be a safety concern for participants, participant vessels, and general public. In response, on March 25, 2024, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation: Red River, Shreveport, LA (89 FR 20577). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. During the comment period that ended April 10, 2024, we received one comment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the high-speed powerboat race would be a safety concern for participants, participant vessels, and general public.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Captain of the Port Sector Lower Mississippi River (COTP) has determined that potential hazards associated with the high-speed powerboat race would be a safety concern for participants, participant vessels, and general public. The purpose of this rule is to ensure safety of vessels and the navigable waters in the regulated area before, during, and after the scheduled event.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received one comment to our NPRM published March 25, 2024. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM. The Coast Guard conducted a National Environmental Policy Act (NEPA) analysis for this marine event and determined not be a danger to the environment. In addition, the Coast Guard will monitor the event via contact with the sponsor and the sponsor will have adequate boat crew on-site.

This rule establishes a temporary special local regulation from 6 a.m. to 6 p.m. each day on May 24, 2024 through May 26, 2024. The temporary special local regulation will cover all navigable waters within from mile marker 228.1 to mile marker 228.8 in Shreveport, LA. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the high-speed powerboat races. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulation, which will impact mile marker 228.1 to mile marker 228.8 on the Red River for 12 hours each day. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the regulated area, breaks in the racing will provide vessels opportunity to transit, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received zero comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions

annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting approximately 12 hours on three separate days that will prohibit entry of persons or vessels during the Red River Rumble F1 Powerboat Showdown high-speed powerboat races. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T08–0177 to read as follows:

§ 100.T08–0177 Red River Rumble F1 Powerboat Showdown, Shreveport, LA.

(a) *Regulated area.* The regulations in this section apply to the following area: A special local regulation is established to encompass all waters of the Red River from mile marker 228.1 to mile marker 228.8.

(b) *Definitions.* As used in this section—

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Lower Mississippi River (COTP) in the enforcement of the regulations in this section.

Participant means all persons and vessels registered with the event sponsor as a participant in the race.

Spectator means all persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the COTP or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by 314–269–2332. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via Broadcast Notice to Mariners and by on-scene designated representatives.

(d) *Enforcement periods.* This section is effective from 6 a.m. on May 24, 2024 until 6 p.m. on May 26, 2024. This section will be subject to enforcement from 6 a.m. to 6 p.m. each day.

Dated: May 6, 2024.

Kristi L. Bernstein,

Captain, U.S. Coast Guard, Captain of the Port Sector Lower Mississippi River.

[FR Doc. 2024–10267 Filed 5–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0245]

RIN 1625–AA87

Safety Zone: Piers Park, Boston Inner Harbor, East Boston, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a portion of the navigable waters of Boston Inner Harbor in the vicinity of Piers Park, East Boston, Massachusetts. The temporary safety zone is needed to protect the maritime public and event participants from potential hazards created by a swim event taking place in a heavily trafficked harbor scheduled for June 9, 2024. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Boston, or a designated representative.

DATES: This rule is effective from 7 a.m. through noon on June 9, 2024.

ADDRESSES: To view documents mentioned in this preamble as being

available in the docket, go to *https://www.regulations.gov* type USCG–2024–0245 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Timothy W. Chase, Sector Boston,Waterways Management, telephone (617) 447–1620, email *Timothy.W.Chase@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Boston
DHS Department of Homeland Security
FR Federal Register
MA Massachusetts
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a Notice of Proposed Rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The Coast Guard was not made aware of the swim event with sufficient time to publish a NPRM, take public comments, consider those comments, and issue a final rule by June 9, 2024, the scheduled date of the event..

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest due to the potential safety hazards associated with with a swim event taking place in heavily traffic harbor.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Boston (COTP) has determined that potential hazards associated with swim events occurring in a heavily traffic harbor in the vicinity of Piers Park, Boston Inner Harbor, East Boston, Massachuesetts. This rule is needed to to facilitate the safety to the martime public and the event participants from the hazards associated with swim events until the conclusion of the event.

IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. to noon on June 9, 2024. The safety zone will cover all the navigable waters of a portion of Boston Inner Harbor in the vicinity of Piers Park, East Boston, specifacly within a box bound by the following coordinates: Corner #1 42°21′41.22″ N, 071°2′22.6″ W, thence to Corner #2 42°21′26.53″ N, 071°2′32.28″ W, thence to Corner #3 42°21′2.59″ N, 071°1′32.92″ W, thence to Corner #4 42°21′13.14″ N, 071°1′24.6″ W', and returning to the point of origin. The duration of the zone is intended to protect event participants, support personnel, vessels and the marine environment in these navigable waters during the swim event. No vessel or person will be permitted to enter the safet zone without obtaining permission from the COTP or a designated representative.

Requests to enter the zone will be considered and reviewed on a case-by-case basis. The COTP may be contacted by telephone at (856) 416–3015 or can be reached by VHF–FM channel 16. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed to minimize wake and comply with all lawful directions issued by the COTP or the designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small designated area of Boston Inner Harbor in the vicinity of Piesr Park, East Boston, MA, in support of a swim event on June 9, 2024. Additionally, this safety zone will be of limited duration, five hours, to minimize any adverse impacts to vessels who seek to transit the navigable waters. Moreover, the Coast Guard will issue a Local Notive to Mariners well in advance of the event and a Broadcast Notice to Mariners via VHF–FM marine channel 16 regarding the zone prior to commencement of the event, and the rule allows vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting for a period of five hours that will prohibit entry within the designated safety zone during a swim event. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T01–0781 to read as follows:

§ 165.T01–0947 Safety Zone; Pier Park, Boston Inner Harbor, East Boston MA.

(a) *Regulated area.* The following area is a safety zone: all navigable waters of a portion of Boston Inner Harbor in the vicinity of Pier Park, East Boston, specifacly within a box bound by the following coordinates: Corner #1 42°21′41.22″ N, 071°2′22.6″ W, thence to Corner #2 42°21′26.53″ N, 071°2′32.28″ W, thence to Corner #3 42°21′2.59″ N, 071°1′32.92″ W, thence to Corner #4 42°21′13.14″ N, 071°1′24.6″ W, and returning to the point of origin.

(b) *Definitions.* As used in this section—

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port New York (COTP) in the enforcement of the regulations in this section.

Participant means all persons registered with the event sponsor as a participant in the event.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's designated via VHF–FM Marine Channel 16 or by contacting the Coast Guard Sector Boston Command Center at (857) 416–3015.Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement periods.* This section will be enforced from 7 a.m. to noon on June 9, 2024.

Kailie J. Benson,

Captain, U.S. Coast Guard, Captain of the Port Sector Boston.

[FR Doc. 2024–10225 Filed 5–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 38

RIN 2900–AR88

Commemorative Plaques and Urns

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations to implement new statutory authority to furnish commemorative plaques and urns for certain veterans whose cremated remains are not interred. This action is necessary to administer the new benefits, which were authorized by the ''Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020'' (the Act).

DATES: This rule is effective June 10, 2024.

FOR FURTHER INFORMATION CONTACT: Eric Powell, Director, Memorial Products Service, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: 202–632–8670 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On November 20, 2023, VA published in the **Federal Register**, at 88 FR 80649, a proposed rule revising its regulations to implement section 2207 of the Act (Pub. L. 116–315), which amended sec. 2306 of title 38, United States Code, by adding a new subsection (h), to create a new memorialization authority for the National Cemetery Administration

(NCA) to furnish, upon request, an urn or commemorative plaque for a veteran whose cremated remains are not interred. The public comment period ended January 19, 2024, and VA received nine comments. VA will address each in greater detail below but notes generally that six commenters expressed concerns with the rulemaking, two commenters supported the rulemaking, and one commenter's comment is considered beyond the scope of the rulemaking.

One commenter criticized the proposed rule as poorly written and lacking in foresight, suggesting the rulemaking was a cost-saving measure at the expense of the veteran community. While the expressed opinions about the regulatory work product are outside the scope of the rulemaking, we address this commenter's remarks about the underlying statutory authority implemented by this final rule. The commenter noted that a veteran who receives a commemorative plaque or urn would be prohibited from interment in a ''national/state'' cemetery in addition to being prohibited from receiving a headstone, marker, or medallion. The commenter also expressed concern about the effect of this outcome on grants for interment and care of remains.

The commenter is partially correct in that, if VA furnishes a commemorate plaque or urn for a veteran, § 38.634(a)(3)(i) and (ii) would prohibit VA from providing a Government headstone or marker and interring the veteran in a VA national cemetery. However, the proposed rule correctly explains this prohibition is based on statutory law, not a budgetary decision. See 38 U.S.C. 2306(d)(4) (authorizing VA to provide a medallion in lieu of a headstone or marker) and (h)(2) (prohibiting VA, after furnishing a plaque or urn, from providing a headstone or marker (and, by extension, a medallion provided in lieu of a headstone or marker) and interring the eligible individual in a VA national cemetery).

Additionally, we clarify for this commenter that VA grant-funded cemeteries are not prohibited from interring an individual who receives a commemorative plaque or urn, as VA national cemeteries are prohibited from doing so in sec. 2306(h)(2)(B); therefore, VA grant-funded cemeteries may inter a veteran who has received a plaque or urn and provide perpetual care of that veteran's gravesite. VA will make no changes based on commenter's concerns about the statutory restrictions in sec. 2306(h) implemented in this final rule.

Three commenters provided detailed feedback on multiple issues, which VA will address by subject matter below.

Adverse Impacts on Eligibility for Other VA Benefits and Cemetery Grant Funding

Commenters expressed concern that when a claimant accepts a Government-furnished commemorative plaque or urn for an eligible deceased veteran, the veteran is prohibited from future interment in a VA national cemetery or receiving a Government-furnished headstone or marker. The commenters noted that acceptance of ''relatively low cost'' items would deny the significant burial benefit and perpetual care of a veteran's gravesite. These commenters generally criticized the proposed rule's disqualification of a veteran's remains from interment in a VA national cemetery or a VA grant-funded cemetery as counter to the larger purpose of ''honoring veterans and providing perpetual care'' of their gravesites. The commenters were concerned that if a VA grant-funded cemetery interred a veteran who received a commemorative plaque or urn, such interment would violate the terms of grant funding under 38 U.S.C. 2408 and adversely impact a cemetery's eligibility to receive the VA plot or interment allowance. The commenters also cited to possible administrative burdens to verify whether a veteran has received a commemorative plaque or urn. The commenters noted financial burdens for VA grant-funded cemeteries to cover costs of furnishing a headstone or marker at their expense to veterans who received a commemorative plaque or urn and are interred in such cemeteries because VA would otherwise provide headstones or markers for veterans interred in those cemeteries.

First, VA reiterates that the purpose of the commemorative plaque and urn benefit is to honor veterans for their service for families that choose not to inter their loved one. The commemorative plaque or urn is authorized as a Federal benefit provided to an eligible deceased veteran instead of a headstone or marker, under sec. 2306(h)(1); and if furnished, VA is prohibited from interring that veteran in a VA national cemetery and providing a headstone or marker for such individual, under sec. 2306(h)(2)(A) and (B).

The commenters implied that because commemorative plaques and urns are ''relatively low cost,'' VA's provision of these items should not affect a veteran's eligibility for burial. VA clarifies that the cost of the commemorative plaque or urn is irrelevant to VA's obligation to follow the law, which prohibits VA from interring an eligible veteran in a VA national cemetery or furnishing a VA headstone or marker if we have furnished a commemorative plaque or urn for that veteran. Consistent with sec. 2306(h)(2), these express prohibitions must be implemented in regulations as proposed.

Additionally, the prohibitions in sec. 2306(h)(2) only affect burial in a VA national cemetery and the provision of a Government headstone or marker. Statutory eligibility for burial in a VA national cemetery is defined in sec. 2402, but sec. 2306(h)(2) prohibits VA from interring such veteran in a national cemetery or providing a Government headstone or marker for that veteran. If a VA grant-funded cemetery receives a request to inter a veteran for whom VA has furnished a commemorative urn or plaque, the cemetery may inter that veteran, and the prohibitions in sec. 2306(h)(2) would have no impact on existing or future VA grant-funding terms and conditions. VA grant-funded cemeteries are operated for the interment of eligible veterans and their eligible family members, including veterans who received a commemorative plaque or urn. Similarly, eligibility of certain cemeteries to receive the VA plot or interment allowance under sec. 2303 for the interments of eligible veterans would be unaffected by VA furnishing a commemorative plaque or urn for veterans interred in those cemeteries. However, if a cemetery, including a VA grant-funded cemetery, inters a veteran for whom VA furnished a commemorative plaque or urn, sec. 2306(h)(2)(A) prohibits VA from providing a Government headstone or marker for such veteran, and the cemetery would need to provide a headstone or marker through some other means.

VA understands the administration and financial burdens raised by the commenters. However, VA's provision of a commemorative plaque or urn for an eligible veteran and the prohibitions in sec. 2306(h) do not directly affect any non-VA national cemetery's decision to inter that veteran.

The commenters expressed uncertainty about processes for VA grant-funded cemeteries or other stakeholders to verify whether a veteran was furnished a commemorative urn or plaque. VA plans to include information on a public facing online tool that stakeholders can use to find such information. We stress that information in such online tool would not be intended to be determinative of a veteran's eligibility for interment in any

cemetery, but instead would be designed to provide stakeholders, which potentially include every cemetery or burial services provider in the nation, information to support their business decisions regarding the interment of a veteran subject to prohibitions under sec. 2306(h).

VA appreciates these comments raising concerns regarding restrictions in the underlying statutory authorities, including sec. 2306(h). However, VA is obligated to implement the current authority as proposed and makes no changes based on these comments.

Impacts on Future Generations and Risk of Increased Unclaimed Remains

The commenters noted the common practice of families delaying interment of cremated remains until surviving spouses and dependents have passed, which could affect long-term chain of custody of the commemorative plaque or urn. They raised concerns that decisions affecting the disposition of remains may fall to a family representative, generations removed, who may be unfamiliar with the prohibitions in sec. 2306(h) and the impact on other VA benefits. Additionally, commenters noted that because a veteran received a plaque or urn in lieu of interment in a VA national cemetery or a Government headstone or marker, there is a risk of the cremated remains of such veterans being unattended, resulting in an increase in those veterans' remains becoming unclaimed. One commenter asserted that the commemorative plaque and urn program would ''not help increase the number of eligible deceased veterans interred in a governmental cemetery.''

VA appreciates these comments, however, as explained, sec. 2306(h)(2) expressly bars VA from interring in a VA national cemetery or furnishing a headstone or marker to a veteran for whom VA has furnished a commemorative plaque or urn. There is no exception to this mandated prohibition.

Further, sec. 2306(h)(4)(A) mandates that any commemorative plaque or urn provided upon request for an eligible deceased veteran ''shall be the personal property of the next of kin or other such individual.'' In our proposed rule, VA specified many practical limitations of our authority to furnish a commemorative plaque or urn to raise the public's awareness. We also proposed an ''applicant'' definition to minimize the potential for unintended forfeitures of benefits, family disputes, and duplicate claims. Additionally, applicants must certify they are authorized to make decisions about the disposition of veteran's remains and certify their awareness of other precluded benefits, before submitting a claim for a plaque or urn. VA will continue to raise awareness of the limitations of sec. 2306(h) by providing detailed information about the commemorative plaque and urn program, following the effective date of this final rulemaking. However, VA has no jurisdiction over a commemorative plaque or urn once it has been furnished and must defer to a veteran's family members to maintain control of a furnished plaque or urn as their personal property.

Similarly, VA has no ability to control circumstances that result in remains of veterans becoming unclaimed by a family member or personal representative. VA has several benefit authorities supporting unclaimed veterans and those who bring remains to VA to ensure dignified burials. However, sec. 2306(h) prohibits VA from interring the unclaimed remains of a veteran for whom VA has furnished a commemorative plaque or urn. Again, the prohibition only applies to interment in VA national cemeteries, not to other cemeteries where burial of the unclaimed remains of a veteran, for whom VA has provided a commemorative plaque or urn, is not expressly prohibited.

Regarding the comment that the rule will not increase interments in ''governmental cemeteries,'' we reiterate that provision of a commemorative plaque or urn would bar interment only in a VA national cemetery. Further, as noted above, the purpose of the law is to provide an appropriate commemorative benefit to families that do not intend to inter their loved one in a cemetery. Finally, regardless of whether the availability of this benefit might affect a family's decision regarding interment in a VA cemetery, VA does not have authority to disregard the express limitations in the statute.

VA will make no changes to the rulemaking based on comments critical of the plaque and urn statutory authority.

Consideration of Suggested ''Reinstatement'' Process

Two commenters suggested including a procedure for returning a commemorative plaque or urn to reestablish eligibility for other veteran burial benefits. They added that not including such a provision would lead to irreversible decisions adversely affecting veterans and their families. Another commenter suggested regulatory procedures for returning a commemorative plaque or urn to governmental control ''whether in National, State, or Tribal cemeteries.'' This commenter suggested VA grant reinstatement ''with legitimate justification as a part of a request to cancel the initial decision to receive a commemorative plaque or urn in lieu of burial.''

VA understands the commentors' concerns, but the concept of reinstatement does not apply because VA has no authority to alter the prohibitions under sec. 2306(h). Further, while provision of a commemorative plaque or urn for an eligible veteran prohibits VA from interring such veteran in a national cemetery or furnishing a headstone or marker for such veteran, it does not invalidate the underlying criteria for a veteran's eligibility for burial in a VA national cemetery. The concept of ''reinstatement'' or ''reversing'' a decision affecting burial eligibility is technically inaccurate because VA furnishes a commemorative plaque or urn to eligible veterans. VA must confirm the individual meets the statutory criteria for eligibility as a veteran who served in the Armed Forces on or after April 6, 1917, who is eligible for a headstone or marker under sec. 2306(d) (or would be so eligible but for the date of the individual's death), and whose cremated remains are not interred. These criteria apply to VA's decision to furnish a requested plaque or urn and have no further impact, except on subsequent requests for burial in a VA national cemetery or a headstone or marker. The provision of either burial in a VA national cemetery or a headstone or marker is prohibited under sec. 2306(h)(2). As explained above, such veterans can be interred in any other cemetery with no impact on other VA benefits, except VA's provision of a headstone or marker. And, under 38 U.S.C. 2402(a)(5), an eligible spouse, surviving spouse, or dependent would not be prohibited from receiving a Government headstone or marker or being interred in a VA national cemetery. VA grant-funded cemeteries and veterans' family members or representatives may still submit claims for other VA benefits that are based on an individual's qualifying military service and other applicable criteria.

Lastly, VA has no authority to cancel a decision granting a requested benefit to allow the claimant to request a different benefit. Revision of a decision on grounds of clear and unmistakable error, renouncement of rights to monetary benefits, and withdrawal of a supplemental claim, higher-level review, or a notice of disagreement do

not apply in the context suggested by the commenter. Even if VA agreed with the commenter's suggestion to implement a return process in this final rule, VA has no authority to do so. VA is bound by sec. 2306(h) requirements and will make no changes based on these comments.

Two commenters expressed concern about the impact of the sec. 2306(h) prohibitions on veterans and their surviving spouses who are both entitled to distinct burial benefits. Both commenters raised the following hypothetical scenario: a veteran's spouse requested and received a commemorative plaque or urn for the deceased veteran; but, upon the death of the veteran's spouse, the family now wants to inter the veteran's spouse in a VA national cemetery or Arlington National Cemetery. Each commenter noted that a short-term decision of a veteran's spouse to not inter the veteran in a VA national cemetery and, instead, request a commemorative plaque or urn has long-term consequences for future surviving family members for whom VA cannot provide burial in a national cemetery or a headstone or marker for the veteran's eligible spouse. We clarify that the prohibition in sec. 2306(h)(2) applies only to burial in VA national cemeteries, not Arlington National Cemetery. However, prior to applying for a commemorative plaque or urn, VA encourages potential applicants to check directly with agencies that operate other cemeteries (including the Department of Defense regarding Arlington National Cemetery) concerning any potential adverse impact on eligibility for interment in such other cemeteries resulting from receipt of VA's plaque or urn benefit. As previously explained in this rulemaking, veterans who receive a commemorative plaque or urn may be interred in any other cemetery with no impact on other VA benefits, except VA's provision of a headstone or marker; and their eligible spouse, surviving spouse, or dependent would not be prohibited from receiving a headstone or marker or being interred in a VA national cemetery, although they would not be interred with the veteran.

One commenter suggested VA allow the veteran to be interred with the spouse if the spouse is already interred in a VA national cemetery, noting that including the urn ''would not add an additional cost to VA'' and would ''be no different than including a memento in the casket.'' While VA agrees that in certain scenarios, there would seemingly be negligible or no ''cost'' to allow such practice, the law explicitly prohibiting interment in a VA national cemetery of a veteran for whom VA has furnished a commemorative plaque or urn does not grant VA the authority to consider cost. VA is mandated to enforce the statutory prohibition. Second, the commemorative urn containing the cremated remains of an eligible veteran is a VA benefit intended to honor the veteran's service and sacrifice to this Nation. As explained in the preamble of the proposed rule, VA cautions families, and will continue to caution families, about the prohibitive impact of requesting a commemorative plaque or urn for a veteran. Once the final rule becomes effective, VA will provide extensive information about the plaque and urn authorities, impacts on VA burial and memorialization, and other critical issues on the VA public-facing web page.

One commenter suggested VA allow families to return the plaque or urn and reinstate eligibility for interment in a VA national cemetery and a Government headstone or marker. The commenter likened the return of a plaque or urn to the return of a Government headstone or marker when a decedent is moved from a VA national cemetery to a private cemetery. As explained in response to a similar comment suggesting reinstatement, this is not currently authorized under sec. 2306. Further, the Government headstone or marker installed in a VA national cemetery is not returned to VA when a family disinters a loved one and reinters the remains in a private cemetery. VA regulations in 38 CFR 38.630(b)(5)(iii) and 38.631(b)(5)(i) and (iii) provide that all Government-furnished burial and memorial headstones and markers remain the property of the United States Government in perpetuity and must be properly disposed of when they are removed from any cemetery, except burial headstones and markers may be relocated to a different gravesite following disinterment. By contrast, sec. 2306(h)(4)(A) mandates that any commemorative plaque or urn furnished for an eligible veteran is the personal property of the next of kin or such other individual as the Secretary considers appropriate. Additionally, sec. 2306(h)(4)(B) provides that the Federal Government shall not be liable for any damage after the date a commemorative plaque or urn is furnished. As explained in the preamble of the proposed rule, VA is aware of the complexity of the plaque and urn benefit, and we will continue to inform families of issues that they may need to manage if their request for a commemorative plaque or urn is granted. However, because these comments attack the statutory mandates implemented in this final rule, VA will make no changes based on these comments.

One commentor wrote that VA's provision of the commemorative urn under sec. 2306(h), as opposed to reimbursing the cost of such an urn, has financial implications for funeral homes, which traditionally sell urns to veteran families. VA acknowledges the commenter's concern and relies on information provided by the U.S. Small Business Administration (SBA) in determining if this regulatory action would have a significant impact on a substantial number of small entities. VA considers 1% or higher of the total number of entities within a North American Industry Classification System (NAICS) industry to be a ''substantial number.'' In determining whether a regulatory action may have a ''significant impact'' on small entities, VA uses a revenue test for each specific NAICS code that may be affected. Any regulatory action that generates a cost of 3% or higher on that NAICS code's annual revenue is deemed to have a ''significant impact. As explained in the Regulatory Flexibility Act (RFA) section of the proposed rule and this final rule, VA's analysis regarding the cost of commemorative plaques and urns, along with the Paperwork Reduction Act (PRA) costs of the rulemaking, yields a potential impact of $234,535.10 on the funeral home industry, which equates to a potential de minimis cost of $139.27 per funeral home ($234,535.10/1,684 estimated caseload). Based on this analysis and revenue test, the rulemaking will not have a significant economic impact on funeral homes.

Further, VA has no alternative but to implement the commemorative plaque or urn benefit in regulation and will make no changes based on this comment.

One of the two commenters who supported the rulemaking also expressed concern about the amount of time required for VA to implement the regulation that is necessary for an applicant to obtain a commemorative plaque or urn, and that an applicant should not be denied the benefit due to the delay in implementation of the authority. VA clarifies that the rule does not establish eligibility criteria that would preclude an eligible applicant from obtaining a commemorative plaque or urn for an eligible veteran who was deceased prior to the implementation of the regulation but on or after April 6, 1917, which is the eligibility date established under section 2306(h)(3). VA proposed the regulation to implement the new authority as expeditiously as possible, and it will

become effective within thirty days of publication of this final rule in the **Federal Register**. VA will update its website to provide information about the new benefit and how to apply for it. No changes to the rulemaking are needed based on these comments.

Finally, VA addresses the comment outside the scope of the rulemaking that requested an amendment to 38 U.S.C. 2306 to provide eligibility for burial for veterans who ''who commit suicide due to PTSD, or possible drug induced impulsiveness.'' VA clarifies that the rule only implements new statutory authority for the commemorative plaque or urn benefit for veterans with qualifying service; it does not establish eligibility criteria that pertain to cause of death. Cause of death has no bearing on eligibility. This means that a veteran who dies by suicide still may be eligible for a plaque or urn or other burial benefit. The comment also requested eligibility for veterans who are not ''registered'' with VA. VA clarifies that veterans do not need to be previously registered or affiliated with VA in any manner for someone to apply for a commemorative plaque or urn for their remains. VA will encourage veterans and family members who are interested in the new benefit to visit the VA web page for more information about how to apply. VA makes no changes based on the comment.

Executive Orders 12866, 13563 and 14094

Executive Orders 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Orders 12866 and 13563. The Office of Information and Regulatory Affairs has determined that this rulemaking is not a significant regulatory action under Executive Order 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This conclusion is based on the cost of commemorative plaques and urns and the Paperwork Reduction Act costs of the rulemaking to arrive at a potential impact of $234,535.10 on the funeral home industry, which equates to a potential de minimis cost of $139.27 per funeral home ($234,535.10/1,684 estimated caseload). Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule includes a provision constituting a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that requires approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review and approval.

This final rule adding 38 CFR 38.634 contains a new collection of information under the Paperwork Reduction Act of 1995. OMB has assigned control number 2900–0937 to this information collection, and this information collection is pending final OMB approval. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If OMB does not approve the collection of information as requested, VA will immediately remove the provision containing a collection of information or take such other action as is directed by OMB.

The collection of information contained in 38 CFR 38.634 is described immediately following this paragraph, under its respective title.

- *Title:* Request for Commemorative Plaque or Urn.
- *OMB Control No:* 2900–0937.
- *CFR Provision:* 38 CFR 38.634.
- *Summary of collection of information:* The new collection of information in proposed § 38.634 would require information necessary to establish the identity of a deceased veteran to verify burial eligibility under 38 U.S.C. 2402 for purposes of furnishing a commemorative plaque or urn, as authorized under 38 U.S.C. 2306(h). It would also require information regarding the applicant's relationship to the deceased veteran, the applicant's certification as to certain factual matters, and the applicant's contact information.
- *Description of need for information and proposed use of information:* The information would be used by VA to verify an individual's service in the Armed Forces on or after April 6, 1917; eligibility for a headstone, marker, or medallion that VA has not yet furnished under sec. 2306(d); and that the individual's remains were cremated and not interred. Information regarding the applicant's relationship to the deceased veteran would be used to verify that the applicant is a family member empowered to make decisions regarding memorialization of the veteran and disposition of any remains.
- *Description of likely respondents:* Veterans' family members.
- *Estimated number of respondents per year:* 1,684.
- *Estimated frequency of responses per year:* This is a one-time collection.
- *Estimated average burden per response:* 10 minutes.
- *Estimated total annual reporting and recordkeeping burden:* VA estimates the total annual reporting and recordkeeping burden to be 280.6667 hours (1,684 respondents × 10 minutes/60 minutes).
- *Estimated cost to respondents per year:* VA estimates the annual cost to respondents to be $8352.64. Using VA's average annual number of 1,684 respondents, VA estimates the total information collection burden cost to be $8352.64 per year (280.6667 burden hours (1,684 respondents × 10 minutes/60 minutes) × $29.76 mean hourly wage).

* To estimate the respondents' total information collection burden cost, VA uses the Bureau of Labor Statistics (BLS) mean hourly wage for ''All Occupations'' of $29.76. This information is available at *https://www.bls.gov/oes/2022/may/oes_nat.htm#00-0000.*

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not satisfying the criteria under 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 38

Administrative practice and procedure, Cemeteries, Claims, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on April 11, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, the Department of Veterans Affairs amends 38 CFR part 38 as follows:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 38 U.S.C. 107, 501, 512, 531, 2306, 2400, 2402, 2403, 2404, 2407, 2408, 2411, 7105.

■ 2. Amend § 38.600 by revising the definition of ''Interment'' to read as follows:

§ 38.600 Definitions.

(a) * * *

Interment means the burial or entombment of casketed or cremated remains, including the placement of cremated remains in a columbarium niche.

* * * * *

■ 3. Add § 38.634 to read as follows:

§ 38.634 Commemorative urns and plaques.

(a) *General.* (1) In lieu of furnishing a headstone, marker, or medallion under this part, the Department of Veterans Affairs (VA) will furnish, when requested—

(i) A commemorative urn; or

(ii) A commemorative plaque.

(2) For the purposes of this section, the following definitions apply:

(i) *Commemorative urn* means a container that signifies the deceased individual's status as a veteran, in which the individual's cremated remains may be placed at private expense.

(ii) *Commemorative plaque* means a tablet that signifies the deceased individual's status as a veteran.

(3) If VA furnishes a commemorative plaque or a commemorative urn for an individual under this section, VA may not provide for such individual—

(i) A headstone, marker, or medallion; or

(ii) Any burial benefit under 38 U.S.C. 2402.

(4) Any commemorative plaque or commemorative urn furnished under this section shall be the personal property of the applicant.

(5) The Federal Government shall not be liable for any damage to a commemorative plaque or urn furnished under this section that occurs after the date on which the commemorative plaque or urn is furnished. VA will not replace a commemorative plaque or urn unless it was damaged during shipping or contains a manufacturing deficiency or inscription error.

(b) *Eligible individuals to be commemorated.* An eligible individual for purposes of this section is a deceased individual:

(1) Who served in the Armed Forces on or after April 6, 1917;

(2) Who is eligible for, but has not received, a headstone, marker, or medallion under 38 U.S.C. 2306(d) (or would be so eligible but for the date of the death of the individual); and

(3) Whose remains were cremated and not interred (see § 38.600 for definition of interment).

(c) *Application process.* (1) *Applicant.* An applicant for a commemorative plaque or urn must be a member of the veteran's family, which includes the veteran's spouse or individual who was in a legal union as defined in § 3.1702(b)(1)(ii) of this chapter with the veteran; a child, parent, or sibling of the veteran, whether biological, adopted, or step relation; and any lineal or collateral descendant of the veteran.

(2) *Application.* An applicant must submit a completed VA Form 40–1330UP, Claim for Commemorative Urn or Commemorative Plaque for Veteran's Cremains Not Interred in a Cemetery. The National Cemetery Administration will verify the decedent's eligibility for a commemorative plaque or urn. Applicants must certify that they have read a statement about other benefits to which the veteran will lose benefit rights, that the decedent's remains were cremated and are not interred at the time of application, that the applicant is a member of the decedent's family authorized to make decisions about the disposition of the decedent's remains, and that the applicant is in possession of the entirety of the cremains. Other required claim information will include documentation of the decedent's eligibility and the applicant's contact information and mailing address. VA's duty to notify claimants of necessary information or evidence under § 3.159(b) of this chapter and duty to assist claimants in obtaining evidence under § 3.159(c) of this chapter will apply.

[FR Doc. 2024–10194 Filed 5–9–24; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0613 and EPA–HQ–OPP–2023–0347; FRL–11898–01–OCSPP]

1-Propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts; and 1-Propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts in Pesticide Formulations; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts (CAS Reg. No. 499781–63–4) when used as an inert ingredient (adjuvant or surfactant) on growing crops and raw agricultural commodities pre- and post-harvest. This regulation also establishes an exemption from the requirement of a tolerance for residues of 1-propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0), also known as cocamidopropyl betaine, when used as an inert ingredient (surfactant) on growing crops pre-harvest. Oxiteno USA, LLC and Bi-PA NV, respectively, each submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance for each of these substances. This regulation eliminates the need to establish a maximum permissible level for residues of 1-propanaminium, 3-

amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts; and cocamidopropyl betaine when used in accordance with the terms of these exemptions.

DATES: This regulation is effective May 10, 2024. Objections and requests for hearings must be received on or before July 9, 2024 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for these actions, identified by docket identification (ID) numbers EPA–HQ–OPP–2021–0613 and EPA–HQ–OPP–2023–0347, are available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2021–0613 or EPA–HQ–OPP–2023–0347 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 9, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2021–0613 or EPA–HQ–OPP–2023–0347, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets#express.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of October 21, 2021 (86 FR 58239) (FRL–8792–04–OSCPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11550) by Spring Regulatory Sciences, on behalf of Oxiteno USA, LLC, 3200 Southwest Freeway, Suite 1200, Houston, TX 77027. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of 1-propanaminium, 3-amino-N-(2-carboxyethyl)- *N,N*-dimethyl-, N-coco acyl derivatives, inner salts (CAS Reg. No. 499781–63–4) when used as an inert ingredient (adjuvant or surfactant) in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest. This document referenced a summary of the petition prepared by Oxiteno USA, LLC, which is available in the docket at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of Wednesday, July 26, 2023 (88 FR 48179) (FRL–10579–06–OSCPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11782) by SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192 on behalf of Bi-PA NV. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of cocamidopropyl betaine (CAS Reg. No. 61789–40–0) when used as an inert ingredient (surfactant) in pesticide formulations pre-harvest at levels up to 10% w/w in pesticide formulations. This document referenced a summary of the petition prepared by Bi-PA NV, which is available in the docket at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing an exemption for residues of 1-propanaminium, 3-amino-N-(2-carboxyethyl)- *N,N*-dimethyl-, N-coco acyl derivatives, inner salts that includes a limitation of 25% w/w in pesticide formulations to account for potential aquatic toxicity. A revised petition was submitted by Oxiteno USA, LLC, to support this change to the petitioned-for exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as

polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. When EPA makes a safety determination for an exemption from the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs the Agency to take into account the considerations in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .'' Section 408(b)(2)(D) lists other factors for EPA's consideration when making safety determinations, including the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine, including exposure resulting from the exemptions established by this action. EPA's assessment of exposures and risks associated with 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicological database of 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts is supported by data regarding cocamidopropyl betaine and to a lesser extent, two other alkylamidopropyl betaines. EPA has determined that it is appropriate to bridge alkylamidopropyl betaine data to assess 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts due to similarities in the manufacturing processes, functional groups/structure, composition, and physical/chemical properties, and among the available human health toxicity and ecological toxicity data of these substances.

1-Propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine exhibit moderate acute toxicity via the oral and dermal routes. No inhalation studies were available but, based on their physical-chemical properties, they are not expected to volatilize and therefore are not expected to be an inhalation toxicant.

They were shown to be a moderate dermal irritant in some studies and a non-irritant in others. They are severe eye irritants. Although some skin sensitization effects were seen in the acute studies, these chemicals contain byproducts that are known to cause sensitization. Therefore, it is possible the effects are from chemical byproducts and with proper manufacturing controls, these irritating components can be decreased.

The repeated-dose toxicity studies showed no concern for systemic effects. Local irritation was seen in the forestomach of dams in subchronic studies and in one developmental toxicity study following gavage administration. This forestomach irritation likely resulted in the decreased maternal body weight gain and food consumption and the associated developmental effects observed at the highest dose tested (*i.e.,* post-implantation loss and decreased mean fetal body weight). Due to the bolus administration of the compound (which may increase the irritation potential of a chemical), the lack of a forestomach in humans, and the developmental effects occurring at very high doses only, the effects observed are not considered relevant for human health risk assessment.

Although no specific neurotoxicity studies were conducted, there was no evidence of neurotoxicity following repeated dosing. The neurotoxicity observed following acute dosing occurred at doses not relevant for risk assessment purposes (*i.e.,* doses >1,000 mg/kg). Furthermore, concern for carcinogenicity is low, based on negative results in mutagenicity studies, and the lack of structural alerts for carcinogenicity.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.*

The hazard profiles of 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine are adequately defined. Overall, these chemicals are of low to moderate acute toxicity, and low subchronic and developmental toxicity. No toxicity relevant for risk assessment was observed up to 1,000 mg/kg/day. Therefore, no toxicological endpoints of concern or PODs were identified and a qualitative risk assessment for 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine was performed.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine, EPA considered exposure under the proposed exemptions from the requirement of a tolerance. EPA assessed dietary exposures from 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine in food as follows.

Dietary exposure (food and drinking water) to 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine may occur following ingestion of foods with residues from their use in accordance with these exemptions. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

1-Propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine may be present in pesticide and non-pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Based on the lack of systemic toxicity in the available database, EPA has not found 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine to share a common mechanism of toxicity with any other substances, and 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine do not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance exemptions, therefore, EPA has assumed that 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on an assessment of 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts or cocamidopropyl betaine, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts or cocamidopropyl betaine residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 1-propanaminium, 3-amino-N-(2-

carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts or cocamidopropyl betaine in or on any food commodities. EPA is establishing a limitation on the amount of 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and cocamidopropyl betaine that may be used in pesticide formulations. This limitation is based on the potential for aquatic toxicity and will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 25% 1-propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts and/or 10% cocamidopropyl betaine in the final pesticide formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of 1-propanaminium, 3-amino-N-(2-carboxyethyl)- *N,N*-dimethyl-, N-coco acyl derivatives, inner salts (CAS Reg. No. 499781–63–4) when used as an inert ingredient (adjuvant or surfactant) up to 25% w/w in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest under 40 CFR 180.910.

An exemption from the requirement of a tolerance is also established for residues of 1-propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0), also known as cocamidopropyl betaine, when used as an inert ingredient (surfactant) up to 10% w/w in pesticide formulations applied to growing crops pre-harvest under 40 CFR 180.920.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 2, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, amend table 1 to 180.910 by adding, in alphabetical order, an entry for ''1-Propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts (CAS Reg. No. 499781–63–4)'' to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * * * * * *		
1-Propanaminium, 3-amino-N-(2-carboxyethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, inner salts (CAS Reg. No. 499781–63–4).	25% w/w in pesticide formulation ..	Adjuvant or surfactant.
* * * * * * *		

■ 3. In § 180.920, amend table 1 to 180.920 by adding, in alphabetical order, an entry for ''1-Propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0)'' to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.920

Inert ingredients	Limits	Uses
* * *	* *	* *
1-Propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0).	10% w/w in pesticide formulation ..	Surfactant.
* * *	* *	* *

[FR Doc. 2024–10182 Filed 5–9–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0887; FRL–11734–01–OCSPP]

Cyflumetofen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyflumetofen in or on the following raw agricultural commodities: berry, low growing, subgroup 13–07G; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; and vegetable, cucurbit, group 9. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 10, 2024. Objections and requests for hearings must be received on or before July 9, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0887, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov//.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0887 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before July 9, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0887, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 23, 2023 (88 FR 11401) (FRL–10579–01–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP 2E9030) by the Interregional Research Project No. 4 (IR–4), North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requests to amend 40 CFR 180.677 by establishing tolerances for residues of cyflumetofen (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), including its metabolites and degradates, in or on the following raw agricultural commodities: berry, low growing, subgroup 13–07G at 0.6 parts per million (ppm); fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.6 ppm; and vegetable, cucurbit, group 9 at 2 ppm. Upon the establishment of these tolerances, IR–4 requested that EPA remove the existing tolerances in 40 CFR 180.677 for residues of cyflumetofen (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate) in or on cucumber at 0.3 ppm; grape at 0.60 ppm; and strawberry at 0.6 ppm. That document referenced a summary of the petition prepared by IR–4, which is available in the docket at *https://www.regulations.gov.* One comment was received in response to the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing one tolerance at a different level than petitioned-for. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyflumetofen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflumetofen follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for cyflumetofen in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to cyflumetofen and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of cyflumetofen, see Unit III.A. of the final rule published in the **Federal Register** of May 8, 2019 (84 FR 20037) (FRL–9990–60).

Toxicological points of departure/Levels of concern. A summary of the toxicological endpoints for cyflumetofen used for human health risk assessment is discussed in Unit III.B. of the May 8, 2019, rulemaking.

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposures from the petitioned-for tolerances. No acute dietary exposure and risk analyses were performed since there were no appropriate toxicological effects attributable to a single dose observed in available toxicity studies for either the general population or for females 13 to 49 years of age. The chronic dietary (food and drinking water) exposure and risk assessment for cyflumetofen was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey/What We Eat in America, (NHANES/WWEIA). An unrefined chronic dietary (food and drinking water) analysis was conducted using tolerance-level residues, default processing factors, empirical processing factors, and 100% crop treated assumptions.

Drinking water exposure. EPA has revised the cyflumetofen drinking water assessment (DWA) since the May 8, 2019, final rule and the final rule published in the **Federal Register** of December 6, 2021 (86 FR 68915) (FRL–9234–01–OCSPP). The DWA provides updated estimated drinking water concentrations (EDWCs) for cyflumetofen residues of concern in surface water and groundwater. The use patterns for current and proposed uses were modeled using new pesticide in water calculator scenarios. The updated EDWCs for use in human health risk assessment are 0.59 µg/L for acute exposures, 0.11 µg/L for non-cancer chronic exposures and 0.10 µg/L for cancer exposures generated from exposure in surface water.

Non-occupational exposure. There are no new proposed residential (non-occupational) uses for cyflumetofen at this time; however, there are registered uses of cyflumetofen on commercial vegetable gardens and ornamental plants. EPA's residential exposure assessment has changed since the May 8, 2019, final rule based on a revised practice. Because all current cyflumetofen labels require handlers to wear personal protective equipment, EPA assumes that cyflumetofen is applied by professional applicators, not residential (homeowner) applicators. Therefore, the current assessment does not consider exposure to residential handlers or exposure from direct homeowner applications to ornamentals or home gardens.

There are registered uses of cyflumetofen to commercially treat garden vegetables that could be subsequently purchased at a retail location for transplant into a residential setting and treated ornamental plants that can be purchased by consumers. EPA considers post-application exposure resulting from this scenario to be negligible because residues are

expected to decline significantly during the time from application in a commercial setting to consumer purchase at a retail location. Also, there is no dermal hazard for cyflumetofen since no systemic effects were observed in the dermal study up to the limit dose. Therefore, a quantitative residential post-application dermal risk assessment is not required.

Cumulative exposures. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyflumetofen and any other substances and cyflumetofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyflumetofen has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the May 8, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risk and Determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

An acute dietary risk assessment was not conducted as toxicological effects attributable to a single dose were not identified. Therefore, cyflumetofen is not expected to pose an acute risk. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; the chronic dietary exposure estimate for all infants, the most highly exposed population subgroup, is 7.6% of the cPAD. Because EPA has determined that there are no residential exposures, the chronic dietary risk is the same as the overall chronic aggregate risk for cyflumetofen and is not of concern.

As stated in Unit III.A. of the May 8, 2019, final rule, EPA concluded that the nonlinear approach for assessing potential cancer risk is appropriate. The chronic risk resulting from aggregate exposure to cyflumetofen is below the Agency's level of concern; therefore, the Agency concludes that there is not a cancer risk of concern from exposure to cyflumetofen.

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyflumetofen residues. More detailed information on this action can be found in the document titled ''Cyflumetofen. Human Health Risk Assessment for the Proposed New Use on Vegetable, Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, subgroup 13–07F.'' in docket ID number EPA–HQ–OPP–2022–0887.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the final rule published in the **Federal Register** of July 1, 2020 (85 FR 39491) (FRL–10009–25).

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

Codex has not established an MRL for residues of cyflumetofen in or on cucurbit vegetable group 9, bell pepper or non-bell pepper. Codex has established MRLs for residues of cyflumetofen in or on strawberry at 0.6 ppm and in or on grape, table and grape, wine at 0.6 ppm. The U.S. tolerances for berry, low growing, subgroup 13–07G and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F are being established at 0.6 ppm and are harmonized with the relevant Codex MRLs.

C. Response to Comments

One comment was received on the notice of filing. The comment is an inquiry from the People's Republic of China, requesting that EPA explain the reasons for removing the existing tolerances for strawberries and grapes and establishing new crop group tolerances for berry, low growing, subgroup 13–07G and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F, thus expanding tolerance coverage for these crops. The commenter also requested that the Agency provide the test data used for risk assessment of the relevant fruits.

Under FFDCA section 408, EPA is authorized to establish tolerances for pesticide chemical residues in food. EPA establishes tolerances for each pesticide based on data on the pesticide residues and assesses the potential risks to human health posed by that pesticide. A tolerance is the maximum permissible residue level established for a pesticide in raw agricultural commodities and processed foods. The crop group regulations currently in 40 CFR 180.40 and 180.41 enable the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. Strawberry is a representative crop for the crop subgroup 13–07G, and grape is a representative crop for the crop subgroup 13–07F.

The data supporting the strawberry and grape tolerances were submitted to the Agency and were reviewed and reported in the document titled ''Cyflumetofen. Petition for the Establishment of Permanent Tolerances and Registration for Use on Citrus (Crop Group 10–10), Pome Fruits (Crop Group 11–10), Tree Nuts (Crop Group 14–12), Grape, Strawberry, and Tomato. Summary of Analytical Chemistry and Residue Data.'', D408531, D. Wilbur, 09-July-2013. In the current action, EPA is expanding the grape tolerance to fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F and expanding the strawberry tolerance to berry, low growing, subgroup 13–07G as stated in the document ''Cyflumetofen. Proposed Section 3 Registration for the New Use on Vegetable Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13–07F. Summary of Analytical Chemistry and Residue Data'' and the document ''Cyflumetofen. Human Health Risk Assessment for the Proposed New Use on Vegetable, Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, subgroup 13–07F.'' All three documents can be found in docket ID number EPA–HQ–OPP–2022–0887.

D. Revisions to Petitioned-For Tolerances

EPA reviewed the available residue data and is establishing the tolerance for

resides of cyflumetofen in or on vegetable, cucurbit, group 9 at 0.3 ppm rather than at 2 ppm as IR–4 requested. IR–4 calculated the tolerance of 2 ppm by including the metabolite B–1 in the residue levels. However, the only residues included in the tolerance expression are for the parent compound, cyflumetofen. Using the residues for cyflumetofen but not metabolite B–1, EPA calculated the tolerance for resides of cyflumetofen in or on vegetable, cucurbit, group 9 to be 0.06 ppm, which is covered by the established tolerance of 0.3 ppm in or on cucumber. Therefore, EPA is establishing the tolerance for residues of cyflumetofen in or on vegetable, cucurbit, group 9 at 0.3 ppm.

V. Conclusion

Therefore, tolerances are established for residues of cyflumetofen: (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), including its metabolites and degradates, in or on berry, low growing, subgroup 13–07G at 0.6 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.6 ppm; and vegetable, cucurbit, group 9 at 0.3 ppm. EPA is removing the established tolerances for strawberry at 0.6 ppm; grape at 0.60 ppm; and cucumber at 0.3 ppm as unnecessary upon the establishment of the new tolerances.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 6, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.677, amend table 1 to paragraph (a) by:

■ a. Adding in alphabetical order an entry for ''Berry, low growing, subgroup 13–07G'';

■ b. Removing the entry for ''Cucumber'';

■ c. Adding in alphabetical order an entry for ''Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F'';

■ d. Removing the entries for ''Grape'' and ''Strawberry''; and

■ e. Adding in alphabetical order an entry for ''Vegetable, cucurbit, group 9''.

The additions read as follows:

§ 180.677 Cyflumetofen; tolerance for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Berry, low growing, subgroup 13–07G	0.6
* * * * *	
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.6
* * * * *	
Vegetable, cucurbit, group 9	0.3

* * * * *

[FR Doc. 2024–10187 Filed 5–9–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1356

RIN 0970–AC89

Foster Care Legal Representation

AGENCY: Children's Bureau (CB), Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This rule allows title IV–E agencies to claim Federal financial participation (FFP) for the administrative costs of: legal representation in foster care proceedings provided by an attorney representing the title IV–E agency or any other public agency (including an Indian tribe) which has an agreement in effect under which the other agency has placement and care responsibility of a title IV–E eligible child; independent legal representation provided by an attorney representing a child in title IV–E foster care, a child who is a candidate for title IV–E foster care (hereafter, referred to as a child ''who is eligible for title IV–E foster care''), the child's parent(s), the child's relative caregiver(s), and the child's Indian custodian(s) in foster care and other civil legal proceedings as necessary to carry out the requirements in the title IV–E agency's title IV–E foster care plan; and legal representation provided by an attorney representing an Indian child's tribe, or representation of an Indian child's tribe provided by a non-attorney, when the child's tribe participates or intervenes in any state court proceeding for the foster care placement or termination of parental rights (TPR) of an Indian child who is in title IV–E foster care or an Indian child who is a candidate for title IV–E foster care.

DATES: This rule is effective on July 9, 2024.

FOR FURTHER INFORMATION CONTACT: Joe Bock, Children's Bureau, (202) 205–8618. Telecommunications Relay users may dial 711 first. Email inquiries to *cbcomments@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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I. Statutory Authority

Section 474(a)(3) of the Social Security Act (the Act) authorizes Federal reimbursement for title IV–E foster care program administrative costs, which are defined as costs ''found necessary by the Secretary for the provision of child placement services and for the proper and efficient administration of the State [title IV–E] plan.'' This authorization applies to an Indian tribe, tribal organization, or tribal consortium that has an approved title IV–E plan, in the same manner as it applies to states.

This rule is published under the authority granted to the Secretary of Health and Human Services (the Secretary) by section 1102 of the Act, 42 U.S.C. 1302. Section 1102 of the Act authorizes the Secretary to publish regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under the Act.

II. Background

Many families that come to the attention of a child welfare agency are in the midst of or recovering from familial, health, housing, or economic challenges or crises. These obstacles can impede a family's ability to provide a safe and stable environment for their children.[1] Addressing these obstacles to restore a family's stability and safety and prevent a child from being removed from their home is critical to a child's well-being. This is because removal, even for a short period of time, exposes the child to a range of trauma and stress.[2] A child who is at risk of entering foster care has better outcomes when they remain safely at home compared to when they are placed into foster care.[3] Access to independent legal representation can help stabilize families, improve safety, and reduce the need for more formal child welfare system involvement, including foster care.[4] For families with children that have been placed in foster care, independent legal representation can expedite reunification and improve permanency or help provide access to needed supports for youth transitioning out of the child welfare system.[5]

HHS regulations at 45 CFR 1356.60(c) detail cost-sharing requirements for the Federal and non-Federal share of title IV–E foster care program expenditures for the cost of administrative activities. A title IV–E agency may claim FFP at the rate of 50 percent for allowable title IV–E foster care administrative costs. A title IV–E agency may also claim FFP for allowable administrative costs incurred by any other public agency or tribe which has an agreement in effect under which the other agency has placement and care responsibility of a title IV–E eligible child pursuant to 472(a)(2)(B)(ii) of the Act. Another ''public agency'' is a child placing agency authorized by state/tribal law to operate services to children and families, with supervision by the title IV–E agency (Child Welfare Policy Manual section (CWPM) 8.1G #1). Examples of other public agencies may be found in section G of the CWPM and could include the state/tribal juvenile justice agency, a court, or state/tribal mental health agency. The regulation at § 1356.60(c)(2) provides examples of allowable title IV–E foster care administrative expenditures that are necessary for the administration of the title IV–E agency's plan, such as preparation for and participation in judicial determinations, referral to services, development of the case plan, case reviews, and case management and supervision.

ACF policy historically allowed title IV–E agencies to claim FFP for the foster care administrative costs of ''preparation for and participation in judicial determinations'' as described in § 1356.60(c)(2)(ii), only for the title IV–E agency's (and if applicable, the Indian tribe or other public agency's) legal representation. However, in 2019, ACF revised the policy to allow title IV–E agencies to also claim FFP for the administrative costs of independent

[1] Chandler CE, Austin AE, Shanahan ME. Association of Housing Stress With Child Maltreatment: A Systematic Review. Trauma Violence Abuse. 2022 Apr;23(2):639–659. doi: 10.1177/1524838020939136. Epub 2020 Jul 17. PMID: 32677550; PMCID: PMC7855012; ACYF–CB–IM–21–02, p.2; ACYF–CB–IM–21–06 p. 12.

[2] Sankaran, Vivek. ''Using Preventive Legal Advocacy to Keep Children from Entering Foster Care.'' Wm. Mitchell L. Rev. 40, (3): 1036–1047, 2014.

[3] Joseph J. Doyle, Jr. ''Causal Effects of Foster Care: An Instrumental Variables Approach.'' Children and Youth Services Review 35(7): 1143–1151, 2013.

[4] Sankaran, Vivek. ''Using Preventive Legal Advocacy to Keep Children from Entering Foster Care.'' Wm. Mitchell L. Rev. 40, (3): 1036–1047, 2014.

[5] Gerber, Lucas A., Pang, Yuk C., Ross, Timothy, Guggenheim, Martin, Pecora, Peter J., & Miller, Joel. ''Effects of an interdisciplinary approach to parental representation in child welfare,'' Children and Youth Services Review, Volume 102, 2019, Pages 42–55, ISSN 0190–7409, *https://doi.org/10.1016/j.childyouth.2019.04.022;* American Bar Association Center on Children and the Law & National Council of Juvenile and Family Court Judges. Supporting Early Legal Advocacy before Court Involvement in Child Welfare Cases (March 2021).

legal representation provided by attorneys representing children who are candidates for title IV–E foster care, children who are in title IV–E foster care, and the children's parent(s) in all stages of foster care legal proceedings (CWPM 8.1B #30, 31, and 32). This policy was revised to ensure that reasonable efforts are made to prevent removal and finalize the permanency plan; and parents and youth are engaged in and complying with case plans. This policy change was well received and generated positive interest from title IV–E agencies and child welfare and legal partners. A ''candidate'' for title IV–E foster care is a child who is potentially eligible for title IV–E foster care maintenance payments and is at serious risk of removal from their home as evidenced by the title IV–E agency either pursuing the child's removal from the home or making reasonable efforts to prevent such removal (section 472(i) of the Act). Further, the agency must document the child's candidacy for title IV–E foster care maintenance payments through one of the three acceptable methods identified in the CWPM, such as a case plan (CWPM 8.1D #2), which we further explain in section IV of this final rule. A child is not considered a candidate for title IV–E foster care when the title IV–E agency has no formal involvement with the child or simply because the child has been described as ''at risk'' due to circumstances such as social or interpersonal problems or a dysfunctional home environment (CWPM 8.1D).

ACF published the September 2023 notice of proposed rulemaking (NPRM) proposing to codify and expand the policy in CWPM 8.1B #30, 31, and 32 (88 FR 66769, Sept. 28, 2023). Recent research, as described in the September 2023 NPRM, demonstrates that providing independent legal representation early in foster care proceedings and other civil legal proceedings can help prevent children from entering foster care, and for youth already in foster care it can improve the rate of reunification and result in more permanent outcomes for the child and the family. The NPRM proposed that providing independent legal representation to a child who is a candidate for or in title IV–E foster care, their parent(s), and their relative caregiver(s), to prepare for and participate in civil legal proceedings is an allowable administrative cost when necessary to carry out the requirements in the agency's title IV–E foster care plan in accordance with section 471(a) of the Act.

For Indian children that have been placed in foster care and are subject to the Indian Child Welfare Act (ICWA), and their families, early representation of an Indian child's tribe in foster care proceedings promotes stability for the child by minimizing unnecessary separation of children and their parents, maximizing placements of the child with extended family and other preferred placements, and avoiding unintended consequences adverse to a child's interests, such as loss of tribal membership and benefits.[6] ICWA was passed by Congress in 1978 to address the long history of failing ''to recognize the essential tribal relations of Indian people and the cultural and social standards prevailing in Indian communities and families'' (25 U.S.C. 1901(5)). ICWA protects the ''best interests of Indian children and promotes the stability and security of Indian tribes and families by the establishment of minimum federal standards for the removal of Indian children from their families and the placement of such children in foster or adoptive homes which will reflect the unique values of Indian culture, and by providing for assistance to Indian tribes in the operation of child and family service programs'' (25 U.S.C. 1902).[7]

As one tribal leader told Congress, tribes cannot long survive as ''self-governing'' communities if they cannot pass their ''heritage'' on to the next generation. *Holyfield* at 34 (citation omitted). Congress thus recognized that, by severing that connection to future generations, the breakup of Indian families threatens ''the continued existence and integrity of Indian tribes.'' 25 U.S.C. 1901(3). The Federal Government has an interest in ensuring that Indian tribes, vested with a statutory right to intervene in state foster care placement proceedings in accordance with 25 U.S.C. 1911(c), have legal representation to preserve and protect the continued existence and integrity of Indian tribes. As the Supreme Court noted in a case interpreting ICWA, ''Congress [ ] found that the breakup of Indian families harmed not only Indian children and their parents, but also their tribes.'' [8]

The information provided by the tribe's attorney provides the cultural and social standards of the child's tribe that are necessary for the court to make essential determinations that reasonable efforts were made as required under the title IV–E plan. For example, the Act requires the court to determine whether the agency made reasonable efforts to finalize a permanency plan. The tribal attorney's representation of the cultural and social standards for family connection, reunification and what permanency looks like in the child's tribe, may be necessary to finalize the permanency plan for an Indian child. For another example, if adoption is the permanency plan for an Indian child, the tribal attorney can provide information on customary adoption, which ensures ''the same stability and permanence of traditional adoption without terminating parental rights.'' [9]

This final rule supports the goal of tribal self-governance by supporting Indian families, both by minimizing unnecessary separations of Indian children from their parents and by maximizing their placement with extended family, other tribal members, or other tribal families when they cannot remain with their parents.

Equity Impact

This final rule advances the Administration's priority of equity for those historically underserved and adversely affected by persistent poverty and inequality (Executive Order 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* [Jan. 20, 2021]). Research documents the overrepresentation of certain racial and ethnic groups in foster care relative to their representation in the general population. African American and American Indian or Alaska Native children are at greater risk than other children of being placed in out-of-home care. They stay in foster care longer and have disparate outcomes. For example, they are less likely to reunify with their families.[10]

[6] Frequently Asked Questions Bureau of Indian Affairs Final Rule: Indian Child Welfare Act (ICWA) Proceedings, June 17, 2016; ICWA Compliance Task Force Report to the California Attorney General's Bureau of Children's Justice, 2017.

[7] ICWA and its implementing regulations define ''Indian child,'' to mean any unmarried person who is under age eighteen and is either a member of an Indian tribe or is eligible for membership in an Indian tribe and is the biological child of a member of an Indian tribe (25 U.S.C. 1903(4)). An ''Indian child's tribe'' means the Indian tribe in which an Indian child is a member or eligible for membership or, in the case of an Indian child who is a member of or eligible for membership in more than one tribe, the Indian tribe with which the Indian child has the more significant contacts (25 U.S.C. 1903(5)). An ''Indian custodian'' means any Indian person who has legal custody of an Indian child under tribal law or custom or under State law or to whom temporary physical care, custody, and control has been transferred by the parent of such child (25 U.S.C.1903(6)).

[8] *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30 at 33–34 (1989).

[9] *Del Norte Cnty. Dep't of Health & Human Servs.* v. *Dylan N.* (In Re H.R.), 208 Cal. App 4th 751 (2012).

[10] Child Welfare Information Gateway (2021). Child welfare practice to address racial disproportionality and disparity. U.S. Department

Continued

Access to legal representation for an Indian child's tribe promotes equity for those historically and adversely affected by inequality by minimizing unnecessary separation of children and their parents, and by maximizing placements of the child with extended family, within the tribal community, and other preferred placements. Research also documents the overrepresentation of children and parents with disabilities in foster care relative to their representation in the general population. Parents with disabilities are more likely than nondisabled parents to have child welfare system involvement. Children with disabilities are institutionalized at higher rates and for longer periods of time. Children of parents with disabilities have higher out-of-home placements than other children. Studies have also found disabled parents have high rates of termination of parental rights (TPR).[11]

Access to independent legal representation early in a case may prevent children from entering foster care, including children of color, American Indian or Alaska Native children and children with disabilities who are disproportionately entering foster care. For children in foster care, it may increase the rate of reunification and provide a quicker timeframe for achieving permanency. For young adults aging out of foster care, such legal representation may provide access to services and supports needed to achieve permanency and long-term stability.

This final rule may also help low-income families adversely affected by persistent poverty who are struggling with unemployment, inadequate income, unstable housing, evictions or homelessness, and food insecurity when confronted with potential removal of a child from the home, or when a relative is caring for a child in their home. According to a 2017 study, 74 percent of low-income households experienced at least one civil legal problem in the previous year, including problems with health care, housing conditions, disability access, veterans' benefits, and domestic violence.[12] Of the low-income households reporting civil legal problems, 92 percent received inadequate or no legal help.[13] Studies also show that when a child is removed from the home, having access to legal representation not only for child welfare proceedings but also for other civil legal issues earlier in a case can improve the rate of reunification, halve the amount of time needed to secure legal guardianship or adoption, and result in more permanent outcomes for the child and the family.[14] That means that parents without independent legal representation in child welfare proceedings and in other civil legal proceedings are at a disadvantage in having their children returned to them. Therefore, providing families adversely affected by poverty with independent legal representation in foster care and other civil legal proceedings necessary to carry out the requirements in the agency's title IV–E foster care plan may improve outcomes related to reunification and permanency.

III. Overview of September 2023 NPRM Comments

We received 122 comments in response to the September 2023 NPRM. We reviewed and analyzed the public comments and considered them in finalizing this rule. The comments are available in the docket for this action on *Regulations.gov*. We received comments from four title IV–E child welfare agencies; 17 state and local government agencies; four American Indian/Native American tribes, tribal consortia, tribal organizations (''tribes'') and entities representing tribal interests; 31 national advocacy, public interest, philanthropic and professional organizations (organizations); 26 providers of legal representation; and 40 individuals and anonymous commenters.

General Comments in Support of the September 2023 NPRM

Summary of Comments on the Benefits of the Final Rule. Of the 122 comments received, 106 commenters supported issuing a final rule with some suggestions and/or clarifications. All of the title IV–E agencies, tribes and organizations representing tribal interests, providers of legal representation, and state and local government agencies that commented supported issuing a final rule. All but three of the organizations and most individual and anonymous commenters also supported issuing a final rule. We address suggestions and clarifications in section IV of this final rule. Overwhelmingly, commenters agreed that the rule as proposed would:

- Minimize barriers to access the support families need to prevent children from entering foster care.[15]
- For children who are in foster care, expedite permanency.[16]
- Support Indian families, both by minimizing unnecessary separations of Indian children from their parents and by maximizing their placement with extended family, other tribal members, or other tribal families when they cannot remain with their parents.

Comments About the Equity Impact of the Rule. Many commenters expressed that the proposal would advance equity for those historically underserved and adversely affected by persistent poverty and inequality. They noted that legal representation in civil proceedings: is critical to achieve equity; protects the rights of families and prevents inequities; promotes equity for LGBTQI+ youth who are overrepresented within the foster care system; and advances equity for parents, children, and families in diverse and historically underserved, disadvantaged, and marginalized identities.

Comments Not in Support of the September 2023 NPRM

Sixteen commenters opposed issuing a final rule. Thirteen individuals opposed issuing a final rule citing negative personal experiences with appointed attorneys, such as receiving ineffective or low-quality legal representation, conflicts of interests among attorneys representing other parties, and insufficient oversight or auditing of cases to ensure attorneys are handling family legal matters properly. Several individuals expressed the view that the purpose of this rule is to financially benefit attorneys. Three organizations opposed issuing a final rule cited to systemic issues with child welfare and family court systems, distrust of appointed attorneys, and lack of attorney oversight by the state.

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of Health and Human Services, Administration for Children and Families, Children's Bureau. *https://www.childwelfare.gov/pubs/issue-briefs/racialdisproportionality/*.

[11] Albert SM, Powell RM. Supporting disabled parents and their families: perspectives and recommendations from parents, attorneys, and child welfare professionals. J Public Child Welf. 2020;15(5):529. doi: 10.1080/15548732.2020.1751771. PMID: 37220548; PMCID: PMC10202498.

[12] Legal Services Corporation. 2022. The Justice Gap: The Unmet Civil Legal Needs of Low-income Americans. Prepared by Mary C. *https://justicegap.lsc.gov/*.

[13] Id.

[14] Thornton, Elizabeth, & Gwin, Betsy. *High-Quality Legal Representation for Parents in Child Welfare Cases Results in Improved Outcomes for Families and Potential Cost Savings.* 46 Fam. L. Q. 139 (2012).

[15] Sankaran, Vivek. ''Using Preventive Legal Advocacy to Keep Children from Entering Foster Care.'' Wm. Mitchell L. Rev. 40, (3): 1036–1047, 2014.

[16] American Bar Association Center on Children and the Law & National Council of Juvenile and Family Court Judges. Supporting Early Legal Advocacy before Court Involvement in Child Welfare Cases (March 2021).

Comments Outside the Scope of the Regulation

We received several comments outside the scope of this regulation, and therefore, we are not addressing those comments here. Some of these comments included requiring the final rule to endorse models of legal representation and include models for effective contracting and agency oversight of contracting and billing with legal providers. Commenters also recommended that the rule address cost-allocation requirements, which are governed by 45 CFR parts 75 and 95. Finally, some commenters suggested that the final rule require training to ensure quality legal representation by attorneys. This is outside the scope of this rule, which is optional for title IV–E agencies, and which does not govern requirements for attorney behavior, but rather provides requirements claiming FFP for administrative costs. However, as we stated in ACYF–CB–IM–21–06, we urge all state and tribal title IV–E agencies, courts, administrative offices of the courts, and Court Improvement Programs to work together to ensure that parents, children and youth, and child welfare agencies, receive high quality legal representation at all stages of child welfare proceedings, and to claim FFP for allowable training costs authorized under section 474(a)(3)(B) of the Act.

Changes to the Final Rule

We made the following changes to the final rule which are further explained in Section-by-Section Response to Comments:

- Title IV–E agencies may claim FFP for the administrative costs of independent legal representation for Indian custodian(s) in foster care and other civil legal proceedings (§ 1356.60(c)(4)(ii)).
- Title IV–E agencies may claim the administrative cost of an attorney or non-attorney representing an Indian child's tribe when the child's tribe participates or intervenes in any state court proceeding for the foster care placement or (TPR) of an Indian child who is in title IV–E foster care or an Indian child who is a candidate for title IV–E foster care (§ 1356.60(c)(4)(iii)).

IV. Section-by-Section Responses to Comments

We respond to the comments we received on the September 2023 NPRM in this section-by-section discussion.

Section 1356.60(c)(2)(xi)

Paragraph (c)(2)(xi) of the final rule references new paragraph (c)(4) and now reads: ''Costs related to legal representation described in paragraph (c)(4) of this section.''

Comment: One commenter suggested we add the word ''civil'' so that paragraph (c)(2)(xi) reads: ''Costs related to *civil* legal representation described in paragraph (c)(4) of this section.''

Response: We did not make this change to the final rule. Paragraph (c)(2)(xi) explains that the costs that are allowable include both *foster care legal proceedings and* other civil legal proceedings.

Section 1356.60(c)(4)

Paragraph (c)(4) identifies allowable administrative costs of legal representation. Although some legal representation costs might be coverable under paragraph (c)(2)(ii) that allows a title IV–E agency to claim IV–E administrative funding for the costs of ''preparation for and participation in judicial determinations,'' new paragraph (c)(4) codifies and expands the list of allowable activities. New paragraph (c)(4) does not include the costs of agency caseworkers preparing for and participating in hearings, which are clearly within the scope of paragraph (c)(2)(ii), and so does not displace paragraph (c)(2)(ii).

Comment: Several comments from national organizations, legal providers, tribes and tribal organizations requested that the final rule explicitly incorporate the examples of allowable activities of professionals that support an attorney providing independent legal representation to prepare for and participate in foster care legal proceedings including paralegals, investigators, peer partners or social workers as identified in CWPM 8.1B #32 and the preamble of the September 2023 NPRM, as well as other professionals.

Response: We confirm that a title IV–E agency may claim title IV–E administrative costs for activities to the extent that they are necessary to support an attorney in providing independent legal representation. However, we decline to change the regulatory text because it is not possible to list all of the activities that may be claimed. We encourage title IV–E agencies to contact CB regional offices for assistance.

Comment: A few commenters requested that the final rule compel state and local child welfare agencies to access title IV–E FFP for the administrative cost of independent legal representation and to fund every eligible provider of legal representation.

Response: We did not make this change to the final rule. As we explained in the September 2023 NPRM, title IV–E does not provide authority to require agencies to provide legal representation. This rule gives title IV–E agencies the flexibility to choose whether to claim FFP for allowable administrative costs of legal representation. This is because title IV–E agencies determine the allowable costs necessary to administer the title IV–E foster care program.

Comment: A few organizations and providers of legal representation suggested that ACF allow other public agencies, organizations, and individuals to access title IV–E funds directly from the Federal Government.

Response: This is not permitted by Federal law and therefore we did not make this change to the final rule. Title IV–E of the Act authorizes only state and tribal title IV–E agencies with an approved title IV–E foster care plan to claim FFP. However, title IV–E agencies may contract with public and private entities to perform administrative functions of the title IV–E foster care program. See CWPM 8.1E and G for more information.

Section 1356.60(c)(4)(i)

Section 1356.60(c)(4)(i) clarifies that a title IV–E agency may claim administrative costs for legal representation by an attorney representing the title IV–E agency or any other public agency, such as a tribe, that has an agreement with the title IV–E agency for placement and care responsibility of a title IV–E eligible child under section 472(a)(2)(B)(ii) of the Act in foster care proceedings.

Comment: Commenters noted that although the preamble to the September 2023 NPRM referred to ''any other public agency or tribe,'' the proposed regulatory text did not include the words ''or tribe.'' Commenters requested that ACF include tribes in the regulatory text.

Response: We agree with commenters, and accordingly have revised the regulation text to include tribes in order to clarify that a tribe may operate as the ''other public agency'' if it has an agreement with the state under section 472(a)(2)(B)(ii) of the Act. This revision to the regulation text does not change its meaning.

Comment: Many commenters requested that ACF clarify the meaning of ''an agreement in effect under which the other agency has placement and care responsibility of a title IV–E eligible child pursuant to 472(a)(2)(B)(ii) of the Act'' as it applies to tribes.

Response: Under this paragraph, a title IV–E agency may claim the FFP for the allowable administrative cost of an attorney providing legal representation of an Indian tribe in foster care legal proceedings only if the Indian tribe has

an agreement under which it takes placement and care responsibility of title IV–E eligible children in foster care and is operating all or part of the title IV–E program on behalf of the title IV–E agency (section 472(a)(2)(B) of the Act). More information on this topic can be found in CWPM 8.1G. We decline the recommendation to change the final regulatory text.

Section 1356.60(c)(4)(ii)

Section 1356.60(c)(4)(ii) permits a title IV–E agency to claim FFP for the administrative costs of independent legal representation provided by an attorney representing a child in title IV–E foster care, a child who is a candidate for title IV–E foster care, the child's parent(s), the child's relative caregiver(s), and the child's Indian custodian(s) in foster care and other civil legal proceedings as necessary to carry out the requirements in the agency's title IV–E foster care plan. Independent legal representation in civil proceedings includes facilitating, arranging, brokering, advocating, or otherwise linking clients with providers and services as identified in the child's case plan pursuant to sections 422, 471(a)(16), and 475 of the Act.

Comment: Several title IV–E agencies and tribal organizations requested that the final rule add ''Indian custodian'' to the list of individuals for whom a title IV–E agency may claim FFP for the administrative costs of independent legal representation in foster care and other civil legal proceedings. This is because ICWA uses the term ''Indian custodian'' to describe Indian persons who have legal custody of a child under tribal law or custom or to whom temporary physical care, custody and control has been transferred by the parent of such child (25 U.S.C. 1903(6); 25 CFR 23.2). As one state commented, the term ''Indian custodian'' may be more ''akin to a parent'' but is not encompassed in the title IV–E definition of parent.[17] The NPRM explained that under title IV–E of the Act, the term ''parent(s)'' means a biological or adoptive parent(s) or legal guardian(s), as determined by applicable state or tribal law (section 475(2) of the Act). Commenters also noted that the ICWA protections that apply to Indian parents generally also apply to Indian custodians. Another commenter indicated that an Indian custodian may align with being a relative caregiver, but not in all instances.

Response: We agree with commenters that it is important for Indian custodians to have equitable access to legal representation, and therefore changed the final rule to include Indian custodians so that title IV–E agencies have the option to claim FFP for independent legal representation of Indian custodians.

As we describe in section II, the Federal Government has an obligation to support the integrity of Indian tribes by minimizing unnecessary separations of Indian children from their parents and by maximizing their placement with extended family, other tribal members, or other tribal families when they cannot remain with their parents (25 U.S.C. 1901(3)). Title IV–E of the Act requires title IV–E agencies to make reasonable efforts to preserve and reunify families (42 U.S.C. 671(a)(15)(B) and (C)). This includes ensuring that Indian children remain with Indian custodians and reducing the need for more formal child welfare system involvement. Providing legal representation to Indian custodians of children in title IV–E foster care may minimize some of the barriers that prevent a child from being placed with an Indian custodian, enable more children to maintain family and tribal connections, stabilize placements and result in more permanent outcomes for the child and the family. Further, Indian custodians often have information essential to helping courts and title IV–E agencies preserve Indian families in the context of the long history of child custody proceedings ''often fail[ing] to recognize the essential tribal relations of Indian people and the cultural and social standards prevailing in Indian communities and families'' (25 U.S.C. 1901(5)).

Comment: Over 55 commenters from organizations and legal providers expressed concern about ''independent legal representation'' as described in the preamble. Some commenters interpreted the NPRM as proposing to allow the title IV–E agency to regulate the practice of law in a way that may be inconsistent with state statutes; court rules; and policies or guidelines of entities regulating attorney practice, including the entity's ethical opinions and rules of professional responsibility. Other commenters thought the NPRM appeared to require the attorney to explain to the client that the title IV–E agency may be paying for the cost of legal representation and to ask the client for their consent. Commenters believe this does not align with how legal aid and public defender offices are funded and would be difficult to implement if an attorney was not aware of the source of funding for the legal representation.

Response: The NPRM proposed that the title IV–E agency may determine what ''independent'' means for the purpose of identifying allowable administrative costs for which a title IV–E agency may claim FFP. Neither the NPRM nor this final rule suggest interpreting the term ''independent'' in a way that attempts to regulate attorneys or the practice of law. ACF has no authority in that area nor does the title IV–E agency, and therefore no changes were made to the final rule. To clarify, for purposes of the final rule, the term ''independent'' conveys that representation is not subject to control or influence by other parties, interested persons, nor the title IV–E agency.

The NPRM also suggested, but did not regulate, some minimum expectations for title IV–E agencies to consider when determining what ''independent'' should mean. For example, the NPRM suggested that agencies ensure the attorney providing legal representation does not have any concurrent conflicts of interest and that there is no interference with the lawyer's professional judgement or relationship with the client. It also suggested, but did not require, that the term ''independent'' mean that an attorney does not accept compensation for representing a client from *someone* other than the client, unless the client gives informed consent.

Comment: Several commenters requested guidance on the amount and type of information that an attorney providing independent legal representation must share with the title IV–E agency to satisfy Federal audit, data, and claims reporting requirements. For example, a title IV–E agency explained that it needs to know the number and names of individuals receiving independent legal representation to ensure eligibility under this final rule. However, a few providers of legal representation expressed concern that a title IV–E agency may ask for too much information as a means to exert undue influence or direct such representation.

Response: We made no changes to the final rule. We would like to clarify that a title IV–E agency should, at a minimum, ensure a legal service provider shares information that is necessary for the title IV–E agency to comply with Federal program requirements and requirements for audits, data and financial reporting as determined necessary by the Secretary (section 471(a)(6) and (13) of the Act). See also 45 CFR part 75 (Unform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards); 45 CFR part 95, subpart E (Cost Allocation Plans). For example, this may include, but is not limited to information the title IV–E agency must report in the Form CB–496 ''Title IV–E

Programs Quarterly Financial Report (Foster Care, Adoption Assistance, Guardianship Assistance, Prevention Services and Kinship Navigator Programs). Title IV–E agencies seeking guidance on allowable claiming practices for FFP should contact their CB regional office.

Comment: Many commenters asked ACF to adopt the definition of ''candidate for title IV–E foster care'' as used in section 475(13) of the Act, to allow title IV–E agencies to claim FFP for the cost of legal representation for children and families who participate in the title IV–E prevention service program.

Response: We made no changes to the final rule. Section 475(13) of the Act defines a candidate for foster care for the title IV–E Prevention Program under section 474(a)(6)(B)(i) of the Act. This is a different definition than a title IV–E foster care candidate under this final rule. Further, this final rule and the September 2023 NPRM proposed allowable administrative costs for legal representation under the title IV–E foster care program as authorized under section 474(a)(3) of the Act. Therefore, administrative costs for legal representation under the title IV–E prevention services program is outside the scope of this final rule.

Comment: Several commenters requested we clarify whether the final rule allows title IV–E agencies to claim FFP for the cost of independent legal representation to resolve a child's or parent's immigration status, including proceedings related to obtaining Special Immigrant Juvenile status, and address other immigration-related barriers that may inhibit successful permanency. Another commenter asked whether a title IV–E agency can claim FFP for the cost of independent legal representation to meet the needs of undocumented caregivers/parents in obtaining relief from deportation, noting that thousands of children have entered the child welfare system because of a parent's deportation.

Response: We understand that immigration issues may lead to foster care placements and could pose barriers to successful reunification, placement, or permanency of a child in foster care. However, a child must be a U.S. citizen or ''qualified immigrant'' as defined in 8 U.S.C.1641(b),[18] among other requirements, to be eligible for title IV–E foster care (Personal Responsibility Work Opportunity Reconciliation Act of 1996 (Public Law 104–193); 8 U.S.C. 1611; CWPM 8.4B). A title IV–E agency may claim independent legal representation for title IV–E eligible children in any proceeding consistent with the requirements of this rule. However, a title IV–E agency may not claim FFP for the administrative cost of independent legal representation of children who are not U.S. citizens or qualified immigrants. A title IV–E agency may claim representation costs for parents of a title IV–E eligible child if such representation is needed to carry out the requirements in the agency's title IV–E foster care plan in relation to the title IV–E eligible child.

Comment: A few commenters expressed concern about potential conflicts that may arise if a title IV–E agency claims FFP for independent legal representation of an eligible child's relative caregiver. Some commenters recommended that we limit reimbursement available under title IV–E for relative caregivers to minimize the potential for a conflict between parents and relative caregivers noting specific concerns about relative caregiver representation in cases involving substance use disorders and also in Indian child welfare cases.

Response: While we appreciate the complex and potentially adverse interests of individuals involved in a child's care, the title IV–E agency may choose whether and what type of independent legal representation to claim FFP for, as described in the final rule. To provide title IV–E agencies with flexibility, we decline to revise the regulatory text. As explained in this final rule and the September 2023 NPRM, we expect that attorneys providing legal representation do not have any concurrent conflicts of interest and that there is no interference with the lawyer's professional judgement or relationship with the client. We expect that attorneys will practice law in a way that is consistent with state statutes; court rules; and the requirements of entities regulating attorney practice, including the entity's ethical opinions and rules of professional responsibility.

Comment: A commenter requested we amend ''civil legal proceedings'' to include ''administrative actions'' necessary to carry out the requirements in the agency's title IV–E foster care plan, because some civil legal issues involve proceedings which are deemed administrative rather than judicial in nature. Specifically, a few commenters asked whether a title IV–E agency may claim the cost of independent legal representation by an attorney in administrative actions for public benefit eligibility determinations, denials and appeals.

Response: In the September 2023 NPRM, we identified allowable civil legal costs to include ''securing public benefits when it is necessary to meet the plan requirement to make reasonable efforts to prevent the unnecessary removal of a child from the home or to finalize a case plan in support of a child's permanency goal as required by section 471(a)(15) of the Act.'' This may include certain public benefit eligibility determinations, denials and appeals that are administrative in nature, and they are considered civil legal proceedings for purposes of this rule. We are maintaining these provisions in this final rule, and as such decline to change the regulatory text.

Comment: Some legal representation providers and organizations made comments indicating a belief that a case plan is the only way to document a child's candidacy for title IV–E foster care, and that a case plan may only be developed after a child enters foster care, thereby preventing the agency from claiming FFP for independent legal representation of a child who is not yet in title IV–E foster care.

Response: A case plan is one of several ways a title IV–E agency may document a child's candidacy for title IV–E foster care and may be developed prior to a child entering foster care. The CWPM 8.1D #2 explains that there are three acceptable methods for documenting candidacy: (1) A defined case plan which clearly indicates that, absent effective preventive services, foster care is the planned arrangement for the child; (2) An eligibility determination form which has been completed to establish the child's eligibility for title IV–E foster care maintenance payments; or (3) Evidence of court proceedings in relation to the removal of the child from the home, in the form of a petition to the court, a court order or a transcript of the court proceedings. This policy provides additional guidance that for purposes of documenting a child's candidacy for title IV–E foster care, a case plan sets foster care as the goal for the child absent effective preventive services is an indication that the child is at serious risk of removal from their home because the title IV–E agency believes that a plan of action is needed to prevent that removal.

Comment: Over 50 organizations and legal providers asked whether a title IV–E agency may claim FFP for independent legal representation for either a child, parent or relative in various scenarios, including: prior to a petition being filed in court to remove a child from home, during the course of a CPS investigation, from the time a petition to remove a child from home is filed through the entire trajectory of the

[18] 8 U.S.C. 1641(b) refers to ''qualified alien.''

case (including appeals), and for youth in extended foster care.

Response: We do not have enough information to be able to provide a definitive answer about the availability for FFP for independent legal representation in case specific scenarios. The allowability of the cost of independent legal representation is not determined based on the status of a petition to remove a child from home or a CPS investigation. A title IV–E agency may choose to claim FFP for allowable administrative costs of independent legal representation as authorized in this rule if:

- A title IV–E agency determined that the child is a candidate for or in title IV–E foster care (or is the parent, relative, or Indian custodian of such child);
- The independent legal representation is provided in a foster care or other civil legal proceeding;
- The title IV–E agency determined that independent legal representation is necessary to carry out the requirements in the agency's title IV–E foster care plan; and
- The independent legal representation in civil legal proceedings is identified in the child's case plan.

Current policy in CWPM 8.1D #2 provides further details about a child who is a candidate for title IV–E foster care that may be useful to these commenters asking about situations where children have not yet been placed in foster care. Specifically, policy clarifies that ''a child may not be considered a candidate for [title IV–E] foster care solely because the title IV–E agency is involved with the child and his/her family. For the child to be considered a candidate for [title IV–E] foster care, the title IV–E agency's involvement with the child and family must be for the specific purpose of either removing the child from the home or satisfying the reasonable efforts requirement with regard to preventing removal.'' The policy also explains decisions made by the U.S. Department of Health and Human Services Department Appeals Board (DAB): ''The fact that a child is the subject of [a child abuse/neglect report] falls far short of establishing that the child is at serious risk of placement in foster care and thus of becoming eligible for IV–E assistance . . . A candidate, in the opinion of the DAB is a child who is at serious risk of removal from his/her home because the title IV–E agency is either pursuing that removal or attempting to prevent it. A child cannot be considered a candidate for foster care when the title IV–E agency has no formal involvement with the child or simply because s/he has been described as 'at risk' due to circumstances such as social/interpersonal problems or a dysfunctional home environment.'' We recommend that if organizations and legal providers have questions about allowable costs for legal representation, they contact the title IV–E agency for more information. Title IV–E agencies may contact the CB regional office specialist for assistance.

Section 1356.60(c)(4)(iii)

Paragraph (c)(4)(iii) permits a title IV–E agency to claim FFP for administrative costs of legal representation provided by an attorney or representation provided by a non-attorney of a title IV–E eligible Indian child's tribe (as defined in 25 U.S.C. 1903(5)), when the child's tribe participates or intervenes in any state court proceeding for the foster care placement or TPR.

Comment: We received several comments on the proposal. A commenter noted that securing attorneys who are knowledgeable about ICWA and tribal customs can be very expensive. Comments indicated that smaller tribes may not have the funding resources to hire attorneys to represent the Indian child's tribe's interest in state court proceedings for the foster care placement of, or TPR to, an Indian child, and thus have historically allowed non-attorneys to represent the tribe. One commenter was supportive of the reimbursement of non-attorneys regardless of whether they are representing the tribe in a case or whether they are providing support to an attorney's preparation for and participation in a case. Another commenter noted that early representation of an Indian child's tribe in child welfare court proceedings can, among other things, facilitate placements in accordance with ICWA placement preference and believes that the expertise independent attorneys bring to foster care proceedings can be a determining factor in whether a family stays together, receives necessary services, or is timely reunified after family separation. Finally, a commenter expressed the view that allowing a tribe to select its own representative supports tribal sovereignty.

Response: We amended the final rule to allow a title IV–E agency to claim the administrative cost of an attorney providing legal representation or a non-attorney representing an Indian child's tribe when the child's tribe participates or intervenes in any state court proceeding for the foster care placement or TPR of an Indian child who is in title IV–E foster care or an Indian child who is a candidate for title IV–E foster care. ACF believes this change may: result in more Federal financial support for a title IV–E eligible Indian child's tribe's participation in state foster care and TPR proceedings, ensure that a tribe's interest is preserved in placement recommendations, and honor tribal sovereignty and self-determination to identify a representative per the tribe's wishes. We believe this change will result in minimal fiscal impact, if any, because the costs of a non-attorney representative will likely be less than for an attorney.

Comment: Several commenters encouraged ACF to allow title IV–E agencies to claim FFP for the administrative cost of representation for a title IV–E eligible Indian child's tribe in state proceedings for foster care placement and TPR even if a tribe does not intervene in accordance with 25 U.S.C. 1911(c). Prior to intervention, a tribe may be involved at key decision points in the child's case. Commenters explained that early in state proceedings for the foster care placement of an Indian child, the tribe's representative works with the child welfare agency and state court to address the needs of the child, their family and the child's tribe. One commenter expressed the view that limiting representation to situations where a tribe has intervened in a case restricts tribes' sovereign decisions with respect to the best interest of tribal children.

Response: We agree with the commenters and revised the final rule to allow a title IV–E agency to claim administrative costs for representation of a title IV–E eligible Indian child's tribe to participate in state court proceedings for foster care placement and termination of parental rights (TPR) when necessary for the proper and efficient administration of the IV–E foster care plan (42 U.S.C. 674(a)(3)). This modification means that a title IV–E agency may claim these administrative costs when the child's tribe participates but does not intervene in a state court proceeding for foster care placement and TPR in accordance with 25 U.S.C. 1911(c).

As explained in section II, the Federal Government has an interest in ensuring that an Indian child's tribe has legal representation to preserve and protect the continued existence and integrity of Indian tribes. As the Supreme Court noted in a case interpreting ICWA, ''Congress [ ] found that the breakup of Indian families harmed not only Indian children and their parents, but also their tribes.'' *Mississippi Band of Choctaw Indians* v. *Holyfield,* 490 U.S. 30 at 33–34 (1989). It is well documented that for Indian children who have been placed in foster care, and their families, early

representation of an Indian child's tribe in state foster care proceedings promotes stability for the child by minimizing unnecessary separation of children and their parents, and by maximizing placements of the child with extended family and other preferred placements (Frequently Asked Questions Bureau of Indian Affairs Final Rule: Indian Child Welfare Act (ICWA) Proceedings, June 17, 2016). As the commenters note, much of a tribe's representation occurs early in state court foster care proceedings without regard to whether a child's tribe intervenes.

However, the Department appreciates the opportunity to clarify that this change applies only when the title IV–E agency determines that representation for the Indian child's tribe to participate in the state court proceeding is necessary for the proper and efficient administration of the title IV–E foster care plan (42 U.S.C. 674(a)(3)). Prior to intervening, tribal attorneys or non-attorney representatives often participate in state court proceedings at key decision points and in judicial determinations that are required by the title IV–E foster care plan. For example, the Act requires the court to determine whether the agency made reasonable efforts to preserve and reunify families. The child's tribe's representation of the cultural and social standards for family connection, reunification and what permanency looks like in the child's tribe, may be necessary to finalize the permanency plan for an Indian child, regardless of whether the child's tribe has intervened.

We believe this change will not result in a fiscal impact. This is because the Adoption and Foster Care Analysis and Reporting System (AFCARS) data provides the number of title IV–E eligible children who identified as American Indian or Alaska Native, alone or in combination. In the September 2023 NPRM we assumed that this population of children is potentially subject to ICWA requirements in state court foster care placement and TPR. We further assumed that each such Indian child's tribe will intervene in such proceedings. Therefore, there will not be a fiscal impact regardless of whether an Indian child's tribe chooses to participate, rather than intervene, in the proceeding as allowed by this final rule.

Comment: Several commenters requested that a final rule ensure that tribal nations have authority to choose the attorney representing an Indian child's tribe in state court proceedings for the foster care placement of, or TPR to, an Indian child for which the title IV–E agency is claiming FFP. The commenters explained the importance of each sovereign tribal nation selecting an attorney to represent an Indian child's tribe who is knowledgeable about the tribe's customs, membership requirements and benefits, culture, placement preferences, social services and other family supports, and is highly skilled in matters related to ICWA.

Response: We did not make changes to the final rule. The final rule provides an option for a title IV–E agency to claim FFP for the cost of an attorney to represent a title IV–E eligible Indian child's tribe and does not require that the title IV–E agency select that attorney. As the commenters noted, it is important that each sovereign tribal nation make that selection. This ensures that the tribe is represented by an attorney who is knowledgeable about the tribe's customs and other matters relevant in state court proceedings. However, a title IV–E agency may decide whether to contract with the attorney selected by a tribal nation.

Comment: Commenters suggested that the final rule require consultation between state title IV–E agencies and tribes to develop agreements for legal representation that are compatible with tribal governance structures.

Response: We did not change the final rule because it is the option of the title IV–E agency to claim title IV–E FFP for administrative costs as described in this final rule. However, we encourage title IV–E agencies that choose to claim title IV–E FFP for the cost of legal representation as described in this final rule to consult with tribes that are interested in developing agreements for this purpose.

V. Regulatory Process Matters

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Based on ACF's estimates of the likely impacts associated with this rule, the Office of Management and Budget (OMB) designated this rule as a significant regulatory action under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. The estimated cost and transfer impacts of this final rule are provided below (see the section titled ''Accounting Statement'').

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (see 5 U.S.C. 605(b) as amended by the Small Business Regulatory Enforcement Fairness Act) requires Federal agencies to determine, to the extent feasible, a rule's impact on small entities, explore regulatory options for reducing any significant impact on a substantial number of such entities, and explain their regulatory approach. This rule does not affect small entities because it is applicable only to state and tribal title IV–E agencies. Therefore, a regulatory flexibility analysis is not required for this rule.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) was enacted to avoid imposing unfunded Federal mandates on state, local, and tribal governments, or on the private sector. That threshold level is currently approximately $183 million. This rule does not contain mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or on the private sector, in excess of the threshold.

Congressional Review

The Congressional Review Act (CRA) allows Congress to review major rules issued by Federal agencies before the rules take effect (*see* 5 U.S.C. 801(a)(1)(A)). The CRA defines a ''major rule'' as one that has resulted, or is likely to result, in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (*see* 5 U.S.C. Chapter 8). OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2).

Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 2000 requires Federal agencies to

determine whether a policy or regulation may negatively affect family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. This regulation does not impose requirements on states or families. This rule will not have any impact on the autonomy or integrity of the family as an institution.

Comment: We received one comment on ACF's assessment, expressing the view that when the ACF proposes a regulation and also conducts the assessment, the result is bias that leads to no detailed study taking place. The commenter requested that ACF conduct a study that ensures a more thorough examination of the potential effects of the proposed rule on families by soliciting input from a diverse range of stakeholders and considering the comments received, especially those emphasizing the impact on family dynamics.

Response: As described in the September 2023 NPRM and above, independent research and data from existing legal programs demonstrate the benefits of providing independent legal representation. Providing representation early in foster care proceedings and other civil legal proceedings can help prevent children from entering foster care, and for youth already in foster care it can improve the rate of reunification and result in more permanent outcomes for the child and the family. We received no additional comments from the public expressing this concern. ACF's Assessment of Federal Regulations on Policy and Family is reviewed by the Secretary of HHS as well as the President's Office of Management and Budget, Office of Information and Regulatory Affairs, which reviews all significant Federal regulations from executive agencies.

Executive Order 13132

Executive Order 13132 prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This rule does not have federalism impact as defined in the Executive order. Shortly after publication of the NPRM, we held a briefing session with states and tribes and any other interested partners on the contents of the NPRM.

Comment: One commenter asked ACF to conduct a thorough re-assessment of the application of Executive Order 13132 because the definition of ''independent legal representation'' should be determined within their respective jurisdictions, rather than being subjected to Federal discretion.

Response: The final rule does not have any federalism implications and thus a re-assessment is not necessary. As discussed earlier, the final rule does not include any mandates or impose a regulatory definition of ''independent legal representation''. Therefore, Executive Order 13132 does not apply.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (Pub. L. 104–13) seeks to minimize government-imposed burden from information collections on the public. In keeping with the notion that government information is a valuable asset, it also is intended to improve the practical utility, quality, and clarity of information collected, maintained, and disclosed.

The Paperwork Reduction Act defines ''information'' as any statement or estimate of fact or opinion, regardless of form or format, whether numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media (5 CFR 1320.3(h)). This includes requests for information to be sent to the government, such as forms, written reports and surveys, recordkeeping requirements, and third-party or public disclosures (5 CFR 1320.3(c)). There is no burden to the Federal Government or to title IV–E agencies as a result of this final regulation. It is optional for a title IV–E agency to claim administrative costs. If the agency elects to do so, there are no new reporting requirements because the agency will continue to make administrative cost claims through the Form CB–496.

Annualized Cost to the Federal Government

Total Projections to Implement Final Rule. The estimate for the final rule was derived using fiscal year (FY) 2019 data from the Adoption and Foster Care Analysis and Reporting System (AFCARS) on the number of title IV–E eligible children who identified as American Indian or Alaska Native, alone or in combination, and FY 2021 claiming data from the Form CB–496 ''Title IV–E Programs Quarterly Financial Report (Foster Care, Adoption Assistance, Guardianship Assistance, Prevention Services and Kinship Navigator Programs).'' We did not use FY 2020 or 2021 data from AFCARS because such data would likely reflect anomalies due to the COVID–19 public health emergency period.

ACF estimates that the Federal cost in the presence of the final rule over ten fiscal years (2024–2033) is estimated to be $2,936,285,160. The combined total for Federal and agency costs over ten fiscal years is estimated to be $5,872,570,319. (These estimates encompass all provisions being codified for the first time by this rule.) It is optional for a title IV–E agency to claim the administrative cost of providing independent legal representation in foster care and civil legal proceedings to eligible children, their parents, their relative caregivers, and their Indian custodians and for representation for an Indian child's tribe that participates or intervenes in state court proceedings for the foster care placement and TPR of an eligible child.

Assumptions: ACF made several assumptions when calculating the administrative costs for this final rule.

- FY 2021 title IV–E foster care administrative cost claims are used as the base year amounts for projection purposes in this final rule and were sourced from Form CB–496 FC part 1. These are actual claims, and not estimates. For the purposes of these burden estimates, we will use the phrase ''candidates'' to refer to the number of children claimed as title IV–E candidates and ''IV–E FC'' for children who are in title IV–E foster care, the two populations of children (and their parents, relative caregivers, and Indian custodians) to which the costs of this final rule apply.
- AFCARS data provides the number of title IV–E eligible children who identified as American Indian or Alaska Native, alone or in combination. In the September 2023 NPRM, we assumed that this population of children is potentially subject to ICWA requirements in state court proceedings for the foster care placement of, or TPR to, an Indian child. We further assumed that each such Indian child's tribe would intervene in state court proceedings for the foster care placement of, or TPR to, an Indian child. As described previously in this final rule, a child's tribe may choose to participate rather than intervene in state court proceedings.
- Title IV–E agencies may claim reimbursement for 50 percent of the administrative costs to provide legal representation in foster care proceedings, including those in which an Indian child's tribe has participated or intervened in state court proceedings for the foster care placement of, or TPR to, an Indian child, and civil

proceedings, and the title IV–E agency must pay its share with state or tribal funds. This non-Federal share will be an equal percentage of 50 percent because a title IV–E agency must match the same amount of funds for which it seeks Federal reimbursement.

- We assume an overall annual one percent caseload growth rate in the population of candidates for title IV–E foster care and IV–E FC for whom title IV–E administrative costs will be claimed in civil legal proceedings and in FC legal proceedings, including those in which an Indian child's tribe has participated or intervened in state court for the foster care placement of, or TPR to, an Indian child. This is based on current title IV–E budgetary projections.
- We assume an annual FFP claims growth factor of 4.7 percent for FY 2024 and 2.3 percent from FY 2025 to FY 2033 for the administrative costs of independent legal representation in FC and in other civil legal proceedings. This is based on current title IV–E budgetary projections of the percentage of change in title IV–E administrative cost claims annually. We assume the calculated FY 2021 title IV–E foster care administration eligibility rate for children classified as American Indian or Alaska Native, alone or in combination, will remain unchanged for the ten FY (FYs 2024–2033) project period.
- An implementation level is used in the calculations for the chart below as an estimated projection for the growth in the number of children (either directly or on behalf of a parent, relative caregiver, or Indian custodian) receiving independent legal representation in foster care legal proceedings or civil legal proceedings. Similarly, an implementation level is used in the calculations for the chart below as an estimated projection for the growth in the number of children whose tribe is receiving legal representation by an attorney, or representation by a non-attorney, in state foster care placement and TPR legal proceedings. The implementation level is different for the cost estimates for foster care legal proceedings and civil legal proceedings, and state court foster care placement legal proceedings in which an Indian child's tribe has participated or intervened as explained below:
  - For independent legal representation in foster care legal proceedings, the implementation level is measured separately for children who are candidates and IV–E FC. The base year (FY 2021) implementation levels are calculated from Form CB–496 FC part 1 which identifies for each title IV–E agency on a quarterly basis the average monthly number of children where independent legal representation for foster care proceedings is being provided for a candidate or IV–E FC. For FY 2021, the independent legal representation for foster care proceedings implementation level is 15.4 percent for IV–E FC and 7.9 percent for candidates. For FYs 2024–2033, the implementation levels are derived from the experience observed in the reported caseload data between FY 2020 and FY 2021 where a 24 percent growth rate occurred for children in title IV–E foster care. We assume that the growth rate will peak in this year and then gradually diminish as more title IV–E agencies take up the option to claim for these costs, and more children are receiving this representation.
  - For legal representation by an Indian child's tribe in state court proceedings for the foster care placement of, or TPR to, an Indian child, a single implementation level is measured for children who are candidates and in IV–E FC. The base year (FY 2021) implementation level is set at zero percent since Federal funding for this cost will not be available until this final rule is implemented by title IV–E agencies. Although there is no known data on the extent to which we anticipate title IV–E agencies will begin providing representation for an Indian child's tribe to participate or intervene in state court proceedings for the foster care placement of, or TPR to, an Indian child, we anticipate that this administrative cost will be made available to five percent of potentially eligible children in FY 2024 and that most of the growth will occur in years two through five (FYs 2025–2028). In FY 2028 we anticipate 35 percent of potentially eligible tribes will receive legal representation. In subsequent FYs, the implementation growth rate will gradually diminish as more title IV–E agencies take up the option to claim for these costs, and thus there are more children on whose behalf a tribe is receiving this representation.
  - For independent legal representation in civil legal proceedings, the implementation level presumes that administrative cost claims will be limited to those children on whose behalf independent legal representation in foster care legal proceedings are claimed. Not all children receiving legal representation in FC proceedings need representation related to civil matters because the reasons for child welfare involvement vary. Additionally, not all title IV–E agencies providing independent legal representation in foster care legal proceedings will opt to also provide such legal representation in civil proceedings. We have no estimate for FY 2021 costs for legal representation in civil legal proceedings as these will be new costs as a result of this final rule. We assume that the proportion of children receiving legal representation for civil legal proceedings (for both candidates and IV–E FC) will be derived from among those receiving representation for foster care legal proceedings. We estimate that the civil legal proceedings title IV–E caseload will grow gradually each FY from 20 percent in FY 2024, to 45 percent in FY 2028 and up to 56 percent in FY 2033 of the children on whose behalf representation is also being provided for foster care legal proceedings. While there is a great deal of interest in providing legal representation in civil legal proceedings the projections take into account that, in most instances, new or revised protocols will need to be developed with various organizations to implement the final rule. There will also be a need to secure state or tribal funds for the non-Federal share of funding, which often requires legislative approvals.

Federal Cost Estimate for Independent Legal Representation in Foster Care Legal Proceedings

Here we describe the individual calculations by line that are in the following chart. All entries in the chart and the narrative below are rounded to the nearest whole number. The calculations to obtain these amounts, however, were performed without applying rounding to the involved factor(s).

Line 1. National number of children (candidates and IV–E FC) receiving legal representation in foster care legal proceedings. Line 1 of the table below provides that the actual number of children receiving independent legal representation in FC proceedings in FY 2021 (extrapolated into the future for the purpose of characterizing the analytic baseline) was 10,477 candidates and 26,092 IV–E FC. Line 1 also includes estimates of the annual number of children receiving independent legal representation in foster care proceedings in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033, the estimated number of children is 29,525 candidates and 73,530 IV–E FC.

Line 2. National average FFP claim per child (candidates and IV–E FC) for independent legal representation in foster care proceedings. Line 2 of the table below displays that in FY 2021, the actual average title IV–E administrative cost claim per child receiving independent legal

representation in foster care legal proceedings was $742 for title IV–E candidates and $2,709 for children in title IV–E foster care. We also provide estimates of the average title IV–E claim per child in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033 the per child average claim is estimated at $3,481 (IV–E FC) and $954 (candidates). We note that IV–E agencies will have an incentive to ensure that the attorneys' fee costs that they submit for IV–E reimbursement are reasonable because the IV–E agency will be responsible for the 50% state share of the cost.

Line 3. Average FFP claims for candidates and children in title IV–E foster care for independent legal representation in foster care legal proceedings. Line 3 of the table below displays that in FY 2021, the actual FFP for children receiving independent legal representation in foster care legal proceedings was $7,777,621 for candidates and $70,689,345 for children in IV–E FC. We also provide estimates of the average annual claims for these children in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033 the estimated cost is $28,160,009 (candidates) and $255,941,062 (IV–E FC).

Line 4. Total Federal costs for independent legal representation in foster care legal proceedings (candidates and IV–E FC). Line 4 of the table below provides that the actual total FFP in FY 2021 was $78,466,966, which is the sum of the costs of independent legal representation in foster care legal proceedings for candidates and IV–E FC. We also provide estimates of the total FFP for these costs in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033 the estimated annual cost is $284,101,071. The estimates for these subsequent FYs were calculated by multiplying line 1 by line 2 for candidates and IV–E FC.

Line 5. Non-Federal costs for independent legal representation in foster care legal proceedings. Line 5 of the table below displays the total FY 2021 non-Federal costs of independent legal representation in foster care proceedings for candidates and IV–E FC was $78,466,966. This number is the same as line 4 because the FFP rate used in these estimates is 50 percent, thus we estimate the costs for Federal and non-Federal to be the same. We also provide estimates of the total non-Federal costs of independent legal representation in foster care legal proceedings in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033 the estimated annual cost is $284,101,071.

Line 6. Total Federal and non-Federal costs of independent legal representation in foster care legal proceedings. Line 6 of the table below is the sum of lines 4 and 5 for the total Federal and non-Federal costs of independent legal representation in foster care legal proceedings for candidates and IV–E FC. The total FY 2021 costs were $156,933,932. We also provide estimates of these total Federal and non-Federal costs in the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033 the estimated annual cost is $568,202,142.

Federal Cost Estimate of Independent Legal Representation in Other Civil Legal Proceedings

Line 7. Number of children (candidates and IV–E FC) receiving independent legal representation in civil legal proceedings. Line 7 of the table below displays the estimated number of children who will receive independent legal representation in civil legal proceedings either directly, or on behalf of a parent, relative caregiver, or Indian custodian in FY 2024 as 10,137 children. There is no estimate for FY 2021 in the chart because these costs were not claimed; these will be new costs as a result of this final rule. We also provide estimates for subsequent years: FYs 2025, 2026, 2028 and in 2033 the estimated number of children is 63,482. This is based on the implementation level which is the percentage of children receiving independent legal representation in foster care legal proceedings who are projected to also receive independent legal representation in civil legal proceedings in the year.

Line 8. National average title IV–E administrative cost claim per child for independent legal representation in civil legal proceedings. Line 8 of the table below displays that in FY 2021, we assumed the average FFP claim per child (candidates and IV–E FC) receiving independent legal representation in civil proceedings to be $1,262. We also provide estimates for these costs for the following subsequent years: FYs 2024, 2025, 2026, 2028 and in 2033, we estimate the average FFP claim per child to be $1,621. These cost estimates were derived from data provided by the ''Detroit Model'' legal services program in which legal representation in civil issues for child welfare clients was calculated as an average yearly amount of $2,524 gross ($1,262 50 percent FFP title IV–E Federal share) per client. We used the Detroit model project because we do not have current title IV–E administrative cost claims reported on the Form CB–496 for civil proceedings that we can use for an estimate of the cost of providing independent legal representation in civil legal proceedings in this rule. This is the only program model known to us providing civil legal representation in pre-petition cases for which average cost data is available, thus the only way for us to estimate these costs.[19] One commenter agreed that the working estimate of an administrative cost claim per child for independent legal representation in civil legal proceedings is plausible. Other commenters noted that the reasonableness of attorney fees may vary across counties, and depend on factors including geography, accessibility, cost of living, and local economies.

Line 9. Federal costs of independent legal representation in civil legal proceedings. Line 9 of the table below provides the estimated Federal administrative costs at 50 percent FFP for independent legal representation in civil legal proceedings for candidates and IV–E FC. These costs were calculated by multiplying the expected average monthly caseload (line 7) by the expected average annual claim per child (line 8). We provide estimated Federal costs of $13,393,972 for FY 2024 and in subsequent years: FYs 2025, 2026, 2028 and in 2033 the estimated Federal cost is $102,928,630.

Line 10. Non-Federal costs of independent legal representation in civil legal proceedings. Line 10 provides the estimated non-Federal share of administrative costs for independent legal representation in civil legal proceedings for candidates and IV–E FC, which is 50 percent of the total on line 11. This number is the same as line 9 because the FFP rate used in these estimates is 50 percent, thus we estimate the costs for Federal and non-Federal to be the same. We provide estimated non-Federal costs of $13,393,972 beginning in FY 2024 and in subsequent FYs: 2025, 2026, 2028 and in 2033 the estimated non-Federal cost is $102,928,630. There is no estimate for FY 2021 in the chart because these costs were not claimed; these will be new costs as a result of this final rule.

Line 11. Total Federal and non-Federal cost of independent legal representation in civil legal proceedings. Line 11 displays the annual estimated total (Federal + non-Federal) costs for independent legal representation for

[19] Detroit Center for Family Advocacy Pilot Evaluation report July 2009–June 2012; Sankaran, Vivek. Case Closed: Addressing Unmet Legal Needs and Stabilizing Families. M.L. Raimon, co-author. Center for the Study of Social Policy [2014] [Detroit model project].

candidates and IV–E FC in civil legal proceedings. This is the sum of lines 9 and 10. We estimate these total costs beginning in FY 2024 as $26,787,943 and in subsequent FYs: 2025, 2026, 2028 and in 2033, the estimate is $205,857,260. There is no estimate for FY 2021 in the chart because these costs were not claimed; these will be new costs as a result of this final rule.

Line 12. Number of Indian children on whose behalf a tribe may receive representation in state foster care legal proceedings (candidates and IV–E FC). Line 12 of the table below provides the estimated number of Indian children for whom legal representation may be received by their tribe in state FC proceedings. In FY 2021 (extrapolated into the future for the purpose of characterizing the analytic baseline) candidates and IV–E FC are not listed since this administrative cost was not available. We estimate that the total number, beginning in 2024 and subsequent FYs 2025, 2026, 2028 and 2033 is 3,342 for candidates and 7,814 for IV–E FC.

Line 13. National average FFP claim per child (candidates and IV–E FC) for tribal representation in state foster care legal proceedings. Line 13 of the table below provides the average title IV–E claim per child for the tribal representation in state foster care proceedings. In FY 2021 (extrapolated into the future for the purpose of characterizing the analytic), the average title IV–E administrative cost claim per child receiving legal representation in state foster care legal proceedings was $1,262 (estimated) for title IV–E candidates and $2,709 (actual) for children in title IV–E foster care. We estimate the total per child claim for subsequent FYs 2024, 2025, 2026, 2028, and 2033 is $1,621(candidates) and $3,481 (IV–E FC).

Line 14. Average FFP for IV–E FC and candidate itemized for tribal representation in state foster care legal proceedings. Line 14 of the table below displays estimates for the average annual claims for children whose tribe is receiving legal representation in state foster care proceedings. In FY 2021, there was no actual FFP for children receiving tribal legal representation in such legal proceedings. For subsequent FYs 2024, 2025, 2026, 2028 and 2033 the estimated cost is $5,419,446 (candidates) and $27,200,314 (IV–E FC).

Line 15. Total FFP for tribal representation in state foster care legal proceedings. Line 15 of the table below provides the total FFP for tribal representation in state foster care legal proceedings by multiplying line 12 for candidates by line 13 for IV–E FC. For FY 2021 (base year), there was no actual FFP for children receiving tribal legal representation in state foster care legal proceedings. Estimates of the total annual FFP for these costs in FYs 2024, 2025, 2026, 2028 and 2033 is $32,619,760.

Line 16. Total non-Federal cost for tribal representation in state foster care legal proceedings. Line 16 provides the estimated non-Federal share of administrative costs for tribal legal representation in state foster care legal proceedings for candidates and IV–E FC by multiplying line 1 by line 2, which is 50 percent of the total on line 17. This number is the same as line 15 because the FFP rate used in these estimates is 50 percent, therefore we estimate the costs for Federal and non-Federal to be the same. We provide estimated non-Federal costs of $2,641,921 beginning in FY 2024 and in subsequent FYs 2025, 2026, 2028 and 2033, the estimated non-Federal cost is $32,619,760. There is no estimate for FY 2021 in the chart because these costs were not claimed; these will be new costs as a result of this final rule.

Line 17. Total cost for state foster care legal proceedings. Line 17 displays the annual estimated total Federal and non-Federal costs for tribal representation for candidates and IV–E FC in state foster care legal proceedings. This is the sum of lines 15 and 16. We estimate these total costs beginning in FY 2024 as $5,283,842 and in subsequent FYs 2025, 2026, 2028 and 2033, the estimate is $65,239,520. There is no estimate for FY 2021 in the chart because these costs were not claimed; these will be new costs as a result of this final rule.

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Year	2021	2024	2025	2026	2028 (Year 5)	2033 (Year 10)
1. National number of children receiving legal representation in foster care legal proceedings (candidates and IV-E FC)	10,447 (candidates) 26,092 (IV-E FC)	13,201 (candidates) 32,876 (IV-E FC)	15,973 (candidates) 39,779 (IV-E FC)	19,328 (candidates) 48,133 (IV-E FC)	24,886 (candidates) 61,976 (IV-E FC)	29,525 (candidates) 73,530 (IV-E FC)
2. National average FFP claim per child (candidates and IV-E for foster care legal proceedings	$742 (candidates) $2,709 (IV-E FC)	$777 (candidates) $2,837 (IV-E FC)	$795 (candidates) $2,902 (IV-E FC)	$813 (candidates) $2,969 (IV-E FC)	$851 (candidates) $3,107 (IV-E FC)	$954 (candidates) $3,481 (IV-E FC)
3. Average FFP for IV-E FC and candidate itemized for foster care legal proceedings	$7,777,621 (candidates) $70,689,345 (IV-E FC)	$10,260,393 (candidates) $93,254,798 (IV-E FC)	$12,700,622 (candidates) $ 115,433,586 (IV-E FC)	$15,721,212 (candidates) $142,887,156 (IV-E FC)	$21,184,501 (candidates) $192,541,977 (IV-E FC)	$28,160,009 (candidates) $255,941,062 (IV-E FC)
4. Total FFP (line 1 x line 2 for combined IV-E FC child and candidate) for foster care legal proceedings	$78,466,966	$103,515,191	$128,134,209	$158,608,368	$213,726,479	$284,101,071
5. Total non-Federal cost (line 1 x line 2 for combined IV-E FC and candidates) for foster care legal proceedings	$78,466,966	$103,515,191	$128,134,209	$158,608,368	$213,726,479	$284,101,071

6. Total cost for foster care legal proceedings (line 4 + line 5)	$156,933,932	$207,030,382	$256,268,417	$317,216,735	$427,452,958	$568,202,142
7. Number of children receiving legal representation in civil legal proceedings	N/A	10,137	18,398	25,972	42,997	63,482
8. National average FFP claim per child for civil legal proceedings	$1,262	$1,321	$1,352a	$1,383	$1,447	$1,621
9. Total FFP for civil legal proceedings (line 7 x line 8)	N/A	$13,393,972	$24,869,190	$35,914,468	$62,222,311	$102,928,630
10. Total non-Federal costs for civil legal proceedings (line 7 x line 8)	N/A	$13,393,972	$24,869,190	$35,914,468	$62,222,311	$102,928,630
11. Total Federal + non-Federal costs for civil legal proceedings (line 9 + line 10)	N/A	$26,787,943	$49,738,380	$71,828,936	$124,444,623	$205,857,260
12. Number of children whose tribe may receive legal representation in state foster care legal proceedings (candidates	N/A	332 (candidates) 777 (IV-E FC)	1,007 (candidates) 2,353 (IV-E FC)	1,694 (candidates) 3,961 (IV-E FC)	2,420 (candidates) 5,657 (IV-E FC)	3,342 (candidates) 7,814 (IV-E FC)

and IV-E FC)						
13. National average FFP claim per child (candidates and IV-E FC) for a tribe in state foster care legal proceedings	N/A	$1,321 (candidates) $ 2,837 (IV-E FC)	$1,352 (candidates) $ 2,902 (IV-E FC)	$1,383 (candidates) $ 2,969 (IV-E FC)	$1,447 (candidates) $ 3,107 (IV-E FC)	$1,621 (candidates) $ 3,481 (IV-E FC)
14. Average FFP for IV-E FC and candidate itemized for a tribe in state foster care legal proceedings	N/A	$438,929 (candidates) $2,202,993 (IV-E FC)	$1,360,543 (candidates) $6,828,594 (IV-E FC)	$2,342,923 (candidates) $11,759,180 (IV-E FC)	$3,501,709 (candidates) $17,575,152 (IV-E FC)	$5,419,446 (candidates) $27,200,314 (IV-E FC)
15. Total FFP (line 12 x line 13 for combined IV-E FC child and candidate) for a tribe in state foster care legal proceedings	N/A	$2,641,921	$8,189,137	$14,102,103	$21,076,861	$32,619,760
16. Total non-Federal cost (line 12 x line 13 for combined IV-E FC and candidates) for a tribe in state foster care legal proceedings	N/A	$2,641,921	$8,189,137	$14,102,103	$21,076,861	$32,619,760
17. Total cost for a tribe in state foster care legal proceedings (line 15 + line 16)	N/A	$5,283,842	$16,378,274	$28,204,206	$42,153,722	$65,239,520

Accounting Statement

From a society-wide perspective, many of the effects estimated above are transfers from either the Federal Government or title IV–E agencies to title IV–E participants. The table immediately below presents annualized estimates of the incremental FFP claims, reported as Federal budget transfers, and estimates of the incremental non-Federal share, reported as other transfers, consistent with the yearly estimates reported in rows 4 and 5 (where applicable) and 9, 10, 15 and 16 in the table above. These estimates cover a 10-year time horizon and apply both a 7% and 3% discount rate.

Estimates comparing against pre-existing operations (summarizing rows 9, 10, 15 and 16 in the table above):

Category	Primary Estimate (millions)	Units		
		Year Dollars	Discount Rate	Period Covered
Federal Budget Transfers (annualized)	$76	2021	7%	10 years
Federal Budget Transfers (annualized)	$80	2021	3%	10 years
From/To	From: Federal Government	To: children eligible for title IV-E foster care		
Other Transfers (annualized)	$76	2021	7%	10 years
Other Transfers (annualized)	$80	2021	3%	10 years
From/To	From: Title IV-E agencies	To: children eligible for title IV-E foster care		

Estimates encompassing all provisions being codified for the first time (summarizing rows 4, 5, 9, 10, 15 and 16 in the table above):				
Category	Primary Estimate (millions)	Units		
		Year Dollars	Discount Rate	Period Covered
Federal Budget Transfers (annualized)	$274	2021	7%	10 years
Federal Budget Transfers (annualized)	$285	2021	3%	10 years
From/To	From: Federal Government	To: children eligible for title IV-E foster care		
Other Transfers (annualized)	$274	2021	7%	10 years
Other Transfers (annualized)	$285	2021	3%	10 years
From/To	From: Title IV-E agencies	To: children eligible for title IV-E foster care		

VI. Tribal Consultation Statement

Executive Order 13175, *Consultation and Coordination with Indian Tribal Governments,* requires agencies to consult with Indian tribes when regulations have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' Similarly, ACF's Tribal Consultation Policy says that consultation is triggered for a new rule adoption that significantly affects tribes, meaning the new rule adoption has substantial direct effects on one on more Indian tribes, on the amount or duration of ACF program funding, on the delivery of ACF programs or services to one or more Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This final rule does not meet either standard for consultation. Executive Order 13175 does not apply to this final rule because it does not impose any burden or cost on tribal title IV–E agencies, nor does it impact the relationship or distribution of power between the Federal Government and Indian Tribes. Rather, it provides title IV–E agencies an option for claiming additional administrative costs for legal representation under title IV–E of the Act. Although not required for this final rule, ACF is committed to consulting with Indian tribes and tribal leadership to the extent practicable and permitted by law. ACF engaged in consultation with tribes and their leadership on the September 2023 NPRM as described below.

Description of Consultation

On September 29th, 2023, ACF issued a letter to tribal leaders announcing the date, purpose, virtual location, and registration information for tribal consultation and shared it widely through a variety of peer groups and email list-serves. Tribal Consultation was held via a Zoom teleconference call on October 30, 2023. A report of the tribal consultation may be found on the CB website at: *https://www.acf.hhs.gov/cb/report/tribal-consultation-nprms-legal-foster-care.* In summary, the consultation participants requested clarifications on allowable administrative costs, access to funding for legal representation provided early in a case, information the tribe will need to report to the title IV–E agency for claiming costs, and additional funding for the cost of representation in state court proceedings for the foster care placement of, or TPR to, an Indian child, which we responded to in section IV. The participants also raised issues that are out of scope of the NPRM and more technical in nature, such as the types of agreements that must be in place to access Federal funding through the title IV–E agency. We would like to note that more information about agreements and contracts is available in CWPM 8.1E and G. ACF will work with title IV–E agencies and interested tribes to provide additional technical assistance on these issues.

Jeff Hild, Principal Deputy Assistant Secretary for the Administration for Children and Families, performing the delegable duties of the Assistant Secretary for Children and Families, approved this document on April 24, 2024.

List of Subjects in 45 CFR Part 1356

Administrative costs, Adoption assistance, Child welfare, Fiscal requirements (title IV–E), Grant programs—social programs, Statewide information systems.

(Catalog of Federal Domestic Assistance Program Number 93.658, Foster Care Maintenance; 93.659, Adoption Assistance; 93.645, Child Welfare Services—State Grants).

Dated: April 30, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

For the reasons set forth in the preamble, ACF amends 45 CFR part 1356 as follows:

PART 1356—REQUIREMENTS APPLICABLE TO TITLE IV–E

■ 1. The authority citation for part 1356 continues to read as follows:

Authority: 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.,* 42 U.S.C. 1302.

■ 2. Amend § 1356.60 by revising paragraphs (c)(2)(viii) through (x) and adding paragraphs (c)(2)(xi) and (c)(4) to read as follows:

§ 1356.60 Fiscal requirements (title IV–E).

* * * * *

(c) * * *

(2) * * *

(viii) Rate setting;

(ix) A proportionate share of related agency overhead;

(x) Costs related to data collection and reporting; and

(xi) Costs related to legal representation described in paragraph (c)(4) of this section.

* * * * *

(4) The following are allowable administrative costs of legal representation:

(i) Legal representation in foster care proceedings provided by an attorney representing the title IV–E agency or any other public agency (including an Indian tribe) which has an agreement in effect under which the other agency has placement and care responsibility of a title IV–E eligible child pursuant to 472(a)(2)(B)(ii) of the Act;

(ii) Independent legal representation provided by an attorney representing a child in title IV–E foster care, a child who is a candidate for title IV–E foster care, the child's parent(s), the child's relative caregiver(s), and the child's Indian custodian(s) in foster care and other civil legal proceedings as necessary to carry out the requirements in the agency's title IV–E foster care plan. Independent legal representation in civil proceedings includes facilitating, arranging, brokering, advocating, or otherwise linking clients with providers and services as identified in the child's case plan pursuant to sections 422, 471(a)(16), and 475 of the Act; and

(iii) Legal representation provided by an attorney representing an Indian child's tribe (as defined by 25 U.S.C.1903(5)), or representation of an Indian child's tribe provided by a non-attorney, when the child's tribe participates or intervenes in any state court proceeding for the foster care placement or termination of parental rights of an Indian child who is in title IV–E foster care or an Indian child who is a candidate for title IV–E foster care.

* * * * *

[FR Doc. 2024–09663 Filed 5–8–24; 4:15 pm]

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AGENCY FOR INTERNATIONAL DEVELOPMENT

48 CFR Parts 727, 742, and 752

RIN 0412–AA90

USAID Acquisition Regulation: Planning, Collection, and Submission of Digital Information; Submission of Activity Monitoring, Evaluation, and Learning Plan to USAID; Correction

AGENCY: U.S. Agency for International Development.

ACTION: Final rule; correction.

SUMMARY: On May 6, 2024, the United States Agency for International Development (USAID) published a final rule amending USAID's Acquisition Regulation (AIDAR) that implements USAID requirements for managing digital information as a strategic asset to inform the planning, design, implementation, monitoring, and evaluation of the Agency's foreign assistance programs. The rule contained two errors which this document is correcting.

DATES: Effective June 5, 2024.

FOR FURTHER INFORMATION CONTACT: Kelly Miskowski, USAID M/OAA/P, at 202–256–7378 or *policymailbox@usaid.gov* for clarification of content or information pertaining to status or publication schedules. All communications regarding this rule must cite AIDAR RIN No. 0412–AA90.

SUPPLEMENTARY INFORMATION:

Correction

In FR Doc. 2024–09373, appearing on page 37948 in the **Federal Register** of Monday, May 6, 2024, the following corrections are made:

■ 1. In the preamble on page 37948, in the first column, in **SUMMARY**, in the first sentence, add the word ''is'' after ''(USAID)''.

727.7003 [Corrected]

■ 2. On page 37961, in the first column, in § 727.7003, in paragraph (a), in the first sentence, remove the words ''to USAID''.

Jami J. Rodgers,

Chief Acquisition Officer.

[FR Doc. 2024–10189 Filed 5–9–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 240506–0128; RTID 0648–XD634]

Pacific Halibut Fisheries of the West Coast; Management Measures for the 2024 Area 2A Pacific Halibut Directed Commercial Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is implementing fishing periods and fishing period limits for the 2024 Pacific halibut non-tribal directed commercial fishery off the West Coast south of Point Chehalis, WA. This action establishes two fishing periods, June 25–27 and July 9–11, 2024. NMFS is also implementing vessel catch limits applicable to eight vessel size classes. These actions are intended to conserve Pacific halibut and provide fishing opportunity where available.

DATES: This rule is effective on June 25, 2024.

FOR FURTHER INFORMATION CONTACT: Heather Fitch, West Coast Region, NMFS, (360) 320–6549, *heather.fitch@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Northern Pacific Halibut Act of 1982 (16 U.S.C. 773–773k) (Halibut Act), gives the Secretary of Commerce responsibility for implementing the provisions of the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (March 29, 1979).

The Secretary of State, with the concurrence of the Secretary of Commerce and on behalf of the United

States, has accepted regulations recommended by the International Pacific Halibut Commission (IPHC), in accordance with the Convention, which govern the Pacific halibut fishery in all regulatory areas, and include the 2024 catch limit for the Area 2A non-tribal directed commercial fishery. The IPHC's Area 2A is located off the coasts of Washington, Oregon and California, and includes the area south of Point Chehalis, WA, (lat. 46°53.30′ N) to the U.S./Mexico border. NMFS published the IPHC regulations in the **Federal Register** on March 18, 2024 (89 FR 19275) to provide notice of their immediate regulatory effectiveness and to inform persons subject to the regulations of their restrictions and requirements (50 CFR 300.62).

In accordance with 16 U.S.C. 773c(c) of the Halibut Act, the Pacific Fishery Management Council (Council) developed a catch sharing plan (CSP) guiding the framework distribution of the overall Area 2A allocation of Pacific halibut across the various sectors. Based on the 2024 Area 2A fishery constant exploitation yield (FCEY) of 1.47 million pounds (667 mt), net weight (*i.e.,* the weight of Pacific halibut that is without gills and entrails, head-off, washed, and without ice and slime), and the allocation framework in the CSP, the non-tribal directed commercial Pacific halibut fishery allocation for 2024 is 249,338 pounds (113 mt), net weight (89 FR 19275, March 18, 2024).

This final rule implements annual management measures for 2024 for the directed commercial Pacific halibut fishery in Area 2A that are not part of the annual IPHC regulations, specifically fishing periods and fishing period limits. This final rule adopts, without changes, the annual management measures from the proposed rule published on March 13, 2024 (89 FR 18368). Specifically, this action establishes two 58-hour fishing periods and four fishing period limits (*i.e.* vessel catch limits) across eight vessel size classes for both fishing periods.

Fishing Periods

Fishing periods, often referred to as fishery openers, are the times during the IPHC coastwide commercial Pacific halibut season when fishing in the non-tribal directed commercial Pacific halibut fishery in Area 2A is allowed. NMFS is implementing two fishing periods open for 58 hours each. The first fishing period will begin on June 25, 2024, at 8 a.m. PDT and close on June 27, 2024, at 6 p.m. PDT. The second fishing period will begin on July 9, 2024, at 8 a.m. PDT and close on July 11, 2024, at 6 p.m. PDT.

Following the initial two fishing periods, NMFS will assess fishery harvest and determine if the fishery has attained the non-tribal directed commercial allocation. If harvest estimates indicate the allocation has not been reached, NMFS may determine that subsequent fishing period(s) are necessary to attain the allocation. If a third fishing period occurs, it would occur no sooner than 3 weeks after the second fishing period. A third fishing period, and any subsequent fishing periods, would be announced in the **Federal Register** through inseason action consistent with 50 CFR 300.63(e).

Fishing Period Limits

A fishing period limit, also called a vessel catch limit, is the maximum amount of Pacific halibut that may be retained and landed by a vessel during one fishing period. Each vessel may retain no more than the current fishing period limit of Pacific halibut for its vessel class, which is determined by vessel length. NMFS is implementing the non-tribal directed commercial fishing period limits shown in table 1 below. Fishing period limits are intended to ensure that the Area 2A directed commercial fishery does not exceed its allocation, while also providing fair and equitable access across participants to an attainable amount of harvest.

If NMFS determines that more than two fishing periods are warranted, NMFS will set new associated fishing period limits and any such fishing period limits for subsequent fishing periods will be set equal across all vessel classes. Any subsequent fishing period limits would be announced in the **Federal Register** through inseason action consistent with 50 CFR 300.63(e).

2024 Non-Tribal Directed Commercial Fishery Fishing Periods and Fishing Period Limits

The Area 2A non-tribal directed commercial fishery, which occurs south of Point Chehalis, WA, (lat. 46°53.30′ N), will open on June 25, 2024, at 8 a.m. PDT and close on June 27, 2024, at 6 p.m. PDT, and will re-open on July 9, 2024, at 8 a.m. PDT and close on July 11, 2024, at 6 p.m. PDT. The fishery's fishing periods may be adjusted inseason consistent with 50 CFR 300.63.

TABLE 1—FISHING PERIOD LIMITS BY SIZE CLASS FOR THE 2024 FIRST AND SECOND FISHING PERIODS OF THE AREA 2A PACIFIC HALIBUT NON-TRIBAL DIRECTED COMMERCIAL FISHERY

Vessel class	Length range in feet (meters)	Fishing period limit in pounds (mt)
A	1–25 (0.3–7.8)	1,800 (0.8164)
B	26–30 (7.9–9.3)	1,800 (0.8164)
C	31–35 (9.4–10.9)	1,800 (0.8164)
D	36–40 (11.0–12.4)	3,000 (1.361)
E	41–45 (12.5–13.9)	3,000 (1.361)
F	46–50 (14.0–15.4)	3,800 (1.724)
G	51–55 (15.5–16.9)	3,800 (1.724)
H	56+ (17.0+)	4,500 (2.041)

Note: Fishing period limits are in dressed weight (head-on, with ice and slime).

Comments and Responses

NMFS published a proposed rule on March 13, 2024 (89 FR 18368) and accepted public comments on the 2024 Area 2A Pacific halibut directed commercial fishery annual management measures through April 12, 2024. NMFS received one public comment.

Comment 1: NMFS received a comment from a member of the public expressing the opinion that retention of a Pacific halibut weighing over 150 pounds should not be allowed.

Response: Size limits were not within the scope of this action. However, NMFS has determined that this action is based on the best scientific information available. For 2024, the IPHC adopted a minimum size limit for commercial fisheries in its annual management

measures (89 FR 19275, March 9, 2024). In addition, the IPHC previously examined maximum size limits [1] and is conducting ongoing research activities examining factors that influence Pacific halibut biomass. Consistent with its statutory and other obligations, NMFS will continue to keep abreast of the IPHC's ongoing research and ensure that its regulatory actions, including its approval of annual Pacific halibut management measures, are based on the best scientific information available.

Classification

Regulations governing the U.S. fisheries for Pacific halibut are developed by the IPHC, the Pacific Fishery Management Council, the North Pacific Fishery Management Council, and the Secretary of Commerce. Section 5 of the Halibut Act of 1982 (Halibut Act, 16 U.S.C. 773c) allows the Regional Council having authority for a particular geographical area to develop regulations governing the allocation and catch of Pacific halibut in U.S. Convention waters as long as those regulations do not conflict with IPHC regulations.

This final rule is exempt from review under Executive Order 12866 because this action contains no implementing regulations.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

Authority: 16 U.S.C. 773–773k.

Dated: May 6, 2024.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2024–10185 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

[1] Stewart, I., A. Hicks, and B. Hutniczak. 2020. Evaluation of directed commercial fishery size limits in 2020. IPHC–2021–AM097–09.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 240506–0129]

RIN 0648–BM46

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Amendment 56

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in Amendment 56 to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico. This final rule revises catch levels for gag, accountability measures for its recreational harvest, and the recreational fishing season. In addition, Amendment 56 establishes a rebuilding plan for the overfished stock, and revises the stock status determination criteria and sector harvest allocations. The purpose of this action is to implement a rebuilding plan for gag and revised management measures to end overfishing and rebuild the stock.

DATES: This final rule is effective on June 1, 2024.

ADDRESSES: An electronic copy of Amendment 56 is available from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/amendment-56-modifications-catch-limits-sector-allocation-and-recreational-fishing-seasons.* Amendment 56 includes an environmental assessment, a fishery impact statement, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review.

FOR FURTHER INFORMATION CONTACT: Dan Luers, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS, with the advice of the Gulf of Mexico Fishery Management Council (Council), manages the reef fish fishery, which includes gag, in Federal waters of the Gulf of Mexico (Gulf), under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The Council prepared the FMP, which the Secretary of Commerce approved, and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On October 18, 2023, NMFS published a notice of availability for the review of Amendment 56 and requested public comment (88 FR 71812). On November 9, 2023, NMFS published a proposed rule for Amendment 56 and requested public comment (88 FR 77246). NMFS approved Amendment 56 on January 17, 2024.

Background

Gag in Gulf Federal waters are found primarily in the eastern Gulf. Juvenile gag are estuarine dependent and often inhabit shallow seagrass beds. As gag mature, they move to deeper offshore waters to live and spawn. Gag is managed as a single stock with a stock annual catch limit (ACL) that is further divided or allocated into commercial and recreational sector ACLs. Currently, that allocation of the stock ACL is 39 percent to the commercial sector and 61 percent to the recreational sector. All weights in this final rule are given in gutted weight.

Commercial fishing for gag is managed under the individual fishing quota (IFQ) program for groupers and tilefishes (GT–IFQ program), which began on January 1, 2010 (74 FR 44732, August 31, 2009; 75 FR 9116, March 1, 2010). Under the GT–IFQ program, the commercial quota for gag is set 23 percent below the gag commercial ACL, and NMFS distributes allocation (in pounds) of gag on January 1 each year to those who hold shares (in percent) of the gag total commercial quota. Both gag and red grouper, another grouper species managed under the GT–IFQ program, have a commercial multi-use provision that allows a portion of the gag quota to be harvested under the red grouper allocation, and vice versa. As explained further in Amendment 56, the multi-use provision is based on the difference between the respective gag and red grouper ACLs and quotas. However, if gag is under a rebuilding plan, as will occur under Amendment 56 and this final rule, the percentage of red grouper multi-use allocation is equal to zero. Commercial harvest of gag is also restricted by area closures and a minimum size limit.

NMFS, with the advice of the Council, manages the recreational harvest of gag with an ACL, an annual catch target (ACT) set approximately 10 percent below the ACL, in-season and post-season accountability measures (AMs) to prevent and mitigate overfishing, seasonal and area closures, a minimum

size limit, and daily bag and possession limits.

The most recent stock assessment for gag was completed in 2021 through Southeast Data, Assessment, and Review 72 (SEDAR 72), and concluded that the gag stock is overfished and is undergoing overfishing as of 2019. Compared to the previous assessment for gag, SEDAR 72 used several improved data sources, including corrections for the potential misidentification between black grouper and gag, which are similar looking species, to better quantify estimates of commercial discards. SEDAR 72 also used updated recreational catch and effort data from the Marine Recreational Information Program (MRIP) Access Point Angler Intercept Survey and Fishing Effort Survey (FES) through 2019. Prior to SEDAR 72, the most recent stock assessment for gag was SEDAR 33 Update (2016), which indicated that gag was not subject to overfishing and was not overfished. The SEDAR 33 Update used recreational catch and effort data generated by the MRIP Coastal Household Telephone Survey (CHTS).

SEDAR 72 also accounted for observations of red tide mortality directly within the stock assessment model. Gag is vulnerable to red tide events and was negatively affected by these disturbances in 2005, 2014, 2018, and projected for 2021. Modeling changes were also made in SEDAR 72 to improve size estimates of gag retained by commercial and for-hire (charter vessels and headboats) fishermen, and private anglers.

The Council's Scientific and Statistical Committee (SSC) reviewed the results of SEDAR 72 in November 2021 and concluded that the assessment was consistent with the best scientific information available and suitable for informing fisheries management. On January 26, 2022, NMFS notified the Council that gag was overfished and undergoing overfishing, and the Council subsequently developed a rebuilding plan for gag through Amendment 56.

At its January 2022 meeting, the Council requested that the NMFS Southeast Fisheries Science Center update the SEDAR 72 base model by replacing MRIP–FES landings estimates for the Florida private angling mode with landings estimates produced by the Florida Fish and Wildlife Conservation Commission's State Reef Fish Survey (SRFS). Historically, SRFS estimates a slightly higher fishing effort, and therefore a larger harvest of gag, by private anglers and state charter vessels (in Florida) than MRIP–CHTS, but SRFS estimates a substantially smaller harvest of gag by private anglers and state charter vessels than MRIP–FES. This alternative model run of SEDAR 72 (''SRFS Run'') used MRIP–FES data for the federally permitted charter vessel and shore modes, and data from the Southeast Region Headboat Survey (SRHS) for federally permitted headboats. The results of the SRFS Run were presented to the Council's SSC at its July 2022 meeting. The SSC found the SEDAR 72 SRFS Run to be consistent with the best scientific information available. The SSC determined that SRFS is a comprehensive survey for the gag private angling component of the recreational sector given that greater than 95 percent of private angling landings of gag are captured by the SRFS sampling frame and the SRFS program's collection protocol has been certified by the NMFS Office of Science and Technology as scientifically rigorous. NMFS worked in conjunction with the State of Florida to develop a calibration model to rescale historic effort estimates so that they could be compared to new estimates from SRFS. This calibration model was peer-reviewed and approved through the NOAA Office of Science and Technology in May 2022. Information about the calibration and the SSC's review of the SEDAR 72 SRFS Run can be found here: *https://gulfcouncil.org/meetings/scientific-and-statistical-meetings/july-2022/*. The results of the SEDAR 72 SRFS Run were consistent with the results of the SEDAR 72 base model in that both concluded that the gag stock is overfished and undergoing overfishing.

At the time that NMFS and the Council developed Amendment 56, the Council recognized that NMFS could not likely implement a potential final rule until 2024. Further, the Council recognized that maintaining the previously implemented catch limits for gag in 2023 would continue to allow overfishing. Therefore, the Council sent a letter to NMFS, dated July 18, 2022 (Appendix A in Amendment 56), requesting that NMFS implement interim measures that would reduce overfishing by reducing the gag stock ACL from 3.120 million pounds (lb) or 1.415 million kilograms (kg) to 661,901 lb (300,233 kg). The Council determined, and NMFS agreed, that for this short-term reduction in harvest it was appropriate to maintain the current allocation of the stock ACL between the sectors of 39 percent commercial and 61 percent recreational, and the availability of red grouper multi-use and gag multi-use under the IFQ program. In addition to the reduction in the catch limits, the Council requested that the recreational fishing season for 2023 begin on September 1 and close on November 10, rather than the existing open season of June 1 through December 31. NMFS agreed and implemented these interim measures through a temporary rule effective on May 3, 2023 (88 FR 27701, May 3, 2023). The measures in the temporary rule were initially effective for 180 days, and then NMFS extended them for up to 186 additional days (through May 2, 2024; 88 FR 69553, October 6, 2023), so NMFS could solicit and review public comments on the proposed rule and Amendment 56, and prepare final regulations as appropriate. Because the SSC's review of the SEDAR 72 SRFS Run occurred after the Council's decision to request interim measures for gag, the recreational catch limits in the temporary rule are consistent with MRIP–FES calibrated landings, and are not directly comparable to the catch limits recommended in Amendment 56 and this final rule.

Based on the results of the SEDAR 72 SRFS Run and SSC recommendations, the Council recommended the following changes for gag through Amendment 56:

- Revise the maximum sustainable yield (MSY) proxy, optimum yield (OY), and status determination criteria (SDC);
- Establish a rebuilding plan for the stock, and revise the overfishing limit (OFL), acceptable biological catch (ABC), and stock ACL consistent with that rebuilding plan;
- Revise the commercial-recreational allocation of the stock ACL and set new commercial and recreational sector ACLs, sector ACTs, and commercial quota;
- Modify the recreational AMs; and
- Revise the Federal recreational fishing season.

The current MSY proxy is based on the yield associated with a fishing mortality rate (F) associated with the maximum yield per recruit (F_{MAX}). The SSC recommended a more conservative MSY proxy using the yield associated with F that would result in a spawning stock biomass (SSB) of 40 percent of the spawning potential ratio (SPR; $F_{40\%SPR}$), where SPR is the ratio of the SSB to its unfished state. This revised MSY proxy of $F_{40\%SPR}$ was used to specify the long-term OY and SDC, and informs the catch level projections produced by the SEDAR 72 SRFS Run.

For gag, the sector allocations of the stock ACL affect the catch level projections produced by SEDAR 72. As more of the stock ACL is allocated to the recreational sector, the proportion of recreational discards and associated

mortality increases. Recreational discard mortality rates of gag are assumed to be less than commercial discard mortality rates but the total number of recreational discards is considerably greater than the number of commercial discards. Generally, a gag caught and released by a recreational fisherman has a greater likelihood of survival than by a commercial fisherman because of how and where they fish. However, because of the much higher numbers of gag that are released by the recreational sector compared to the commercial sector, the total number of discarded fish that die from recreational fishing exceeds dead discards from commercial fishing. This results in additional mortality for the stock and a lower projected annual yield, which means a lower OFL, ABC, and stock ACL. However, higher number of dead discards is not due to any change in how the recreational sector operates in the fishery but occurs because the SEDAR 72 SRFS Run data estimated greater fishing effort, and consequently a greater number of fish being caught, which included discards and the associated mortality from discarding fish.

After analyzing multiple alternatives for allocating the stock ACL between the fishing sectors, the Council determined and recommended to NMFS that using the allocation of 35 percent commercial and 65 percent recreational would best represent the historic landings for each sector while accounting for the change from data produced by the Marine Recreational Fisheries Statistics Survey (MRFSS) to SRFS data. Based on the results of the SEDAR 72 SRFS Run and the allocation ratio, the Council recommended OFLs and ABCs for gag during 2024–2028, and recommended the stock ACL be set equal to the ABC.

Management Measures Contained in This Final Rule

This final rule will modify the gag stock and sector ACLs, sector ACTs, commercial quota (which is equivalent to the commercial ACT), recreational AMs, and recreational fishing season as described further.

Annual Catch Limits and Annual Catch Targets

The 2023 temporary rule for gag implemented the current commercial ACL and commercial quota of 258,000 lb (117,027 kg) and 199,000 lb (90,265 kg), respectively, and the recreational ACL and ACT of 403,759 lb (183,142 kg) and 362,374 lb (164,370 kg), respectively. These catch limits are based on the results of the initial SEDAR 72 base model run, which included recreational landings estimates generated using MRIP–FES.

Amendment 56 and this final rule will set the stock ACL for gag at 444,000 lb (201,395 kg) in 2024, and will allocate approximately 35 percent to the commercial sector and approximately 65 percent to the recreational sector. This results in a 155,000-lb (70,307-kg) commercial ACL and a 288,000-lb (130,635-kg) recreational ACL for 2024. As explained in the proposed rule and in this final rule, these catch limits are based on the results of the SEDAR 72 SRFS Run. Because of the different surveys used to estimate recreational landings that were then used to determine the current catch limits and the catch limits in this final rule, the catch limits are not directly comparable. However, the catch limits in this rule are a significant reduction compared to the catch limits that would go back into effect if the 2023 temporary rule expires with no further action. Catch levels will be set from 2024 through 2028, which increase during the time series. The 2028 catch levels will continue after 2028 unless modified by subsequent rulemaking. All of the catch levels recommended by the Council in Amendment 56 were rounded down to the nearest thousand pounds. Therefore, the sum of the sector ACLs does not equal the stock ACL.

Based on the Council's recommendation, this final rule will set the commercial quota equal to the commercial ACT, and the commercial quota will be approximately 5 percent below the commercial ACL. The current buffer between the commercial ACL and commercial quota is 23 percent. The Council recommended reducing this buffer, because there have been considerable improvements in the estimation of commercial landings and discards of gag since NMFS implemented the buffer in 2012. Further, the fraction of gag discarded compared to the total number of gag caught by the commercial sector has remained low. NMFS does not expect the actions in Amendment 56 and this final rule to significantly increase commercial discards of gag. Therefore, the commercial quota, the amount of gag allocation that NMFS distributes annually to IFQ shareholders, will be approximately 95 percent of the commercial ACL.

For the recreational sector, the current buffer between the ACL and ACT is approximately 10 percent. The Council recommended a more conservative ACT than if they had applied the ACL and ACT control rule, which would have resulted in a 10 percent buffer between the ACL and ACT. Instead, the Council recommended doubling that buffer to increase the probability of rebuilding gag by accounting for uncertainty in managing the recreational harvest and further reducing fishing mortality and discards that result from directed harvest. NMFS agrees, thus, this final rule will implement a recreational ACT that is approximately 20 percent below the recreational ACL. Table 1 shows the catch levels recommended in Amendment 56, and except for the stock ACL, these catch levels are included in the regulatory text at the end of this rule.

TABLE 1—STOCK ACL AND SECTOR CATCH LEVELS BY YEAR FOR GAG

Year	Stock ACL lb (kg)	Com ACL lb (kg)	Rec ACL lb (kg)	Com ACT & Quota lb (kg)	Rec ACT lb (kg)
2024	444,000 (201,395)	155,000 (70,307)	288,000 (130,635)	147,000 (66,678)	230,000 (104,326)
2025	615,000 (278,959)	215,000 (97,522)	399,000 (180,983)	204,000 (92,533)	319,000 (144,696)
2026	769,000 (348,813)	269,000 (122,016)	499,000 (226,343)	255,000 (115,666)	399,000 (180,983)
2027	943,000 (427,738)	330,000 (149,685)	613,000 (278,052)	313,000 (141,974)	490,000 (222,260)
2028	1,156,000 (524,353)	404,000 (183,251)	751,000 (340,648)	383,000 (173,726)	600,000 (272,155)

Note: Values are displayed in gutted weight. Abbreviations used in this table: Com means commercial and Rec means recreational. Lb is pounds and kg is kilograms. Catch levels for 2028 will continue after 2028 unless changed.

Recreational Accountability Measures

Currently for the recreational sector, the AMs require NMFS to prohibit harvest of gag for the rest of the fishing year when recreational landings reach its ACL. The AMs also state that if the recreational ACL for gag is exceeded in a fishing year, then in the following fishing year, NMFS will maintain the

prior year's ACT at the same level, unless the best scientific information available determines that is unnecessary, and the fishing season duration will be set based on the recreational ACT. In addition to the previous measures, if gag is overfished and the recreational ACL is exceeded in a fishing year, NMFS will reduce the ACL and ACT in the following fishing year by the amount of the ACL overage, unless the best scientific information available determines that is unnecessary. Amendment 56 and this final rule change the recreational AMs to require that NMFS prohibit harvest when the recreational ACT is projected to be met regardless of whether there was an overage of the recreational ACL in the prior year. NMFS and the Council expect this change, in combination with the increased buffer between the recreational ACL and ACT, to decrease the likelihood of recreational harvest exceeding the recreational ACL. The larger buffer between the recreational ACL and ACT will also reduce the level of discards associated with directed harvest, increasing the probability of meeting the 18-year rebuilding time.

This final rule will also remove the recreational AM that requires the previous year's ACT to be maintained in the year following an overage of the recreational ACL. Because the stock is overfished and NMFS is required to reduce the ACL and ACT by any overage, an additional adjustment that retains the lower ACT is unnecessary.

Recreational Fishing Season

Before NMFS implemented the temporary recreational fishing season for gag in 2023, the recreational season for gag was open each year from June 1 through December 31 (79 FR 24038, April 25, 2016). During the effective period of the temporary rule, the recreational fishing season opened on September 1 and was to close on November 10, 2023, unless NMFS projected the recreational ACL would be harvested prior to that date. On October 4, 2023, NMFS published a temporary rule in the **Federal Register** closing the recreational harvest of gag effective on October 19, 2023 (88 FR 68495).

This final rule will modify the recreational fishing season for gag so the season begins each year on September 1. Unlike the season implemented by the temporary rule, Amendment 56 and this final rule do not establish a predetermined season closure date. Consistent with the changes to the AMs, NMFS will close the gag recreational season when landings reach the recreational ACT. NMFS will use the best data available to project the duration of the recreational season in 2024 and in following years. NMFS expects to have better estimates of recreational fishing effort and catch of gag for a season beginning September 1 after data from 2023 are finalized. This should reduce the uncertainty in projecting an appropriate closure date for the 2024 recreational fishing season. Once the recreational ACT for gag is projected to be met and harvest is closed, recreational fishing for gag would not resume before the end of the year because data would not be available in time for NMFS to determine whether landings did reach the ACT and potentially reopen harvest.

Management Measures in Amendment 56 That Will Not Be Codified in Regulations by This Final Rule

In addition to the measures that will be codified in regulations through this final rule, Amendment 56 revises the MSY proxy, OY, and SDC for gag. Further, Amendment 56 revises the gag OFL, ABC, and sector allocations of the stock ACL.

Maximum Sustainable Yield, Optimum Yield, and Status Determination Criteria

Based on the results of SEDAR 72, Amendment 56 revises MSY proxy, OY, and the SDC used to determine whether overfishing is occurring or the stock is overfished. The proxy for MSY is defined as the yield when fishing at $F_{40\%SPR}$, where SPR is the ratio of SSB to its unfished state. The maximum fishing mortality threshold (MFMT) is equal to $F_{40\%SPR}$. The minimum stock size threshold (MSST) is defined as 50 percent of the biomass at the new MSY proxy. The OY is conditional on the rebuilding plan, such that if the stock is under a rebuilding plan, OY is equal to the stock ACL; and if the stock is not under a rebuilding plan, OY is equal to 90 percent of MSY or its proxy. Currently, MSY is defined in the FMP as F assuming F_{MAX}, and the MFMT is F_{MAX}. The MSST is defined as 50 percent of the biomass at F_{MAX}. The OY is defined as 75 percent of the yield at F_{MAX}. The changes to the MSY, OY, and SDC represent a more conservative approach to management that will rebuild the gag stock to a more robust size, which should be more resilient to episodic mortality from environmental factors including red tide and other harmful algal blooms, and sustainable levels of fishing mortality.

Stock Rebuilding Plan Timeline and Modification of OFL, ABC, and Sector Allocations

Amendment 56 establishes a rebuilding plan and sets the rebuilding time for gag at 18 years, which is based on the amount of time the stock is expected to take to rebuild if fished at 75 percent of the MSY proxy (yield at $F_{40\%SPR}$). Amendment 56 evaluated two other rebuilding times: 11 years, which is the minimum time to rebuild in the absence of fishing mortality; and 22 years, which is twice the minimum time. In addition, the Council initially considered an alternative rebuilding time of 19 years, which is based on the minimum rebuilding time plus one generation time (8 years for gag). Because this option resulted in a rebuilding time similar to fishing at 75 percent of the MSY proxy, the Council removed this alternative from further consideration (Appendix C in Amendment 56). The Council also discussed whether to consider in more detail a rebuilding time between 11 years and 18 years. The Council decided not to add an additional alternative because a slightly shorter rebuilding time would provide minimal benefits to the stock but increase the negative impacts to fishing communities.

Consistent with the rebuilding time recommended by the Council, Amendment 56 revises the OFL and ABC, and sets the stock ACL equal to the ABC. In addition, Amendment 56 revises the sector allocation percentages of the stock ACL from 39 percent commercial and 61 percent recreational to 35 percent commercial and 65 percent recreational, and revises the sector ACLs consistent with the revised allocations as stated earlier in this final rule. The OFL and ABC values by year from 2023 through 2028 are shown in table 2. However, the OFL and ABC values in 2023 are not directly comparable to the OFLs and ABCs from 2024 through 2028, because they are based, in part, on recreational landings estimates produced by the different surveys discussed earlier. Values in 2028 will continue for subsequent fishing years unless modified through another action by the Council or NMFS.

TABLE 2—OFLS AND ABCS VALUES BY YEAR FOR GAG

Year	OFL in pounds (kg)	ABC in pounds (kg)
2023	4,180,000 (1,896,016)	3,120,000 (1,415,208)
2024	591,000 (268,073)	444,000 (201,395)
2025	805,000 (365,142)	615,000 (278,959)
2026	991,000 (449,510)	769,000 (348,813)
2027	1,200,000 (544,311)	943,000 (427,738)
2028	1,454,000 (659,523)	1,156,000 (524,353)

Note: Values are displayed in gutted weight. Kg is kilograms. The ABC values also equal the stock ACL values for gag. Catch levels for 2028 will continue after 2028 unless changed.

Administrative Change to Codified Text Not in Amendment 56

NMFS also clarifies the regulations at 50 CFR 622.8(c) with this final rule. These regulations allow NMFS to re-open harvest for a stock in the same fishing year if data indicate that a quota or ACL was not reached as previously projected. Several stocks have ACTs that are also codified in regulation as quotas. However, some ACTs, such as the recreational ACT for gag, do not have corresponding quotas, and therefore may not appear to be included in the current authority to re-open. NMFS is modifying the regulations in section 622.8(c) to provide a more general reference to allowable harvest levels. This will be consistent with the framework procedures in the relevant fishery management plans that allow NMFS to re-open harvest if additional data show that NMFS closed a season prematurely.

Comments and Responses

NMFS received 33 comments in response to the notice of availability for Amendment 56, and 10 comments were received on the proposed rule. Comments ranged widely in scope, with some supporting Amendment 56 without modification, while others urging disapproval. In general, recreational fishermen and groups supporting recreational fishing are in favor of the revised allocation percentages of the stock ACL for gag between the commercial and recreational sectors in Amendment 56 and this final rule. Commercial fishermen, commercial fishing organizations, and environmental groups generally supported maintaining the current allocation percentages of the stock ACL for gag between the commercial and recreational sectors. Some comments that NMFS received were outside the scope of this action. These comments included suggestions that the for-hire component of the recreational sector be moved to the commercial sector; concern that predation and depredation by sharks and goliath grouper are responsible for much of the decline in abundance of gag and reef fish abundance in general; concern of interspecies competition with red snapper and triggerfish on the reefs due to perceived inadequate management of these species; concern that fertilizer runoff is a causal factor in the decline of gag; NMFS should provide an annual health check to ensure the rebuilding plan for gag is on track; and NMFS and the Council should be managing the reef ecosystem as a whole rather than just by individual fish species. Comments specific to Amendment 56 and the proposed rule are grouped as appropriate and summarized below, each followed by NMFS' respective response.

Comment 1: Several commenters did not support the proposed recreational season. Suggested alternatives included a June 1 start date; seasons from November through February, and October to January; or shorter, intermittent season openings (*e.g.,* a season open a few weeks at a time throughout the summer and fall).

Response: The Council recommended, and NMFS approved, the recreational season start date in Amendment 56 of September 1 to try to provide the longest season possible. The analysis in Amendment 56 indicated that beginning the season on September 1 would result in the longest recreational fishing season of the alternatives considered. For example, initial estimates are that a June 1 start date would result in a recreational season lasting only 16 days. Regarding the suggested October through January season and November through February season, NMFS estimated that the high fishing effort and catch rates during October through December would result in fewer fishing days than a September 1 starting date. Shorter seasons, including intermittent season openings, are more likely to result in derby-like (race to fish) fishing, where greater effort and greater numbers of fish are harvested in a shorter period, and fishermen may decide to go out in more dangerous weather and sea conditions. The September season start date promotes safety of human life at sea to the extent practicable, consistent with National Standard 10 (NS 10) of the Magnuson-Stevens Act.

Comment 2: The recreational season should be fixed, and NMFS should not prohibit harvest before the established closure date.

Response: NMFS disagrees that it is appropriate to allow fishing until a fixed annual closure date. The Magnuson-Stevens Act requires AMs, which the NS 1 guidelines explain are management controls to prevent ACLs, including sector ACLs from being exceeded [50 CFR 600.310(g)]. The recreational AMs for gag at 50 CFR 622.41(d)(2)(i) require NMFS to prohibit further harvest when NMFS estimates that recreational landings will reach or have reached the applicable catch limit. Allowing fishing to continue until a date certain after NMFS determines that landings would reach the catch limit would not be consistent with the AMs. In 2023, the Council recommended and NMFS implemented, a recreational fishing season for gag that opened on September 1 and was to close no later than November 10, for a maximum of 70 days. However, NMFS explained that if the best available data indicated that the catch limit would be harvested before the end of the 70-day period, NMFS would implement a recreational closure prohibiting harvest of gag for the remainder of the fishing year. When NMFS analyzed in-season data that became available during the 2023 open season, NMFS determined that the 2023 ACL for gag had been harvested and closed the recreational season on October 19, 2023. Amendment 56 and this final rule do not specify an end date to the recreational season, which has an opening date of September 1, 2024. Consistent with the AMs, NMFS will use the best scientific information available to determine when recreational harvest will reach the applicable catch limit and close the season on that date.

Comment 3: Several commenters suggested closing commercial and recreational fishing for reef fish for a year or making gag catch and release only until the population rebuilds. Another commenter suggested further reductions to the gag catch limits for the commercial and recreational sectors.

Response: As described in Amendment 56, the NMFS Southeast Fisheries Science Center produced models to predict the effect of reducing gag catch to different levels and estimate how quickly those reduced catch levels would rebuild the gag stock. The models estimated that even if there were no fishing mortality, including no dead discards, the stock would take 11 years to rebuild. Thus, implementing a total fishing closure for 1 year, including no catch and release fishing (and thus no landed catch), or further reducing landed catch limits would not be expected to result in a substantial reduction in the time needed to rebuild the stock. In addition, a complete closure of gag fishing would result in the loss of important fishery-dependent and biological information that help monitor stock rebuilding and in determining appropriate management of gag and other reef fish species. In addition, prohibiting fishing for 1 year or further reducing the catch limits would increase adverse social and economic effects on fishermen and communities that are reliant on gag. (See the response to *Comment 4* for more information on the expected economic effects of Amendment 56 and this rule.)

Comment 4: The low quotas are causing economic hardships for commercial fishermen who cannot pay their bills.

Response: NMFS agrees that the significant reduction in the commercial quota for gag is expected to have adverse economic effects on commercial fishing businesses, and some commercial vessels and fishing businesses may not be earning an economic profit. However, the most recent available data does not indicate that the average commercial fishing vessel that harvests gag or the average commercial fishing business that possesses quota shares for gag is not able to cover its costs or earn an economic profit. Available data suggests that vessels harvesting gag earn economic profits equal to about 32 percent of their annual gross revenue on average. Further, available data suggests that expected economic profits from the harvest of IFQ species (red snapper, groupers, and tilefishes) for all commercial fishing businesses that possess gag shares are at least $29.4 million. This estimate does not account for any economic profits that may accrue to businesses with gag shares that also own commercial fishing vessels that harvest non-IFQ species. Such profits are likely to be small because harvest of IFQ species accounts for around 84 percent of commercial IFQ vessels' annual revenue and economic profits from the harvest of non-IFQ species tend to be smaller than those from IFQ species. Given that there are 455 commercial fishing businesses that possess gag quota shares, the average annual expected economic profit per commercial fishing business is at least $64,620.

Most of these expected economic profits (84 percent) are the result of owning IFQ quota shares for red snapper. Only approximately 1.7 percent of their expected economic profits is thought to be due to the ownership of gag quota shares, and NMFS expects this rule to affect economic profits only from the ownership of gag shares. More specifically, the action to change the sector allocation, implement a rebuilding plan, and change the stock ACL will reduce the commercial quota from 939,000 lb to 212,000 lb (425,923 kg to 96,162 kg) on average from 2024 through 2028. However, average annual commercial landings of gag from 2017 through 2021 were only 492,401 lb (223,349 kg), which is noticeably below the current commercial quota. Therefore, the expected average reduction in annual commercial landings is 280,401 lb (127,188 kg), far less than the reduction in the commercial quota. In addition, the expected reduction in commercial landings is expected to initially increase the average ex-vessel price of gag from $6.10 per lb to $7.78 per lb in 2024, and then gradually decrease to $6.96 per lb in 2028. This increase in the ex-vessel price is expected to partially offset the adverse effects of the expected landings reduction. Thus, the expected reduction in ex-vessel revenue for gag on average is approximately $1.57 million per year. Given an average annual allocation price of $1.03 per lb for gag, the expected reduction in commercial landings of gag is expected to reduce economic profits to these commercial fishing businesses by about $288,813, or by approximately $635 per commercial fishing business. Thus, NMFS expects the reduction in economic profits to be around 1 percent on average per commercial fishing business as a result of the action to change the sector allocation, implement a rebuilding plan, and change the stock ACL. NMFS does not expect a 1 percent reduction in economic profits to cause an economic hardship for the average commercial fishing business that possesses quota shares for gag.

Comment 5: The gag population is healthy. The catch level reductions for gag are unnecessary.

Response: NMFS disagrees that the reduction in the gag catch limits are unnecessary. The most recent stock assessment for gag (SEDAR 72), completed in 2021, is the best scientific information available, indicates that the gag stock is overfished and undergoing overfishing, and that a reduction in the catch limits is necessary to rebuild the stock. The assessment included a multi-day data review workshop and several webinars, was peer reviewed, and was reviewed by the Council's SSC. NMFS recognizes that the abundance of gag varies across locations. However, gag is managed as a single stock in the Gulf, and the stock assessment, which used Gulf-wide data, concluded that the overall abundance has declined since the previous gag stock assessment was completed in 2016. This conclusion is supported by the inability of both the commercial and recreation sectors to harvest their allotted catch limits of gag. In the last 5 years covered by SEDAR 72 (2015 through 2019), the combined commercial and recreational harvest exceeded 50 percent of the gag stock ACL only once (2016).

Comment 6: Recreational data used in making decisions for gag management, such as the assessment and catch-per-unit-effort calculations, have too much error and should not be used. NMFS should only use recreational data that have less than 25 percent standard error.

Response: The Magnuson-Stevens Act requires that fishery conservation and management decisions be based on best scientific information available. The percent standard error associated with an estimate reflects the uncertainty in that estimate. Although NMFS recognizes that reducing standard error in recreational catch estimates for gag would be beneficial, the estimates for recreational catch that are used in Amendment 56 are based on best scientific information available, and are thus appropriate to be used in management. Sometimes the data determined to be the best scientific information available do not have a PSE of less than 25 percent, but the data are necessary and appropriate to be used for management. NMFS sets catch levels (such as ABC and ACL) to address both scientific and management uncertainties. As newer and better data become available, NMFS will update analyses and methodologies to reduce

uncertainty in future management decisions. However, the management measures implemented through this final rule are based on best scientific information available at the time they were developed.

Comment 7: Gag shortages are caused by man-made red tide caused by pollution. Red tides are one of the primary drivers of mortality and the cause of overfishing. Red tide is not sufficiently addressed in the management actions within Amendment 56 as required by the Magnuson-Stevens Act and the NS 1 guidelines. In addition, the amendment should include management actions that address climate change impacts. The climate vulnerability analysis (CVA) indicates that gag has a high overall vulnerability to climate change impacts, yet no management considerations are suggested to alleviate the risks. An MSY proxy of 40 to 50 percent of the SPR is a more appropriate baseline for conservation of the stock but does not directly mitigate impacts from environmental conditions and therefore is not a sufficient management action to address the environmental conditions that are contributing to overfishing.

Response: NMFS recognizes that red tide is one of the primary drivers of mortality for gag, and that gag are highly susceptible to negative impacts of climate change (as indicated by the CVA for gag). Red tide has occurred throughout the known history of the Gulf, and while not man-made, there is evidence suggesting that human induced factors, including pollution, may increase the intensity of red tide events. Still, despite extensive research on causes and factors exacerbating red tide events, much is unknown about these events and how to reduce the negative effects they have on the environment and, specifically, on gag. Further, the timing, location, and intensity of red tide is intermittent, not predictable, and highly variable, as are their effects on gag. For example, while red tide can be associated with large mortality events for gag, it is also often associated with higher than normal recruitment of gag in the following year (presumably due to density dependence mechanisms of gag ecology, such as less competition for food or ideal habitat).

Regarding climate change, the CVA for gag identified the sensitivities and exposures that contribute to the stock's high vulnerability. However, the analysis recognized that few studies have examined the effect of climate factors on the population productivity and distribution of gag, and that it is unclear how any changes will impact abundance and distribution of the stock. Thus, although NMFS is concerned about the increasing negative impacts of climate change on gag as estimated by the CVA and how these factors, in addition to red tide, may negatively affect gag population dynamics in the future, NMFS has determined that Amendment 56 includes measures that sufficiently address the uncertainty related to these impacts.

The SEDAR 72 gag stock assessment directly considered the expected mortality associated with red tide but NMFS models do not account for the increased recruitment associated with these events due to the high level of uncertainty associated with this process. This is because while increased recruitment after a red tide event is predictable, the magnitude of the increase is not.

Despite the uncertainty, Amendment 56 contains management changes to take a more precautionary approach, such as using rebuilding catch projections that are based on the SSB for males and females combined as opposed to just female SSB, and modifying the MSY proxy to be $F_{40\%SPR}$. These changes are expected to help mitigate the adverse effects of both red tide events and climate change by directly accounting for male SSB, which has been recognized as a limitation on rebuilding, and rebuilding the stock to a larger size stock size based on the revised MSY proxy. NMFS does not agree that the MSY proxy should be set at a more conservative level. As explained in Section 1.1 of Amendment 56, the SSC recommended an MSY proxy of $F_{40\%SPR}$ based on gag's susceptibility to episodic mortality from red tide and guidance from a 2019 study by Harford *et al.* The SSC concluded that an MSY proxy of $F_{40\%SPR}$ would allow the stock to rebuild to a more robust level of SSB making it more resilient to environmental influences like red tide and to changes in fishing mortality. NMFS agrees with the SSC that an MSY of $F_{40\%SPR}$ is sufficiently conservative to address current and foreseeable mortality due to fishing and environmental factors.

Comment 8: Amendment 56 and this final rule violate section 303(a)(15) of the Magnuson-Stevens Act, which requires hard catch limits and AMs that will ensure that ACLs will not be exceeded and overfishing will not occur in the fishery. There is no certainty that the measures included in Amendment 56 and the proposed rule will end overfishing. While Amendment 56 includes a 20 percent buffer between the recreational ACL and ACT, the ACT is not an effective recreational AM because it does little to address discards either in or out of season, and targeted recreational catch is not driving overfishing. Further, by admitting that an exact accounting of total gag mortality cannot be determined at this time, NMFS concedes that Amendment 56 does not include legally sufficient ACLs and AMs.

Response: Amendment 56 and the FMP are consistent with the requirements of section 303(a)(15) of the Magnuson-Stevens Act, which requires the FMP to include ACLs, at a level such that overfishing does not occur, and AMs. With respect to discarded fish, there is no requirement in this provision to separately specify or monitor discard mortality. The NS 1 guidelines define catch as including both landed fish and dead discards [50 CFR 600.310(f)(1)(i)]. However, the NS 1 guidelines also state that the ABC, on which the ACLs are based, may be expressed in terms of landings as long as estimates of bycatch and any other fishing mortality not accounted for in the landings are incorporated into the determination of ABC [50 CFR 600.310(f)(3)(i)]. The OFL, ABC, and ACLs specified in Amendment 56 are derived from SEDAR 72 SRFS Run, which accounted for dead discards estimates that were derived from the best scientific information available. Thus, an exact accounting of total mortality is not necessary to apply the AMs to constrain harvest to the ACLs, which are expressed in terms of landed fish only. In addition, as explained in response to *Comment 10,* NMFS recognizes that a significant portion of past gag recreational catch occurred when the recreational season is closed, and is thus discarded, but NMFS expects the significant reduction in the stock ACL as well as the larger buffer between the recreational ACL and ACT, to result in much lower overall gag mortality as required by the rebuilding plan.

Comment 9: The rebuilding plan is legally insufficient because there are no interim measures to monitor the total mortality from discards, as only landings are used for management in non-assessment years.

Response: NMFS disagrees that the rebuilding plan is not legally sufficient. It is unnecessary to monitor discards directly because the rebuilding catch limits are expressed as landed fish. Discard mortality is incorporated into the determination of these catch limits through the SEDAR 72 SRFS Run, which is consistent with the best scientific information available.

Comment 10: The management measures in Amendment 56 and the proposed rule are insufficient to provide at least a 50 percent probability of

rebuilding the gag stock because they do not adequately address discard mortality resulting from recreational sector bycatch. The projections from the stock assessment assume that discards will be reduced proportionally to landed catch but this assumption has been proven false. The private recreational sector discards an estimated 90 percent of gag that are caught, suggesting that the majority of gag interactions occur as non-target interactions. The actions in the amendment do not reduce discards, and Amendment 56 suggests these actions are likely to increase discards, because under the rebuilding plan, increased regulatory discarding of gag would occur during any open fishing season for co-occurring target species (*e.g.,* red grouper, red snapper). In order to reduce discards to appropriate levels, fishery managers must rely on the improbable scenario that individual anglers take action to intentionally avoid gag and therefore reduce their collective discard rates.

Response: NMFS disagrees that the measures being implemented do not provide at least a 50 percent probability of rebuilding the stock. While NMFS recognizes that a significant portion of past gag recreational catch occurred when the recreational season is closed and, therefore, was discarded, the basis for the commenter's assumption that the majority of gag interactions occur as non-target interactions is unclear. Further, NMFS does not agree that this means imposing new stricter catch limits will not rebuild the stock as projected.

With respect to the recreational sector, this rule will further reduce the allowable harvest by increasing the buffer between the recreational ACL and the ACT by 10 percent more than necessary to account for the uncertainty in constraining recreational harvest. This additional 10 percent reduction in recreational harvest will further reduce mortality and increase the probability of rebuilding.

NMFS also disagrees that the assumption that discards will be reduced proportionally to landed catch ''has been proven false.'' NMFS does not have comparable catch or effort data to test this assumption because of the lower catch limits and changes in the dates of the recreational season. Thus, NMFS cannot precisely predict the effects of the management measures in this final rule until we have appropriate data, which will likely be after a few years of rebuilding (including the changes in recruitment, *etc.*) has been completed. Further, many factors affect angler behavior and discards, including changes in the number of fish recruiting (entering) the fishery, open and closed seasons for other reef fish species, and prevailing economic conditions which can affect the amount of angler fishing effort and catch and discard rates.

NMFS expects the change to a September 1 opening date for the recreational season to result in recreational fishermen targeting gag in shallower and colder waters than the previous season, which should further increase survivability of released fish and result in additional escapement contributing to rebuilding the stock. Consistent with section 304(e)(7) of the Magnuson-Stevens Act, NMFS will review rebuilding plan progress. If NMFS determines that adequate progress is not being made because fishing mortality (both landings and discards) exceeds the level necessary to rebuild the gag stock, NMFS will notify the Council and recommend further conservation and management measures, including potential development and implementation of a new or revised rebuilding plan.

Comment 11: The rebuilding plan is legally insufficient because the rebuilding projections (and increases in the ACL) are dependent on the assumption that the sectors will operate as they have in recent years, which we know to be a false assumption.

Response: The stock assessment model requires assumptions about future fishing behavior to produce appropriate catch limit recommendations. The SEDAR 72 SRFS Run assessment projections assume that selectivity, discarding, and retention were the same as the most recent year, which was 2019. This is the best available scientific information at the time those projections were developed. NMFS does not have any data to determine the extent or magnitude of any potential changes to fishing practices. As new data become available on any changes in fishing practices, NMFS can revisit the assessment assumptions as appropriate. NMFS can also use any new data to improve in-season management. For example, NMFS recognizes that changing the start date of the recreational fishing season from June 1 to September 1 is likely to change how the recreational sector operates both during and outside of the open season. While the scope of the effects from the change are not well understood, NMFS is in the process of fully analyzing 2023 data, during which the gag catch limits were reduced and the recreational season started on September 1. Since the 2023 interim regulations are more directly comparable to those being implemented in Amendment 56 and the final rule, NMFS will be more able to accurately predict and anticipate factors such as recreational fishing effort, harvest rates, in-season and out-of-season bycatch rates, and other variables that may result in differential effects to the gag population. Thus, as more appropriate and comparable data are collected, NMFS has the ability to mitigate negative impacts and can take steps to ensure the schedule to rebuild the gag stock is maintained.

Comment 12: Amendment 56 is insufficient to provide at least a 50 percent probability of rebuilding success because it would increase the ACLs each year after 2024. By 2027, the commercial ACL will be only approximately 50 percent of 2022 commercial landings but the recreational ACL will be greater than 2022 recreational landings as estimated by MRIP–CHTS. NMFS should implement a precautionary constant catch approach for gag that would maintain catch at baseline levels and would not proceed with increases until there are tangible signs of stock improvement. A constant catch approach paired with more frequent interim assessments and monitoring of discarding and red tide trends would add baseline protection to this highly vulnerable stock and improve the likelihood of rebuilding success.

Response: NMFS disagrees that because the catch limits for gag increase over time, the probability of rebuilding success will be less than 50 percent and that a more precautionary constant catch approach is appropriate. First, the rebuilding plan is based on the stock assessment, which was informed by the more conservative MSY proxy of $F_{40\%SPR}$ and the recommendations from the Council and SSC that include the increases to the commercial and recreational ACLs adopted in this final rule. Second, NMFS will set the recreational season length based on when the recreational ACT is projected to be met as specified in the revised AMs. It is inappropriate to compare the MRIP–CHTS recreational landings estimate from 2022 to the 2027 recreational ACT, which is based in part on SRFS data. Using consistent recreational data from SRFS, the recreational ACT increases from 230,000 lb (104,326 kg) in 2024 to 600,000 lb (272,155 kg) in 2028, which is well below average recreational landings from 2017 through 2021, which were over 1.2 million lb (544,311 kg). Even if the ACL were the management target, the recreational ACL for 2028 is only 751,000 lb (340,648 kg), which is approximately 63 percent less than the

1.2 million-lb (544,311-kg) average. Finally, a constant catch approach that keeps the stock ACL at the 2024 baseline level would increase the adverse economic and social effects on fishery participants and fishing communities, without significant benefits to stock. As explained in Amendment 56, a rebuilding plan that is based on no fishing mortality would be expected to rebuild the stock in 11 years, as opposed to the 18-year rebuilding plan implemented in this final rule. Thus, a constant catch rebuilding plan that keeps the 2024 stock ACL of 444,000 lb (201,395 kg) is unlikely to result in a significant reduction of the projected rebuilding time but would increase the negative social and economic impacts as discussed in Chapters 4, 5, and 6 of Amendment 56. This would not be consistent with section 304(e)(4) of the Magnuson-Stevens Act, which requires that the rebuilding period for an overfished stock be as short as time possible, taking into account both the biology of the stock and the needs of fishing communities or NS 8, which requires, in pertinent part, that conservation and management measures minimize adverse economic impacts on such fishing communities to the extent practicable.

Comment 13: Amendment 56 is insufficient to provide at least a 50 percent probability of rebuilding success because it fails to address the key biological vulnerabilities of the gag stock including reducing mortality of older, male fish and improving male recruitment (escapement of females and transitioning males) from nearshore reefs so that a greater percentage can become older and transition to male.

Response: NMFS disagrees with the premise that male gag mortality and recruitment need to be addressed directly for the rebuilding plan to have a least a 50 percent chance of success. Amendment 56 includes several measures that address concerns related to male gag mortality and recruitment. A long history of harvesting large males and large fecund females is a large part of the issue with the current sex ratio of gag. Amendment 56 substantially reduces allowable harvest of gag for both the commercial and recreational sectors, which is expected to reduce overall mortality of gag, including that of older adult male fish, and increase male recruitment. In addition, the discard mortality rate is relatively low in the recreational sector due to the generally shallower depth of fishing when compared to the commercial sector, so there would be reduced mortality from reduced catch limits contributing to rebuilding the stock in the long run. Further, NMFS expects the commercial sector to be able to avoid large individuals specifically due to more selective fishing practices as they manage their limited individual fishing quota allocations, which should result in improvements in the stock by reducing pressure on these large gag. Reduced catch limits are also expected to result in greater recruitment of male gag because they will result in more fish in the population, and thus more fish will be available to move to deeper offshore waters to transition to male.

In addition to the lower catch limits, the change in the recreational fishing season from a June 1 start date to a September 1 start date is expected to result in reduced harvest of male gag, which are found almost exclusively in deep water. Fishermen have often reported at Council meetings that gag feed more aggressively when water temperatures are cooler, and particularly when nearshore waters are cooler. Further, studies have shown that discard mortality is lower when fish are caught and released into cool surface water compared to warm surface water. Thus, capturing and releasing gag during summer months, especially from deeper water where barotrauma becomes an increasingly influential factor on discard mortality for gag, is likely to result in increased discard mortality compared to capturing and releasing gag during comparatively cooler fall and winter months. Because directed fishing effort for gag in summer months is typically conducted in greater average depths than in fall months, the probability of harvesting or discarding dead a male gag is higher by comparison in these summer months. Therefore, changing to a September opening of the recreational season is expected to contribute to a reduced mortality of adult male gag.

Comment 14: Amendment 56 violates Magnuson-Stevens Act NS 9 because it allocates fish to the recreational sector and away from the commercial sector. NMFS data estimates that the commercial sector was responsible for less than 1 percent of all gag discards between 1993 and 2019. Choosing an alternative that provides a lower catch limit to the recreational sector and consequently provides a higher gag stock ACL would allow for less waste, more landings, and minimize discards. In addition, the Bycatch Practicability Analyses (BPA) in Amendment 56 does not analyze whether the FMP contains measures to reduce bycatch to the extent practicable, and has no discussion of other measures that could reduce bycatch or bycatch mortality, for example, whether requiring larger circle hooks could reduce catch of smaller grouper; and time or area closures and the effects on bycatch. Other significant discard analyses, including projections, should have been considered and included in the rebuilding plan. Examples include projections at higher and lower discard rates than is assumed, higher uncertainty, *etc.,* to identify at what level of discarding may be occurring on an annual basis. A thorough discard analysis is critical to ensuring the proposed management measures will end overfishing and rebuild the stock. Additional analysis should also have been done to minimize out-of-season discarding through other measures, such as spatial closures or discarding rates during other species' open seasons, and the ABC should reflect any uncertainty from these analyses.

Response: NS 9 requires that conservation and management measures, ''to the extent practicable: (1) minimize bycatch; and (2) to the extent bycatch cannot be avoided, minimize the mortality of such bycatch.'' Conservation and management measures must also be consistent with all of the other National Standards and maximization of net benefits to the Nation. As the National Standard guidelines explain, 10 factors should be considered when determining consistency with NS 9. Some of these factors include population effects for the bycatch species; changes in the economic, social, or cultural value of fishing activities, and non-consumptive uses of fishery resources; changes in the distribution of benefits and costs; and social effects [50 CFR 600.305(d)(3)]. Thus, NS 9 does not require that management measures result in the greatest stock size as the comment appears to suggest. Rather, NMFS must consider and account for the different economic, social, and cultural objectives of the commercial and recreational sectors when determining whether management measures minimize bycatch and bycatch mortality to the extent practicable. Participants in the commercial sector tend to seek to maximize harvest and efficiency while participants in the recreational sector tend to seek to maximize access and fishing opportunities. The sectors operate differently to achieve those objectives, and these differences impact fishing behavior, which generally results in more discards by the recreational sector.

The BPA (Appendix H in Amendment 56) provides information about gag bycatch and bycatch mortality, and discusses the 10 factors in the NS 9

guidelines at 50 CFR 600.350(d)(3), which include summaries of the biological, economic, and social effects presented in Chapter 4 of Amendment 56. As noted in Section 4.2.2 of Amendment 56, the impacts to the gag stock are similar under both allocation alternatives because the overfishing limits are based on a fixed level of fishing mortality. The recreational sector is responsible for more discards and more dead discards than the commercial sector. Therefore, Preferred Alternative 3 (Preferred Option 2b) in Action 2, which changes the allocation percentages, allows for slightly less total harvest than Alternative 2 (Option 2b), which would retain the current allocation percentages, reducing the stock ACL by approximately 9,000 lb (4,082 kg) in 2024 (about 2 percent). However, NMFS expects both Alternative 2 and Alternative 3 in Action 2 to reduce discards when compared to Alternative 1 (no action) due to the substantial reduction in catch limits, and the numbers and rates of discards and discard mortality between Alternatives 2 and 3 are expected to be similar. NMFS also expects an additional reduction in recreational discards associated with directed fishing as a result of the increase in the buffer between the recreational ACL and ACT from 10.25 to 20 percent, and the requirement that NMFS prohibit recreational harvest when the ACT is projected to be met.

With respect to the economic and social effects on both the commercial and recreational sectors, the expected negative impacts are a result of the need to implement a rebuilding plan that requires a significant reduction in the total allowable harvest of gag (see Amendment 56 BPA Criterion 6, 8, 9, and 10, and Sections 4.2.3 and 4.2.4). The new allocation percentages result in an increase in those negative effects for the commercial sector and a decrease in those effects for the recreational sector. However, the revised allocation represents the historical harvest of the two sectors during the same time period as the original allocation (1986 through 2005) updated only to reflect that there has been a change in the survey used to estimate recreational landings. Given the need to account for the different objectives of the commercial and recreational sectors, and provide for the greatest overall benefit to the Nation with respect to both food production and recreational opportunities NMFS has determined that gag bycatch and bycatch mortality are minimized to the extent practicable in both the FMP and Amendment 56.

While NMFS agrees that additional research and analyses could be conducted in the future to determine more precise impacts that bycatch may have on the catch projections or if there are other measures that could further reduce gag bycatch and bycatch mortality, NMFS is required to implement a rebuilding for gag within 2 years of notification to the Council that gag is overfished and, consistent with NS 2, NMFS used the best scientific information available to develop the rebuilding plan for gag and address the various requirements of the Magnus-Stevens Act, including NS 9. As discussed at the Council's January 2024 meeting, NMFS and the Council intend to review additional data and analyses to determine whether additional measures to reduce bycatch of gag (*e.g.,* time or area closures) are practicable. The Council initially considered including additional measures, such as increasing the number of area closures, to Amendment 56 but determined that it was not practicable to do so because before implementing new time or area closures, it was necessary to gather further data and analysis was needed on the impacts of the current closed areas (*i.e.,* Madison-Swanson and Steamboat-Lumps marine protected areas). In addition, after the rebuilding plan has been in effect for a few years, it may be possible to perform alternative stock assessment analyses that incorporate new information on discards in the recreational sector and use the results from those additional analyses to inform the bycatch practicability analysis.

Comment 15: NMFS needs to clarify how dead discards are accounted for in setting the MSY and OY.

Response: Dead discards are accounted for in specifying both the MSY and OY for the gag stock through the stock assessment. The NS 1 guidelines define MSY as ''the largest long-term average catch or yield that can be taken from a stock or stock complex under prevailing ecological, environmental conditions and fishery technological characteristics (*e.g.,* gear selectivity), and the distribution of catch among fleets.'' 50 CFR 600.310(e)(1)(i)(A). OY is the long-term average desired yield from a stock that provides ''the greatest overall benefit to the Nation, particularly with respect to food production and recreational opportunities,'' is reduced from the MSY to take into account economic, social, and ecological factors, and in the case of an overfished fishery, provides for rebuilding to a level consistent with producing the MSY in such fishery. 16 U.S.C. 1802(33); see also 50 CFR 600.310(e)(3)(i). Amendment 56 defines MSY as the yield when fishing at $F_{40\%SPR}$ and defines OY based on rebuilding status, such that: if the stock is under a rebuilding plan, OY is equal to the stock ACL; if the stock is not under a rebuilding plan, OY is equal to 90 percent of MSY or its proxy. The catch projections produced from the SEDAR 72 SRFS Run are based on the MSY proxy specified in Amendment 56 and account for discard mortality. As explained in Amendment 56, during the rebuilding plan OY is set equal to the stock ACL because this is the amount of fish that, over the rebuilding time, would allow the stock to rebuild to a level that is consistent with producing MSY. When rebuilding is complete the OY will be set at 90 percent of the MSY or proxy, which is consistent with the OY set for other reef fish species in Amendment 48 to the FMP (87 FR 34811 June 8, 2022). As explained in Amendment 48, an OY of 90 percent of the MSY or proxy is an intermediate level (between 85 and 95 percent of the MSY of proxy) that balances the need to protect the stock and allow for both food production and recreational opportunities. After the stock rebuilds and if new information indicates that that this OY may not be appropriate, NMFS and the Council can consider that new information and whether to revise the OY.

Comment 16: Amendment 56 will cause hardship to recreational fishermen but will not hurt commercial fishermen. Recreational fishing seasons are getting shorter, as demonstrated by both the recreational gag and red grouper seasons in 2023. However, commercial harvest goes on unabated. Commercial and recreational regulations should be the same.

Response: NMFS disagrees that it is appropriate to have the same regulations for commercial and recreational fishing, and that Amendment 56 only negatively affects recreational anglers. Amendment 56 and this final rule will reduce the commercial and recreational ACLs for gag for each sector to levels substantially lower than average landings from 2017 through 2021. In addition, although both the commercial and recreational sectors have failed to catch or even approach their respective catch limits in recent years, the percent reduction for each sector ACL in this rule compared to their respective recent landings is similar. Commercial fishing is managed differently than recreational fishing to address the economic, social, and cultural goals of each sector. Recreational fishing is managed primarily with bag limits, size limits, and seasons to allow the maximum number of participants the opportunity

to fish. The commercial sector operates under an IFQ program, which allows commercial fishermen to harvest their share of the gag quota at any time during the year. So, unlike the recreational sector, there is no closed commercial season. Because the IFQ program gives individual commercial fishermen the flexibility to fish any time during the year, it prevents ''derby-like'' fishing that can create unsafe fishing conditions as fishermen race to catch as many fish as possible before a catch limit is reached. In addition, the IFQ program allows fishermen to supply fish over the course of the season, which allows for consumers to be able to purchase the fish throughout the year. However, regardless of when they fish during the year, fishing by both sectors is constrained by their respective annual harvest limits.

Comment 17: Amendment 56 and this final rule violate NS 4 of the Magnuson-Stevens Act because they allocate fish away from the commercial sector to account for the discards in the recreational sector, which is not fair and equitable and does not promote conservation.

Response: NMFS has determined that Amendment 56 and the final rule are fair and equitable and reasonably calculated to promote conservation, consistent with NS 4. The Council initially reviewed allocation options based on six different times series of landings data, but removed some options from further consideration because they resulted in relatively minor differences. In Amendment 56, the Council evaluated retaining the existing allocation percentages and updating those percentages using the SRFS recreational landings estimates calibrated to the same time series (1986 through 2005) that was used in setting the original allocation percentages. The Council determined, and NMFS agrees, that updating the allocation percentages using the SRFS calibrated recreational landings results is fair and equitable because it accounts for the transition to using SRFS data to estimate recreational catch while maintain the same referenced time series.

As explained in response to *Comment 14,* recreational fishing for gag (and many other reef fish species) typically involves higher numbers of discards than for the commercial sector, and the sector allocation percentages approved in Amendment 56 (*i.e.,* Alternative 3, Option 2b in Action 2) reduce the total ACL by approximately 9,000 lb (4,082 kg) when compared to the percentages proposed in Alternative 2b. However, the OY includes both recreational opportunities and food production, and the commercial and recreational sectors have different objectives, and operate differently to achieve those objectives. The Council and NMFS must consider and account for these differences when determining whether an allocation fairly and equitably allocates fishing privileges and provides the greatest overall benefit to the Nation with respect to both food production and recreational opportunities. Further, the large reduction in the total allowable harvest in Amendment 56 is not a result of the shift in sector allocation of the stock ACL but the result of SEDAR 72 and the determination that the stock is overfished and undergoing overfishing.

Comment 18: The Council failed to follow its allocation review policy by combining the allocation decision with decisions related to catch limits and rebuilding times. The Council's allocation policy requires a comprehensive allocation review and an after-the-fact determination that Amendment 56 includes that review is not sufficient. Further, the Council and NMFS suggest that the ''sector allocation ratio in Alternative 2 results in a de facto reallocation to the commercial sector of approximately 4 percent,'' but no allocation review was performed to evaluate this reallocation. If de facto reallocation arguments are to be used as justifications for management changes, then their use must be consistent with all NMFS and Gulf Council allocation policies and guidance.

Response: The process for evaluating and changing the commercial-recreational allocation percentages through Amendment 56 was consistent with NMFS and Gulf Council policies and guidance. The Council's Allocation Review Guidelines address the situation that resulted in Amendment 56, recognizing that, ''[i]n some instances, *e.g.,* following a stock assessment, the Council may elect to skip a formal allocation review and directly proceed with the development of an FMP amendment. In these cases, these guidelines would not apply.'' The most recent stock assessment (SEDAR 72) indicated that the gag stock was overfished and undergoing overfishing, and incorporated the updated SRFS recreational catch estimates. Therefore, the Council and NMFS used Amendment 56 to develop a rebuilding plan and review the sector allocations to determine whether an adjustment was appropriate. The review incorporated into Amendment 56 included an evaluation of allocation options, and all of the relevant ecological, economic, social, and performance factors identified in the relevant Council and NMFS polices and guidance, including the Council's Allocation Policy and NMFS' Procedural Directive 01–119–01.

Comment 19: Automatic reallocation based on SRFS is arbitrary, and retrospectively adjusting historical landings estimates from 30 years ago is fraught with uncertainty. Allocation decisions should not be based on SRFS data until the accuracy of the data is resolved.

Response: NMFS disagrees that there was an automatic reallocation and that is not appropriate to use SRFS data to adjust the commercial-recreational allocation percentages in Amendment 56. Amendment 56 included an alternative to retain the current allocation percentages and an alternative to adjust those percentages using SRFS calibrated landings. As explained in response to *Comment 17,* the Council recommended, and NMFS agrees, that it is appropriate to adjust the allocation to 65 percent recreational: 35 percent commercial based on the same 1986 through 2005 time series with updated SRFS landings estimates. Although there is uncertainty related to the SRFS calibration, as explained previously, this was reviewed and approved by peer-review through the NMFS Office of Science and Technology in May 2022. NMFS has determined that SRFS landings estimates are best scientific information available, and thus that it was appropriate to use these estimates to inform the allocation decision recommended by the Council in Amendment 56 and being implemented in this final rule.

Comment 20: Revised estimates of recreational landings based on SRFS do not provide all of the necessary information for allocation decisions. Had SRFS been used initially in the stock assessment, it would have generated higher OFLs, ABCs, and ACLs for both sectors, allowing the commercial sector to increase its harvest.

Response: NMFS disagrees that it is appropriate to speculate on possible changes to commercial landings and the commercial-recreational allocation had SRFS data been available to use in prior stock assessments. NS 2 requires that management measures be based on the best scientific data available and calibrated SRFS recreational catch estimates were not available to use prior to the SEDAR 72 SRFS Update. Even if it were appropriate and correct to assume that the stock ACL would have been higher had this new data been available previously, it does not automatically follow that commercial harvest would have been larger. As noted in the Regulatory Flexibility Act

Analysis in Chapter 6 of Amendment 56, the average commercial landings of gag from 2017 through 2021 were only 492,401 lb (223,349 kg), well below the commercial quota of 939,000 lb (425,923 kg).

Comment 21: The Council passed a motion to delay implementing new use of FES until the pilot study examining issues with the design of FES has been completed and deemed consistent with best scientific information available. If this analysis was done for SRFS, it is reasonable to assume the same result, so proceeding with reallocation in Amendment 56 is premature and inconsistent with recent Council actions.

Response: At its January 2024 meeting, the Council passed a motion to delay decisions about whether to change allocations of ACLs between the commercial and recreational sectors that were based on MRIP–FES data. SEDAR 72 and Amendment 56 both use recreational landings data based on SRFS to recommend catch levels for the recreational harvest of gag. NMFS disagrees that approving and implementing Amendment 56 is inconsistent with the Council's decision to delay potential actions that involve commercial-recreational allocations and use data generated from MRIP–FES or that it is reasonable to assume that the results of the pilot studies are applicable to SRFS. The MRIP–FES collects recreational trip information for specified 2-month periods, and over the course of the previous year. The Council's motion was in response to the results of one pilot study conducted by the NMFS Office of Science and Technology that evaluated a potential source of bias in MRIP–FES effort questions; specifically, the order in which two questions were presented. This pilot study found that estimates for private angler effort were generally 30 to 40 percent lower for shore and private boat modes than produced from the current design. However, the study was conducted over a relatively short period (6 months) using a smaller sample size than the full FES sample. NMFS is currently conducting a larger scale follow-up study. It is unknown whether this larger scale study will produce the same results as the initial pilot study. Information about the study, next steps, and the anticipated timeline can be found at *https://www.fisheries.noaa.gov/recreational-fishing-data/fishing-effort-survey-research-and-improvements.*

The Council's motion reflects the Council's intention to defer recommendations related to any changes to commercial-recreational allocations that incorporate MRIP–FES data until the ongoing research to determine the impacts of these changes to the survey is complete. The motion is not relevant to NMFS' review and implementation of the updated allocation percentages in Amendment 56, which are based in part on the calibrated time series of SRFS estimates of private recreational effort as incorporated into the SEDAR 72 SRFS Run and are separate from MRIP–FES. SRFS creates a universe of reef fish anglers by requiring anyone who harvests certain reef fish from a private vessel in Florida to obtain the State Reef Fish Angler designation, which, makes an angler eligible to receive a questionnaire in the mail that asks about their fishing activity in the previous month. More information on the SRFS questionnaire can be found at *https://myfwc.com/research/saltwater/fishstats/srfs/program/.* The SRFS questionnaire is more narrowly focused than the MRIP–FES questionnaire. Therefore, NMFS does not believe it is reasonable to assume that the potential bias identified with the MRIP–FES questionnaire would be indicative of similar bias with SRFS.

Comment 22: Action 3 in Amendment 56, which reallocates gag away from commercial fishermen to the recreational sector, is not consistent with the purpose and need of Amendment 56 and violates the Magnuson-Stevens Act. Providing greater allocation to the recreational sector, which accounts for the vast majority of discards and discard mortality, will not allow the stock to rebuild as projected in this rebuilding plan.

Response: The allocation percentages recommended by the Council in Amendment 56 do not reduce the probability of rebuilding the gag stock. The OFLs and ABCs recommended by the SSC were derived from SEDAR 72, which accounts for dead discards by both sectors, and the risk of overfishing the stock is the same for both of the allocation alternatives considered by the Council. As explained in response to *Comment 10,* NMFS expects the combined management measures in Amendment 56 (*i.e.,* reduction in catch limits, increased buffer between the recreational ACL and ACT, and change in recreational season start date) to rebuild the stock as projected. Therefore, NMFS has determined that the allocation percentages recommended in Amendment 56 are consistent with the purpose and need statement.

Comment 23: The rule does not clarify how any overage of the recreational ACL in 2023 will be addressed in 2024 given that the 2023 ACL is derived in part from MRIP–FES data and the 2024 ACL is derived in part from SRFS data. The amendment should include clarity surrounding the calibration and consistency of the catch limits [of data used from the different recreational surveys].

Response: Regulations at 50 CFR 622.41(d)(2)(iii) require that if gag are overfished and gag recreational landings exceed the applicable ACL, NMFS will reduce the ACL for that following year by the amount of the ACL overage in the prior fishing year, and reduce the ACT by the amount of the ACL overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary. NMFS has determined that recreational landings in 2023 exceeded the recreational ACL as specified in the interim regulations and that adjustments to the 2024 recreational ACL and ACT are appropriate. To reconcile the different data used to specify the 2023 and 2024 ACLs, NMFS has determined what the 2023 recreational ACL would have been after calibrating from MRIP–FES to SRFS data, and intends to use 2023 SRFS estimates to determine the overage of that recreational ACL. That overage will then be deducted from the 2024 recreational ACL and ACT as specified in Amendment 56 and this final rule. The 2024 commercial ACL and ACT will not be effected, and the rebuilding projections as specified in Amendment 56 will also remain unchanged. More information will be made available when NMFS publishes the temporary rule specifying the 2024 recreational catch limits.

Reference

Harford, W.J., S.R. Sagarese, and M. Karnauskas. 2019. Coping with information gaps in stock productivity for rebuilding and achieving maximum sustainable yield for grouper–snapper fisheries. Fish and Fisheries 20(2):303–321.

Classification

Pursuant to section 304(b)(3) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with Amendment 56, the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

There is good cause under 5 U.S.C. 553(d)(3) to establish an effective date for this final rule of less than 30 days after the date of publication. On November 28, 2023, NMFS published a temporary rule to withhold a portion of

the commercial allocation of gag for the 2024 fishing year in anticipation of the reduction in the commercial quota in this final rule (88 FR 83040). If this final rule is not effective on June 1, 2024, the regulations at 50 CFR 622.22(a)(4) require NMFS to distribute the previously withheld commercial allocation to shareholders. NMFS was unable to publish this final rule 30 days in advance of June 1, 2024, because NMFS received several significant comments on the proposed rule, which required more time than anticipated to consider and provide responses. If allocation is distributed on or after June 1, NMFS would be unable to withdraw that allocation from the shareholder accounts and commercial harvest would not be constrained to the reduced catch limits for gag in his final rule. Allowing this additional commercial harvest would be contrary to the public interest because it could result in overfishing of gag and would be inconsistent with the approved rebuilding plan in Amendment 56 that was developed as required by section 304(e)(4) of the Magnuson-Stevens Act. Further, a 30-day delay in the effective date of this final rule would also cause confusion by allowing the recreational season for gag to open for a brief period beginning on June 1, 2024. And if this rule became effective after a 30-day delay, the recreational season would close again and not reopen until September 1, 2024. Having this final rule effective on June 1, 2024, avoids any confusion about when recreational fishing is allowed.

This final rule has been determined to be not significant for purposes of Executive Order 12866. The Magnuson-Stevens Act provides the legal basis for this final rule. No duplicative, overlapping, or conflicting Federal rules have been identified.

A final regulatory flexibility analysis (FRFA) was prepared. The FRFA incorporates the initial regulatory flexibility analysis (IRFA), a summary of the significant issues raised by the public comments in response to the IRFA, NMFS' responses to those comments, and a summary of the analyses completed to support the action. NMFS' response to one public comment regarding the Executive Order 12866 analysis is in the **SUPPLEMENTARY INFORMATION** section of the preamble (see *Comment 4* in the Comments and Responses section). A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the FRFA follows.

The objective of this final rule is to use the best scientific information available to end overfishing of gag and rebuild the stock to a level commensurate with MSY, consistent with the authority under the Magnuson-Stevens Act. All monetary estimates in the following analysis are in 2021 dollars.

Amendment 56 revises the MSY, OY, and SDC for gag based on the results of the updated SEDAR 72 SRFS Run as reviewed by the Council's SSC. The definition of MSY changes from F_{MAX} to the yield when fishing at $F_{40\neq SPR}$. The definition of MFMT changes from being equal to F_{MAX} to being equal to the fishing mortality at the MSY proxy (*i.e.,* $F_{40\neq SPR}$). The definition of MSST changes from 50 percent of the biomass at F_{MAX} to 50 percent of the biomass at the new MSY proxy. OY is currently defined as 75 percent of the yield at F_{MAX}. The new definition of OY is conditional on whether a rebuilding plan is in place. Specifically, if the stock is under a rebuilding plan, OY will be equal to the stock ACL. However, if the stock is not under a rebuilding plan, OY will be equal to 90 percent of MSY or its proxy.

Amendment 56 also revises the sector allocation of the stock ACL from 39 percent commercial and 61 percent recreational to approximately 35 percent commercial and 65 percent recreational. Amendment 56 also establishes a rebuilding plan based on the amount of time the stock is expected to take to rebuild based on the yield when fishing at 75 percent of $F_{40\neq SPR}$, which is equal to 18 years. In turn, the rebuilding plan in combination with the new sector allocation changes the OFL, ABC, stock ACL, commercial ACL, and the recreational ACL. Based on the current allocation of the stock ACL between sectors, the OFL, ABC, stock ACL, commercial ACL, recreational ACL, commercial quota, and recreational ACT would be 4.180 million lb (1.896 million kg), 3.120 million lb (1.415 million kg), 3.120 million lb (1.415 million kg), 1.217 million lb (0.552 million kg), 1.903 million lb (0.863 million kg), and 0.939 million lb (0.426 million kg), and 1.708 million lb (0.775 million kg), respectively, in 2024 and future years if no action was taken. The recreational portion of the OFL, ABC, stock ACL, the recreational ACL, and the recreational ACT would be based on MRIP–CHTS data. Under the new sector allocation and rebuilding plan, the OFL, ABC, stock ACL, recreational ACL, commercial ACL, recreational ACT, and commercial quota are reduced in 2024 but subsequently increase through 2028 as indicated in tables 1 and 2 earlier in this rule. The recreational portion of the revised OFL, ABC, stock ACL, the recreational ACL, and the recreational ACT are based on recreational landings estimates used in the SEDAR 72 SRFS Run. Therefore, the different stock ACLs and recreational ACLs and ACTs are not directly comparable.

This final rule also revises the buffer between the recreational ACL and ACT, which is currently 10.25 percent (*i.e.,* the recreational ACT is 89.75 percent of the recreational ACL). Under this final rule, the buffer between the recreational ACL and ACT is approximately 20 percent (*i.e.,* the recreational ACT is approximately 80 percent of the recreational ACL).

In addition, this final rule also modifies the buffer between the commercial ACL and quota, and sets the quota equal to the ACT. The commercial quota is currently set at approximately 77 percent of the commercial ACL. The commercial ACT is not codified in regulations. This final rule sets the commercial ACT equal to approximately 95 percent of the commercial ACL and sets commercial quota equal to the commercial ACT. Thus, the commercial quota is approximately 95 percent of the commercial ACL.

Lastly, this final rule changes the recreational season start date and modifies the recreational AMs for gag. Specifically, the recreational season start date is changed from June 1 to September 1 each year. The current AM requires NMFS to prohibit harvest when the recreational ACL is projected to be met, whereas this final rule requires NMFS to prohibit harvest when the recreational ACT is projected to be met. The current AM also requires NMFS to maintain the recreational ACT for the following fishing year at the level of the prior year's ACT unless the best scientific information available determines that maintaining the prior year's ACT is unnecessary. This provision is removed under this final rule. Given these individual actions, this final rule is expected to regulate commercial fishing businesses that possess gag shares in the GT–IFQ program and for-hire fishing businesses that target gag.

The gag commercial quota is allocated annually based on the percentage of gag shares in each IFQ account. For example, if an account possesses 1 percent of the gag shares and the commercial quota is 1 million lb (0.45 million kg), then that account would receive 10,000 lb (4,536 kg) of commercial quota for gag. Although it is common for a single IFQ account with gag shares to be held by a single business, some businesses have multiple IFQ accounts with gag shares. As of July 8, 2021, there were 536 IFQ accounts, of which 506 IFQ accounts held gag shares. These accounts and gag

shares were owned by 455 businesses. Thus, NMFS assumes this final rule would regulate 455 commercial fishing businesses.

A valid charter vessel/headboat permit for Gulf reef fish is required to legally harvest gag on a recreational for-hire fishing trip. NMFS does not possess complete ownership data regarding businesses that hold a charter vessel/headboat permit for Gulf reef fish, and thus potentially harvest gag. Therefore, it is not currently feasible to accurately determine affiliations between vessels and the businesses that own them. As a result, for purposes of this analysis, NMFS assumes each for-hire vessel is independently owned by a single business, which is expected to result in an overestimate of the actual number of for-hire fishing businesses regulated by this final rule.

NMFS also does not have data indicating how many for-hire vessels actually harvest gag in a given year. However, in 2020, there were 1,289 vessels with valid charter vessel/headboat permits for Gulf reef fish. Further, gag is only targeted and almost entirely harvested in waters off the west coast of Florida. Of the 1,289 federally permitted vessels, 803 were homeported in Florida. Of these 803 federally permitted vessels, 62 are primarily used for commercial fishing rather than for-hire fishing purposes, and thus are not considered for-hire fishing businesses (*i.e.,* 1,227 vessels are for-hire fishing businesses). In addition, 46 of these permitted vessels are considered headboats, which are considered for-hire fishing businesses. However, headboats take a relatively large, diverse set of anglers to harvest a diverse range of species on a trip, and therefore do not typically target a particular species exclusively. Therefore, NMFS assumes that no headboat trips would be canceled, and thus no headboats would be directly affected by this final rule.

However, charter vessels often target gag. Of the 803 vessels with a valid charter vessel/headboat permit for Gulf reef fish that are homeported in Florida, 695 vessels are charter vessels. A recent study reported that 76 percent of charter vessels with a valid charter vessel/headboat permit in the Gulf were active in 2017, *i.e.,* 24 percent were not fishing. A charter vessel would only be directly affected by this final rule if it is used to go fishing. Given this information, NMFS' best estimate of the number of charter vessels that are likely to harvest gag in a given year is 528, and thus NMFS estimates this final rule would regulate 528 charter fishing businesses.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (50 CFR 200.2). A business primarily involved in the commercial fishing industry is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts (revenue) are not in excess of $11 million for all of its affiliated operations worldwide. NMFS does not collect revenue data specific to commercial fishing businesses that have IFQ accounts; rather, revenue data are collected for commercial fishing vessels in general. It is not possible to assign revenues earned by commercial fishing vessels back to specific IFQ accounts and the businesses that possess them because quota is often transferred across many IFQ accounts before it is used by the business on a vessel for harvesting purposes, and specific units of quota cannot be tracked. However, from 2017 through 2021, the maximum annual gross revenue earned by a single commercial fishing vessel was about $3.25 million. Based on this information, all commercial fishing businesses regulated by this final rule are determined to be small entities for the purpose of this analysis.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the United States, including for-hire businesses (North American Industry Classification System code 487210). A business primarily involved in for-hire fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has annual receipts (revenue) not in excess of $12.5 million for all its affiliated operations worldwide. The maximum annual gross revenue for a single headboat in the Gulf was about $1.38 million in 2017. On average, annual gross revenue for headboats in the Gulf is about three times greater than annual gross revenue for charter vessels, reflecting the fact that businesses that own charter vessels are typically smaller than businesses that own headboats. Based on this information, all charter fishing businesses regulated by this final rule are determined to be small businesses for the purpose of this analysis.

NMFS expects this final rule to regulate 455 of the 536 businesses with IFQ accounts, or approximately 85 percent of those commercial fishing businesses. Further, NMFS expects this final rule would regulate 528 of the 1,227 for-hire fishing businesses with valid charter vessel/headboat permits for Gulf reef fish, or approximately 43 percent of those for-hire fishing businesses. NMFS has determined that, for the purpose of this analysis, all regulated commercial and for-hire fishing businesses are small entities. Based on this information, NMFS expects the final rule to affect a substantial number of small entities.

Because NMFS does not collect revenue and cost data for the commercial fishing businesses that are expected to be regulated by this final rule, direct estimates of their economic profits are not available. However, economic theory suggests that annual allocation (quota) prices should reflect expected annual economic profits, which allows economic profits to be estimated indirectly. Further, the 455 businesses with gag shares also own shares in the other IFQ share categories and thus are expected to earn profits from their ownership of these shares as well, *i.e.,* red snapper, red grouper, shallow-water grouper, deep-water grouper, and tilefish.

However, economic profits will only be realized if the allocated quota is used for harvesting purposes. For example, practically all of the commercial quota of red snapper has been used for harvesting in recent years, and so it is assumed that all of that quota will be harvested in the foreseeable future. Important management changes have occurred for red grouper, which partly resulted in 96 percent of the commercial quota being harvested in 2021. Thus, this analysis also assumes that all of the red grouper quota will be harvested in the future as well. However, only 82 percent of the deep-water grouper quota, 38 percent of the shallow-water grouper quota, and 73 percent of the tilefish quota was harvested from 2017 through 2021, and that is expected to continue in the foreseeable future. For gag, the quota utilization rate from 2017 through 2021 was approximately 52 percent. Given these quota utilization rates in combination with average annual allocation prices from 2017 through 2021 and annual commercial quotas in 2021, NMFS estimates that the total expected economic profits for commercial fishing businesses with gag shares are at least $29.4 million per year at the present time. This estimate does not account for any economic profits that may accrue to businesses with gag shares that also own commercial fishing vessels that harvest non-IFQ species. Such profits are likely to be small because harvest of IFQ species accounts for around 84 percent of commercial IFQ vessels' annual revenue and

economic profits from the harvest of non-IFQ species tend to be smaller than those from IFQ species. Given that there are 455 businesses with gag shares, NMFS expects the average annual economic profit per commercial fishing business is at least $64,620.

Most of these economic profits (84 percent) are the result of owning red snapper shares. Only approximately $502,930 (or 1.7 percent) of the expected economic profits is due to the ownership of gag shares. This final rule is only expected to affect economic profits from the ownership of gag shares.

Specifically, the action that changes the sector allocation of the stock ACL and implements a rebuilding plan, which changes the stock ACL, reduces the commercial ACL and commercial quota from 1.217 million lb (552,022 kg) and 939,000 lb (425,923 kg) to 275,000 lb (124,738 kg) and 212,000 lb (96,162 kg) on average from 2024 through 2028. However, average annual commercial landings of gag from 2017 through 2021 were only 492,401 lb (223,349 kg), noticeably below the commercial quota. Because average annual landings exceed the commercial quotas for 2024 through 2028, it is assumed all of the proposed commercial quota will be harvested in each year through 2028, and the expected average reduction in annual commercial landings will be 280,401 lb (127,188 kg). Initially, NMFS expects the reduction in commercial landings to increase the average ex-vessel price of gag from $6.10 per lb to $7.78 per lb, or by $1.68 per lb, in 2024. However, NMFS expects the increase in ex-vessel price to gradually decrease through 2028 as the quota and landings increase, resulting in an ex-vessel price of $6.96 in 2028. The increase in the ex-vessel price would partially offset the adverse effects of the landings reduction. Based on the above information, NMFS expects a reduction in annual ex-vessel revenue for gag of approximately $1.57 million on average, or about $3,451 on average per commercial fishing business. Given an average annual allocation price of $1.03 per lb for gag from 2017 through 2021, NMFS expects the reduction in commercial landings of gag to reduce economic profits to these commercial fishing businesses by about $288,813, or by approximately $635 per commercial fishing business. Thus, NMFS expects economic profits to be reduced by around 1 percent on average per commercial fishing business as a result of the action to change the sector allocation and implement a rebuilding plan that reduces the stock ACL.

The action that sets the commercial ACT equal to 95 percent of the commercial ACL and sets the commercial quota equal to the commercial ACT causes the commercial quota to be equal to 95 percent of the commercial ACL as opposed to approximately 77 percent of the commercial ACL. As such, this action is expected to increase the commercial quota relative to what it would be otherwise. The increase still yields commercial quotas below the recent average commercial landings, and thus NMFS assumes all of the expected increase in the quota will be harvested. Specifically, NMFS expects the average annual increase in the commercial quota and landings from 2024 through 2028 to be about 48,527 lb (22,011 kg), which would increase average annual revenue by $267,371, or by about $588 per commercial fishing business. Again, assuming an average annual allocation price of $1.03 per lb, NMFS expects economic profit to commercial fishing businesses to increase by $49,983 per year, or about $110 per commercial fishing business, as a result of this action.

Combining these expected increases in revenue and profits with the decreases discussed earlier, NMFS expects this final rule to decrease average revenue for commercial fishing businesses by about $1.31 million per year from 2024 through 2028, or by $2,868 per commercial fishing business. The total reduction in economic profits for commercial fishing businesses is expected to be $238,830, or $525 per commercial fishing business, which represents a decrease of about 0.8 percent.

According to the most recent estimates of economic returns for charter vessels, average annual economic profit per charter vessel is $27,948. The action to change the sector allocation and implement a rebuilding plan, which would change the stock ACL, would change the gag recreational ACL from its current value of 1.903 million lb (863,186 kg) to 510,000 lb (231,332 kg) on average from 2024 through 2028. As explained previously, the current and new recreational ACLs are not directly comparable because they are based, in part, on recreational landings estimates derived from different surveys. However, average recreational landings from 2017 through 2021 were approximately 1.265 million lb (573,794 kg). Given that average recreational landings have been considerably greater than the recreational ACT in this final rule, all of the recreational ACT is expected to be harvested in the future. NMFS expects the reduction in the recreational ACT to reduce the recreational season length from 214 days to 25 days in 2024. However, the season length is expected to steadily increase to 120 days by 2028 and the average season length from 2024 through 2028 is expected to be 64 days. The reduction in the season length would reduce the number of angler trips targeting gag on charter vessels. From 2024 through 2028, the average reduction in angler trips targeting gag on charter vessels is expected to be 20,976 trips per year. Net Cash Flow per Angler Trip (CFpA) is the best available estimate of profit per angler trip by charter vessels. According to a recent study (available from NMFS see **ADDRESSES**), CFpA on charter vessels is estimated to be $150 per angler trip. Thus, NMFS estimates the total reduction in charter vessel profits from this action to be $3.146 million per year. The average reduction in economic profit per charter fishing business would therefore be about $5,960, or approximately 21.3 percent of their current economic profit, per year.

In combination with the action to require NMFS to close the recreational season based on when the recreational ACT, rather than the recreational ACL, is projected to be met, the action to increase the buffer between the recreational ACL and recreational ACT from 10.25 percent to 20 percent is expected to reduce the recreational season length further from the action to change the sector allocation and implement a rebuilding plan. Specifically, the season length is expected to be further reduced by 2 days in 2024 (open for 23 days instead of 25), though this reduction is expected to gradually increase to 24 days by 2028 (open for 96 days instead of 120 days). The average additional reduction in the recreational season length per year is expected to be 12 days (open for 52 days instead of 64). Again, a reduction in the season length is expected to reduce the number of angler trips targeting gag on charter vessels. From 2024 through 2028, the average reduction in angler trips targeting gag on charter vessels is expected to be 2,125 trips per year. Based on an estimate of $150 in economic profit per angler trip, NMFS estimates the reduction in charter vessel profits from this action to be $318,690 per year. The average reduction in economic profit per charter vessel $604 per year, or about 2.2 percent on average per charter fishing business.

The action that changes the recreational season start date from June 1 to September 1 is expected to increase the recreational season length from 23 days to 59 days in 2024, and from 52 days to 81 days on average from 2024 through 2028. However, because there

are many fewer charter trips targeting gag in the fall months (September through December) compared to the summer months (June through August), this action is expected to further decrease the number of angler trips targeting gag on charter vessels. Although the reduction in trips from 2024 through 2028 varies slightly from year to year, the average reduction per year is 1,610 trips. Based on an estimate of $150 in economic profit per angler trip, NMFS expects this action to decrease economic profits for charter vessels by about $241,500 per year, or by $456 per charter vessel. This would result in a decrease of economic profits by around 1.6 percent on average per charter fishing business.

Based on the above, NMFS expects the total reduction in target trips by charter vessels per year as a result of this final rule to be 24,711 trips. NMFS expects this reduction in trips to reduce economic profits for charter vessels by a total of about $3.707 million per year, or approximately $7,020 per charter vessel. Thus, annual economic profit per charter fishing business is expected to be reduced by approximately 25.1 percent on average.

Six alternatives, including the status quo, were considered for the actions to change the sector allocation of the stock ACL to 35 percent to the commercial sector and 65 percent to the recreational sector, establish a rebuilding plan of 18 years based on the amount of time the stock is expected to take to rebuild if fished at the yield from fishing at 75 percent of $F_{40\%SPR}$, and change the catch levels for 2024 through 2028 as specified in table 1. The status quo alternative would have retained the current sector allocation of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector based on MRIP–CHTS recreational landings data. The status quo alternative would not have established a rebuilding plan or modified any of the catch limits based on MRIP–FES and SRFS landings estimates. This alternative was not selected because the sector allocation would have been based in part on MRFSS recreational landings estimates, which is no longer consistent with the best scientific information available and would effectively result in a reallocation to the commercial sector of approximately four percent, which the Council did not consider to be equitable. This alternative also would not have rebuilt the gag stock or ended overfishing as required by the Magnuson-Stevens Act.

A second alternative would have also retained the current sector allocation of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector, but would have established a rebuilding plan of 11 years assuming a fishing mortality rate of zero. This alternative would have revised the OFL based on the projections from the SEDAR 72 SRFS Run and would have set all of the other catch levels through 2028 at zero. However, as with the status quo alternative, the sector allocation would have been based in part on MRFSS recreational landings data. Further, prohibiting harvest of gag would not be expected to eliminate all fishing mortality, as some gag would still be expected to be discarded and die as fishermen continue fishing for other species that live in similar habitats as gag. This alternative was not selected because, as discussed above, MRFSS is not consistent with the best scientific information available, and would result in a de facto reallocation from the recreational to the commercial sector of approximately four percent, which the Council did not considerable to be equitable. Further, because it is not feasible to eliminate dead discards of gag when fishermen are targeting other species, it is unlikely the stock would actually be rebuilt in 11 years. This alternative would have also resulted in significantly larger adverse economic effects on commercial and charter fishing businesses compared to the action in this final rule.

A third alternative would have also retained the current sector allocation of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector. But, like the action in this final rule, the third alternative would have established a rebuilding plan of 18 years and changed the catch levels based on the projections from the SEDAR 72 SRFS Run. This alternative would have ended overfishing and rebuilt the stock in 18 years. But, as with the status quo and the second alternative, the sector allocation of the stock ACL would be based on MRFSS recreational landings data. Thus, this alternative was not selected because MRFSS is not the best scientific information available, and would effectively result in a reallocation from the recreational sector to the commercial sector of approximately four percent.

A fourth alternative would have also retained the current sector allocation of the stock ACL of 39 percent to the commercial sector and 61 percent to the recreational sector, but would have established a rebuilding plan of 22 years and changed the catch limits based on the projections from the SEDAR 72 SRFS Run. This alternative would have ended overfishing and rebuilt the stock while allowing greater harvest and resulting in smaller adverse economic effects on commercial and charter fishing businesses compared to the action in this final rule. However, it was not selected because the stock is expected to take 4 more years to rebuild compared to the action in this final rule, and the Magnuson-Stevens Act requires overfished stocks to be rebuilt in as short a time period as possible, taking into account various factors. This alternative was also not selected because the use of MRFSS recreational landings data is not consistent with the best scientific information available, and would effectively result in a reallocation to the commercial sector of approximately four percent.

Like the action in this final rule, a fifth alternative would have changed the sector allocation of the stock ACL to 35 percent to the commercial sector and 65 percent to the recreational sector based in part on recreational landings estimates from MRIP–FES, SRHS, and SRFS for 1986 through 2005. As with the second alternative, the fifth alternative would have also established a rebuilding plan of 11 years assuming a fishing mortality rate of zero and used SEDAR 72 SRFS Run projections to change the OFL. The other catch limits would have been set at zero. As discussed earlier, prohibiting harvest of gag would not be expected to eliminate all fishing mortality, as some gag would still be expected to be discarded and die as fishermen continue fishing for other species that live in similar habitats as gag. This alternative was not selected because it is not feasible to eliminate dead discards of gag when fishermen are targeting other species, and therefore it is unlikely the stock would rebuild in 11 years. This alternative would have also resulted in significantly larger adverse economic effects on commercial and for-hire fishing businesses compared to the proposed action.

Like the action in this final rule, a sixth alternative would have changed the sector allocation of the stock ACL to 35 percent to the commercial sector and 65 percent to the recreational sector based in part on recreational landings estimates from MRIP–FES, SRHS, and SRFS data for 1986 through 2005. However, this alternative would have also established a rebuilding plan of 22 years. This alternative would be based on the best scientific information available, end overfishing, and rebuild the stock. This alternative would have also resulted in higher catch limits and therefore resulted in small adverse economic effects on commercial and for-

hire fishing businesses compared to the proposed action. However, this alternative was not selected because it is expected to take 4 more years to rebuild compared to the action in this final rule, and the Magnuson-Stevens Act requires overfished stocks to be rebuilt in as short a time as possible, taking into account various factors.

Two alternatives, including the status quo, were considered for the action to increase the buffer between the recreational ACL and recreational ACT from 10.25 percent to 20 percent. The status quo alternative would have maintained the buffer between the recreational ACL and recreational ACT at 10.25 percent based the yield at 75 percent of F_{MAX}. However, as explained previously, use of F_{MAX} as a proxy for F_{MSY} is not consistent with the best scientific information available.

The second alternative would have revised the recreational ACT using the Council's ACL and ACT Control Rule based on recreational landings data from 2018 through 2021. This alternative would have resulted in a 10 percent buffer between the recreational ACL and ACT, which would have left the buffer essentially unchanged. This alternative was not selected because the Council concluded it was necessary to increase the buffer between the ACL and ACT to reduce the probability of the recreational sector exceeding its ACL, reduce the likelihood of overfishing, and reduce the level of discards associated with directed harvest, which together are expected to increase the probability of meeting the 18-year timeline for rebuilding the gag stock.

Two alternatives, including the status quo, were considered for the action to set the commercial ACT equal to 95 percent of the commercial ACL and set commercial quota equal to the commercial ACT. The status quo alternative would have maintained commercial ACT, which is based on the yield at 75 percent of F_{MAX}, and a commercial quota set at 86 percent of the commercial ACT. This alternative was not selected because it is based on F_{MAX}, which is no longer consistent with the best scientific information available.

The second alternative would have set the commercial ACT equal to 86 percent of the commercial ACL and, like the action in this final rule, set the commercial quota equal to the commercial ACT. This alternative was not selected because the Council determined that a 14 percent buffer between the commercial ACL and ACT is too high and unnecessarily limits commercial harvest due to reduced uncertainty in the estimates of commercial landings and discards.

Three alternatives, including the status quo, were considered for the action to change the recreational season start date from June 1 to September 1 and require NMFS to close the recreational season based on when the recreational ACT is projected to be met rather than the recreational ACL. The status quo alternative would have maintained the recreational season start date of June 1 and required NMFS to close the recreational season based on when the recreational ACL is projected to be met. This alternative was not selected mainly because it would have resulted in a shorter average recreational season length (75 days) compared to the action in this final rule (81 days) for 2024 through 2028. In general, a longer fishing season would result in more fishing opportunities for both the private and for-hire components of the recreational sector. Further, shifting fishing effort to a historically low-effort month (September) may reduce the overall magnitude of recreational discards compared to starting the season in June. Shifting fishing pressure to the fall would also be expected to reduce directed effort for gag in deeper waters, which may further reduce the probability of harvesting or discarding dead male gag.

The second alternative would have retained the June 1 start date for the recreational season. But, like the action in this final rule, this alternative would have required NMFS to close the recreational season based on when the recreational ACT is projected to be met. This alternative was not selected mainly because it would have resulted in a shorter average recreational season length (52 days) compared to the action in this final rule (81 days) for 2024 through 2028. In general, a longer fishing season would result in more fishing opportunities for both the private recreational and for-hire components of the fishery. Further, shifting fishing effort to a historically low-effort month (September) may reduce the overall magnitude of recreational discards compared to starting the season in June. Shifting fishing pressure to the fall would be expected to reduce directed effort for gag in deeper waters, which may further reduce the probability of harvesting or discarding dead male gag.

The third alternative would have changed the recreational season start date to October 1. But, like the action in this final rule, this alternative would have required NMFS to close the recreational season based on when the recreational ACT is projected to be met. This alternative was not selected because it would have resulted in a shorter average recreational season length (63 days) compared to the action in this final rule (81 days) for 2024 through 2028 and would have also resulted in greater adverse effects to charter fishing businesses. In general, a longer fishing season would be expected to result in more fishing opportunities for both the private and for-hire components of the recreational sector.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, NMFS prepared a fishery bulletin, which also serves as a small entity compliance guide. Copies of this final rule are available from the Southeast Regional Office, and the guide, *i.e.,* fishery bulletin, will be sent to all known industry contacts in the Gulf reef fish fishery and be posted at: *https://www.fisheries.noaa.gov/tags/small-entity-compliance-guide?title=&field_species_vocab_target_id=&field_region_vocab_target_id%5B1000001121%5D=1000001121&sort_by=created.* The guide and this final rule will be available upon request.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Gag, Gulf of Mexico.

Dated: May 6, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 622 as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.8, revise paragraph (c) to read as follows:

§ 622.8 Quotas—general.

* * * * *

(c) *Reopening.* When a species, species group, sector, or sector component has been closed based on a projection of the applicable catch limit (ACL, ACT, or quota) specified in this part being reached and subsequent data indicate that the catch limit was not reached, the Assistant Administrator may file a notification with the Office of the Federal Register. Such notification may reopen the species, species group, sector, or sector component to provide an opportunity for the catch limit to be harvested.

3. In § 622.34, revise paragraph (e) to read as follows:

§ 622.34 Seasonal and area closures designed to protect Gulf reef fish.

* * * * *

(e) *Seasonal closure of the recreational sector for gag.* The recreational harvest of gag in or from the Gulf EEZ is closed from January 1 through August 31. During the closure, the bag and possession limits for gag in or from the Gulf EEZ are zero.

* * * * *

■ 4. In § 622.39, revise paragraph (a)(1)(iii)(B) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(iii) * * *

(B) *Gag.* See table 1.

TABLE 1 TO PARAGRAPH (a)(1)(iii)(B)

Year	Commercial quota in lb (kg)
2024	147,000 (66,678)
2025	204,000 (92,533)
2026	255,000 (115,666)
2027	313,000 (141,974)
2028+	383,000 (173,726)

* * * * *

■ 5. In § 622.41, revise paragraph (d) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(d) *Gag*—(1) *Commercial sector.* See table 1 for the commercial ACLs in gutted weight. The commercial ACT for gag is equal to the applicable commercial quota specified in § 622.39(a)(1)(iii)(B). The IFQ program for groupers and tilefishes in the Gulf of Mexico in § 622.22 serves as the accountability measure for the commercial harvest of gag.

TABLE 1 TO PARAGRAPH (d)(1)

Year	Commercial ACL in lb (kg)
2024	155,000 (70,307)
2025	215,000 (97,522)
2026	269,000 (122,016)
2027	330,000 (149,685)
2028+	404,000 (183,251)

(2) *Recreational sector.* (i) See table 2 for the recreational ACLs and ACTs in gutted weight.

TABLE 2 TO PARAGRAPH (d)(2)(i)

Year	Recreational ACL in lb (kg)	Recreational ACT in lb (kg)
2024	288,000 (130,635)	230,000 (104,326)
2025	399,000 (180,983)	319,000 (144,696)
2026	499,000 (226,343)	399,000 (180,983)
2027	613,000 (278,052)	490,000 (222,260)
2028+	751,000 (340,648)	600,000 (272,155)

(ii) If the NMFS SRD estimates that gag recreational landings have reached or are projected to reach the applicable recreational ACT specified in paragraph (d)(2)(i) of this section, the AA will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year. On and after the effective date of such a notification, the bag and possession limits for gag in or from the Gulf EEZ are zero. These bag and possession limits apply in the Gulf on board a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued without regard to where such species were harvested, *i.e.,* in state or Federal waters.

(iii) In addition to the measures specified in paragraph (d)(2)(ii) of this section, if the NMFS SRD estimates that gag recreational landings have exceeded the applicable ACL specified in paragraph (d)(2)(i) of this section and gag is overfished based on the most recent Status of U.S. Fisheries Report to Congress, the following measure will apply. The AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year, to reduce the recreational ACL for that following year by the amount of the ACL overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

* * * * *

[FR Doc. 2024–10208 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 92
Friday, May 10, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0259]

RIN 1625–AA00

Safety Zone; Tennessee River, Saltillo, TN

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of the Tennessee River. This action is necessary to provide for the safety of life on these navigable waters near Saltillo, TN, during fireworks display on July 4th, 2024. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 10, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0259 using the Federal Decision-Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST3 Joshua D Carter, Waterways Management Division; *Joshua.D.Carter@uscg.mil* or 615–736–5421 x2104.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
MM Mile marker
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On March 4, 2024, the Town of Saltillo notified the Coast Guard that it will be conducting fireworks display from 8 p.m. to 10 p.m. on July 4, 2024. The fireworks are to be launched from land next to the Tennessee River at Mile Marker (MM) 170, with firework fallout encroaching on the river channel. Hazards from firework displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 100-yard radius of the barge, and as such is establishing a safety zone from MM169 to MM171 of the Tennessee River.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 1-mile radius of the fireworks launch zone before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from 8 p.m. to 10 p.m. on July 4, 2024. The safety zone would cover all navigable waters from MM 169 to MM 171 of the Tennessee River. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit this stretch of waterways before and after the implementation of the safety zone which would impact a small designated area of the Tennessee River for less than 2 hours during the night when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see

ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting 2 hours that would prohibit entry within 1 mile of a fireworks launch site. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2024–0259 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0259 to read as follows:

§ 165.T08–0259 Safety Zone; Tennessee River, Saltillo, TN.

(a) *Location.* The following area is a safety zone: all navigable waters of the

Tennessee River from Mile Markers 169 to 171.

(b) *Enforcement period.* This section will be enforced from 8 p.m. to 10 p.m. on July 4, 2024.

(c) *Regulations.* (1) According to the general regulations in § 165.23 of this part, entry into this temporary safety zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.

(2) Persons or vessels seeking to enter the safety zone must request permission from the COTP on VHF–FM channel 16 (156.8 MHz) or by telephone at 361–939–0450.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(d) *Information broadcasts.* The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts, as appropriate.

Dated: April 23, 2024.

H.R. Mattern,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2024–09923 Filed 5–9–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO–P–2024–0003]

RIN 0651–AD76

Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The USPTO proposes to amend the rules of practice to add a new requirement for an acceptable terminal disclaimer that is filed to obviate (that is, overcome) nonstatutory double patenting. The proposed rule change would require terminal disclaimers filed to obviate nonstatutory double patenting to include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made. This action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art.

DATES: Comments must be received by July 9, 2024 to ensure consideration.

ADDRESSES: For reasons of government efficiency, comments must be submitted through the Federal eRulemaking Portal at *www.regulations.gov.* To submit comments via the portal, one should enter docket number PTO–P–2024–0003 on the homepage and click ''search.'' The site will provide search results listing all documents associated with this docket. Commenters can find a reference to this proposed rule and click on the ''Comment'' icon, complete the required fields, and enter or attach their comments. Attachments to electronic comments will be accepted in Adobe® portable document format (PDF) or Microsoft Word® format. Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

Visit the Federal eRulemaking Portal for additional instructions on providing comments via the portal. If electronic submission of or access to comments is not feasible due to a lack of access to a computer and/or the internet, please contact the USPTO using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, at 571–272–7711; or Nicholas Hill, Legal Advisor, Office of Patent Legal Administration, at 571–270–1485.

SUPPLEMENTARY INFORMATION: Under U.S. law, a person is entitled to a patent, absent certain exceptions, for an invention that is new and not obvious as of the effective filing date of the claimed invention. Because a patent owner may file continuing applications and obtain follow-on patents with claims that have the same effective filing date as those of the original patent, patent owners may pursue multiple patents with claims that vary in only minor ways from each other. A patent owner may also, under certain circumstances (for example, when two applications are filed on the same day), obtain patents that are not part of the same patent family for obvious variants of an invention. As a result, obviousness-type double patenting (also referred to as nonstatutory double patenting) may exist between patents and/or applications in the same patent family or in a different patent family. Under the doctrine of obviousness-type double patenting, the USPTO rejects patentably indistinct claims filed in patent applications when these applications and the applications and/or patents whose claims form the basis of the nonstatutory double patenting: (1) have the same inventive entity, at least one common (joint) inventor, a common applicant, and/or a common owner/assignee; or (2) are not commonly owned but are owned by parties to a joint research agreement.

Under current practice, a patent applicant or patent owner (also referred to as a patentee) may, in most instances, obviate nonstatutory double patenting by filing a terminal disclaimer meeting the requirements of 37 CFR 1.321(c) or (d). A terminal disclaimer will ensure that the term of the patent with the terminal disclaimer will not extend beyond the term of the patent forming the basis of the nonstatutory double patenting. To prevent the harassment of an alleged infringer by multiple parties, under current 37 CFR 1.321(c) or (d) a terminal disclaimer must state that the patent in which the terminal disclaimer is filed shall be enforceable only for and during the period that the patent is commonly owned, or commonly enforced, with the patent which formed the basis for the nonstatutory double patenting.

Even with the protections currently provided by a terminal disclaimer, multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings.

Currently, a terminal disclaimer filed to obviate nonstatutory double patenting over a conflicting patent must include a disclaimer of term, if any, extending beyond the term of the conflicting patent and a common ownership or common enforcement agreement. Under

the proposed rule, the USPTO will not issue a patent to a common owner or inventor with a claim that conflicts with a claim of a second patent unless the terminal disclaimer includes an additional agreement that the patent with the terminal disclaimer will not be enforced if any claim of the second patent is invalidated by prior art. That means to resolve a dispute where there are multiple patents tied by terminal disclaimers, competitors could focus on addressing the validity of the claims of a single patent. As is the case under current practice, a terminal disclaimer under the proposed rule would be unidirectional, encumbering only the patent with the terminal disclaimer and not the conflicting patent. The reason for this is that a terminal disclaimer is signed only by the owner of the patent with the terminal disclaimer, and that patent and the conflicting patent might not be commonly owned when the terminal disclaimer is filed. See 35 U.S.C. 253 (providing for filing of a terminal disclaimer by the owner of the patent in which it is filed). The proposed rule is intended to promote competition by lowering the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers. The proposed rule furthers the objectives of Executive Order 14036 on ''Promoting Competition in the American Economy,'' 86 FR 36987 (July 14, 2021).

As an example of how the proposed rule would lower costs of challenging multiple related patents, in a litigation in which a patent owner is enforcing a patent along with several other patents that are tied by one or more terminal disclaimers to that patent, a competitor could seek to have the court narrow any validity disputes to address only that patent. Narrowing validity disputes in litigation to only one such patent could result in more focused claim construction hearings, lower litigation costs, and faster resolution. Similarly, a competitor could petition for an inter partes or post-grant review of just a single patent to which multiple patents are tied by one or more terminal disclaimers with the proposed agreement. The outcome of the post-grant challenge to the claims in the selected patent may also resolve the enforceability of the multiple patents tied to that selected patent. Because only one patent can be challenged per post-grant petition, the proposed terminal disclaimer rule would lower the cost of administrative proceedings by enabling a challenger to seek the freedom to operate through the review of only one patent, as opposed to seeking the review of a number of patents claiming obvious variants of a single invention.

I. Background

A. Request for Comments on Whether Any Changes Need To Be Made to the Patent System Regarding Nonstatutory Double Patenting

In a recent request for comments, the USPTO sought public input on whether changes are needed in terminal disclaimer practice to help ensure that the U.S. patent system properly and adequately protects innovation while not unnecessarily harming competition. *See Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights,* 87 FR 60130 (October 4, 2022) (''Request for Comments''). In the Request for Comments, the USPTO recognized that existing practice may not adequately address concerns that multiple patents directed to obvious variants of an invention could deter competition if the number of patents is prohibitively expensive to challenge in post-grant proceedings before the PTAB or in district court. To address this issue, the Request for Comments asked whether applicants seeking patents on obvious variations to prior claims should be required to stipulate that the claims are not patentably distinct from the previously considered claims as a condition of filing a terminal disclaimer to obviate an obviousness-type double patenting rejection. The Request for Comments also recognized that, under current practice, patents tied together with a terminal disclaimer after an obviousness-type double patenting rejection must be separately challenged on validity grounds. The Request for Comments asked whether the filing of a terminal disclaimer in these patents should be an admission of obviousness and, if so, whether the patents, when their validity is challenged after issuance, should stand and fall together.

The USPTO received comments expressing a range of views on the questions posed in the Request for Comments. Some comments supported the stipulation requirement and the proposition that the filing of a terminal disclaimer should be an admission of obviousness such that patents tied by terminal disclaimers should stand and fall together. These include comments suggesting that a stipulation could clarify the intrinsic record or simplify subsequent litigation. Some comments stated that a stipulation or admission could reduce the cost and risk of challenging multiple duplicative patents and lower drug prices for drugs that are no longer considered innovative. Some comments also indicated that a stipulation could create an incentive for applicants to address nonstatutory double patenting questions on the merits and that this would encourage innovators to create more inventions, stimulating investment into innovation.

Other comments opposed the stipulation requirement and the proposition that the filing of a terminal disclaimer should be an admission of obviousness such that patents tied by terminal disclaimers should stand and fall together. These include comments asserting that the decision of whether to file a terminal disclaimer is often driven by a desire to expedite prosecution and reduce costs rather than by the merits of the nonstatutory double patenting rejection, that a stipulation requirement would cause delays and increase burdens on applicants, and/or that a stipulation requirement would encourage applicants to file a large number of claims in a single application. Comments opposed to treating the filing of a terminal disclaimer as an admission of obviousness include comments citing *SimpleAir, Inc.* v. *Google LLC,* 884 F.3d 1160 (Fed. Cir. 2018), or earlier Federal Circuit cases, for the proposition that a terminal disclaimer should not be considered an admission or give rise to a presumption/estoppel. Comments opposing the changes in terminal disclaimer practice discussed in the Request for Comments also include comments asserting the following: validity is determined on a claim-by-claim basis; claims are presumed valid under 35 U.S.C. 282; the fact that prior art invalidates a claim in one of two patents tied together by a terminal disclaimer does not necessarily mean that the same prior art would invalidate a claim in the other patent; and/or these changes raise questions of due process and fairness.

In addition, some comments broadly opposed any changes to terminal disclaimer practice. Commenters were concerned that such changes would increase the burden on applicants. Some commenters asserted that the stipulation requirement described in the Request for Comments would be a substantive rule that the USPTO does not have authority to make.

Upon consideration of the comments, the USPTO has opted not to propose a rule requiring a stipulation that the claims are not patentably distinct or an agreement by the disclaimant that filing a terminal disclaimer is an admission of obviousness. The proposed rule does not concern the validity of claims.

Instead, the proposed rule would require an agreement by the disclaimant that the patent with the terminal disclaimer will be enforced only under certain conditions. To the extent an applicant believes claims are patentably distinct, they may either challenge the rejection or move those claims to an application in which a terminal disclaimer has not been, and will not be, filed. A rule requiring that terminal disclaimers filed to obviate nonstatutory double patenting include language placing conditions upon enforcement was previously upheld as within the USPTO's rulemaking authority. See *In re Van Ornum,* 686 F.2d 937 (CCPA 1982).

B. Current Practice

Nonstatutory double patenting may be obviated, in most instances, by filing a terminal disclaimer. The terminal disclaimer will ensure that the term of the patent with the terminal disclaimer will not extend beyond the term of the patent forming the basis of the nonstatutory double patenting. In addition, the enforcement provision of the terminal disclaimer will prevent the harassment of an alleged infringer by multiple parties. Under current USPTO regulations, two types of terminal disclaimers may be used to obviate nonstatutory double patenting. The first type is filed pursuant to 37 CFR 1.321(c) and must include a provision that the patent in which the terminal disclaimer is filed (that is, the subject patent) or any patent granted on the application in which the terminal disclaimer is filed (that is, any patent granted on the subject application) shall be enforceable only for and during the period that the subject patent or any patent granted on the subject application is commonly owned with the reference patent or any patent granted on the reference application which formed the basis for the nonstatutory double patenting. The second type is filed pursuant to 37 CFR 1.321(d) and must include a provision that the subject patent or any patent granted on the subject application shall be enforceable only for and during such period that the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application which formed the basis for the nonstatutory double patenting are not separately enforced. The second type obviates nonstatutory double patenting based on a non-commonly owned reference patent or application that is excepted or disqualified as prior art as a result of the subject matter of the reference patent or application and the claimed invention in the subject patent or application being treated as commonly owned on the basis of a joint research agreement.

Currently, claims in patents tied by a terminal disclaimer filed under 37 CFR 1.321(c) or (d) to obviate nonstatutory double patenting must be separately challenged on validity grounds. See 35 U.S.C. 282(a); see also *SimpleAir, Inc.* v. *Google LLC,* 884 F.3d 1160, 1167–68 (Fed. Cir. 2018) (''[O]ur cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims.''); *Motionless Keyboard Co.* v. *Microsoft Corp.,* 486 F.3d 1376, 1385 (Fed. Cir. 2007) (''A terminal disclaimer simply is not an admission that a later-filed invention is obvious.''); *Ortho Pharm. Corp.* v. *Smith,* 959 F.2d 936, 941 (Fed. Cir. 1992) (rejecting the argument that the patent applicant admitted to obviousness-type double patenting by filing a terminal disclaimer); *Quad Envtl. Techs. Corp.* v. *Union Sanitary Dist.,* 946 F.2d 870, 874 (Fed. Cir. 1991) (''[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.''). The current state of the law exposes competitors attempting to enter the market to potentially high costs because they may have to defend against patents to obvious variants of a single invention despite the presence of terminal disclaimers.

II. Proposed Changes

A. Changes to Current Practice

The USPTO proposes to revise the enforcement provisions in 37 CFR 1.321(c) and (d) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the subject patent or any patent granted on the subject application shall be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: (1) any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 (statutory provisions for anticipation or obviousness as referred to in the **SUMMARY** above) by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or (2) a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made. The new requirement for a terminal disclaimer in this proposed rule differs from the stipulation described in the Request for Comments discussed above. See 87 FR at 60134. Specifically, the proposed rule does not require an applicant or a patentee to make a statement in the terminal disclaimer regarding conflicting claims being patentably indistinct. The new requirement has the likely advantages of reducing litigation and administrative proceeding costs and increasing predictability compared with the stipulation requirement in the Request for Comments because a comparison of claims is not necessary to determine which claims are subject to a stipulation (or an agreement), including claims that are amended during prosecution after the terminal disclaimer is filed. The proposed agreement would not affect the validity of the claims in the subject patent or any patent granted on the subject application because it is a voluntary agreement by the patentee that the patent with the terminal disclaimer will be enforceable only under certain conditions and does not touch on the validity of the claims. The new requirement solves the current problem of requiring a competitor to invalidate multiple patents tied by terminal disclaimers in order to have the freedom to operate. To the extent an applicant believes claims are patentably distinct, they may either challenge the rejection or move those claims to an application in which a terminal disclaimer has not been, and will not be, filed.

(1) Meaning of Direct and Indirect Tying

a. Direct Tying—By One Terminal Disclaimer

The subject patent or any patent granted on the subject application is tied directly by a terminal disclaimer to another patent when: (1) the terminal disclaimer is filed in the subject patent or application; and (2) the other patent, or the application that issued as the other patent, is the reference patent or application identified in the terminal disclaimer. The tying by a terminal disclaimer is unidirectional and is effective only for the patent with the terminal disclaimer. Therefore, a terminal disclaimer that directly ties a subject patent or any patent granted on a subject application to a reference patent or any patent granted on a reference application does not directly tie the reference patent or any patent granted on the reference application to the subject patent or any patent granted on the subject application. Direct tying is illustrated by example 1 in section (II)(A)(3) below.

If timely requested, a recorded terminal disclaimer may be withdrawn

before the application in which it is filed issues as a patent, or if a terminal disclaimer is filed in a reexamination proceeding, before the reexamination certificate issues. See section 1490, subsection VIII of the Manual of Patent Examining Procedure (MPEP) (Ninth Edition, Revision 07.2022, February 2023). After a patent or reexamination certificate issues, a recorded terminal disclaimer will not be nullified. *Id.* For a terminal disclaimer filed in a patent, the recorded terminal disclaimer is considered part of the original patent. See 35 U.S.C. 253(b) and 37 CFR 1.321(a). By contrast, a terminal disclaimer filed in a reexamination proceeding is a proposed amendment to the patent that does not take effect until the reexamination certificate issues. See MPEP 2288.

Where a terminal disclaimer is filed in an application, if the terminal disclaimer is withdrawn before a patent issues from the application, then the patent containing the withdrawn terminal disclaimer is not tied and has never been tied to the patent identified in the withdrawn terminal disclaimer (or to any patent granted on the application identified in the withdrawn terminal disclaimer).

b. Indirect Tying—By Two or More Terminal Disclaimers

The subject patent or any patent granted on the subject application is tied indirectly by two terminal disclaimers to another patent when: (1) a terminal disclaimer filed in the subject patent or application identifies an intermediate patent/application as the reference patent or application; and (2) a terminal disclaimer filed in the intermediate patent/application identifies the other patent, or the application that issued as the other patent, as the reference patent or application. This is illustrated by example 2 in section (II)(A)(3) below.

As discussed above with respect to direct tying, terminal disclaimers may be withdrawn from an application in certain circumstances. The following four illustrations show the effect on tying of withdrawing a terminal disclaimer from an intermediate application where a terminal disclaimer is also filed in a subject application.

(1) Where the terminal disclaimer filed in the intermediate application identifies the other patent and is withdrawn *before* a patent is granted on the subject application, the patent granted on the subject application was never tied indirectly to the other patent.

(2) Where the terminal disclaimer filed in the intermediate application identifies the other patent and is withdrawn *after* a patent is granted on the subject application, the indirect tying to the other patent is undone but the patent granted on the subject application was at one point tied indirectly to the other patent.

(3) Where the terminal disclaimer filed in the intermediate application identifies the application that later issues as the other patent and is withdrawn *before* a patent is granted on the subject application or *before* the other patent issues, the patent granted on the subject application was never tied indirectly to the other patent.

(4) Where the terminal disclaimer filed in the intermediate application identifies the application that later issues as the other patent and is withdrawn *after* a patent is granted on the subject application and *after* the other patent issues, the indirect tying to the other patent is undone but the patent granted on the subject application was at one point tied indirectly to the other patent.

Tying by more than two terminal disclaimers is illustrated by example 3 in section (II)(A)(3) below.

(2) Meaning of ''A Claim Has Been Finally Held Unpatentable or Invalid''

The term ''finally held unpatentable'' refers to a final determination by the USPTO in a trial established by the Leahy-Smith America Invents Act (AIA) (Pub. L. 112–29 (2011)) or a reexamination proceeding that one or more claims in a patent are unpatentable after all appeals have been concluded or appeal rights exhausted. The term ''finally held . . . invalid'' relates to a final decision entered in a Federal court in a civil action holding one or more claims of a patent invalid after all appeals have been concluded or appeal rights exhausted. The proposed agreement is independent of the relative timing of the terminal disclaimer and the final holding of unpatentability or invalidity over prior art. Additionally, the proposed agreement cannot be avoided by filing a statutory disclaimer of a claim under 35 U.S.C. 253(a) after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

(3) Examples

The following examples illustrate the meaning of: (1) direct and indirect tying in the proposed rule, and (2) the possible consequences of the agreement in the proposed rule.

In the examples, all terminal disclaimers include the agreement in the proposed rule and are filed to obviate nonstatutory double patenting, unless otherwise noted.

A single capital letter identifies both an application and any patent that issues from that application, with the letter ''A'' in parentheses used to identify the application and the letter ''P'' in parentheses used to identify the patent. Thus, X(P) is any patent that has issued from application X(A).

An arrow represents a terminal disclaimer filed to obviate nonstatutory double patenting. The arrow starts at the subject patent or application and points toward the reference patent or application.

The patents and applications in these examples may be in the same patent family or in a different patent family.

The enumeration of the terminal disclaimers using terms such as ''first,'' ''second,'' etc. does not refer to when the terminal disclaimers are filed but is instead used for identification purposes.

Example 1

The subject patent or any patent granted on the subject application is tied directly to the reference patent or any patent granted on the reference application by a terminal disclaimer filed in the subject patent or application to obviate nonstatutory double patenting based on the reference patent or application.

Thus, if a terminal disclaimer is filed in X(P) or X(A) identifying W(P) or W(A) as a reference patent or application, then X(P) is tied directly to W(P). Example 1 may be represented visually as:

$W \leftarrow X$

The tying by a terminal disclaimer is unidirectional. Therefore, in this example, W(P) is not tied to X(P) by the terminal disclaimer filed in X.

In this example, X(P) is the subject patent or any patent granted on the subject application, and W(P) is the reference patent or any patent granted on the reference application. As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art, X(P) may not be enforced. However, if a claim of X(P) is finally held unpatentable or invalid over prior art, W(P) may still be enforced because a terminal disclaimer with the agreement in the proposed rule was not filed in W identifying X as a reference patent or application.

If the terminal disclaimer filed in X(A) is withdrawn before X(A) issues as a patent, then X(P) may be enforced even if a claim in W(P) is finally held unpatentable or invalid over prior art because X(P) was never tied to W(P).

We can further explain example 1 in practical terms. For instance, applicant overcomes a nonstatutory double

patenting rejection in application X(A) based on reference patent W(P) by filing a terminal disclaimer with the agreement in the proposed rule, thereby obtaining patent X(P). Under the current rule, both patents X(P) and W(P) may block competitors and need to be separately invalidated or licensed to gain freedom to operate. Under the proposed rule, if a claim of patent W(P) is finally held invalid or unpatentable over prior art, competitors would avoid the enforcement of patent X(P) based on the agreement in the proposed rule in the terminal disclaimer in patent X(P). However, if a claim of patent X(P) is finally held invalid or unpatentable over prior art, competitors would not be able to, solely on this basis, avoid the enforcement of patent W(P) because a terminal disclaimer containing the proposed agreement was not filed in W identifying X as a reference patent or application.

Additionally, multiple subject patents or applications may have terminal disclaimers identifying the same reference patent or application. Under the proposed rule, if a claim of the reference patent or any patent granted on the reference application is finally held invalid or unpatentable over prior art, competitors would avoid the enforcement of these multiple patents based on the proposed agreement in the terminal disclaimers filed in these patents.

Example 2

Extending example 1 (where the terminal disclaimer filed in X includes the proposed agreement), if a second terminal disclaimer is filed in Y(P) or Y(A) identifying X(P) or X(A) as a reference patent or application, then Y(P) is tied indirectly to W(P). This would be the case even if X(A) is abandoned or remains pending. Example 2 may be represented visually as:

$W \leftarrow X \leftarrow Y$

Consistent with example 1, Y(P) is tied directly to X(P), and X(P) is tied directly to W(P). In this example, X(P) or X(A), as the case may be, is an intermediate patent/application because the two terminal disclaimers tie Y(P) to W(P).

In this example, W(P) is not tied to X(P) or Y(P), and X(P) is not tied to Y(P).

In this example, Y(P) is a subject patent or any patent granted on a subject application for the terminal disclaimer filed in Y, and W(P) is a reference patent or any patent granted on a reference application for the terminal disclaimer filed in X. In this example, X is an intermediate patent/application that is the reference patent or application for the terminal disclaimer filed in Y and the subject patent or application for the terminal disclaimer filed in X. As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art, and the terminal disclaimer in Y(P) contains the proposed agreement, Y(P) may not be enforced.

As in example 1, if a claim of W(P) is finally held unpatentable or invalid over prior art, X(P) may not be enforced. Similarly, if a claim of X(P) is finally held unpatentable or invalid over prior art, Y(P) may not be enforced.

If the terminal disclaimer filed in X(A) identifying W(P) is withdrawn before Y(A) issues as a patent, then Y(P) would still be enforceable in the event that a claim in W(P) is finally held unpatentable or invalid over prior art because Y(P) was never tied to W(P). On the other hand, if the terminal disclaimer filed in X(A) identifying W(P) is withdrawn after Y(A) has issued as a patent, then Y(P) may not be enforced in the event that a claim in W(P) is finally held unpatentable or invalid over prior art because Y(P) was once tied to W(P).

Note that even if the terminal disclaimer filed in X did not contain the proposed agreement (because it was filed prior to the implementation of this proposed rule), Y(P) is still tied to W(P). In this situation, if a claim in W(P) is finally held unpatentable or invalid over prior art, X(P) may still be enforced (because the terminal disclaimer filed in X does not contain the proposed agreement) even though Y(P) may not be enforced.

Example 3

Indirect tying may also occur through multiple intermediate patents/applications. Extending example 2, if a third terminal disclaimer is filed in Z(P) or Z(A) identifying Y(P) or Y(A) as a reference patent or application, then Z(P) is tied indirectly to W(P). This would be the case even if X(A) and/or Y(A) are/is abandoned or remain(s) pending. Example 3 may be represented visually as:

$W \leftarrow X \leftarrow Y \leftarrow Z$

In this example, all the tying relationships of example 2 remain.

Also in this example, Z(P) is a subject patent or any patent granted on a subject application for the terminal disclaimer filed in Z, and W(P) is a reference patent or any patent granted on a reference application for the terminal disclaimer filed in X. X(P) or X(A) and Y(P) or Y(A), as the case may be, are intermediate patents/applications because the three terminal disclaimers tie Z(P) to W(P). As a result, if a claim of W(P) is finally held unpatentable or invalid over prior art and if the terminal disclaimer filed in Z(A) contains the proposed agreement, Z(P) may not be enforced.

As in example 2, if a claim of W(P) is finally held unpatentable or invalid over prior art, Y(P) and X(P) may not be enforced; if a claim of X(P) is finally held unpatentable or invalid over prior art, Y(P) and Z(P) may not be enforced; and if a claim of Y(P) is finally held unpatentable or invalid over prior art, Z(P) may not be enforced.

Example 4

This example shows three patents tied directly and indirectly by terminal disclaimers. In this example, a first terminal disclaimer is filed in X(P) or X(A) identifying W(P) or W(A) as a reference patent or application, directly tying X(P) to W(P).

$W \leftarrow X$

A second terminal disclaimer is filed in W(P) or W(A) identifying X(P) or X(A) as a reference patent or application, directly tying W(P) to X(P).

$W \leftrightarrows X$

A third terminal disclaimer is filed in Y(P) or Y(A) identifying X(P) or X(A) as a reference patent or application, directly tying Y(P) to X(P).

$W \leftrightarrows X \leftarrow Y$

A fourth terminal disclaimer is filed in X(P) or X(A) identifying Y(P) or Y(A) as a reference patent or application, directly tying X(P) to Y(P).

$W \leftrightarrows X \leftrightarrows Y$

A fifth terminal disclaimer is filed in Y(P) or Y(A) identifying W(P) or W(A) as a reference patent or application, directly tying Y(P) to W(P).

$W \leftarrow Y$

A sixth terminal disclaimer is filed in W(P) or W(A) identifying Y(P) or Y(A) as a reference patent or application, directly tying W(P) to Y(P).

$W \leftrightarrows Y$

Example 4 may be represented visually as:

$W \leftrightarrows X \leftrightarrows Y$ and $W \leftrightarrows Y$

In this example, in addition to W(P), X(P), and Y(P) each being directly tied to one another, they each are indirectly tied to one another. As a result, if a claim in any one of W(P), X(P), or Y(P) is finally held unpatentable or invalid over prior art and if the terminal disclaimers filed in W, X, and Y contain the proposed agreement, the other two patents may not be enforced.

Example 5

The following example illustrates two patents that are not indirectly tied by

terminal disclaimers even though each has a terminal disclaimer identifying the same reference patent or application, due to the unidirectionality of tying by a terminal disclaimer.

In this example, a first terminal disclaimer is filed in X(P) or X(A) identifying Y(P) or Y(A) as a reference patent or application, and a second terminal disclaimer is filed in Z(P) or Z(A) identifying Y(P) or Y(A) as a reference patent or application. Example 5 may be represented visually as:

$X \rightarrow Y \leftarrow Z$

In this example, X(P) and Z(P) are both tied directly to Y(P). As a result, if a claim in Y(P) is finally held unpatentable or invalid over prior art and if the proposed agreement is contained in the terminal disclaimers filed in X and Z, X(P) and Z(P) cannot be enforced.

However, Z(P) is not tied to X(P), X(P) is not tied to Z(P), and Y(P) is not tied to either X(P) or Z(P). Thus, if a claim in X(P) or Z(P) is finally held unpatentable or invalid over prior art, there is no effect on whether the other two patents may be enforced.

(4) Ways To Address Nonstatutory Double Patenting

To obviate nonstatutory double patenting, patent owners and applicants can voluntarily file a terminal disclaimer with the proposed agreement. If applicants and patent owners are concerned about the new requirement and seek to avoid the consequences of the proposed agreement, applicants and patent owners have the option of not filing a terminal disclaimer with the proposed agreement. The nonstatutory double patenting may be dealt with in a number of ways.

An applicant facing a nonstatutory double patenting rejection in an application has a number of options to avoid filing a terminal disclaimer with the proposed agreement such as:

(1) combining the conflicting claims into a single application,

(2) canceling or amending any conflicting claims in the application or in the other application containing the conflicting claims that formed the basis of the nonstatutory double patenting,

(3) arguing that rejected claims in the application are patentably distinct from the claims of the reference patent or application, or

(4) filing a reissue application of the patent whose claims formed the basis of the nonstatutory double patenting in order to add canceled conflicting claims from the application into the reissue application, provided that the added claims do not introduce new matter into the reissue application.

Alternatively, an applicant may separate the patentably distinct claims into another application and file a terminal disclaimer with the proposed agreement in the application with the indistinct claims.

If the applicant amends the claims after the filing of the terminal disclaimer such that the claims no longer conflict with the claims in the reference patent or application, the applicant may file a petition under 37 CFR 1.182 to withdraw the terminal disclaimer prior to the issuance of the application to avoid the effect of the proposed agreement on patentably distinct claims and any potential loss of patent term. As discussed above, after patent grant, a recorded terminal disclaimer will not be withdrawn. See MPEP 1490, subsection VIII.

B. Changes Consistent With Current Practice

(1) Who May File a Disclaimer

The proposed rule makes no change to who may file a terminal disclaimer. Consistent with 35 U.S.C. 253, the USPTO proposes to refer to the party with the ownership interest making the disclaimer in 37 CFR 1.321 as the ''disclaimant'' rather than the patentee, applicant, assignee, or grantee as currently prescribed in the regulations.

(2) Clarify That a Terminal Disclaimer Can Be Filed in a Patent To Obviate Nonstatutory Double Patenting

Current 37 CFR 1.321(c) and (d) state that a terminal disclaimer may be filed in an application or in a reexamination proceeding but do not explicitly state that the terminal disclaimer to obviate nonstatutory double patenting can be filed in a patent not subject to a reexamination proceeding. Consistent with the guidance set forth in the MPEP, a terminal disclaimer may be filed in a patent under 37 CFR 1.321(c) or (d) that is not subject to a reexamination proceeding. See MPEP 1490, subsection II. Proposed 37 CFR 1.321(c) and (d) are amended to explicitly state that a terminal disclaimer may be filed in a patent to obviate nonstatutory double patenting.

(3) Changes To Reflect Current Terminology in the MPEP

Consistent with current usage in the MPEP (see, for example, chapters 800 and 1400), the USPTO proposes the following changes in 37 CFR 1.321: (1) replace ''judicially created double patenting'' with the phrase ''nonstatutory double patenting,'' (2) refer to the patent in which a terminal disclaimer is filed and the patent subject to a reexamination proceeding in which the terminal disclaimer is filed as the ''subject patent,'' (3) refer to the application in which a terminal disclaimer is filed as the ''subject application,'' and (4) refer to the patent or application forming the basis for the nonstatutory double patenting as the ''reference patent or application.''

(4) Changes To Conform With Current Language in the MPEP

MPEP 1490, subsection VII, provides examples of acceptable terminal disclaimer language to use for terminal disclaimers filed under 37 CFR 1.321(c) or (d). In a few of the examples, the language states that the patentee/applicant agrees to the enforcement provision of current 37 CFR 1.321(c)(3) or (d)(3). Consistent with this guidance set forth in the MPEP, the USPTO proposes to amend 37 CFR 1.321(c)(3) and (d)(3) by adding ''agreeing'' in the enforcement provision.

III. Discussion of Proposed Rules

The following is a discussion of proposed amendments to 37 CFR part 1:

The USPTO proposes to amend § 1.321(a) and (b) by replacing ''grantee'' with ''disclaimant.''

The USPTO proposes to amend § 1.321(a)(3) by replacing ''patentee's ownership interest'' with ''the disclaimant's ownership interest.''

The USPTO proposes to amend § 1.321(b)(1) by redesignating current § 1.321(b)(1) as § 1.321(b)(1)(i) and adding new subparagraph § 1.321(b)(1)(ii) to incorporate the requirements of § 1.321(b)(1) in effect on September 15, 2012. This proposal eliminates the need for the public to consult § 1.321 in effect on September 15, 2012, when filing a terminal disclaimer in an application filed before September 16, 2012, and makes the proposed § 1.321 applicable to all applications, regardless of their filing date. ''Inventor'' and ''applicant'' are no longer synonymous for applications filed on or after September 16, 2012. See MPEP 605 and *Changes To Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act,* 77 FR 48776, 48778–79 (August 14, 2012) (final rule). The term ''applicant'' in proposed § 1.321(b)(1)(i) can include an inventor(s), an assignee(s), or others with a sufficient proprietary interest, whereas the term ''applicant'' in proposed § 1.321(b)(1)(ii) refers to the inventor(s).

The USPTO proposes to amend § 1.321(b)(3) by replacing ''applicant's

ownership interest'' with ''the disclaimant's ownership interest.''

The USPTO proposes to amend § 1.321(c) by replacing ''judicially created double patenting'' with ''nonstatutory double patenting.''

Additionally, proposed § 1.321(c) would explicitly provide for the filing of a terminal disclaimer in a patent not subject to a reexamination proceeding. As is the case today, when a terminal disclaimer under proposed § 1.321(c) is filed to obviate nonstatutory double patenting in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file. See 37 CFR 1.321(c) and MPEP 1490, subsection III.A.

The USPTO proposes to amend § 1.321(c)(3) by adding ''agreeing,'' which is consistent with current practice (see MPEP 1490, subsection VII).

The USPTO proposes to amend § 1.321(d) to specify that the type of double patenting that may be obviated by filing a terminal disclaimer is ''nonstatutory double patenting.''

Additionally, proposed § 1.321(d) would explicitly provide for the filing of a terminal disclaimer in a patent not subject to a reexamination proceeding. As is the case today, when a terminal disclaimer under proposed § 1.321(d) is filed to obviate nonstatutory double patenting in a reexamination proceeding, it should be filed in the reexamination proceeding and not in the patent file. See 37 CFR 1.321(d) and MPEP 1490, subsection III.A.

The USPTO proposes to amend § 1.321(d)(3) by adding ''agreeing,'' which is consistent with current practice (see MPEP 1490, subsection VII).

The USPTO proposes to amend § 1.321(c), (c)(3), (d), and (d)(3) to identify the patent or application forming the basis for the nonstatutory double patenting as the ''reference patent or application.''

The USPTO proposes to amend § 1.321(c)(2), (c)(3), (d)(2), and (d)(3) to identify an application in which a terminal disclaimer is filed to obviate nonstatutory double patenting as a ''subject application'' and a patent in which a terminal disclaimer is filed to obviate nonstatutory double patenting as a ''subject patent.'' The term ''subject patent'' includes both patents that are undergoing a reexamination proceeding and patents that are not undergoing a reexamination proceeding.

The USPTO proposes to amend § 1.321(c)(3) and (d)(3) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which the terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: (1) any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or (2) a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

IV. Rulemaking Considerations

A. Administrative Procedure Act

The changes proposed by this rulemaking involve rules of agency practice and procedure, and/or interpretive rules, and do not require notice-and-comment rulemaking. See *Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 97, 101 (2015) (explaining that interpretive rules ''advise the public of the agency's construction of the statutes and rules which it administers'' and do not require notice and comment when issued or amended); *Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice-and- comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice''); and *JEM Broadcasting Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (explaining that rules are not legislative because they do not ''foreclose effective opportunity to make one's case on the merits'').

Nevertheless, the USPTO is publishing this proposed rule for comment to seek the benefit of the public's views on the Office's proposed regulatory changes.

B. Regulatory Flexibility Act (RFA)

For the following reasons, the Senior Counsel for Regulatory and Legislative Affairs of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b).

The USPTO is proposing to revise the enforcement provisions in § 1.321(c) and (d) to require that a terminal disclaimer filed to obviate nonstatutory double patenting include an agreement by the disclaimant that the subject patent, or any patent granted on the subject application, shall be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting: (1) in which any claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or (2) in which a statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made. Thus, the rulemaking does not propose to substantively change when an applicant or patent owner may file a terminal disclaimer under § 1.321.

The Small Business Administration (SBA) small business size standards that are applicable to most analyses conducted to comply with the RFA are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a specified maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. As provided by the RFA, and after consulting with the SBA, the USPTO formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the RFA for patent-related regulations. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations,* 71 FR 67109 (Nov. 20, 2006), 1313 *Off. Gaz. Pat. Office* 60 (Dec. 12, 2006). The USPTO's alternate small business size standard is SBA's previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. See 13 CFR 121.802. If patent applicants identify themselves on a patent application as qualifying for reduced patent fees, the USPTO captures this data in its patent application data repository (formerly the Patent Application Monitoring and Locating (PALM) system and now called the One Patent Service Gateway (OPSG) system), which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, the size standard for the USPTO is not industry specific. The Office's definition of a small business concern for RFA purposes is a business or other concern that: (1) meets the SBA's definition of a ''business concern or concern'' set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity:

(a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern that would not qualify as a nonprofit organization or a small business concern under this definition. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations,* 71 FR at 67112 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office at 63 (Dec. 12, 2006). For purposes of this certification, the USPTO defines small entities to include entities who are paying small or micro entity fee rates at the USPTO.

The USPTO estimates that approximately 20% of applicants and patent owners (including small entity applicants and patent owners, who account for approximately 27% of patent filings) that are considering the filing of a terminal disclaimer to obviate nonstatutory double patenting will opt not to file a terminal disclaimer containing the proposed agreement, at least during an initial period after the effective date of the final rule. As mentioned earlier herein, applicants and patent owners who choose not to file a terminal disclaimer with the proposed agreement have a number of alternatives to obviate nonstatutory double patenting. The USPTO estimates that the vast majority of applicants and patent owners who choose not to file a terminal disclaimer with the proposed agreement will opt to argue and/or amend claims to obviate nonstatutory double patenting.

The number of instances in which applicants and patent owners have to obviate nonstatutory double patenting is relatively low. The USPTO issues roughly 650,000 nonfinal and final Office actions per fiscal year, of which 175,500 (or 27%) are issued to small entities. Of the 175,500 Office actions issued to small entities, approximately 14%, or approximately 24,570, contain at least one nonstatutory double patenting rejection, and approximately 4%, or approximately 7,020, contain only a nonstatutory double patenting rejection(s).

To estimate the potential impact on small entities from this proposed rulemaking, the USPTO refers to the 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association, which estimates a median cost of $3,500 per Office action response.[1]

For purposes of this certification, the USPTO estimates that all of the approximately 20% of the small entity applicants and patent owners who the USPTO estimates will choose not to file a terminal disclaimer with the proposed agreement will opt to argue and/or amend claims to obviate the nonstatutory double patenting rejection(s). The USPTO therefore estimates that the proposed rulemaking could have a potential annual cost to small entities of $17,199,000 (24,570 × 20% × $3,500) for responding to an Office action containing at least one nonstatutory double patenting rejection by arguing and/or amending claims, rather by than filing a terminal disclaimer.

Furthermore, the USPTO estimates that, on the upper range, approximately 50%, or approximately 2,457 (24,570 × 20% × 50%), of the responses filed will fail to obviate at least one nonstatutory double patenting rejection. These cases may potentially incur the additional cost to small entities of $8,599,500 (2,457 × $3,500) to respond to an additional Office action. Therefore, the USPTO estimates that the upper range of cost that the proposed rulemaking could have on the approximately 20% of potentially impacted small entities is $25,798,500 ($17,199,000 + $8,599,500). The estimated cost will therefore not affect a substantial number (approximately 20%) of small entities.

For at least two reasons, the USPTO believes these estimates to represent the upper range of the potential impact on small entities. First, the preceding estimates do not account for the cost savings, including filing fee savings, from not filing a terminal disclaimer. The USPTO charges a fee of $170 for filing a terminal disclaimer. Based on the estimated 4,914 small entity applicants that opt to not file a terminal disclaimer, the USPTO estimates terminal disclaimer filing fee savings of $835,380. In addition, the USPTO estimates that it takes an estimated 0.25 hours (15 minutes) for applicants and patent owners to file a terminal disclaimer. The 2023 Report of the Economic Survey estimates an hourly attorney fee of $447. Based on the estimated 4,914 small entity applicants that opt to not file a terminal disclaimer, the USPTO estimates cost savings of $549,140. Therefore, the total cost savings for those not filing a terminal disclaimer because of the proposed rulemaking is $1,384,520.

Second, the preceding cost estimates are based on all Office actions containing at least one nonstatutory double patenting rejection, including Office actions containing at least one other rejection that is not a nonstatutory double patenting rejection. As stated above, the USPTO estimates that 7,020 Office actions contain only a nonstatutory double patenting rejection(s). Thus, in 17,550 (24,570 − 7,020) Office actions, small entity applicants and patent owners would have to respond to at least one rejection that is not a nonstatutory double patenting rejection. It therefore follows that at least some portions of the annual costs in the preceding estimates for these 17,550 Office actions should be excluded as they would be attributed to responding to those other rejection(s).

Thus, the total upper range of estimated cost to the 24,570 small entity applicants and patent owners impacted by this rule would be $24,413,980 ($25,798,500 − $1,384,520). The USPTO does not have the data to determine the distribution of this cost across the 24,570 small entity applicants and patent owners that would be impacted by this rule. Thus, for purposes of this certification, the USPTO estimates an average of less than $1,000 in impact to the 24,570 small entities. However, as mentioned above, this estimate is likely to be overstated as some of that impact would be attributed to costs related to responding to a rejection that is not a nonstatutory double patenting rejection.

For the foregoing reasons, the changes proposed in this rulemaking will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be not significant under Executive Order 12866 (September 30, 1993), as amended by Executive Order 14094 (April 6, 2023).

D. Executive Order 13563 (Improving Regulation and Regulatory Review)

The USPTO has complied with Executive Order 13563 (January 18, 2011). Specifically, and as discussed above, the USPTO has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance

[1] This cost represents the report's median charges for services categorized as ''Application amendment/argument, relatively complex—biotech/chemical'' and ''Application amendment/argument, relatively complex—electrical/computer.''

objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism)

This rulemaking pertains strictly to Federal agency procedures and does not contain policies with federalism implications sufficient to warrant the preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

F. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) have substantial direct effects on one or more Indian Tribes; (2) impose substantial direct compliance costs on Indian Tribal governments; or (3) preempt Tribal law. Therefore, a Tribal summary impact statement is not required under Executive Order 13175 (November 6, 2000).

G. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (February 5, 1996).

I. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (April 21, 1997).

J. Executive Order 12630 (Taking of Private Property)

This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (March 15, 1988).

K. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes proposed in this rulemaking are not expected to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a ''major rule'' as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995

The changes proposed in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

M. National Environmental Policy Act of 1969

This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

N. National Technology Transfer and Advancement Act of 1995

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

O. Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking involves information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

This proposed rulemaking impacts the rules of practice pertaining to terminal disclaimers. The general provisions pertaining to terminal disclaimers have been reviewed and approved by the OMB under OMB control number 0651–0031 and are accounted for under the line item Statutory Disclaimers (including terminal disclaimers) as contained in 0651–0031. In a 60-day notice published January 29, 2024 (89 FR 5500), for the renewal of 0651–0031, the USPTO provided estimates for this line item and those estimates appear below.

Under this proposed rulemaking, the USPTO proposes to modify terminal disclaimers to include the additional agreement as discussed in the preamble. The USPTO estimates that approximately 20% of applicants and patent owners that are considering the filing of a terminal disclaimer to obviate nonstatutory double patenting will opt not to file a terminal disclaimer containing the proposed agreement, at least during an initial period after the effective date of the final rule. Therefore, the USPTO proposed estimates below take into account the anticipated 20% reduction in terminal disclaimer filings.

The USPTO will be accounting for this impact in a proposed new information collection that has been submitted to the OMB. The proposed new information collection will reflect an estimated total decrease of 9,990 respondents, 2,498 burden hours and $1,698,300 in filing fees with respect to terminal disclaimers, because some applicants and patent owners will choose not to file a terminal disclaimer with the proposed agreement. A summary of the change in burden to terminal disclaimers follows. The proposed new information collection will be available at the OMB's Information Collection Review website (*www.reginfo.gov/public/do/PRAMain*).

Estimated Data Published in the 60-day Notice for 0651–0031 (January 29, 2024):

Estimated number of annual respondents for statutory disclaimers (including terminal disclaimers): 49,950.

Estimated number of annual responses for statutory disclaimers (including terminal disclaimers): 49,950.

Estimated total annual respondent burden hours for statutory disclaimers (including terminal disclaimers): 12,488.

Estimated total annual respondent hourly cost burden for statutory disclaimers (including terminal disclaimers): $5,582,136.

Estimated total annual respondent non-hourly cost burden for statutory disclaimers (including terminal disclaimers): $8,491,500 in the form of filing fees.

Proposed New Information Collection Associated with RIN 0651–AD76:

OMB control number: 0651–NEW.

Title of collection: Terminal disclaimers.

Needs and uses: The changes under proposed § 1.321 on the filing of terminal disclaimers would be used by an owner (in whole or in part) of a patent or a patent to be granted to agree that the patent in which the terminal disclaimer is filed, or any patent granted on an application in which a terminal disclaimer is filed, will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: any claim has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.

The changes would be used by the USPTO to ensure it does not issue a patent to a common owner or inventor with a claim that conflicts with a claim of a second patent, unless the terminal disclaimer includes the additional agreement that the patent with the terminal disclaimer will not be enforced if any claim of the second patent is invalidated by prior art.

The changes would be used by the public to focus on addressing the validity of the claims of a single patent to resolve a dispute where there are multiple patents tied by terminal disclaimers.

Impacted forms in this information collection:

- PTO/AIA/25 (Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection Over a Pending ''Reference'' Application)
- PTO/SB/25 (Terminal Disclaimer to Obviate a Provisional Double Patenting Rejection over a Pending Second Application)
- PTO/SB/25a (Terminal Disclaimer in a Patent or Proceeding in view of an Application)
- PTO/AIA/26 (Terminal Disclaimer to Obviate a Double Patenting Rejection Over a ''Prior'' Patent)
- PTO/SB/26 (Terminal Disclaimer to Obviate a Double Patenting Rejection over a Prior Patent)
- PTO/SB/26a (Terminal Disclaimer in a Patent or Proceeding in view of Another Patent)
- PTO/AIA/63 (Terminal Disclaimer to Accompany Petition under 37 CFR 1.137 in a Design Application Filed on or after September 16, 2012)
- PTO/SB/63 (Terminal Disclosure to Accompany Petition)

Type of review: New.

Affected public: Private Sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated number of annual respondents for statutory disclaimers (including terminal disclaimers): 39,960.

Estimated number of annual responses for statutory disclaimers (including terminal disclaimers): 39,960.

Estimated total annual respondent burden hours for statutory disclaimers (including terminal disclaimers): 9,990.

Estimated total annual respondent hourly cost burden for statutory disclaimers (including terminal disclaimers): $4,465,530.

Estimated total annual respondent non-hourly cost burden for statutory disclaimers (including terminal disclaimers): $6,793,200 in the form of filing fees.

The USPTO is soliciting public comments to:

(a) evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information;

(c) enhance the quality, utility, and clarity of the information to be collected; and

(d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting the electronic submission of responses.

Please submit comments on this new collection of information at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review'' or by using the search function and entering the title of the collection. Please send a copy of your comments to the USPTO using the method described under **ADDRESSES** at the beginning of this document.

All comments submitted in response to this proposed rulemaking are a matter of public record. The USPTO will include or summarize the comments received in the request to the OMB to approve the new information collection requirements.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.

P. E-Government Act Compliance

The USPTO is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, the USPTO proposes to amend 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

■ 2. Revise § 1.321 to read as follows:

§ 1.321 Statutory disclaimers, including terminal disclaimers.

(a) A patentee owning the whole or any sectional interest in a patent may disclaim any complete claim or claims in a patent. In like manner any patentee may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted. Such disclaimer is binding upon the

disclaimant and its successors or assigns. A notice of the disclaimer is published in the Official Gazette and attached to the printed copies of the specification. The disclaimer, to be recorded in the Patent and Trademark Office, must:

(1) Be signed by the patentee, or an attorney or agent of record;

(2) Identify the patent and complete claim or claims, or term being disclaimed. A disclaimer which is not a disclaimer of a complete claim or claims, or term will be refused recordation;

(3) State the present extent of the disclaimant's ownership interest in the patent; and

(4) Be accompanied by the fee set forth in § 1.20(d).

(b) An applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of a patent to be granted. Such terminal disclaimer is binding upon the disclaimant and its successors or assigns. The terminal disclaimer, to be recorded in the Patent and Trademark Office, must:

(1)(i) For patent applications filed under 35 U.S.C. 111(a) or 363 on or after September 16, 2012, be signed by the applicant or an attorney or agent of record; or

(ii) For patent applications filed under 35 U.S.C. 111(a) or 363 before September 16, 2012, be signed:

(A) By the applicant;

(B) If there is an assignee of record of an undivided part interest, by the applicant and such assignee;

(C) If there is an assignee of record of the entire interest, by such assignee; or

(D) By an attorney or agent of record;

(2) Specify the portion of the term of the patent being disclaimed;

(3) State the present extent of the disclaimant's ownership interest in the patent to be granted; and

(4) Be accompanied by the fee set forth in § 1.20(d).

(c) Except as provided for in paragraph (d) of this section, a terminal disclaimer, when filed in a patent, a reexamination proceeding, or a patent application to obviate nonstatutory double patenting of a claimed invention based on a reference patent or application, must:

(1) Comply with the provisions of paragraphs (b)(2) through (4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application (the subject application) or in accordance with paragraph (a)(1) of this section if filed in a patent or in a reexamination proceeding (the subject patent); and

(3) Include a provision agreeing that the subject patent or any patent granted on the subject application shall be enforceable:

(i) Only for and during such period that the subject patent or any patent granted on the subject application is commonly owned with the reference patent or any patent granted on the reference application; and

(ii) Only if the subject patent or any patent granted on the subject application is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which:

(A) A claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or

(B) A statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

(d) A terminal disclaimer, when filed in a patent, a reexamination proceeding, or a patent application to obviate nonstatutory double patenting of a claimed invention based on a reference patent or application that is not commonly owned but was disqualified as prior art as set forth in either § 1.104(c)(4)(ii) or (c)(5)(ii) as the result of activities undertaken within the scope of a joint research agreement, must:

(1) Comply with the provisions of paragraphs (b)(2) through (4) of this section;

(2) Be signed in accordance with paragraph (b)(1) of this section if filed in a patent application (the subject application) or be signed in accordance with paragraph (a)(1) of this section if filed in a patent or in a reexamination proceeding (the subject patent); and

(3) Include a provision waiving the right to separately enforce the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application, and agreeing that the subject patent or any patent granted on the subject application shall be enforceable:

(i) Only for and during such period that the subject patent or any patent granted on the subject application and the reference patent or any patent granted on the reference application are not separately enforced; and

(ii) Only if the subject patent or any patent granted on the subject application is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which:

(A) A claim has been finally held unpatentable or invalid under 35 U.S.C. 102 or 103 in a Federal court in a civil action or at the USPTO, and all appeal rights have been exhausted; or

(B) A statutory disclaimer of a claim is filed after any challenge based on 35 U.S.C. 102 or 103 to that claim has been made.

Katherine K. Vidal,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2024–10166 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 240502–0125]

RIN 0648–BM69

Fisheries of the Exclusive Economic Zone Off Alaska; Amendment 113 to the Fishery Management Plan for the Groundfish of the Gulf of Alaska; Central Gulf of Alaska Rockfish Program Adjustments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement amendment 113 to the Fishery Management Plan (FMP) for the Groundfish of the Gulf of Alaska (GOA). If approved, amendment 113 and this proposed rule would modify specific provisions of the Central Gulf of Alaska (CGOA) Rockfish Program (RP) to change the season start date, remove the catcher vessel (CV) cooperative holding cap, and revise the processing and harvesting caps. This action is necessary to provide increased flexibility and efficiency, and help ensure the rockfish total allowable catch (TAC) is fully harvested and landed in Kodiak while maintaining the intent of the RP. Amendment 113 is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the GOA FMP, and other applicable laws.

DATES: Submit comments on or before June 10, 2024.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/*

NOAA-NMFS-2023-0149. You may submit comments on this document, identified by NOAA–NMFS–2023–0149, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2023–0149 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Gretchen Harrington, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Electronic copies of amendment 113 to the FMP, the Environmental Assessment and Regulatory Impact Review prepared for this action (the Analysis), and the Finding of No Significant Impact prepared for this action may be obtained from *https://www.regulations.gov* and the NMFS Alaska Region website at *https://www.fisheries.noaa.gov/region/alaska.*

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted to NMFS at the above address and to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Joel Kraski, 907–586–7228, *joel.kraski@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for Action

NMFS manages the groundfish fishery in the exclusive economic zone in the GOA according to the FMP for Groundfish of the Gulf of Alaska prepared by the North Pacific Fishery Management Council (Council) under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

A notice of availability (NOA) for amendment 113 was published in the **Federal Register** on April 4, 2024 (89 FR 23535), with comments invited through June 3, 2024. All relevant written comments received by the end of the comment period (See **DATES**), whether specifically directed to the NOA or this proposed rule, will be considered by NMFS in the approval/disapproval decision for amendment 113. Commenters do not need to submit the same comments on both the NOA and this proposed rule. Comments submitted on this proposed rule by the end of the comment period (See **DATES**) will be considered by NMFS in our decision to implement measures recommended by the Council and will be addressed in the response to comments in the final rule.

Background

Following is a description of the Central GOA Rockfish Program (RP) and the need for this proposed rule.

The Rockfish Program

This section provides a brief overview of the RP, which is a limited access privilege program (LAPP). The Council designed the RP to meet the requirements for limited access privileges in section 303A of the Magnuson-Stevens Act. The RP was developed to enhance resource conservation and improve economic efficiency in the CGOA rockfish fisheries. A detailed description of the RP and its development is provided in the preambles to the proposed and final rules implementing the RP from 2012 through 2021 (76 FR 52147, August 19, 2011 and 76 FR 81248, December 27, 2011).

Originally, the RP was developed to recognize historic participation of fishing vessels and processors. It established a set-aside for participants not eligible to participate in the Rockfish Pilot Program (RPP) and catch limits of species incidentally harvested: northern rockfish, pelagic shelf rockfish (since redefined as dusky rockfish), and Pacific ocean perch.

The RP, which includes the CGOA rockfish species of Pacific ocean perch, northern rockfish, and pelagic shelf rockfish, is based on the recognition of historical participation of fishing vessels and processors in the CGOA rockfish fisheries from 1996 to 2002. The RP provides catch limits for non-rockfish species and non-target rockfish species harvested with the CGOA rockfish species, based upon historical harvest levels of these incidentally caught species; and sets aside up to 5 percent of the TAC of the CGOA rockfish fisheries for CVs that are not eligible to participate in the program. The RP apportions TAC to cooperatives formed by individuals holding a License Limitation Program (LLP) license with rockfish quota share (QS). Fishing under cooperative management resulted in a slower-paced fishery that allowed harvesters to choose when to fish and provided greater stability for processors by spreading out production over a longer period of time.

The RP provides exclusive harvesting privileges for vessels using trawl gear to harvest a specific set of ''rockfish primary species'' and associated ''rockfish secondary species'' (defined at 50 CFR 679.2) incidentally harvested to the rockfish primary species in the CGOA, an area from 147° W long. to 159° W long. The rockfish primary species are northern rockfish, Pacific ocean perch, and dusky rockfish. The rockfish secondary species are Pacific cod, rougheye rockfish, shortraker rockfish, and sablefish. The RP also allocates a portion of the halibut bycatch mortality limit for the GOA trawl fisheries to RP participants.

Need for Amendment 113 and This Proposed Rule

In June 2022, the Council recommended that the Secretary approve amendment 113 to the GOA FMP. Amendment 113 and this proposed rule would address changes in, and potentially resolve associated impacts to, the RP fishery since the RP was reauthorized in 2021.

Cumulative changes since the start of the RP in 2012 have impacted the CGOA fisheries, resulting in difficulties harvesting and processing the CV cooperative quota (CQ), especially later in the season as processors approach the limit of their current processing cap or close for seasonal maintenance. Seasonal fishing activity is the driving force for the planning of vessels and processing staff needs. From the processors' perspective, one of the primary reasons for implementing the RP was to allow the rockfish fishery to be prosecuted prior to the start of the pink salmon fishery, which begins in July. Previous overlaps in the timing of various fisheries led to processing capacity and labor issues. Processors were unable to sustain production when overwhelmed with landings from various overlapping fisheries or were

unable to expand or shrink their production-line employee pools in association with landings. The RP's early opening date allowed excess processor capacity and labor to be utilized more efficiently. Additionally, since 2021, the CGOA flatfish market prices have declined partially due to increased foreign trade tariffs levied by China, leading to a negative financial impact on Kodiak processors due to labor planning issues and lack of sustained deliveries to keep processing crews active. Given these RP processing facility issues, the Council chose to recommend measures that would provide processors increased flexibility, as described below, and allow the RP fishery to adapt to unforeseen challenges.

Seven individual Kodiak rockfish processors, each associated with one or more cooperatives, participated in the RP from 2012 through 2014. One RP processor was acquired in 2014 by another processing company, reducing the total number RP processors to six but leaving the number of RP cooperatives unchanged. Later, in 2018, a rockfish processor ceased processing and the associated cooperative disbanded. In 2020, a merger between processors, and a third processor deciding not to take any RP deliveries, reduced the total number to four processors. In late 2023, one of the four remaining processors announced the intent to sell the rockfish processing plant located in Kodiak, which may leave 10 percent of the TAC unable to be processed, as each of the remaining three processors are limited to processing 30 percent of the TAC.

Amendment 113 and this proposed rule would also provide additional flexibility for trawl vessels to participate in the RP during April, and could keep rockfish processors fully operational, thus mitigating impacts from changes in market conditions. The change in season start date from May 1 to April 1 annually would likely help maintain processing capacity for other non-trawl fisheries through workforce stability, which was observed during the 2021 rockfish season under the emergency rule (86 FR 14851, March 19, 2021) when NMFS temporarily moved the season start date to April 1, 2021.

The term ''use cap'' or ''cap'' is the limit on the quota that can be caught or processed by participants in the RP. This proposed rule would implement the amendment 113 change to three of the RP use caps to remove constraints on the amount of CQ that can be caught or processed by participants, while still maintaining the Council's original intent of preventing consolidation and meeting the overall goal of prosecuting this fishery in a sustainable and functional manner. These changes to the FMP regulations would improve the likelihood that the TACs for the rockfish primary species and the rockfish secondary species would be fully harvested and landed in Kodiak.

In addition to providing additional flexibility to RP processors and harvesters, this proposed rule would implement the amendment 113 update to terminology in the FMP regulations for one species grouping by changing ''pelagic shelf rockfish'' to ''dusky rockfish.'' This would resolve an overlooked species grouping reference that was not completely resolved with the final rule to implement amendment 111 to the GOA FMP (86 FR 11895, March 1, 2021). This is a change in name only; it was effectively made in May 2012 during the 2012 and 2013 harvest specifications (77 FT 15194, March 14, 2012), when the GOA FMP was revised by removing widow rockfish and yellowtail rockfish from the ''pelagic shelf rockfish'' species grouping, thus leaving only dusky rockfish.

Finally, this proposed rule would revise to the regulations to allow for increased flexibility, consistency, and clarity, as described in the *Other Regulatory Changes* section below.

This Proposed Rule

Change in Rockfish Program Season Start Date

This proposed rule would change the start date for this fishery from May 1 to April 1, specified at § 679.80(a)(3)(ii) for a rockfish cooperative, to enhance flexibility for processing plants and vessel operators participating in the RP.

This proposed rule would also change associated references to RP season start dates in §§ 679.5(r)(10), 679.7(n)(3)(i), 679.7(n)(6)(vi), 679.51(a)(2)(vi)(D)(*1*), 679.81(i)(3), 679.84(g)(1), and 679.84(g)(2). The changes in § 679.5(r)(10) would add April to the reporting period of the Rockfish Ex-vessel Volume and Value Report. The changes in § 679.7(n)(3)(i) and (n)(6)(vi) would extend the requirement to use a Vessel Monitoring System (VMS) during the month of April while operating in the RP fishery. The changes in § 679.51(a)(2)(vi)(D)(*1*) would extend the observer requirements for RP from May to the month of April. The changes in §§ 679.81(i)(3), 679.84(g)(1) and 679.84(g)(2) would extend when catch of the rockfish primary species and rockfish secondary species are deducted from CQ from May to the month of April. These provisions all reference the season start date for RP and the changes in this proposed rule would make the regulations consistent with the change to the season start date and would eliminate references to the prior start date of May 1.

Remove the Catcher Vessel Cooperative Rockfish CQ Use Cap

This proposed rule would remove § 679.82(a)(3), thereby eliminating the CV cooperative rockfish CQ use cap that prevents a CV rockfish cooperative from holding or using an amount of rockfish primary species CQ during a calendar year that is greater than an amount resulting from 30.0 percent of the aggregate rockfish primary species QS initially assigned to the CV sector. Removing this use cap would allow cooperatives to reduce the administrative and management costs associated with managing the cooperatives. RP CVs are currently free to join any RP cooperative and each RP cooperative can associate with any processor, and any processor can associate with more than one cooperative. The Council determined, and NMFS agrees, that the RP's processing use cap provides the intended protection from over consolidation, as discussed below, and removing the 30 percent CV cooperative CQ cap would remove duplication and increase efficiencies for cooperatives.

Therefore, this proposed rule would relieve the unnecessary administrative burden caused by preventing RP CVs from joining together into larger cooperatives, while providing more flexibility within the RP fishery for CVs.

Increase the Use Caps for Rockfish Processors

This proposed rule would revise § 679.82(a)(5) to increase the use cap for rockfish processors from 30 percent to 40 percent of the CV QS pool for rockfish primary species, Pacific cod, and sablefish, which ensures that a minimum of three Kodiak processors would be necessary to process all the RP CQ. As noted above, seven individual Kodiak rockfish processors, each associated with one or more cooperatives, participated in the RP from 2012 through 2014. The reduction from seven rockfish processors down to the four that are currently required was not a result of consolidation; it occurred because of plant closures due to various market conditions since 2014. There are currently four rockfish processors operating in Kodiak, Alaska. One of those four rockfish processors announced in December 2023 that their Kodiak processing plant would be listed for sale, resulting in uncertainty for

vessels having a market for rockfish CQ deliveries. Increasing the processor use cap could allow consolidation of RP processing activity to three rockfish processors in Kodiak, Alaska. This could reduce the number of operating rockfish processors; however, increasing the processing cap to 40 percent would continue to limit processor consolidation and provide additional flexibility, allowing all of the CV CQ to be harvested and processed for the primary aggregated rockfish species, Pacific cod, and sablefish.

Revise CV Aggregated Rockfish Harvesting Cap

This proposed rule would revise § 679.82(a)(4) pertaining to the 8 percent harvest vessel use cap for catcher vessels. This proposed rule would not change the harvest vessel use cap for catcher/processor vessels.

This change would delete the phrases ''rockfish primary species'' and ''aggregate rockfish primary species'' in paragraph (4) and replace them with the phrase ''Pacific ocean perch'', thus effectively removing dusky rockfish and northern rockfish from the calculation of the 8 percent harvest vessel use cap, so that the cap would apply only to a CV's harvest of Pacific ocean perch. This change is intended to increase harvest under the RP and more fully utilize the dusky rockfish and northern rockfish TACs, which are consistently underharvested. This would provide an increased opportunity to CVs to harvest a larger portion of dusky rockfish and northern rockfish CQ. In the past, one to three CVs have approached the harvest vessel use cap, but never exceeded that use cap. CVs that have approached the aggregated rockfish harvesting cap limit primarily catch Pacific ocean perch. As a result, maintaining the 8 percent harvest vessel use cap for Pacific ocean perch, but removing it for dusky and northern rockfish, would continue to restrict the catch of Pacific ocean perch quota while simultaneously allowing RP CVs to harvest a greater portion of the dusky rockfish and northern rockfish CQ.

Other Regulatory Changes

In addition to the regulatory changes necessary to implement amendment 113, NMFS proposes the below revisions to the FMP regulations on the RP for clarity, efficiency, and technical consistency, pursuant to the authority of section 305(d) of the Magnuson-Stevens Act. These revisions would:

- Replace all relevant instances of ''pelagic shelf rockfish'' with ''dusky rockfish'' in § 679.7(n)(4), 679.7(n)(6)(vi), and table 37 in part 679. This change would clarify that the regulations apply only to one species, dusky rockfish. This would resolve an overlooked species grouping reference. Recommendations were made by the Council during the 2012 and 2013 harvest specifications process to align the GOA FMP with the Stock Assessment and Fisheries Evaluation report for the GOA. In May 2012, the GOA FMP was revised to remove widow rockfish and yellowtail rockfish from the ''pelagic shelf rockfish'' assemblage, leaving only dusky rockfish (77 FR 15194, March 14, 2012). The final rule to implement amendment 111 to the GOA FMP changed references from ''pelagic shelf'' rockfish to ''dusky'' rockfish throughout 50 CFR part 679 to update the GOA FMP regulations consistent with changes that have occurred to species categories since 2012 and consistent with the implementation of the Rockfish Program (86 FR 11895, March 1, 2021). However, the final rule implementing the Rockfish Program did not change § 679.7(n)(4), 679.7(n)(6)(vi), and table 37 in part 679. Tables or other sections that refer to a specific year in which all three species were present in the assemblage would not be changed.
- Revise § 679.5(r)(8)(i)(A) and (B) to allow vessel operators to submit the check in/out reports on behalf of the rockfish cooperative for additional flexibility. The designated representative of a rockfish cooperative, or vessel operator authorized by the rockfish cooperative, would be able to conduct the check in/out process for the rockfish cooperative vessel.
- Remove the website address for the NMFS Alaska Region website in § 679.5(r)(10)(v). Because the website address is included in the definition of ''NMFS Alaska Region website'' at § 679.2, it is no longer necessary (and it may be confusing) to also include the website in § 679.5(r)(10)(v).
- Revise § 679.81(f)(4) by removing the requirement to submit all listed documents for the Annual Application for the RP. Thus, all documents would be required to be submitted with an initial application, while applicants would be required to resubmit only those documents from the initial application that contain new or changed information. This change would help reduce the reporting burden for subsequent annual applications.
- Regulations at § 679.81(g)(2)(i) and (ii) by removing ''Transfer Key'' from the application for inter-cooperative transfer of cooperative quota, as Transfer Keys are no longer used by the RP.

Classification

Pursuant to sections 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the GOA FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment. Pursuant to MSA section 305(d), this action is necessary to carry out amendment 113 to the GOA FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, and to revise regulations associated with the RP for clarity and technical consistency. Section 305(d) grants the authority to make technical changes to existing regulations, updating cross-references, and clarifications to facilitate pre-planned efficiencies. This proposed rule has been determined to be not significant for the purposes of Executive Order 12866.

A Regulatory Impact Review was prepared to assess costs and benefits of available regulatory alternatives. A copy of this analysis is available from NMFS (see **ADDRESSES**). The Council recommended amendment 113, and NMFS proposes these regulations based on those measures that maximize net benefits to the Nation. Specific aspects of the economic analysis are discussed below in the Initial Regulatory Flexibility Analysis section.

Initial Regulatory Flexibility Analysis

This Initial Regulatory Flexibility Analysis (IRFA) was prepared for this proposed rule, as required by Section 603 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603), to describe the economic impact this proposed rule, if adopted, would have on small entities. This IRFA describes the action; the reasons why this proposed rule is proposed; the objectives and legal basis for this proposed rule; the number and description of directly regulated small entities to which this proposed rule would apply; the recordkeeping, reporting, and other compliance requirements of this proposed rule; and the relevant Federal rules that may duplicate, overlap, or conflict with this proposed rule. This IRFA also describes significant alternatives to this proposed rule that would accomplish the stated objectives of the Magnuson-Stevens Act, and any other applicable statutes, and that would minimize any significant economic impact of this proposed rule on small entities. The description of the proposed action, its purpose, and the legal basis are explained above in the **SUPPLEMENTARY INFORMATION** section of

this proposed rule, and are not repeated here.

For Regulatory Flexibility Act purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

Number and Description of Small Entities Regulated by This Proposed Rule

This proposed rule would directly regulate the owners and operators of CVs and catcher/processor vessels eligible to participate in the CGOA RP. In 2022 (the most recent year of complete data), 57 vessels participated in the RP, 26 of which are considered small entities based on the $11 million threshold. None of the nine catcher/processor vessels that participate in the RP are classified as small entities because their combined gross income through affiliation with the amendment 80 cooperative exceeds the $11 million first wholesale value threshold for combined annual receipts for all affiliated operations worldwide. Additional detail is included in Sections 2.9 in the Analysis prepared for this rule (see **ADDRESSES**).

Description of Significant Alternatives That Minimize Adverse Impacts on Small Entities

In recommending amendment 113 and this proposed rule, the Council considered two alternatives, with multiple elements, including the ''no action'' alternative (Alternative 1); and an action alternative (Alternative 2) to modify the RP with four options to address a suite of potential management revisions. The Council selected, and this proposed rule would implement, Alternative 2, and all options under that alternative, which would increase net benefits to the nation in comparison to the status quo. Those options, which are described (along with a description of the benefits of each option) above in the section entitled, ''This Proposed Rule,'' are to: (1) change the season start date from May 1 to April 1; (2) remove the CV cooperative rockfish CQ use cap; (3) increase the use caps for rockfish processors; and (4) revise the CV aggregated rockfish harvesting cap. As described above in the ''This Proposed Rule'' section, these options enhance flexibility (options 1, 2 and 3), relieve unnecessary administrative burdens for participants in the RP (option 2), and provide increased opportunities to harvest a larger portion of the dusky rockfish and northern rockfish CQ (option 4). The option to increase the processor use cap from 30 to 40 percent could allow consolidation of RP processing activity to three rockfish processors in Kodiak. This allows for the reduction of the number of operating rockfish processors from four to three. The expected result of this option to increase the processing cap would be continued limiting of processor consolidation while also allowing for additional flexibility compared to the status quo. These adjustments to the current CGOA RP would allow additional flexibility to adapt to changing market and environmental conditions, both on the water and in processing capacity within the community, as discussed in the ''This Proposed Rule'' section. The proposed action is intended to meet the overall goal of prosecuting this fishery in a sustainable and functional manner, and to better ensure that the TACs for the primary rockfish species and other allocated species are fully harvested and landed in Kodiak. As noted by the Council in its purpose and need statement, this proposed action includes relatively small changes to the regulations but could have a meaningful impact to the fishery and the Kodiak community.

Based upon the best available scientific data, and in consideration of the Council's objectives of this action, there are no significant alternatives to Alternative 2, which would be implemented by this proposed rule, that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes, and that have the potential to minimize any significant adverse economic impact of the proposed rule on small entities. After consideration of input from the public, the Council and NMFS concluded that the proposed action would best accomplish the stated objectives articulated above in the **SUPPLEMENTARY INFORMATION** section of this proposed rule, and in applicable statutes, and would minimize any significant economic impact of the proposed rule on small entities.

Duplicate, Overlapping, or Conflicting Federal Rules

NMFS has not identified any duplication, overlap, or conflict between this proposed rule and existing Federal rules.

Recordkeeping, Reporting, and Other Compliance Requirements

This proposed rule would modify recordkeeping and reporting requirements under the RP to: (1) Add the month of April to the Rockfish Ex-vessel Volume and Value Report; (2) modify cooperative check-in/out procedures to allow vessel operators to perform the check-in/out; (3) prohibit operation of a vessel that is assigned to a rockfish cooperative and fail to use functioning VMS equipment at all times when operating in a reporting area off Alaska for the month of April; and (4) require documentation for the Annual Application for the RP on the initial application, while subsequently requiring less documentation. Subsequent applications will only be required to resubmit documents for the application if information has changed. These recordkeeping and reporting changes would clarify existing provisions of the RP and remove unnecessary reporting requirements, with the result of slightly reducing the reporting burden for all directly regulated entities including small entities. The impact of these changes is described in more detail in Section 2.8.2 of the Analysis prepared for this proposed rule (See **ADDRESSES**).

Collection-of-Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, two collections of information (and the requirements therein) would continue to apply with no changes: Office of Management and Budget (OMB) Control Number 0648–0445, NMFS Alaska Region VMS Program; and OMB Control Number 0648–0711, Alaska Cost Recovery and Fee Programs. This proposed rule does not contain a change to the requirements contained in these two collections.

This proposed rule contains one collection-of-information requirement subject to review and approval by the OMB under the PRA. This proposed rule would revise the existing requirements for the collection of information OMB Control Number 0648–0545, entitled ''Central Gulf of Alaska Rockfish Program: Permits and Reports.'' As described below, the revisions made by this proposed rule to OMB Control Number 0648–0545 would not result in a change in estimated burden hours. Because of a concurrent action (submitted for three-year renewal) for 0648–0545, the revision to that collection of information for this rule will be assigned a temporary control number that will later be merged into 0648–0545.

Specifically, this proposed rule would revise the requirements for the Application for Rockfish Cooperative Fishing Quota to require the documents listed at § 679.81(f)(4)(i) to be submitted only with the initial application. In subsequent applications, applicants would need to resubmit these documents only if information has changed. This would not modify the respondents, responses, or the burden related to this application. This proposed rule would also allow vessel operators to conduct the check-in and check-out process for the rockfish cooperative vessel check-in and check-out reports. Currently this can only be done by the RP cooperative representative. This revision would add 10 vessel operators as new respondents for the rockfish check-in and check-out reports, but would not change the number of responses or the burden.

The public reporting burden for the Application for Rockfish Cooperative Fishing Quota is estimated to average two hours and the check-in and check-out reports are estimated to average 10 minutes each. These burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding whether existing collections of information 0648–0445 and 0648–0711, and collection of information 0648–0545 as proposed for revision by this action, are necessary for the proper performance of the functions of the agency, including whether the information to be collected will have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at *https://www.reginfo.gov/public/do/PRAMain.*

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Date: May 2, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 679 as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

■ 2. In § 679.5, revise of paragraphs (r)(8)(i)(A) introductory text, (r)(8)(i)(B) introductory text, (r)(8)(ii), and (r)(10)(ii) and (v) to read as follows:

§ 679.5 Recordkeeping and reporting (R&R).

* * * * *

(r) * * *

(8) * * *

(i) * * *

(A) *Vessel check-in.* The designated representative of a rockfish cooperative must designate any vessel that is authorized to fish under the rockfish cooperative's CQ permit, or, if authorized by the rockfish cooperative, the operator of a vessel must do so, before that vessel may fish under that CQ permit through a check-in procedure. The designated representative for a rockfish cooperative or operator of the vessel must submit to NMFS, in accordance with paragraph (r)(8)(ii) of this section, a check-in designation for a vessel:

* * * * *

(B) *Vessel check-out.* The designated representative of a rockfish cooperative must designate any vessel that is no longer fishing under a CQ permit for that rockfish cooperative, or, if authorized by the rockfish cooperative, the operator of the vessel must do so, through a check-out procedure. A check-out report must be submitted to NMFS, in accordance with (r)(8)(ii) of this section, within 6 hours after the effective date and time the rockfish cooperative ends the vessel's authority to fish under the CQ permit.

* * * * *

(ii) *Submittal.* The designated representative of the rockfish cooperative or, if authorized by the rockfish cooperative, the operator of a vessel must submit a vessel check-in or check-out report electronically. The rockfish cooperative's designated representative or vessel operator must log into the online system and create a vessel check-in or vessel check-out request as indicated on the computer screen. By using the NMFS ID password and submitting the transfer request, the designated representative or vessel operator certifies that all information is true, correct, and complete.

* * * * *

(10) * * *

(ii) *Reporting period.* The reporting period of the Rockfish Ex-vessel Volume and Value Report shall extend from April 1 through November 15 of each year.

* * * * *

(v) *Submittal.* The rockfish processor must complete and submit online by electronic submission to NMFS the Rockfish Ex-vessel Volume and Value Report available at the Alaska Region website.

* * * * *

■ 3. Amend § 679.7 by

■ a. Revising paragraph (n)(3)(i) introductory text; and

■ b. Removing the phrase ''pelagic shelf rockfish'' and adding, in its place, the phrase ''dusky rockfish'' in paragraphs (n)(4) and (n)(6)(vi).

The revision reads as follows:

§ 679.7 Prohibitions.

* * * * *

(n) * * *

(3) * * *

(i) Operate a vessel that is assigned to a rockfish cooperative and fail to use functioning VMS equipment as described at § 679.28(f) at all times when operating in a reporting area off Alaska from April 1:

* * * * *

■ 4. In § 679.51, revise paragraph (a)(2)(vi)(D)(*1*) to read as follows:

§ 679.51 Observer and Electronic Monitoring System requirements for vessels and plants.

(a) * * *

(2) * * *

(vi) * * *

(D) * * *

(*1*) *Rockfish cooperative.* A catcher/processor that is named on an LLP license that is assigned to a rockfish cooperative and is fishing under a CQ permit must have at least two observers aboard for each day that the vessel is used to catch or process fish in the Central GOA from April 1 through the earlier of November 15 or the effective date and time of an approved rockfish cooperative termination of fishing declaration. At least one observer must be endorsed as a lead level 2 observer. More than two observers must be aboard if the observer workload restriction

would otherwise preclude sampling as required.

* * * * *

■ 5. In § 679.80, revise paragraph (a)(3)(ii) to read as follows:

§ 679.80 Allocation and transfer of rockfish QS.

* * * * *

(a) * * *

(3) * * *

(ii) *Rockfish cooperative.* Fishing by vessels participating in a rockfish cooperative is authorized from 1200 hours, A.l.t., April 1 through 1200 hours, A.l.t., November 15.

* * * * *

■ 6. In § 679.81, revise paragraphs (f)(4) introductory text, (f)(4)(i) introductory text, (g)(2)(i) and (ii), and (i)(3)(viii) and (xxii) read as follows:

§ 679.81 Rockfish Program annual harvester privileges.

* * * * *

(f) * * *

(4) *Contents of the Application.* A completed application must contain the information specified on the Application for Rockfish Cooperative Fishing Quota identifying the rockfish cooperative, members of the cooperative, and processor associate of a catcher vessel rockfish cooperative, with all applicable fields accurately filled-in and all required documentation attached. The initial application must contain all documents specified at paragraph (f)(4)(i) of this section. Subsequent applications will only be required to resubmit documents specified at paragraph (f)(4)(i) if information they contain has changed.

(i) *Additional documentation.* For the cooperative application to be considered complete, the following documents must be attached to the initial application:

* * * * *

(g) * * *

(2) * * *

(i) The transferor's designated representative must log into NMFS' online system and create a transfer request as indicated on the computer screen. By using the transferor's NMFS ID and password, and submitting the transfer request, the designated representative certifies that all information is true, correct, and complete.

(ii) The transferee's designated representative must log into the online system and accept the transfer request. By using the transferee's NMFS ID and password, the designated representative certifies that all information is true, correct, and complete.

* * * * *

(i) * * *

(3) * * *

Requirement	Catcher vessel sector	Catcher/processor sector
* * *	* * *	
(viii) Is there a season during which designated vessels may catch CQ?	Yes, any vessel designated to catch CQ for a rockfish cooperative is limited to catching CQ during the season beginning on 1200 hours, A.l.t., on April 1 through 1200 hours, A.l.t., on November 15.	
* * *	* * *	
(xxii) When does catch count against my CQ permit?	Any vessel fishing checked-in (and therefore fishing under the authority of a CQ permit must count any catch of rockfish primary species, rockfish secondary species, or rockfish halibut PSC against that rockfish cooperative's CQ from April 1 until November 15, or until the effective date of a rockfish cooperative termination of fishing declaration that has been approved by NMFS).	
* * *	* * *	

* * * * *

■ 7. In § 679.82, remove and reserve paragraph (a)(3) and revise paragraphs (a)(4)(i) and (a)(5) to read as follows:

§ 679.82 Rockfish Program use caps and sideboard limits.

(a) * * *

* * * * *

(4) * * *

(i) A catcher vessel may not harvest an amount of Pacific ocean perch CQ greater than 8.0 percent of the Pacific ocean perch CQ issued to the catcher vessel sector during a calendar year.

* * * * *

(5) *Use cap for rockfish processors.* (i) A rockfish processor may not receive or process an amount of rockfish primary species harvested with CQ assigned to the catcher vessel sector greater than 40.0 percent of the aggregate rockfish primary species CQ assigned to the catcher vessel sector during a calendar year.

(ii) A rockfish processor may not receive or process an amount of Pacific cod harvested with CQ assigned to the catcher vessel sector greater than 40.0 percent of Pacific cod CQ issued to the catcher vessel sector during a calendar year.

(iii) A rockfish processor may not receive or process an amount of sablefish harvested with CQ assigned to the catcher vessel sector greater than 40.0 percent of sablefish CQ issued to the catcher vessel sector during a calendar year.

(iv) * * *

* * * * *

§ 679.84 [Amended]

■ 8. Amend § 679.84 by removing the word ''May'' and add, in its place, the word ''April'' in paragraphs (g)(1) and (2).

■ 9. Revise table 37 to § 679 to read as follows.

TABLE 37 TO PART 679—GOA AMENDMENT 80 SIDEBOARD LIMIT FOR GROUNDFISH FOR THE AMENDMENT 80 SECTOR

In the following management areas in the GOA and in adjacent waters open by the State of Alaska for which it adopts a Federal fishing season . . .	The sideboard limit for . . .	Is . . .
Area 610	Pollock	0.3% of the TAC.

TABLE 37 TO PART 679—GOA AMENDMENT 80 SIDEBOARD LIMIT FOR GROUNDFISH FOR THE AMENDMENT 80 SECTOR—Continued

In the following management areas in the GOA and in adjacent waters open by the State of Alaska for which it adopts a Federal fishing season . . .	The sideboard limit for . . .	Is . . .
Area 620	Pollock	0.2% of the TAC.
Area 630	Pollock	0.2% of the TAC.
Area 640	Pollock	0.2% of the TAC.
West Yakutat District	Pacific cod	3.4% of the TAC.
	Pacific ocean perch	96.1% of the TAC.
	Dusky rockfish	89.6% of the TAC.
Central GOA	Pacific cod	4.4% of the TAC.
	Pacific ocean perch	Subject to regulations in subpart G to this part.
	Dusky rockfish	Subject to regulations in subpart G to this part.
	Northern rockfish	Subject to regulations in subpart G to this part.
Western GOA	Pacific cod	2.0% of the TAC.
	Pacific ocean perch	99.4% of the TAC.
	Dusky rockfish	76.4% of the TAC.
	Northern rockfish	100% of the TAC.

[FR Doc. 2024–09953 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 89, No. 92
Friday, May 10, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meeting Notice of the National Agricultural Research, Extension, Education, and Economics Advisory Board

AGENCY: Research, Education, and Economics.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Agricultural Research, Extension, and Teaching Policy Act of 1977, and the Agriculture Improvement Act of 2018, the United States Department of Agriculture (USDA) announces a meeting of the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board. The Board will meet to continue to determine its advice and recommendations on the top priorities and policies for food and agricultural research, education, extension, and economics; discuss progress on their 'Relevance and Adequacy' evaluation of USDA's precision nutrition efforts; and visit the North Carolina Agriculture and Technology (A&T) University Center for Post Harvest Technologies and the North Carolina Food Innovation Lab.

DATES: The NAREEE Advisory Board will meet in person June 3–4, 2024. The date and times the meeting is open to the public on June 3, 2024, is from 8:30–11:45 a.m. and 3:00 p.m. to 5:45 p.m. EDT. The time for public oral comments is 5:30 p.m.–5:45 p.m. EDT. The meeting is not open to the public from 11:45 a.m.–3:00 p.m. for administrative purposes.

The date and times that the meeting is open to the public on June 4, 2024, is from 8:30–noon EDT. The time for public oral comments is 11:45 a.m.–noon EDT. The meeting is not open to the public from noon–3:00 p.m. EDT for administrative purposes.

Public Participation/Oral Comments: Interested individuals may participate in-person or virtually. To attend the meeting via Zoom and/or make oral comments, you must contact Ms. Michele Simmons at email: *nareee@usda.gov* at least five business days prior to the meeting (no later than May 27, 2024).

Written Comments: The public may file written comments no later than May 27, 2024. Written comments from the public may be submitted via email at *nareee@usda.gov* to the attention of Ms. Michele Simmons. Public written comments will be considered by the NAREEE Advisory Board at the meeting. All written public comments will be available for review at the meeting. Duplicate comments from multiple individuals will appear as one comment, with a notation that multiple copies of the comment were received. The comments will be maintained in the public record of the federal advisory committee at USDA. Please visit *https://nareeeab.ree.usda.gov* to learn more about the agenda for or reports resulting from this meeting.

All statements will become a part of the official record of the NAREEE Advisory Board and will be kept on file for public review in the NAREEE Advisory Board's Office. Written comments by attendees and other interested stakeholders will be welcomed for the public record before and up to two weeks following the Board meeting (no later than 5 p.m. eastern standard time on Wednesday, June 19, 2024).

ADDRESSES: *Meeting Location:* The Board meeting will take place North Carolina Research Campus; Core Laboratory Building (Events Room); 150 Research Campus Drive, Kannapolis, NC 28081.

FOR FURTHER INFORMATION CONTACT: Ms. Kate Lewis, Executive Director/Designated Federal Official, or Ms. Michele Simmons, Program Support Coordinator, National Agricultural Research, Extension, Education, and Economics Advisory Board; telephone: (202) 579–6610 or email: *nareee@usda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Federal Advisory Committee Act, 5 U.S.C. 10, Section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3123), and the Agriculture Improvement Act of 2018, the United States Department of Agriculture (USDA) announces a meeting of the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board.

Purpose of the meeting: The Board will meet to continue to determine its advice and recommendations on the top priorities and policies for food and agricultural research, education, extension, and economics; discuss progress on their 'Relevance and Adequacy' evaluation of USDA's precision nutrition efforts; and visit the North Carolina Agriculture and Technology (A&T) University Center for Post Harvest Technologies and the North Carolina Food Innovation Lab.

An agenda for this two-day meeting may be received by sending an email to the attention of Ms. Michele Simmons at *nareee@usda.gov.*

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the FACA Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American

people, including underserved communities. USDA is an equal opportunity provider, employer, and lender.

Dated: May 6, 2024.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2024–10211 Filed 5–9–24; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program (SNAP) Repayment Demand and Program Disqualification

AGENCY: Food and Nutrition Service (FNS), Department of Agriculture.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a revision of currently approved information collection requirements associated with initiating collection actions against individuals/households (I/HH) who have received an overissuance in SNAP.

DATES: Written comments must be received on or before July 9, 2024.

ADDRESSES: Comments may be sent to: Maribelle Balbes, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via email to *snapsab@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Jennifer Ragan at *snapsab@usda.gov,* 703–457–6786.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program Repayment Demand and Program Disqualification.

Form Number: N/A.

OMB Control Number: 0584–0492.

Expiration Date: 07/31/2024.

Type of Request: Revision of a currently approved collection.

Abstract: Section 13(b) of the Food and Nutrition Act of 2008, as amended (7 U.S.C. 2022(b)), and SNAP regulations at 7 CFR 273.18 require State agencies to initiate collection action against I/HH that have been overissued benefits. To initiate collection action, State agencies must provide an affected I/HH with written notification informing the I/HH of the claim and demanding repayment. This process is automated in most State agencies.

SNAP regulations at 7 CFR 273.16(e)(3) require State agencies to investigate any case of suspected fraud and, where applicable, make an Intentional Program Violation (IPV) determination either administratively or judicially. Notifications and activities involved in the IPV process include:

—The State agency providing written notification informing an individual suspected of committing an IPV of an impending administrative disqualification hearing or court action;

—An individual opting to accept the disqualification and waiving the right to an administrative disqualification hearing or court action by signing either a waiver to an administrative disqualification hearing or a disqualification consent agreement in cases of deferred adjudication and returning it to the State agency; and

—Once a determination is made regarding an IPV, the State agency sending notification to the affected individual of the action taken on the administrative disqualification hearing or court decision.

SNAP regulations at 7 CFR 273.16 require State agencies to use disqualified recipient data to ascertain the correct penalty for IPVs, based on prior disqualifications. State agencies determine this by accessing and reviewing records located in the Electronic Disqualified Recipient System (eDRS). eDRS is an automated system developed by the Food and Nutrition Service that contains records of disqualifications in every State. State agencies are also responsible for updating the system, as required at 7 CFR 237.16, which includes reporting disqualifications in eDRS as they occur and updating eDRS when records are no longer accurate, relevant, or complete.

This information collection covers activities associated with initiating overissuance collections and IPV determinations. The burden associated with reporting collections and other claims management information on the FNS–209 form is covered under the Food Program Reporting System, OMB control number 0584–0594, expiration date 09/30/2026. The burden associated with referring delinquent claims and receiving collections through the Treasury Offset Program is covered under currently approved OMB control number 0584–0446, expiration date 09/30/2025.

Summary of Estimated Burden

The burden consists of two major components: the initiation of overissuance collections and actions associated with IPV determinations. As an exception, due to the variances in data associated with implementing COVID flexibilities during the Public Health Emergency, a 3-year average for fiscal years 2021–2023 has been used to compare against the currently approved burden. The estimated total 3-year average annual burden for this collection is 99,786.9643 hours (69,343.3710 State agency reporting hours + 14,910.3556 I/HH reporting hours + 15,533.2377 State agency recordkeeping hours). The net aggregate change to this collection is a decrease of 35,739.02 total burden hours from the currently approved burden of 135,525.9843 hours. The estimated total annual responses for this collection is 1,498,759.9962 responses (547,029.3333 State agency reporting total annual response + 486,663.6667 I/HH reporting total annual responses + 465,066.9962 State agency recordkeeping total annual records). The burden hours associated with overissuance collection initiation and IPV activity have decreased due to a decrease in the number of claims established and the number of States initiating IPV activity against SNAP I/HH over the last 3 fiscal years (2021–2023).

Reporting

Affected Public: State, Local and Tribal government (State agency); I/HH.

Respondent Type: SNAP participants.

State Agency Reporting Burden

States have done these activities for many years. Based on prior experience in how long these activities take, FNS estimates it will take the 53 State agencies an average 7 minutes (0.1268 hours) to issue each letter or notice or take the actions described below. The following is a summary total for the activities described below.

Estimated Number of Respondents: 53.

Estimated Total Number of Responses per Respondent: 10,321.3082.

Estimated Total Annual Responses: 547,029.3333.

Estimated Time per Response: 0.1268.

Estimated Total Annual Reporting Burden: 69,343.3710.

Demand Letter for Overissuance 7 CFR 273.18 (a)(2)

Based on many years of doing these activities, FNS estimates it will take the 53State agencies 8 minutes (0.1336 hours) to issue a Demand Letter, and that they will issue 7,339.2642 letters each, for a total of 51,967.8616 hours. The prior approval included 74,787.2760 hours. The new burden estimate is 22,819.4144 fewer hours than the previously approved burden amount due to program adjustments. (53 State agencies * 7,339.2642 letters each * 8 minutes (0.1336 hours) = 51,967.8616 hours). Prior approval 74,787.2760 hours − 51,967.8616 hours = 22,819.4144 hours less than the currently approved burden amount).

Notice for Hearing or Prosecution 7 CFR 273.16(e)(3)

FNS estimates that 53 State agencies will issue 745.3333 Notices for Hearing or Prosecution for a total of 39,502.6667 responses. FNS estimates it will take approximately 8 minutes (0.1336 hours) to issue a Notice for Hearing or Prosecution for an estimated 5,277.5563 total hours. The previously approved burden was 5,716.6104 hours. This represents a change of 439.0541 fewer hours associated with this burden due to program adjustments. (53 State agencies * 745.3333 responses * 8 minutes (0.1336 hours) = 5,277.5563 hours). Prior approval 5,716.6104 hours − 5,277.5563 hours = 439.0541 hours less than previously approved burden.)

Action Taken on Hearing or Court Decision: For IPV Findings 7 CFR 273.16(e)(9)

FNS estimates that 53 State agencies will take action on 690.2516 IPV findings for a total of 36,583.3333 responses. FNS estimates that it will take approximately 10 minutes (0.1670 hours) for a State agency to take action on a court decision for IPV findings for a total of 6,109.4167 annual burden hours. This represents a change of 419.7823 fewer hours from the previously approved burden of 6,529.1990 hours due to program adjustments. (53 State agencies * 690.2516 responses * 10 minutes (0.167 hours) = 6,109.4167 hours). Prior approval hours 6,529.1990 − 6,109.4167 hours = 419.7823 hours less than previously approved burden.)

Action Taken on Hearing or Court Decision: For No IPV Findings 7 CFR 273.16(e)(9)

FNS estimates that 53 State agencies will take action on 83.1258 instances of no IPVs as a result of a hearing or court decision for a total of 4,405.6667 total responses. FNS estimates that it will take approximately 5 minutes (0.0835 hours) for a State agency to take action on a hearing or court decision for no IPV findings for a total of 367.8732 annual burden hours. This represents a change of 59.5912 additional burden hours from the previously approved burden of 308.2820 hours due to program adjustments. (53 State agencies * 83.1258 responses * 5 minutes (0.0835 hours) = 367.8732 hours). Prior approval 308.2820 hours − 367.8732 hours = 59.5912 additional burden hours than previously reported.)

Electronic Disqualified Recipient System Breakout For eDRS Reporting 7 CFR 273.16(i)(2)(i)

FNS estimates that 53 State agencies will generate reporting from their eDRS system 690.2516 times for a total of 36,583.3333 annual responses. FNS estimates that it will take approximately 5 minutes (0.0835 hours) for a State agency to generate reporting from eDRS for a total of 3,054.7083 burden hours. This represents a change of 209.8912 fewer burden hours from the previously approved burden of 3,264.5995 hours due to program adjustments. (53 State agencies * 690.2516 responses * 5 minutes (0.0835 hours) = 3,054.7083 hours). Prior approval of 3,264.5995 hours − 3,054.7083 hours = 209.8912 fewer burden hours than previously reported.)

Electronic Disqualified Recipient System Breakout: For Editing and Resubmission 7 CFR 272.1(f)(3)

FNS estimates that 53 State agencies will edit and resubmit reporting to the eDRS system 82.8302 times for a total of 4,390.0000 annual responses. FNS estimates that it will take approximately 10 minutes (0.167 hours) for a State agency to edit and resubmit reporting to eDRS for a total of 733.1300 burden hours. This represents a change of 50.3739 fewer burden hours from the previously approved 783.5039 hours due to program adjustments. (53 State agencies * 82.8302 responses * 10 minutes (0.167 hours) = 733.1300 hours). Prior approval of 783.5039 hours − 733.1300 = 50.3739 fewer burden hours than previously reported.)

Electronic Disqualified Recipient System Breakout: For Penalty Checks using Mainframe 7 CFR 273.16(i)(4)

FNS estimates that 53 State agencies will use eDRS for penalty checks using the mainframe 690.2516 times for a total of 36,583.3333 annual responses. FNS estimates that it will take approximately 3 minutes (0.0501 hours) for a State agency to run a penalty check using the mainframe for a total of 1,832.8250 burden hours. This represents a change of 125.9347 fewer burden hours from the previously approved 1958.7597 hours due to program adjustments. (53 State agencies * 690.2516 responses * 3 minutes (0.0501 hours) = 1,832.8250 hours). Prior approval of 1958.7597 hours − 1,832.8250 hours = 125.9347 less annual burden hours than previously reported.)

I/HH Reporting Burden

Based on prior experience in how long these activities take, FNS estimates it will take the 486,663.6667 I/HH respondents an average of less than 2 minutes (0.0306 hours) to respond as requested by the State agency. The following is a summary total for the activities related to I/HH reporting requirements as described below.

Estimated Number of Respondents: 486,663.6667.

Estimated Number of Responses per Respondent: 1.

Total Number of Annual Responses: 486,663.6667.

Estimated Time per Response: 0.0306.

Estimated Total Annual Reporting Burden: 14,910.3556.

Initiation of Overissuance Collection 7 CFR 273.18(a)(2)

Based on many years of reporting these activities, FNS estimates approximately 388,981.0000 respondents will respond 1 time for a demand letter for overissuance for a total of 388,981.0000 annual responses. FNS estimates that it will take approximately 2 minutes (0.0334 hours) for a respondent to respond to a demand letter for a total estimate of 12,991.9654 annual burden hours. This represents a change of 5,704.8536 fewer annual burden hours from the previously

approved burden of 18,696.8190 hours due to a program adjustment. (388,981.0000 respondents * 1 response per respondent * 2 minutes (0.0334 hours) = 12,991.9654 hours). Prior approval of 18,696.8190 − 12,991.9654 = 5,704.8536 fewer annual burden hours than previously reported for I/HH.)

Notice for Hearing or Prosecution 7 CFR 273.16(e)(3)

FNS estimates approximately 39,502.6667 respondents will respond 1 time for a notice for hearing or prosecution for a total of 39,502.6667 annual responses. FNS estimates that it will take approximately 1 minute (0.0167 hours) for a respondent to read a notice for hearing or prosecution for a total estimate of 659.6945 annual burden hours. This represents a change of 57.8818 fewer annual burden hours from the previously approved burden of 714.5763 hours due to a program adjustment. (39,502.6667 respondents * 1 response per respondent * 1 minute (0.0167 hours) = 659.6945 hours). Prior approval of 714.5763 − 659.6945 = 54.8818 fewer annual burden hours than previously reported for I/HH.)

Administrative Disqualification Hearing Waiver 7 CFR 273.16(i)(2)

FNS estimates approximately 14,542.6667 respondents will respond 1 time for an administrative disqualification hearing waiver for a total of 14,542.6667 annual responses. FNS estimates that it will take approximately 2 minutes (0.0334 hours) for a respondent to submit an administrative disqualification hearing waiver for a total estimate of 485.7251 annual burden hours. This represents a change of 37.4525 fewer annual burden hours from the previously approved burden of 523.1776 hours due to a program adjustment. (14,542.6667 respondents * 1 response per respondent * 2 minutes (0.0334 hours) = 485.7251 hours). Prior approval of 523.1776 − 485.7251 = 37.4525 fewer burden hours than previously reported for I/HH.)

Disqualification Consent Agreement 7 CFR 273.16(i)(2)

FNS estimates approximately 2,648.3333 respondents will respond 1 time for a disqualification consent agreement for a total of 2,648.3333 annual responses. FNS estimates that it will take approximately 2 minutes (0.0334 hours) for a respondent to submit a disqualification consent agreement for a total estimate of 88.4543 annual burden hours. This represents a change of 8.3389 fewer annual burden hours from the previously approved burden of 96.7932 hours due to a program adjustment. (2,648.3333 respondents * 1 response per respondent * 2 minutes (0.0334 hours) = 88.4543 hours). Prior approval of 96.7932 − 88.4543 = 8.3389 fewer burden hours than previously reported for I/HH.)

Action Taken on Hearing or Court Decision: For IPV Findings 7 CFR 273.16(e)(9)

FNS estimates approximately 36,583.3333 respondents will respond 1 time for an action taken on hearing or court decision for IPV findings for a total of 36,583.3333 annual responses. FNS estimates that it will take approximately 1 minute (0.0167 hours) for a respondent to submit an action taken on hearing or court decision for IPV findings for a total estimate of 610.9417 annual burden hours. This represents a change of 41.9782 fewer annual burden hours from the previously approved burden of 652.9199 hours due to a program adjustment. (36,583.3333 respondents * 1 response per respondent * 1 minute (0.0167 hours) = 610.9417 hours). Prior approval of 652.9199 − 610.9417 = 41.9782 fewer burden hours than previously reported for I/HH.)

Action Taken on Hearing or Court Decision: For No IPV Findings 7 CFR 273.16(e)(9)

FNS estimates approximately 4,405.6667 respondents will respond 1 time for an action taken on hearing or court decision for no IPV findings for a total of 4,405.6667 annual responses. FNS estimates that it will take approximately 1 minute (0.0167 hours) for a respondent to submit an action taken on a hearing or court decision for no IPV findings for a total estimate of annual 73.5746 burden hours. This represents a change of 11.9182 additional annual burden hours from the previously approved burden of 61.6564 hours due to a program adjustment. (4,405.6667 respondents * 1 response per respondent * 1 minute (0.0167 hours) = 73.5746 hours). Prior approval 61.6564 − 73.5746 = 11.9182 additional burden hours than previously reported for I/HH.)

Recordkeeping

State Agency Recordkeeping Burden

States have done these activities for many years. Based on prior experience in how long these activities take, FNS estimates it will take the 53 State agencies an average of 2 minutes (0.0334 hours) to perform the required recordkeeping. The following is a summary total for the activities described below.

Estimated Number of Recordkeepers: 53.

Estimated Total Records per Recordkeeper: 8,774.8490.

Estimated Total Annual Records: 465,066.9962.

Estimated Average # of Hours per Response: 0.0334.

Estimated Total Recordkeeping Hours: 15,533.2377.

Initiation of Overissuance Collection 7 CFR 272.1(f)

Based on many years of performing these activities, FNS estimates that 53 State agencies will perform recordkeeping for initiating a collection action approximately 7,339.2642 times for a total of 388,981.0000 annual records. FNS estimates that it will take approximately 2 minutes (0.0334 hours) for a State agency to perform recordkeeping for initiation of a collection action for a total of 12,991.9654 burden hours. This represents a change of 5,704.8536 fewer burden hours from the previously approved burden of 18,696.8190 hours due to program adjustments. (53 State agencies * 7,339.2642 records * 2 minutes (0.0334 hours) = 12,991.9654 hours). Prior approval of 18,696.8190 hours − 12,991.9654 hours = 5,704.8536 fewer annual burden hours than previously reported.)

IPV Determinations 7 CFR 272.1(f)

FNS estimates that 53 State agencies will perform recordkeeping for IPVs 1,435.5848 times for a total of 76,085.9962 annual records. FNS estimates that it will take approximately 2 minutes (0.0334 hours) for a State agency to update records for IPVs for a total of 2,541.2723 annual burden hours. This represents a change of 193.7201 fewer annual burden hours from the previously approved burden of 2,734.9924 hours due to program adjustments. (53 State agencies * 1,435.5848 records * 2 minutes (0.0334 hours) = 2,541.2723 hours). Prior approval of 2,734.9924 hours − 2,541.2723 = 193.7201 fewer annual burden hours than previously reported.)

Overall Grand Total Reporting and Recordkeeping Burden for All Affected Public

Estimated Overall Total Number of Respondents: 486,769.6667.

Estimated Overall Responses per Respondents: 3.0790.

Estimated Overall Total Annual Responses: 1,498,759.9962.

Estimated Overall Time per Response: 0.0666.

Estimated Overall Grand Total Annual Reporting and Recordkeeping Burden: 99,786.9643.

Respondent category (affected public)	Type of respondents	Burden activity	CFR Section of regulations	Estimated number of respondents	Responses per respondent	Total annual responses (Col. ExF)	Estimated avg. number of hours per response	Estimated total hours (Col. GxH)
REPORTING								
State Agency Reporting								
State Government	State Agency	Demand Letter for Overissuance	273.18(a)(2)	53	7,339.2642	388,981.0000	0.1336	51,967.8616
		Notice for Hearing or Prosecution	273.16(e)(3)	53	745.3333	39,502.6667	0.1336	5,277.5563
		Action Taken on Hearing or Court Decision: For IPV Findings.	273.16(e)(9)	53	690.2516	36,583.3333	0.1670	6,109.4167
		Action Taken on Hearing or Court Decision: For No IPV Findings.	273.16(e)(9)	53	83.1258	4,405.6667	0.0835	367.8732
		Electronic Disqualified Recipient System Breakout: For eDRS Reporting.	273.16(i)(2)(i)	53	690.2516	36,583.3333	0.0835	3,054.7083
		Electronic Disqualified Recipient System Breakout: For Editing and Resubmission.	272.1(f)(3)	53	82.8302	4,390.0000	0.1670	733.1300
		Electronic Disqualified Recipient System Breakout: For Penalty Checks using Mainframe.	273.16(i)(4)	53	690.2516	36,583.3333	0.0501	1,832.8250
State Agency Reporting Sub-Total				53	10,321.3082	547,029.3333	0.1268	69,343.3710
Individuals/Household Reporting								
Individuals/Household	SNAP Households ..	Demand Letter for Overissuance	273.18(a)(2)	388,981.0000	1	388,981.0000	0.0334	12,991.9654
		Notice for Hearing or Prosecution	273.16(e)(3)	39,502.6667	1	39,502.6667	0.0167	659.6945
		Administrative Disqualification Hearing Waiver.	273.16(i)(2)	14,542.6667	1	14,542.6667	0.0334	485.7251
		Disqualification Consent Agreement	273.16(i)(2)	2,648.3333	1	2,648.3333	0.0334	88.4543
		Action Taken on Hearing or Court Decision: For IPV Findings.	273.16(e)(9)	36,583.3333	1	36,583.3333	0.0167	610.9417
		Action Taken on Hearing or Court Decision: For No IPV Findings.	273.16(e)(9)	4,405.6667	1	4,405.6667	0.0167	73.5746
Individuals/Household Reporting Sub-Total				486,663.6667	1	486,663.6667	0.0306	14,910.3556
Total Reporting				486,716.6667	10,322.3082	1,033,693.0000	0.0815	84,253.7267
Recordkeeping								
State Government	State Agency	Recordkeeping Breakout: For initiating Collection Action.	*272.1(f)*	53	7,339.2642	388,981.0000	0.0334	12,991.9654
		Recordkeeping Breakout: For IPVs	*272.1(f)*	53	1,435.5848	76,085.9962	0.0334	2,541.2723
Total Recordkeeping				53	8,774.8490	465,066.9962	0.0334	15,533.2377
TOTAL BURDEN								
Grand Total Reporting and Recordkeeping				486,769.6667	3.0790	1,498,759.9962	0.0666	99,786.9643

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2024–10204 Filed 5–9–24; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sierra Vista Ranger District; Coronado National Forest; Arizona; Hermosa Critical Minerals Project

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA Forest Service, Coronado National Forest, is preparing an environmental impact statement (EIS) to evaluate and disclose the potential environmental effects from the proposed Hermosa Critical Minerals Exploration and Mine Plan of Operations, submitted by South32 Hermosa Inc. (proponent), to occupy and use National Forest System lands for operations associated with an expansion of an underground polymetallic development. The proposed mine plan of operations (MPO) may also require an amendment to the 2018 Coronado National Forest Land and Resource Management Plan (forest plan) to include site-specific exceptions to plan direction to accommodate the proposed exploration and mining operations. The Forest Service is providing this public scoping opportunity to gather information to inform the environmental review and decision-making process.

DATES: Comments concerning the scope of the analysis must be received by June 10, 2024. The draft EIS is expected May 2025 and the final EIS is expected February 2026.

ADDRESSES: Comments can be submitted electronically using the Public Comment Form at *https://cara.fs2c.usda.gov/Public//CommentInput?Project=65668.* Written comments may be submitted via mail or hand delivery (Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays) to Kerwin S. Dewberry, Forest Supervisor, Coronado National Forest, ATTN: Hermosa Critical Minerals Project, 300 West Congress Street, Tucson, AZ 85701. Written comments may also be submitted during public scoping meetings (see ''Scoping Comments and the Objection Process'').

FOR FURTHER INFORMATION CONTACT: Edwin Monin, Project Manager, Coronado National Forest, 300 West Congress Street, Tucson, AZ 85701, by email at *edwin.monin@usda.gov* or by phone at 520–388–8300, between 8 a.m. and 4:00 p.m. Mountain Standard Time, Monday through Friday. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The proposed MPO was submitted by the proponent in accordance with 36 CFR part 228, subpart A. The Forest Service finished the review process for MPO completeness for elements required under 36 CFR 228.4(c). The MPO dated December 1, 2023, was formally accepted as administratively complete on December 15, 2023. For complete details, please refer to the proposed MPO online at *https://www.fs.usda.gov/project/coronado/?project=65668.*

After evaluating the proposed MPO, the Forest Service determined that the decision for whether to approve use of National Forest System lands would be a major Federal action subject to the National Environmental Policy Act (NEPA), as defined in 40 CFR 1508.1. Accordingly, the Forest Service will prepare an EIS to document key issues associated with the MPO, consider and assess reasonable alternatives, evaluate and disclose potential environmental effects, propose mitigation necessary to minimize adverse impacts, and ensure compliance with applicable laws, regulations, and policy. Therefore, the Forest Service is fulfilling statutory requirements and agency policy and direction to comply with NEPA and other relevant authorities.

Purpose and Need for Action

The Forest Service's purpose for the action is to decide whether to approve the proponent's December 1, 2023, proposed MPO for surface use of National Forest System lands in connection with operations authorized by U.S. mining laws (30 U.S.C. 21–54).

The Forest Service's need for action is established by the agency's responsibility under the General Mining Law of 1872, as amended, and the agency's locatable mineral regulations (36 CFR part 228, subpart A). In accordance with 36 CFR 228.5, the Forest Service must analyze and provide timely response to the submittal of an MPO. Furthermore, the Forest Service must assess whether the proposed operations will be conducted so as, where feasible, to minimize adverse environmental impacts on national forest surface resources in accordance with 36 CFR 228.8.

Proposed Action

The Forest Supervisor for the Coronado National Forest (responsible official) must decide whether to approve the MPO submitted by the proponent, and whether to require any modifications determined necessary through the analysis to comply with applicable laws and regulations. As described in the MPO, the proposed action would affect Federal and private lands comprised of patented mining claims owned by the proponent. However, the Forest Service only has the authority to regulate surface operations on National Forest System lands and does not have jurisdiction to regulate mining operations underground or those that occur on private land. Nevertheless, the EIS will consider and disclose environmental effects of any connected action, including mining-related operations that would occur on private lands. Other actions potentially related to the MPO will be considered in the process, including but not limited to Clean Water Act permitting by the U.S. Army Corp of Engineers and the Arizona Department of Environmental Quality in addition to related amendments to the Coronado National Forest Land and Resource Management Plan.

Project Location

The proposed MPO (project) is located within the Patagonia Mountains in southern Arizona. The project is located in an unincorporated part of central Santa Cruz County, approximately 6 miles southeast of the town of Patagonia and about 8 miles north of the U.S.-Mexico international border. Nearby communities include Kino Springs, Nogales, Rio Rico, and Sonoita.

Project Description

The proposed action would continue the historic production of minerals within the Harshaw Mining District. The primary minerals targeted by the proponent are manganese and zinc, which are identified by the United States Geological Survey as critical minerals in the 2022 Final List of Critical Minerals (87 FR 10381). The Energy Act of 2020 defines a ''critical mineral'' as a non-fuel mineral or mineral material essential to the economic or national security of the United States and which has a supply chain vulnerable to disruption. The proponent's proposed activities on or beneath National Forest System lands are an expansion of the current operations on the proponent's adjacent private land, with a proposed surface

disturbance of 480.5 acres, an underground disturbance of 223 acres, and restricted access to 353.4 acres. Figure 2–1 included in the MPO depicts the proposed site plan and facilities on both private and National Forest System lands. The following MPO activities are proposed on or beneath National Forest System lands.

Surface exploration—

- Continued definition of the ore body within the footprint of tailings storage facility 2 and in other locations. This includes construction of temporary drill pads and access roads. Where future surface disturbance is not contemplated, drill pads and access roads would be reclaimed.

Underground exploration, mining, and support operations—

- Construction of underground tunnels and infrastructure.
- Underground mining of ore using the long-hole open stoping method, as well as hauling and crushing of sulfide ore so it can be brought to the surface.
- Use of approximately half of the tailings for mixing of cemented paste backfill (comprising filtered tailings, cement, and water) and return of material via pipe for backfill underground.
- Underground equipment use and maintenance.
- Continued definition of the orebody through exploration drilling from underground workings.

Surface storage of tailings and waste rock—

- Geotechnical drilling and test pits to support development of tailings storage facility 2, a lined dry-stack tailings storage facility on National Forest System land.
- Construction, use, and closure of the lined dry-stack tailings storage facility 2 for storage of both filtered tailings and waste rock, as well as other small quantities of materials such as solids from the water treatment plants. The lined tailings storage facility includes infrastructure for management of stormwater runoff and seepage.
- Construction, use, and closure of an underdrain collection pond for the lined dry-stack tailings storage facility 2, including a lined drainage conveyance channel leading to the storage facility's underdrain collection pond.
- Transportation and placement of filtered tailings and waste rock materials into tailings storage facility 2.
- Construction and use of water distribution pipelines and associated tailings storage facility 2 underdrain collection pond to convey collection pond water for treatment.
- Construction and use of the project electrical distribution lines, including lines to tailings storage facility 2 and the storage facility's underdrain collection pond.

Water management activities—

- Construction of groundwater management wells on the surface and construction of water management infrastructure (sumps, pumps) underground.
- Collection of water for groundwater management purposes to reduce hydrostatic pressures to allow underground exploration and mining, either by pumping groundwater management wells or by collection underground.
- Construction, operation, and maintenance of piping and power lines associated with groundwater management wells.
- Construction of permanent monitoring wells to observe water quality and level and comply with regulatory requirements.
- Recharge of treated water in areas that would benefit the aquifer using rapid infiltration basins, including water delivery pipelines.
- Construction of stormwater controls to reroute non-contact runoff and contain contact water.

Roads and transportation—

- Geotechnical drilling and/or test pits to support construction of the primary access road.
- Construction of a new and permanent primary access road from the project area to State Route 82 (where feasible, limiting new disturbance by improving existing Forest Road segments).
- Construction of temporary access roads including (1) those associated with facility access and exploration that would be closed and reclaimed during the operational mine life, causing a short-term temporary disturbance (short-term temporary access roads); and (2) those associated with facility access, groundwater management wells, monitoring wells, connecting haul roads, or rapid infiltration basins that would remain through the operational mine life until closure, involving a long-term disturbance (long-term temporary access roads).
- Upgrade of some existing roads to meet similar criteria used for temporary access roads.
- Transportation of equipment, materials, supplies, and personnel to and from the project area using existing Forest Roads, the primary access road, and temporary access roads.
- Transportation of filtered zinc and lead and silver concentrates off-site in sealed containers.
- Transportation of crushed oxide ore in sealed containers to beneficiation facilities on private land distal from the project area.
- Construction and maintenance of fencing and berms as required for worker and public safety. This includes construction of temporary roads along four planned fence locations for construction and maintenance.

Reclamation and closure activities—

- Salvage and storage of growth media for use in reclamation.
- Closure of the dry-stack tailings storage facility 2 and storage facility's underdrain collection pond upon completion of operations, including placing a closure cap and growth media on tailings storage facility 2, implementing passive treatment for seepage associated with the storage facility, and stormwater management controls.
- Abandonment (proper closure) of groundwater management wells, and closure and reclamation of groundwater management well pads.
- Closure and reclamation of all temporary access roads, exploration drill holes, pads, and rapid infiltration basins.
- Long-term monitoring activities.

Preliminary Alternatives

In addition to the proposed action, two additional alternatives have been identified for detailed study including the no-action alternative and alternative 1. The no-action alternative is the alternative where the Forest Service does not approve the proposed MPO and represents what operations could still occur on private land. This alternative serves as the baseline for the comparison among the action alternatives. Alternative 1 includes the MPO and a proposal from UniSource Energy Services to construct a 138-kV overhead transmission line to serve the project area and support service reliability for UniSource customers in the San Rafael Valley, Washington Camp, and Lochiel areas of southeastern Arizona. Comments received in response to this Notice of Intent may result in identification of additional reasonable alternatives.

Plan Amendment

The proposed action includes activities that may require a forest plan amendment to include site-specific exceptions to plan direction to accommodate the proposed action. The proposed action may include, but is not limited to, a forest plan amendment to allow a reduction in the scenic integrity objectives for the project area (2018 Coronado National Forest Land and Resource Management Plan, page 82). Additionally, a forest plan amendment

may be required to allow major aboveground utility corridor development outside of the area identified and mapped in the 2008 West-Wide Energy Corridor Programmatic EIS as referenced in the 2018 Coronado National Forest Land and Resource Management Plan (pages 83 and 85).

The responsible official plans to release the draft record of decision in conjunction with the final EIS. The draft decision would be subject to 36 CFR part 218, ''Project-Level Pre-decisional Administrative Review Process.'' Depending on the nature of the forest plan amendment(s) required, the draft decision may also be subject to 36 CFR part 219, subpart B, ''Pre-decisional Administrative Review Process.'' Following resolution of objections to the draft decision, the final decision would be issued.

Expected Impacts

It is anticipated that there would be impacts to water quality and quantity; scenery; threatened, endangered, and other special status species and their habitats; effects from drilling and mining activities such as noise and lights used for nighttime drilling; impacts to air quality; and increased traffic. This is a preliminary issues list with additional issues to be identified through the scoping process.

Lead and Cooperating Agencies

The Forest Service is the lead agency for the proposed action and compliance with NEPA. The Coronado National Forest has identified, invited, and received acceptance from four cooperating agencies to include the U.S. Army Corps of Engineers, the U.S. Fish and Wildlife Service, the Arizona Department of Environmental Quality, and the Arizona State Historic Preservation Office.

Responsible Official

The responsible official for the decision on this project is Kerwin S. Dewberry, Forest Supervisor, Coronado National Forest, 300 West Congress Street, Tucson, Arizona 85701.

Scoping Comments and the Objection Process

This notice of intent initiates the scoping process, which guides the development of the EIS. In this process, the agency is requesting comments on potential issues and alternatives in addition to identification of any relevant information, studies, or analyses of any kind concerning impacts affecting the quality of the human environment.

Public scoping meetings in an open house format will be held as follows:

1. May 20, 2024, 4:30 to 6:30 p.m., Patagonia Union High School, 200 Naugle Ave., Patagonia, Arizona
2. May 21, 2024, 4:30 to 6:30 p.m., Quality Hotel Americana, 639 N Grand Ave., Nogales, Arizona

Meeting details will also be posted on the Coronado National Forest website and advertised in the *Arizona Daily Star, Herald/Review, Nogales International,* and *Patagonia Regional Times.*

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the EIS; therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. Commenting during scoping and any other designated opportunity to comment provided by the responsible official as prescribed by the applicable regulations will also govern eligibility to object once the final EIS and draft record of decision has been published. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, they will not be used to establish eligibility for the objection process.

Objections will be accepted only from those who have previously submitted specific written comments regarding the proposed project during scoping or other designated opportunity for public comment in accordance with 36 CFR 218.5(a). Issues raised in objections must be based on previously submitted timely, specific written comments regarding the proposed project unless based on new information arising after designated opportunities.

Permits, Licenses, or Other Authorizations Required

The MPO may require other permits, licenses, and authorizations including but not limited to a Clean Water Act Section 404 Permit from the U.S. Army Corps of Engineers; an Underground Injection Control Permit from the U.S. Environmental Protection Agency; an Encroachment Permit from the Arizona Department of Transportation; a Reclamation Plan and annual renewal from the Arizona State Mine Inspector; and the following permits from the Arizona DEQ—Air Quality Permit, Arizona Pollutant Discharge Elimination System Permit, Aquifer Protection Permit, Arizona Water Quality Certification under section 401 of the Clean Water Act, and Resource Conservation and Recovery Act Subtitle C Site Identification Form.

Nature of Decision To Be Made

Based on environmental analysis and disclosure documented in the EIS, the responsible official will decide: (1) whether to approve the MPO as proposed or modified, or as described in an alternative; (2) what mitigation measures, if needed, would be required; (3) what monitoring, if any, would be required; and (4) whether approval of an action alternative would be consistent with the 2018 Coronado National Forest Land and Resource Management Plan or whether an amendment to the forest plan would be required.

Substantive Provisions

Any proposed forest plan amendment(s) would meet the substantive requirements for sustainability (36 CFR 219.8), species diversity (36 CFR 219.9), multiple use (36 CFR 219.10), and timber (36 CFR 219.11).

Dated: May 2, 2024.

Troy Heithecker,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–10048 Filed 5–9–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed Recreation Fee Site

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The Inyo National Forest is proposing to establish a recreation fee site. Proposed recreation fees collected at the proposed recreation fee sites would be used for operation, maintenance, and improvement of the sites. An analysis of nearby recreation fee sites with similar amenities shows the proposed recreation fees that would be charged at the new recreation fee sites are reasonable and typical of similar recreation fee sites in the area.

DATES: If approved, the proposed recreation fees would be established no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Inyo National Forest, Attention: Recreation Fees, 351 Pacu Lane, Suite 200, Bishop, CA 93514.

FOR FURTHER INFORMATION CONTACT: Andrew Kennedy, Forest Recreation

Officer, (760) 920–3522, *andrew.kennedy@usda.gov.*

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (16 U.S.C. 6803(b)) requires the Forest Service to publish a six-month advance notice in the **Federal Register** of establishment of proposed recreation fee sites. In accordance with Forest Service Handbook 2309.13, Chapter 30, the Forest Service will publish the proposed recreation fee sites and proposed recreation fees in local newspapers and other local publications for public comment. Most of the proposed recreation fees would be spent where they are collected to enhance the visitor experience at the proposed recreation fee sites.

A special recreation permit recreation fee of $20 per permit is proposed for the Inyo National Forest Christmas Tree Permits. The 4th Grade Pass would be honored for a free permit.

Expenditures of recreation fees collected at the proposed recreation fee sites would enhance recreation opportunities, improve customer service, and address maintenance needs. Once public involvement is complete, the proposed recreation fee sites and proposal recreation fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Dated: May 6, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–10246 Filed 5–9–24; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: Commission on Civil Rights.

ACTION: Notice of Commission public briefing.

SUMMARY: Notice of Commission public briefing, *The Federal Role in Enforcing Religious Freedoms in Prison,* Notice of Commission business meeting, and call for public comments.

DATES: Friday, May 17, 2024, 10 a.m. ET.

ADDRESSES: The briefing is open to the public and can be attended via live stream on the Commission's YouTube page at: *https://www.youtube.com/usccr.*

FOR FURTHER INFORMATION CONTACT: Angelia Rorison (202) 376–8359; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Commission on Civil Rights on whether prisoners' religious freedom rights are being protected and enforced in accordance with constitutional and statutory provisions. This is an update to the Commission's 2008 statutory enforcement report, *Enforcing Religious Freedom in Prison.*

At this public briefing, the Commission will hear from subject matter experts such as government officials, religious leaders, academics, prisoners' rights advocates, religious liberty organizations, and legal experts. The Commission will accept written materials from the public for consideration as we prepare our report; submit to *rfip@usccr.gov* no later than Monday, June 17, 2024.

This briefing is open to the public and is accessible via live stream at *https://www.youtube.com/usccr.* (* Streaming information subject to change.)

Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, May 17, 2024, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

To request additional accommodations, persons with disabilities should email *access@usccr.gov* by Monday, May 13, 2024, indicating ''accommodations'' in the subject line.

Briefing Agenda for Civil Rights Implications of the Federal Use of Facial Recognition Technology

10:00 a.m.–3:15 p.m.

All times Eastern Standard Time

I. Introductory Remarks: 10:00–10:10 a.m.
II. Panel 1: Constitutional and Legal Experts: 10:10–11:25 a.m.
III. Break: 11:25–11:35 a.m.
IV. Panel 2: Religious Leaders & Direct Service Providers: 11:35 a.m.–12:50 p.m.
V. Lunch: 12:50–1:50 p.m.
VI. Panel 3: Prisoners' Religious Rights Advocates: 1:50 p.m.–3:05 p.m.
VII. Closing Remarks: 3:05–3:15 p.m.
VIII. Adjourn Meeting.

** Public Comments will also be accepted through written testimony.

* Schedule is subject to change.

Call for Public Comments

In addition to the testimony collected on Friday, May 17, 2024, via public briefing, the Commission welcomes the submission of material for consideration as we prepare our report. Please submit such information to *rfip@usccr.gov* no later than June 17, 2024, or by mail to OCRE/Public Comments, ATTN: RFIP, U.S. Commission on Civil Rights, 1331 Pennsylvania Ave. NW, Suite 1150, Washington, DC 20425.

Dated: May 17, 2024.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2024–10409 Filed 5–8–24; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–815]

Carbon Steel Flanges From Spain: Preliminary Results of Antidumping Duty Administrative Review and Rescission of Review in Part; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that carbon steel flanges from Spain were sold in the United States at prices below normal value. The period of review (POR) is June 1, 2022, through May 31, 2023. We are also rescinding this administrative review, in part, with respect to seven companies because the requests for administrative review were timely withdrawn. We invite interested parties to comment on these preliminary results.

DATES: Applicable May 10, 2024.

FOR FURTHER INFORMATION CONTACT: Jacob Waddell or Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1369 or (202) 482–6312, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2017. Commerce issued an antidumping duty order on finished carbon steel flanges from Spain.[1] On August 3, 2023, based on timely requests for administrative review, Commerce initiated an administrative review of the *Order.*[2] All requests for administrative review were timely withdrawn with regard to seven

[1] *See Finished Carbon Steel Flanges from Spain: Antidumping Duty Order,* 82 FR 27229 (June 14, 2017) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023) (*Initiation Notice*).

companies,[3] leaving ULMA Forja, S.Coop (ULMA) as the sole mandatory respondent in this review.[4] On February 9, 2024, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the preliminary results of review until June 28, 2024.[5]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[6] A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Scope of the Order

The product covered by the *Order* is carbon steel flanges from Spain. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(2) of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication of the notice of initiation of the requested review. As noted above, all requests for an administrative review were timely withdrawn for all companies except ULMA. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this administrative review with respect to seven of the eight companies named in the *Initiation Notice*.[7]

Preliminary Results of Review

Commerce preliminarily finds the following estimated weighted-average dumping margin exists for the period June 1, 2021, through May 31, 2023:

Exporter/producer	Weighted-average dumping margin (percent)
ULMA Forja, S.Coop	2.02

Disclosure and Public Comment

We intend to disclose to interested parties the calculations performed for these preliminary results within five days after public announcement of the preliminary results, or if there is no public announcement, within five days of the publication of these preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[8] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[9] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings, we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide, at the beginning of their briefs, a public executive summary for each issue raised in their briefs.[11] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[13] Requests should contain: (1) the party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Assessment Rate

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[14]

For any individually examined respondents whose weighted-average dumping margin is above *de minimis* (*i.e.,* greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales to that importer, and we will instruct CBP to assess antidumping duties on all appropriate entries covered by this review. For entries of subject merchandise during the POR produced by each respondent for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others

[3] *See* Weldbend Corporation's Letter, ''Withdrawal of Request for Administrative Review,'' dated September 5, 2023.

[4] *See* Memorandum, ''Identification of Mandatory Respondent for the 2022–2023 Administrative Review of the Antidumping Duty Order on Finished Carbon Steel Flanges from Spain,'' dated September 15, 2023.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 9, 2024.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review; 2022–2023'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* Appendix II for a list of these companies.

[8] *See* 19 CFR 351.309(c)(ii).

[9] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[12] *See APO* and *Service Final Rule*.

[13] *See* 19 CFR 351.310(c).

[14] *See* 19 CFR 351.212(b)(1).

rate if there is no rate for the intermediate company(ies) involved in the transaction.[15] Where the individually-selected respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies listed in Appendix II for which we are rescinding this review, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue these rescission instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**.[16] If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2) of the Act: (1) the cash deposit rate for the companies listed in the final results of review will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 2.02 percent, the all-others rate established in the less-than-fair-value investigation.[17] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results of review, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: May 6, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Administrative Review, In Part
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

Appendix II

Companies for Which This Administrative Review is Being Rescinded

1. Aleaciones De Metales Sinterizados S.A.
2. Central Y Almacenes
3. Farina Group Spain
4. Friedrich Geldbach Gmbh
5. Grupo Cunado
6. Transglory S.A.
7. Tubacero, S.L.

[FR Doc. 2024–10233 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–DS–P

[15] For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[16] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 884 (January 15, 2021).

[17] *See Order,* 82 FR at 27230.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Final Results of Antidumping Duty Administrative Review; 2021–2022

SUMMARY: The U.S. Department of Commerce (Commerce) determines that sales of steel concrete reinforcing bar (rebar) from Mexico were made at less than normal value during the period of review (POR), November 1, 2021, through October 31, 2022.

DATES: Applicable May 10, 2024.

FOR FURTHER INFORMATION CONTACT: Patrick Barton or Kyle Clahane, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0012 or (202) 482–5449, respectively.

SUPPLEMENTARY INFORMATION:

Background

On November 8, 2023, Commerce published the *Preliminary Results* for this review in the **Federal Register** and invited interested parties to comment on those results.[1] The review covers five companies, including two mandatory respondents, Deacero S.A.P.I. de C.V. (Deacero), and I.N.G.E.T.E.K.N.O.S. Estructurales, S.A. de C.V. (Ingetek) (collectively, Deacero Group), and Acerero S.A. de C.V. (Acerero). From January 5 to 10, 2024, interested parties submitted case and rebuttal briefs.[2] For a complete summary of the events that have occurred since Commerce

[1] *See Steel Concrete Reinforcing Bar from Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 77079 (November 8, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Rebar Trade Action Coalition's Letter, ''RTAC's Case Brief,'' dated January 5, 2024; *see also* Deacero Group's Letter, ''Case Brief,'' dated January 5, 2024; Gerdau Corsa, S.A.P.I. de C.V. and Sidertul S.A. de C.V.'s Letter, ''Letter in Lieu of Case Brief of Gerdau Corsa, S.A.P.I. de C.V. and Sidertul S.A. de C.V.,'' dated January 5, 2024; Acerero's Letter, ''Rebuttal Brief of Grupo Acerero S.A. de C.V.,'' dated January 10, 2024; and Deacero Group's Letter, ''Rebuttal Brief,'' dated January 10, 2024.

published the *Preliminary Results,* as well as a full discussion of the issues raised by parties for these final results, *see* the Issues and Decision Memorandum.[3] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The product covered by the *Order* is rebar from Mexico. For a complete description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum is attached in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain changes to the preliminary weighted-average dumping margins calculated for Deacero Group and Acerero. For a detailed discussion of these changes, *see* the Issues and Decision Memorandum.[5]

Rate for Non-Individually Examined Companies

The Act and Commerce's regulations do not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which not selected for individual examination in an administrative review.

Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

For these final results of review, we calculated weighted-average dumping margins for both respondents, Deacero Group and Acerero, that are not zero, *de minimis,* or based entirely on the basis of facts available. Accordingly, consistent with section 735(c)(5)(A) of the Act, we determined the weighted-average dumping margin for each of the non-selected companies based on the weighted-average dumping margins calculated for the mandatory respondents.[6]

Final Results of Review

Commerce determines that the following weighted-average dumping margins exist for the period August 1, 2021, through July 31, 2022:

Exporter or producer	Weighted-average dumping margin (percent)
Deacero S.A.P.I. de C.V./I.N.G.E.T.E.K.N.O.S. Estructurales, S.A. de C.V	1.16
Grupo Acerero S.A. de C.V	6.21
Grupo Simec S.A.B. de C.V./Aceros Especiales Simec Tlaxcala, S.A. de C.V./Compania Siderurgica del Pacifico S.A. de C.V./Fundiciones de Acero Estructurales, S.A. de C.V./Grupo Chant S.A.P.I. de C.V./Operadora de Perfiles Sigosa, S.A. de C.V./Orge S.A. de C.V./Perfiles Comerciales Sigosa, S.A. de C.V./RRLC S.A.P.I. de C.V./Siderúrgicos Noroeste, S.A. de C.V./Siderurgica del Occidente y Pacifico S.A. de C.V./Simec International, S.A. de C.V./Simec International 6 S.A. de C.V./Simec International 7 S.A. de C.V./Simec International 9 S.A. de C.V	2.11
Gerdau Corsa, S.A.P.I. de C.V	2.11
Sidertul S.A. de C.V	2.11

Disclosure

Commerce intends to disclose the calculations performed for these final results to interested parties in this review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by this review. In accordance with 19 CFR 351.212(b)(1), where the respondents reported the entered value of their U.S. sales, Commerce calculated importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales. Where the respondents did not report entered value, we calculated a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also calculated an importer-specific *ad valorem* ratio based on estimated entered values. Where either a respondent's weighted-average dumping margin is zero or *de minimis,* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the

[3] *See* Memorandum, ''Steel Concrete Reinforcing Bar from Mexico: Issues and Decision Memorandum for the Final Results of Antidumping Duty Administrative Review; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Steel Concrete Reinforcing Bar from Mexico: Antidumping Duty Order,* 79 FR 65925 (November 6, 2014) (*Order*).

[5] *Id.*

[6] *See* Memorandum, ''Final Results of the Antidumping Duty Administrative Review of Steel Concrete Reinforcing Bar from Mexico: Calculation of the Rate for Non-Selected Respondents,'' dated concurrently with this notice.

appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR for which the examined companies did not know that the merchandise they sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

The assessment rate for antidumping duties for each of the companies not selected for individual examination will be equal to the weighted-average dumping margin identified above in the ''Final Results of Review'' section.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[7]

Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rates for the companies identified above in the ''Final Results of Review'' will be equal to the company-specific weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by a company not covered in this administrative review but covered in a completed prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review or completed prior segment of this proceeding but the producer is, the cash deposit rate will be the company-specific rate established for the most recently-completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 20.58 percent, the rate established in the investigation of this proceeding.[8]

These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the term of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: May 3, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–10192 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* section 751(a)(2)(C) of the Act.

[8] *See Order,* 79 FR at 65926.

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will hold a virtual meeting via web conference on Thursday, September 12, 2024, from 8:30 a.m. to 5:00 p.m. Eastern Time. The primary purposes of this meeting are to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, and on the progress of the NCST investigation focused on the Champlain Towers South partial building collapse that occurred in Surfside, Florida. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

DATES: The NCST Advisory Committee will meet on Thursday, September 12, 2024, from 8:30 a.m. to 5:00 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: The meeting will be held via web conference. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tanya Brown-Giammanco, Disaster and Failure Studies Program, Engineering

Laboratory, NIST. Tanya Brown-Giammanco's email address is *Tanya.Brown-Giammanco@nist.gov* and her phone number is (301) 975–2822.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (Pub. L. 107–231, codified at 15 U.S.C. 7301 *et seq.*). The Committee is currently composed of eight members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Team program. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1001 *et seq.,* notice is hereby given that the NCST Advisory Committee will meet on the date(s) and at the time(s) set forth in the **DATES** section of this notice. The meeting will be open to the public and will be held via web conference. Interested members of the public will be able to participate in the meeting from remote locations. The primary purposes of this meeting are to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, and on the progress of the NCST investigation focused on the Champlain Towers South partial building collapse that occurred in Surfside, Florida. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

This meeting will be recorded. Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately twenty minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Taylor Avery at *taylor.avery@nist.gov* by 5:00 p.m. Eastern Time, Monday September 9, 2024. Any member of the public is also permitted to file a written statement with the advisory committee; speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to *disaster@nist.gov.*

Anyone wishing to attend this meeting via web conference must register by 5:00 p.m. Eastern Time, Monday, September 9, 2024, to attend. Please submit your full name, the organization you represent (if applicable), email address, and phone number to Taylor Avery at *taylor.avery@nist.gov.*

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–10234 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD904]

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Coastal Pelagic Species Management Team (CPSMT) and Coastal Pelagic Species Advisory Subpanel (CPSAS) will hold public meetings.

DATES: The CPSMT meeting will be held Wednesday, May 29, 2024, from 9 a.m. to 12 p.m., Pacific Daylight Time or until business for the day has been completed.

The CPSAS meeting will be held Thursday, May 30, 2024, from 1 p.m. to 4 p.m., Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: These meetings will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Jessi Doerpinghaus, Staff Officer, Pacific Council; telephone: (503) 820–2415.

SUPPLEMENTARY INFORMATION: The primary purpose of the CPSMT and CPSAS online meetings are to discuss and develop work products and recommendations for the Pacific Council's June 2024 meeting. Topics will include terms of reference for CPS stock assessments, Council operations and priorities, and marine planning. Other items on the Pacific Council's June agenda may be discussed as well. The meeting agendas will be available on the Pacific Council's website in advance of the meetings. No management actions will be decided by the CPSMT or CPSAS. CPSMT and CPSAS recommendations will be considered by the Pacific Council at their June Council meeting.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10239 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD936]

Fisheries of the U.S. Caribbean; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 84 Assessment Webinar III for U.S Caribbean Yellowtail Snapper and Stoplight Parrotfish.

SUMMARY: The SEDAR 84 assessment process of U.S. Caribbean yellowtail snapper and stoplight parrotfish will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 84 assessment webinar III will be held May 29, 2024, from 2 p.m. to 4 p.m., Eastern Time.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment webinar III are as follows:

Panelists will review and discuss initial assessment modeling to date.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10238 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD887]

Fisheries of the South Atlantic, Gulf of Mexico, and Caribbean; Southeast Data, Assessment, and Review (SEDAR) Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of the SEDAR Steering Committee meeting.

SUMMARY: The SEDAR Steering Committee will meet to discuss the SEDAR stock assessment process and assessment schedule. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR Steering Committee will meet Thursday, May 30, 2024, from 10 a.m. until 12 p.m., Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the SEDAR process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie Neer (See Contact Information Below) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405. *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Program Manager, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The SEDAR Steering Committee provides guidance and oversight of the SEDAR stock assessment program and manages assessment scheduling.

The items of discussion for this webinar are as follows:

SEDAR Projects Schedule
SEDAR Process Review and Discussions
Other Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, those

issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10237 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD899]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 88 Red Tide Topical Working Group Webinar II for Gulf of Mexico Red Grouper.

SUMMARY: The SEDAR 88 assessment of Gulf of Mexico red grouper will consist of a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 88 Red Tide Topical Working Group Webinar II will be held May 30, 2024, from 1 p.m. to 4 p.m., Eastern.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; phone: (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the webinar are as follows:

Participants will discuss red tide modeling work and provide recommendations for is use in the assessment of Gulf of Mexico red grouper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 7, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10240 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD942]

Marine Mammals and Endangered Species

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits and permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Ph.D. (Permit Nos. 27099–01 and 27424), Malcolm Mohead (Permit No. 27671), and Shasta McClenahan, Ph.D. (Permit Nos. 27548, 27921, and 27938), at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to *https://www.federalregister.gov* and search on the permit number provided in table 1 below.

TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
27099–01	0648–XC782	Pacific Whale Foundation, 300 Ma'alaea Road, Suite 211, Wailuku, HI 96793 (Responsible Party: Jens Curie).	89 FR 1908, January 11, 2024.	April 26, 2024.
27424	0648–XD4063	Point Blue Conservation Science, 3820 Cypress Drive No. 11, Petaluma, CA 94954 (Responsible Party: Grant Ballard, Ph.D.).	88 FR 66815, September 28, 2023.	April 22, 2024.
27548	0648–XD804	Lars Bejder, Ph.D., University of Hawaii at Manoa, 46–007 Lilipuna Road, Kaneohe, HI 96744.	89 FR 18906, March 15, 2024.	April 30, 2024.
27671	0648–XD796	Northwest Fisheries Science Center, Marine Forensic Laboratory, 2725 Montlake Blvd. East, Seattle, WA 98112 (Responsible Party: Kevin Werner, Ph.D.).	89 FR 18397, March 13, 2024.	April 26, 2024.
27921	0648–XD805	Joshua Schiffman, M.D., University of Utah, 2000 Circle Of Hope Drive, Salt Lake City, UT 84112.	89 FR 18906, March 15, 2024.	April 30, 2024.
27938	0648–XD793	BBC Studios, Ltd., Whiteladies Road, Bristol, BS8 2LR, UK (Responsible Party: Emily-Kate Moorhead).	89 FR 18378, March 13, 2024.	April 30, 2024.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permits was based on a finding that such permits: (1) were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: May 7, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–10217 Filed 5–9–24; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and delete product(s) previously furnished by such agencies.

DATES: Comments must be received on or before: June 09, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20064.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

In accordance with 41 CFR 51–5.3(b), the Committee intends to add this services requirement to the Procurement List as a mandatory purchase only for DEPT OF THE AIR FORCE, FA3300 42 CONS CC at Maxwell AFB (including Gunter Annex and Vigilant Warrior Training Site), Montgomery, AL with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent to geographically limit this services requirement.

The following service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Service(s)

Service Type: Custodial and Related Services
Mandatory for: US Air Force, Maxwell AFB (including Gunter Annex and Vigilant Warrior Training Site), Montgomery, AL
Authorized Source of Supply: Global Connections to Employment, Inc., Pensacola, FL
Contracting Activity: DEPT OF THE AIR FORCE, FA3300 42 CONS CC

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
1670–01–578–6771—Deployment Bag, Parachute, 35 Feet (T–10R)
Authorized Source of Supply: Georgia Industries for the Blind, Bainbridge, GA
Authorized Source of Supply: Winston-Salem Industries for the Blind, Inc, Winston-Salem, NC
Contracting Activity: DLA AVIATION, RICHMOND, VA

Michael R. Jurkowski,

Deputy, Business Operations.

[FR Doc. 2024–10209 Filed 5–9–24; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0216]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Process for FSA ID Account Creation for Individuals Without a Social Security Number in Connection With Person Authentication Service (PAS)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 10, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Process for FSA ID Account Creation for Individuals without a Social Security Number in Connection with Person Authentication Service (PAS).

OMB Control Number: 1845–0179.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 3,500.

Total Estimated Number of Annual Burden Hours: 1,155.

Abstract: Applicants, parents, and borrowers establish an FSA ID, which includes a username and password. The FSA ID is used for the purposes of verifying the identity of the user; allowing users to establish an account with FSA; safeguarding their personally identifiable and financial information; signing applications and loan related documents; providing users access to their information and applications; allowing users to customize or update their accounts with FSA; renewing or revoking a user's account with FSA; and supporting the Federal Student Aid Information Center (FSAIC) help desk functions.

The specific questions that applicants are asked to answer in the FSA ID creation process are described separately in the Creating FSA–ID document, which explains the use of the questions in the application. As part of the standard process, users' information is matched with information from the Social Security Administration (SSA) to confirm their SSA status.

In the event of individuals who do not have a SSN to match, they are instructed to the contact the Department and provide one of the following documents (U.S. State/Territory Driver's License; U.S. State or City Identification Card; Foreign Passport; Municipal identification card; Community ID; or a Consular identification card) and a signed attestation of their identity under the penalty of perjury, as instructed by the Privacy Act.

This collection provides the process and application that individuals without an SSN may use to acquire an FSA ID to access the statutory and regulatory benefits of the Title IV, HEA student financial assistance programs.

Dated: May 6, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10202 Filed 5–9–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0124]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of the Toolkit to Support Evidence-Based Algebra Instruction in Middle and High School

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 10, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Eric Mason, (202) 987–1355.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate;

(4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluation of the Toolkit to Support Evidence-Based Algebra Instruction in Middle and High School.

OMB Control Number: 1850–0988.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Responses: 1,029.

Total Estimated Number of Annual Burden Hours: 358.

Abstract: The current authorization for the Regional Educational Laboratories (REL) program is under the Education Sciences Reform Act of 2002, part D, section 174, (20 U.S.C. 9564), administered by the Department of Education, Institute of Education Sciences (IES), National Center for Education Evaluation and Regional Assistance (NCEE). The central mission and primary function of the RELs is to support applied research and provide technical assistance to state and local education agencies within their region (ESRA, part D, section 174[f]). The REL program's goal is to partner with educators and policymakers to conduct work that is change-oriented and supports meaningful local, regional, or state decisions about education policies, programs, and practices to improve outcomes for students.

Even prior to the COVID–19 pandemic, Algebra 1 proved challenging for many students because of the extensive abstract thinking it requires (Katz, 2007; Susa et al., 2014). To help students succeed in Algebra 1, REL Central is developing a toolkit of professional learning supports to help Algebra 1 teachers learn about, make sense of, plan for, and implement three evidence-based Algebra 1 teaching practices that were identified in the related What Works Clearinghouse (WWC) Practice Guide, ''Teaching Strategies for Improving Algebra Knowledge in Middle and high School Students.'' The toolkit contains the following three parts: (1) Initial Diagnostic and On-going Monitoring Instruments, (2) Professional Development Resources, and (3) Steps for Institutionalizing Supports for Evidence-Based Practice.

This study will assess whether implementing the toolkit improves teacher and student outcomes and will describe the implementation of the toolkit in study schools that use it. Using a school-level randomized controlled trial during the 2024–2025 school year, the study will estimate the impact of the toolkit on teachers' self-efficacy and their understanding and use of the promising practices, as well as on students' algebraic content knowledge, self-efficacy, and mathematical mindsets. To provide context for the impact estimates and inform future use of the toolkit, the study will also describe the implementation of the toolkit. The study plans to include 20 schools from up to three school districts. To disseminate these findings, REL Central will produce a report for school leaders and teachers who are potential users of the toolkit.

The original information collection request received approval for recruitment activities. This revision requests clearance for data collection activities.

Dated: May 6, 2024.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10193 Filed 5–9–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0039]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; US Department of Education Pre-Authorized Debit Account Brochure and Application

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 10, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, (202) 377–4018.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: US Department of Education Pre-Authorized Debit Account Brochure and Application.

OMB Control Number: 1845–0025.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 637.

Total Estimated Number of Annual Burden Hours: 51.

Abstract: The Pre-authorized Debit Account Brochure and Application (PDA Application) serves as the means by which an individual with a defaulted federal education debt (student loan or grant overpayment) that is held by the U.S. Department of Education (ED) requests and authorizes the automatic debiting of payments toward satisfaction of the debt from the borrower's checking or savings account. The PDA Application explains the automatic debiting process and collects the individual's authorization for the automatic debiting and the bank account information needed by ED to debit the individual's account.

Dated: May 6, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10195 Filed 5–9–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0022]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; The College Assistance Migrant Program (CAMP) Annual Performance Report (APR)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 10, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Andrew Brake, (202) 453–6136.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: The College Assistance Migrant Program (CAMP) Annual Performance Report (APR).

OMB Control Number: 1810–0727.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 1,380.

Abstract: This information collection request revises the 1810–0727 College Assistance Migrant Program (CAMP) Annual Performance Report (APR) collection. These changes include language replacements, removals, and additions intended to ensure compliance with 34 CFR 75.110 and OMB Circular A–110, improve clarity of instructions and data collection, and remove duplicative language. Substantive changes include the addition of a data element related to mode of instruction and the removal of a data element related to the SAT and ACT. For a complete list of revisions, please see the attached summary, which will be shared with the public and Office of Management and Budget (OMB) as a supplemental document.

The Office of Migrant Education (OME) collects information for the CAMP, which is authorized under Title IV, Section 418A of the Higher Education Act of 1965, as amended by Section 408 of the Higher Education Opportunity Act (HEOA) (20 U.S.C. 1070d–2) (special programs for students whose families are engaged in migrant and seasonal farmwork), and 2 CFR 200.328, which requires that recipients of discretionary grants submit an APR to best inform improvements in program outcomes and productivity.

Although the Education Department continues to use the generic 524B, the OME requests continued use of a customized APR that goes beyond the generic 524B APR to facilitate the collection of more standardized and comprehensive data to inform performance measure indicators, to improve the overall quality of data collected, and to increase the quality of data that can be used to inform policy decisions.

Dated: May 6, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10207 Filed 5–9–24; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Technical Guidelines Development Committee (TGDC) Notice of Vacancy

AGENCY: Election Assistance Commission.

ACTION: Notice of vacancy.

SUMMARY: Pursuant to the Help America Vote Act (HAVA) and the Charter of the EAC Technical Guidelines Development Committee (TGDC), the EAC is posting this notice of vacancy for an individual with technical and scientific expertise relating to voting systems and voting equipment. The vacancy shall be filled jointly by the EAC and the Director of the National Institute of Standards and Technology (NIST).

ADDRESSES: Pursuant to the TGDC Charter, the EAC will post the notice on the EAC website: *https://www.eac.gov.* Interested, qualified individuals should contact the Alternate Designated Federal Official by email, *jpanek@eac.gov.*

SUPPLEMENTARY INFORMATION:

TGDC Appointment Process

The Technical Guidelines Development Committee (TGDC) is a non-discretionary Federal Advisory Committee established by the Help America Vote Act of 2002 (HAVA), Public Law 107–252, 116 Stat. 1666 (2002). The TGDC assists the EAC in developing the Voluntary Voting System Guidelines (VVSG). The chairperson of the TGDC is the director of the National Institute of Standards and Technology (NIST). The TGDC is composed of 14 other members appointed jointly by EAC and the director of NIST.

HAVA mandates that the 14 other members appointed jointly by the EAC and NIST shall include individuals with technical and scientific expertise relating to voting systems and voting equipment. The TGDC Charter requires that notice of vacancies on the Committee for those individuals jointly appointed by EAC and NIST be published in the **Federal Register** as well as on the Commission's website. Pursuant to HAVA and the TGDC charter, the EAC is publishing this notice of vacancy on the TGDC. This

vacancy shall be filled through a joint appointment by the EAC and NIST.

This notice will remain active through May 24, 2024.

Camden Kelliher,

Acting General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2024–10226 Filed 5–9–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Update on Reimbursement for Costs of Remedial Action at Uranium and Thorium Processing Sites

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of acceptance of title X claims during fiscal year (FY) 2024.

SUMMARY: This Notice announces the Department of Energy's (DOE) acceptance of claims in FY 2024 from eligible uranium and thorium processing site licensees for reimbursement under title X of the Energy Policy Act of 1992. The FY 2024 DOE Office of Environmental Management's Congressional Budget Request included $24.4 million for the Title X Uranium and Thorium Reimbursement Program; however, the Congressional appropriation for FY 2024 is zero dollars ($0.00). Thus, the claims received in FY 2023 and claims received in FY 2024 cannot be reimbursed until there is a new appropriation from Congress.

DATES: The closing date for the submission of FY 2024 title X claims is July 8, 2024. DOE will review claims for eligibility and claims will be processed for payment together with any eligible unpaid approved claim balances from prior years, based on availability of funds from future congressional appropriations. If the total approved claim amounts exceed the available funding, the approved claim amounts will be reimbursed on a prorated basis. All reimbursements are subject to the availability of funds from congressional appropriations.

ADDRESSES: Claims must be submitted by certified or registered mail, return receipt requested, to Charlee Anne Boger, U.S. DOE Department of Energy, Office of Legacy Management, 2597 Legacy Way, Grand Junction, Colorado 81503. Two copies of the claim should be included with each submission. In addition to the mailed hardcopies, claims may be submitted electronically to *Charlee.Boger@lm.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Amie Robinson, Title X Program Lead at (240) 243–5550 or email*: amie.robinson@em.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE published a final rule under 10 CFR part 765 in the **Federal Register** on May 23, 1994, (59 FR 26714) to carry out the requirements of title X of the Energy Policy Act of 1992 (sections 1001–1004 of Pub. L. 102–486, 42 U.S.C. 2296a *et seq.*) and to establish the procedures for eligible licensees to submit claims for reimbursement. DOE amended the final rule on June 3, 2003, (68 FR 32955) to adopt several technical and administrative amendments (*e.g.,* statutory increases in the reimbursement ceilings). Title X requires DOE to reimburse eligible uranium and thorium licensees for certain costs of decontamination, decommissioning, reclamation, and other remedial action incurred by licensees at active uranium and thorium processing sites. The eligible licensees incurred these costs to remediate byproduct material, generated as an incident of sales to the United States Government of uranium or thorium that was extracted or concentrated from ores processed primarily for their source material contents. To be reimbursable, costs of remedial action must be for work that is necessary to comply with applicable requirements of the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 *et seq.*) or, where appropriate, with requirements established by a State pursuant to a discontinuance agreement under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021). Claims for reimbursement must be supported by reasonable documentation as determined by DOE in accordance with 10 CFR part 765. Funds for reimbursement will be provided from the Uranium Enrichment Decontamination and Decommissioning Fund established at the Department of Treasury pursuant to section 1801 of the Atomic Energy Act of 1954 (42 U.S.C. 2297g). Payment or obligation of funds shall be subject to the requirements of the Anti-Deficiency Act (31 U.S.C. 1341).

Authority: Section 1001–1004 of Pub. L. 102–486, 106 Stat. 2776 (42 U.S.C. 2296a *et seq.*).

Signing Authority

This document of the Department of Energy was signed on May 3, 2024, by Amie Robinson, Office of Waste Disposal, Office of Environmental Management, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 6, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–10186 Filed 5–9–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Availability of Preliminary List of Potential National Interest Electric Transmission Corridors; Request for Comments

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of availability of preliminary list; request for comments.

SUMMARY: The U.S. Department of Energy (DOE) gives notice of availability of the preliminary list of potential National Interest Electric Transmission Corridors (NIETCs). This issuance initiates Phase 2 of the NIETC designation process outlined in the guidance DOE released on December 19, 2023. NIETC designation focuses public and policymaker attention on the areas of greatest transmission need and unlocks valuable Federal financing and permitting tools to advance transmission development. Additional information on one of those tools—Transmission Facility Financing—is also included with the preliminary list.

DATES: Interested parties may submit comments on the preliminary list of potential NIETCs and information and recommendations focused on those potential NIETCs based on the list of information requested for Phase 2 in the NIETC Guidance by 5:00 p.m. ET on June 24, 2024.

FOR FURTHER INFORMATION CONTACT: Gretchen Kershaw, U.S. Department of Energy, Grid Deployment Office, at (202) 586–2006; or *NIETC@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE's Grid Deployment Office (GDO) is announcing the availability of the *Initiation of Phase 2 of National Interest Electric Transmission Corridor (NIETC) Designation Process: Preliminary List of Potential NIETCs.* Section 216(a)(2) of

the Federal Power Act (FPA), as amended by section 40105 of the Infrastructure Investment and Jobs Act (IIJA), requires DOE to issue a report not less frequently than once every three years, which may designate as a NIETC any geographic area that is experiencing or is expected to experience electric energy transmission capacity constraints or congestion that adversely affects consumers. DOE must base any NIETC designation on the findings of DOE's triennial nationwide study required by FPA section 216(a)(1), which DOE refers to as the National Transmission Needs Study (Needs Study), or other information relating to electric energy transmission capacity constraints or congestion. In addition, the FPA requires DOE to consider alternatives and recommendations from interested parties (including an opportunity for comment from affected States and Indian Tribes) and to consult with regional entities when designating a NIETC. FPA section 216(a)(4) allows DOE to also consider several additional factors in designating a NIETC.

On December 19, 2023, DOE released final guidance (NIETC Guidance) that describes DOE's intended implementation of this statutory authority and initiated the process for designating one or more NIETCs following issuance of the Needs Study released in October 2023. The NIETC Guidance sets forth a four-phase process, which begins with DOE evaluating the results of the most recent Needs Study to begin identifying potential geographic areas for NIETC designation and concurrent 45-day Phase 1 information submission window. During this window, interested parties may submit information and recommendations on the narrow geographic boundaries of potential NIETCs, the present or expected transmission capacity constraints or congestion within those geographic boundaries, and the relevant discretionary factors in FPA section 216(a)(4). For this iteration of the NIETC designation process, that window opened with issuance of the final guidance on December 19, 2023, and closed on February 2, 2024.

Phase 2 of the NIETC designation process begins with DOE's issuance of a preliminary list of potential NIETCs, which is the subject of this notice. The preliminary list identifies which potential NIETCs DOE is continuing to consider, provides a high-level explanation of the basis for those potential NIETCs, and opens a public comment period to gather information specific to the listed potential NIETCs. DOE may narrow the list of potential NIETCs as the designation process proceeds to Phase 3. DOE plans to prioritize which potential NIETCs move to Phase 3 based on the available information on geographic boundaries and potential impacts on environmental, community, and other resources and preliminary review of comments. During Phase 3, DOE continues to independently assess the basis for NIETC designation, initiates any needed environmental reviews, and conducts robust public engagement, culminating in the release of one or more draft designation reports and draft environmental documents, as needed, for public comment. Phase 4 is the conclusion of the NIETC designation process, with issuance of one or more final designation reports and final environmental documents, as needed.

The preliminary list of potential NIETCs was informed by numerous Phase 1 information submissions and recommendations from interested parties and DOE's internal preliminary analysis of known possible environmental, community, and other resource impacts. DOE preliminarily finds that the geographic areas depicted in the preliminary list of potential NIETCs constitute targeted, high-priority areas where NIETC designation is likely to catalyze transmission development to alleviate transmission capacity constraints or congestion and the associated adverse effects on consumers, thereby making the most efficient and effective use of DOE's resources. DOE intends to employ NIETC designation in one or more of these geographic areas to further the timely buildout of a reliable, resilient, and efficient transmission system that facilitates the achievement of national energy policy goals while reducing consumer energy costs.

During the 45-day comment period on the preliminary list of potential NIETCs, DOE invites interested parties to comment on the information contained within the preliminary list of potential NIETCs. This includes commenting on the present or expected transmission capacity constraints or congestion relevant to the potential NIETCs in the preliminary list as well as the adverse effects on consumers resulting therefrom (*i.e.,* the consumer harms resulting from inadequate transmission within the potential NIETCs).

In addition, DOE invites interested parties to submit further information on the thirteen resource report categories listed in the NIETC Guidance for Phase 2: (1) geographic boundaries; (2) water use and quality; (3) fish, wildlife, and vegetation; (4) cultural resources; (5) socioeconomics; (6) Tribal resources; (7) communities of interest; (8) geological resources; (9) soils; (10) land use, recreation, and aesthetics; (11) air quality and environmental noise; (12) alternatives; and (13) reliability and safety. The Phase 2 information submission window is focused on gathering additional information on geographic boundaries and potential impacts on environmental, community, and other resources to facilitate DOE's environmental review, which starts in Phase 3. Interested parties may submit information related to one or more of the thirteen categories listed.

NIETC designation focuses public and policymaker attention on the areas of greatest transmission need and unlocks valuable federal financing and permitting tools to advance transmission development. These include DOE authorities under the IIJA, the Inflation Reduction Act, and the Energy Policy Act of 2005, as well as the Federal Energy Regulatory Commission's permitting authority under FPA section 216(b). Additional information on one of those tools—Transmission Facility Financing—is included with the preliminary list of potential NIETCs, including eligibility criteria. DOE invites input on the scope of eligible projects, as explained further in the document.

Members of the public can visit GDO's website to access the preliminary list of potential NIETCs at: *https://www.energy.gov/gdo/national-interest-electric-transmission-corridor-designation-process.* Additionally, the NIETC Guidance remains available at: *https://www.energy.gov/sites/default/files/2023-12/2023-12-15%20GDO%20NIETC%20Final%20Guidance%20Document.Vpdf.*

Signing Authority

This document of the Department of Energy was signed on May 7, 2024, by Maria D. Robinson, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. The administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 7, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–10251 Filed 5–9–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1941–000]

Liberty County Solar Project, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Liberty County Solar Project, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 28, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10222 Filed 5–9–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN79–6–000]

FERC Form 580 Interrogatory on Fuel and Energy Purchase Practices, Notice of Request for Partial Waiver

Take notice that on May 1, 2024, pursuant to Rule 207(a)(5) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure,[1] Sierra Pacific Power Company submitted a request for a partial waiver of the requirement to respond to the 2024 FERC Form 580 Interrogatory on Fuel and Energy Purchase Practices, as more fully explained in the request.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comment Date: 5:00 p.m. Eastern time on May 22, 2024.

Dated: May 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10220 Filed 5–9–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.207 (2020).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR24–69–000.
Applicants: Intermountain Gas Company.
Description: § 284.123 Rate Filing: Revised Statement of Operating Conditions to be effective 6/1/2024.
Filed Date: 5/6/24.
Accession Number: 20240506–5055.
Comment Date: 5 p.m. ET 5/28/24.

Docket Numbers: RP24–757–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: Compliance filing: Compliance with CP23–492–000 South Louisiana Project to be effective 6/3/2024.
Filed Date: 5/3/24.
Accession Number: 20240503–5099.
Comment Date: 5 p.m. ET 5/15/24.

Docket Numbers: RP24–758–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: Compliance filing: OFO Penalty Waiver Request 2024 to be effective N/A.
Filed Date: 5/3/24.
Accession Number: 20240503–5142.
Comment Date: 5 p.m. ET 5/15/24.

Docket Numbers: RP24–759–000.
Applicants: Double E Pipeline, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate & Non-Conforming Agreements—EOG Resources, Inc. (Backhaul) to be effective 5/4/2024.
Filed Date: 5/3/24.
Accession Number: 20240503–5145.
Comment Date: 5 p.m. ET 5/15/24.

Docket Numbers: RP24–760–000.
Applicants: Gulf South Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Remove Expired Agreements eff 5–3–2024 to be effective 5/3/2024.
Filed Date: 5/3/24.
Accession Number: 20240503–5148.
Comment Date: 5 p.m. ET 5/15/24.

Docket Numbers: RP24–761–000.
Applicants: ANR Pipeline Company.
Description: § 4(d) Rate Filing: ANR—Citadel 140600 Negotiated Rate Agreement to be effective 5/3/2024.
Filed Date: 5/3/24.
Accession Number: 20240503–5149.
Comment Date: 5 p.m. ET 5/15/24.

Docket Numbers: RP24–762–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Remove Expired Agreements eff 5–3–2024 to be effective 5/3/2024.
Filed Date: 5/3/24.
Accession Number: 20240503–5154.
Comment Date: 5 p.m. ET 5/15/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system: (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: May 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10223 Filed 5–9–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC24–11–000]

Commission Information Collection Activities (FERC–576) Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–576, OMB Control Number 1902–0004, which will be submitted to the Office of Management and Budget (OMB) for review.

DATES: Comments on the collection of information are due June 10, 2024.

ADDRESSES: Send written comments on FERC–576 to OMB through *www.reginfo.gov/public/do/PRAMain.* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Number (1902–0004) in the subject line of your comments. Comments should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Please submit copies of your comments to the Commission. You may submit copies of your comments (identified by Docket No. IC24–11–000 and FERC–576) by one of the following methods:

Electronic filing through *https://www.ferc.gov,* is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain.* Using the search function under the ''Currently Under Review'' field, select Federal Energy Regulatory Commission; click ''submit,'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *https://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket

may do so at *https://www.ferc.gov/ferc-online/overview.*

FOR FURTHER INFORMATION CONTACT: Jean Sonneman may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–6362.

SUPPLEMENTARY INFORMATION:

Title: FERC–576, Report of Service Interruptions or Damage to Facilities.

OMB Control No.: 1902–0004.

Type of Request: Three-year extension of the FERC–576 information collection requirements with no changes to the current reporting requirements.

Abstract: Per 18 CFR 260.9, natural gas pipeline companies must report (i) damage to any jurisdictional natural gas facilities other than liquefied natural gas facilities caused by a hurricane, earthquake or other natural disaster or terrorist activity that results in a loss of or reduction in pipeline throughput or storage deliverability; and (ii) serious interruptions of service to any shipper involving jurisdictional natural gas facilities other than liquefied natural gas facilities.

The notifications, made to the Director, Division of Pipeline Certificates via email or fax as soon as feasibly possible, must state: (1) The location of the service interruption or damage to natural gas pipeline or storage facilities; (2) The nature of any damage to pipeline or storage facilities; (3) Specific identification of the facilities damaged; (4) The time the service interruption or damage to the facilities occurred; (5) The customers affected by the service interruption or damage to the facilities; (6) Emergency actions taken to maintain service; and (7) Company contacts and telephone numbers. The information provided by these notifications are kept by the Commission and are not made part of the public record.

In addition, if the Department of Transportation requires an incident report [1] under the Natural Gas Pipeline Safety Act (49 U.S.C. 60101 through 60143), a copy of such report must be submitted to the Director of the Commission's Division of Pipeline Certificates, within 30 days of the reportable incident. Natural gas companies must also send a copy of submitted incident reports to each state commission for the state(s) in which the reported service interruption occurred.[2] If the Commission did not collect this information, it would lose a data point that assists in the monitoring of transactions, operations, and reliability of interstate pipelines.

The Commission published a 60-day notice for FERC–576 on May 4, 2024 (89 FR 15569), with a due date of May 3, 2024. The Commission received no public comments in response.

Type of Respondents: Natural gas companies experiencing service interruptions or damage to facilities.

Estimate of Annual Burden: The Commission estimates the average annual burden [3] and cost [4] for this information collection as follows.

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden hrs. & cost ($) per response	Total annual burden hrs. & total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Notification of Incident—Service Interruption.	50	1	50	1 hr.; $100.00	50 hrs.; $5,000.00	$100.00
Notification of Incident—Damage.	22	1	22	0.25 hrs.; $25.00	5.5 hrs.; $550.00	25.00
Submittal of DOT Incident Report.	10	1	10	0.25 hrs.; $25.00	2.5 hrs.; $250.00	25.00
Total	82				58 hrs.; $5,800	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: May 6, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10221 Filed 5–9–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–125]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed April 29, 2024 10 a.m. EST

Through May 6, 2024 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20240078, Draft Supplement, BLM, USFWS, UT, Supplemental Environmental Impact Statement to

[1] The Department of Transportation defines ''incident'' at 49 CFR 191.3. The regulatory thresholds for an ''incident report'' include (1) A death, or personal injury necessitating in-patient hospitalization; (2) Estimated property damage of $122,000 or more; (3) Unintentional estimated gas loss of three million cubic feet or more; (4) Emergency shutdown of a facility; or (5) An event that is significant in the judgment of the operator.

[2] *See* 18 CFR 260.9(d) and 260.9(e).

[3] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR part 1320.

[4] The Commission staff estimates that the average respondent for FERC–576 is similarly situated to the Commission, in terms of salary plus benefits. Based on FERC's current annual average of $207,786 (for salary plus benefits), the average hourly cost is $100/hour.

Reconsider a Highway Right-of-Way Application and Associated Amendment of an Incidental Take Permit, Washington County, Utah, Comment Period Ends: 06/24/2024, Contact: Dawna Ferris-Rowley 435–688–3200.

EIS No. 20240079, Final, NMFS, NC, Final Amendment 15 to the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan, Review Period Ends: 06/10/2024, Contact: Steve Durkee 301–427–8503.

Dated: May 6, 2024.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024–10218 Filed 5–9–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1294; FR ID 218850]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before July 9, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1294.

Title: FCC Authorization for Radio Service License—3.45 GHz Band Service.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, state, local, or tribal government, and not for profit institutions.

Number of Respondents and Responses: 52 respondents, 8,197 responses.

Estimated Time per Response: 5–20 hours.

Frequency of Response: Third party disclosure requirement; on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 151, 152, 154, 154(i), 155(c), 157, 201, 202, 208, 214, 301, 302a, 303, 307, 308, 309, 310, 311, 314, 316, 319, 324, 331, 332, 333, 336, 534, 535, and 554 of the Communications Act of 1934.

Total Annual Burden: 9,198 hours.

Total Annual Cost: $10,353,000.

Needs and Uses: On March 17, 2021, the Federal Communications Commission (''Commission'' or ''FCC'') adopted a Second Report and Order, FCC 21–32, GN Docket No. WT–19–348 (Second Report and Order) that establishes rules for flexible-use wireless access to the 100 megahertz in the 3450–3550 MHz (3.45 GHz) band, creating the new 3.45 GHz Service. The rules will create additional capacity for wireless broadband allowing full-power operations across the band in the entire contiguous United States, while also ensuring full protection of incumbent Federal operations remaining in particular locations. As part of this process, the Commission also adopted rules related to the relocation of incumbent non-Federal radiolocation operations, and reimbursement of expenses related to such relocation.

Sections 2.016 and 27.1603 require a 3.45 GHz Service licensee whose license area overlaps with a Cooperative Planning Area or Periodic Use Area, as defined in those sections, to coordinate deployments pursuant to those licenses in those areas with relevant Federal agencies. This coordination may take the form of a mutually acceptable operator-to-operator coordination agreement between the licensee and the relevant Federal agency. In the absence of such an agreement, this coordination will include a formal request for access through a Department of Defense online portal, which will include the submission of information related to the technical characteristics of the base stations and associated mobile units to be used in the covered area. It does not require a revision to the FCC Form 601.

Section 27.1605 requires non-Federal, secondary radiolocation operations which are relocating from the 3.45 GHz band to alternate spectrum to clear the band for new flexible-use wireless operations to submit certain information to a clearinghouse in order to ensure their relocation costs are fairly reimbursed. It does not require a revision to the FCC Form 601.

Section 27.1607 requires 3.45 GHz Service licensees to share certain information about their network operations in that band with operators in the adjacent Citizens Broadband Radio Service in order to enable the latter to synchronize their operations to reduce the risk of harmful interference. In response to a request by a Citizens Broadband Radio Service operator, a 3.45 GHz Service licensee must provide information to enable Time Division Duplex synchronization. The exact nature of the information to be provided will be determined by a negotiation between the two entities, conducted on a good faith basis. The 3.45 GHz Service licensee must keep the information current as its network operations change. This does not require a revision to the FCC Form 601.

Section 27.14(w) requires 3.45 GHz Service licensees to provide information on the extent to which they provide service in their license areas. Licensees are required to file two such reports: The first four (4) years after its initial license grant and the second eight (8) years after such grant, unless they failed to meet the first set of performance requirements, in which case the second report is due seven (7) years after the initial grant. These reports are filed

alongside the Form 601 and require no revisions to it.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–10263 Filed 5–9–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1050; FR ID 218851]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before July 9, 2024. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1050.

Title: Section 97.303, Frequency Sharing Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households.

Number of Respondents: 5,000 respondents; 5,000 responses.

Estimated Time per Response: 20 minutes (.33 hours).

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154, 301, 302(a) and 303(c), and (f) of the Communications Act of 1934, as amended.

Total Annual Burden: 1,650 hours.

Total Annual Cost: No cost.

Needs and Uses: The Commission established a recordkeeping procedure in section 97.303(s) that required that amateur operator licensees using other antennas must maintain in their station records either manufacturer data on the antenna gain or calculations of the antenna gain.

The amateur radio service governed by 47 CFR part 97 of the Commission's rules, provides spectrum for amateur radio service licensees to participate in a voluntary noncommercial communication service which provides emergency communications and allows experimentation with various radio techniques and technologies to further the understanding of radio use and the development of technologies. The information collection is used to calculate the effective radiated power (ERP) that the station is transmitting to ensure that ERP does not exceed 100 W PEP.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–10262 Filed 5–9–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than June 10, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Lowndes Bancshares, Inc., Valdosta, Georgia;* to merge with FMB Bancshares, Inc., and thereby indirectly acquire Farmers & Merchants Bank, both of Lakeland, Georgia.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–10257 Filed 5–9–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10767]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 9, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10767 Patient Access through Application Programming Interfaces (API)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Patient Access through Application Programming Interfaces (API); *Use:* This final rule is the first phase of policies centrally focused on advancing interoperability and patient access to health information using the authority available to the Centers for Medicare & Medicaid Services (CMS). We believe this is an important step in advancing interoperability, putting patients at the center of their health care, and ensuring they have electronic access to their health information. We are committed to working with stakeholders to solve the issue of interoperability and getting patients access to information about their health care, and we are taking an active approach to move participants in the health care market toward interoperability and the secure and timely exchange of electronic health information by adopting policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and qualified health plan (QHP) issuers on the individual market Federally-facilitated Exchanges (FFEs). For purposes of this rule, references to QHP issuers on the FFEs excludes issuers offering only stand-alone dental plans (SADPs). Likewise, we are also excluding QHP issuers only offering QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF–SHOPs) from the provisions of this rule. This rule requires these impacted payers to maintain and use standards-based APIs to make certain information available to enrollees. CMS regulations at 42 CFR 417.414, 417.416, 422.112(a)(1)(i), and 422.114(a)(3)(ii) require that all Medicare Advantage organizations (MAOs) offering coordinated care plans, network-based private fee-for-service (PFFS) plans, and as well as section 1876 cost organizations, maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To enforce this requirement, CMS regulations at § 422.116 outline network adequacy criteria which set forth the minimum number of providers and maximum travel time and distance from enrollees to providers, for required provider specialty types in each county in the United States and its territories. Organizations must be in compliance with the current CMS network adequacy criteria guidance, which is updated and published annually on CMS's website. This collection of information is essential to appropriate and timely compliance monitoring by CMS, in order to ensure that all active contracts offering network-based plans maintain an adequate network. *Form Number:* CMS–10767 (OMB control number: 0938–1412); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 345; *Number of Responses:* 345; *Total Annual Hours:* 589,950. (For policy questions regarding this collection contact Lorraine Doo at 410–786–6597.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–10256 Filed 5–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10164 A/B]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 10, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change; *Title of Information Collection:* Medicare Electronic Data Interchange (EDI) Registration and Electronic Data Interchange Enrollment Form; *Use:* The purpose of this collection is to obtain information that will be subsequently used during transaction exchange for identification of Medicare providers/suppliers and authorization of requested electronic data interchange (EDI) functions. The EDI Registration Form and the Medicare Enrollment Forms are completed by Medicare providers/suppliers and submitted to CMS Medicare Administrative Contractors (MACs). Authorization is needed for providers/suppliers to send/receive Health Insurance Portability and Accountability Act (HIPAA) standard transactions directly (or through a designated 3rd party) to/from Medicare contractors. Medicare contractors will use the information for initial set-up and maintenance of the access privileges. CMS has allowed each MAC to create their own organization specific forms given they are comparable in terms of content of forms 10164A and 10164B, to transmit data files electronically between themselves and their trading partners. The Standards for Electronic Transactions final rule, 45 CFR part 162 Subpart K § 162.1101 through Subpart R § 162.1802, (hereinafter referred to as ''Transactions Rule'') published August 17, 2000 adopted standards for health care transactions and code sets.[1] Subsequent to the Transactions Rule, CMS–0003–P and CMS–0005–P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry. Currently, MACs have a process in place to enroll providers for electronic billing and other EDI transactions. In support of the HIPAA Transactions Rule, the purpose of this Paperwork Reduction Act (PRA) request is to establish a prescribed amount of data that must be submitted by providers/suppliers that is sufficient to address all HIPAA transactions. *Form Number:* CMS–10164 A/B (OMB control number: 0938–0983); *Frequency:* Once; *Affected Public:* Private and Business or other for-profits; *Number of Respondents:* 1,181,209; *Total Annual Responses:* 1,181,209; *Total Annual Hours:* 393,706. (For policy questions regarding this collection contact Charlene Parks at (410) 786–8684 or *Charlene.Parks@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–10255 Filed 5–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Risk Determination Hearings for Unaccompanied Children (New Collection)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting approval from the Office of Management and Budget (OMB) and inviting public comments on the proposed information collection. The request consists of several forms that will allow the Unaccompanied Children (UC) Program to implement a new set of hearings (''Risk Determination hearings''), which

[1] *https://www.federalregister.gov/documents/2000/08/17/00-20820/health-insurance-reform-standards-for-electronic-transactions.*

will serve as due process protections for children in ORR care.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR plans to create a new information collection containing five instruments in order to implement the new risk determination hearings for unaccompanied children. This new information collection will replace the *Flores* bond hearing process. The new instruments will not take effect until the underlying regulations at 45 CFR part 410 on which they are based take effect. The UC Program issued a notice of proposed rulemaking in October 2023, which aims to adopt and replace regulations relating to key aspects of the placement, care, and services provided to unaccompanied children referred to ORR. The UC Program has adjudicated public comments received and has announced its intention to publish the Final Rule on April 30th, 2024; the Final Rule will take effect 60 days after publishing.

Risk Determination Hearing Forms: These forms are provided to unaccompanied children placed in ORR custody by their case manager or by individuals associated with the HHS Departmental Appeals Board (DAB), which is responsible for the actual day-to-day logistical operations of these hearings. These instruments are provided to unaccompanied children placed in a restrictive setting (heightened supervision facilities and residential treatment center facilities) upon a finding by ORR that a child would present a danger to the community if released, and to unaccompanied children placed in other types of facilities upon request. They will be translated into Spanish and other languages, as needed.

- Request for Risk Determination Hearing (Form RDH–1): The unaccompanied child, the child's parent/legal guardian, or the child's representative may use this instrument to request a Risk Determination Hearing.
- Risk Determination Hearing Opt-Out (Form RDH–2): The unaccompanied child or the child's representative may use this instrument to opt-out of a Risk Determination Hearing.
- Appointment of Representation for Risk Determination Hearing (Form RDH–3): The unaccompanied child or the child's parent/legal guardian may use this instrument to appoint a representative to act on the child's behalf throughout the Risk Determination Hearing process and consent to the release of any records that are related to the child's case to that representative.
- Risk Determination Hearing Transcript Request (Form RDH–4): The unaccompanied child, the child's parent/legal guardian, or the child's representative may use this instrument to request a written transcript of the Risk Determination Hearing.
- Request for Appeal of Risk Determination Hearing (Form RDH–5): The unaccompanied child, the child's parent/legal guardian, or the child's representative may use this instrument to appeal the decision of the hearing officer.

Once the new Risk Determination Hearing forms are in effect, the UC Program will prepare a non-substantive change request to the Office of Management and Budget (OMB) to discontinue the use of three instruments currently approved under the Legal Services for Unaccompanied Children information collection (OMB# 0970–0565). The forms to be replaced by the Risk Determination Hearing forms include the following:

- Request for a Flores Bond Hearing (Form LRG–7)
- Motion Requesting a Bond Hearing—Secure or Staff Secure (Form LRG–8A)
- Motion Requesting a Bond Hearing—Non-Secure (Form LRG–8B)

Respondents: ORR grantee and contractor staff, unaccompanied children, parents/legal guardians of unaccompanied children, attorneys of record, and legal service providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual total burden hours
Request for Risk Determination Hearing (Form RDH–1)	250	1	0.17	42.5
Risk Determination Hearing Opt-Out (Form RDH–2)	250	1	0.17	42.5
Appointment of Representative for Risk Determination Hearing (Form RDH–3)	1000	1	0.17	170
Risk Determination Hearing Transcript Request (Form RDH–4)	16	1	0.17	2.7
Request for Appeal of Risk Determination Hearing (Form RDH–5)	3	1	0.17	.5

Estimated Total Annual Burden Hours: 258.2.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–10188 Filed 5–9–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0408]

Modified Risk Tobacco Product Application: Renewal Application for IQOS 3.0 System Holder and Charger, Heated Tobacco Product, Submitted by Philip Morris Products S.A.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity to provide public comment on a modified risk tobacco product application (MRTPA). The application is for renewal of an existing modified risk tobacco product (MRTP) order for the IQOS 3.0 System Holder and Charger, a Heated Tobacco Product (HTP), submitted by Philip Morris Products S.A.

DATES: Electronic or written comments on the application may be submitted beginning May 10, 2024. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0408 for ''Modified Risk Tobacco Product Application: Renewal application for the IQOS 3.0 System Holder and Charger, Heated Tobacco Product (HTP), Submitted by Philip Morris Products S.A.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Adrian Mixon or Dhanya John, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of MRTPs. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, Philip Morris Products S.A., is seeking a renewal under section 911(g)(2) of an order previously issued under section 911(g)(2) of the FD&C Act.

FDA may issue an order under section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not

satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;
- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for obtaining an order under section 911(g)(1) of the FD&C Act;
- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- The magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- Issuance of the exposure modification order is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that the MRTPA for the following product submitted by Philip Morris Products S.A. has been filed and is being made available for public comment:

- MR0000254.PD3: IQOS 3.0 System Holder and Charger

The applicant is seeking renewal of the authorization to market the IQOS 3.0 System Holder and Charger, a product that previously received authorization under section 911(g)(2) of the FD&C Act [1] to be marketed as a modified risk tobacco product with reduced exposure claims. For purposes of premarket review, FDA has identified these tobacco products as heated tobacco products (HTPs). HTPs meet the definition of a cigarette, but the tobacco is heated and not combusted (products that do not exceed 350° C). The applicant is including information from the previous MRTPA by cross-reference.

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of information in the MRTPA that has not been available for public comment as part of the previously authorized MRTPA for the IQOS system.

FDA will notify the public about the availability of additional application documents and comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (*https://www.fda.gov/about-fda/contact-fda/get-email-updates*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Update'', and click ''Submit.'' FDA does not intend to issue additional notices in the **Federal Register** regarding the availability of additional application documents, including amendments, or the comment period for this MRTPA. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

[1] The notice of availability for the IQOS 3 System Holder and Charger MRTPA that received a modified risk granted order appeared in the **Federal Register** of May 14, 2021 (86 FR 26530), and the docket containing notices and public comments, FDA–2021–N–0408, is accessible at: *https://www.regulations.gov/document/FDA-2021-N-0408-0001.*

II. Electronic Access

Persons with access to the internet may obtain the document(s) at *https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications.*

Dated: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10055 Filed 5–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–3001]

Modified Risk Tobacco Product Application: Renewal Applications for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks, and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products and Heated Tobacco Product Consumables, Submitted by Philip Morris Products S.A.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity to provide public comment on modified risk tobacco product applications (MRTPAs). The applications are for the renewal of existing MRTP orders for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products (HTPs) and HTP Consumables,

submitted by Philip Morris Products S.A.

DATES: Submit either electronic or written comments on the application beginning May 10, 2024. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–3001 for ''Modified Risk Tobacco Product Applications: Renewal Applications for IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks, Marlboro Green Menthol HeatSticks and Marlboro Blue Menthol HeatSticks, Heated Tobacco Products (HTPs) and HTP Consumables, Submitted by Philip Morris Products S.A.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Adrian Mixon or Dhanya John, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (2). The applicant, Philip Morris Products S.A., is seeking a renewal under section 911(g)(2) of an order previously issued under section 911(g)(2) of the FD&C Act.

FDA may issue an order under section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;
- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for

obtaining an order under section 911(g)(1) of the FD&C Act;

- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- The magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- Issuance of the exposure modification order is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that the MRTPAs for the following products submitted by Philip Morris Products S.A. have been filed and are being made available for public comment:

- MR0000254.PD1: IQOS 2.4 System Holder and Charger
- MR0000254.PD5: Marlboro Amber HeatSticks
- MR0000254.PD6: Marlboro Green Menthol HeatSticks
- MR0000254.PD7: Marlboro Blue Menthol HeatSticks

The applicant is seeking renewal of the authorization to market the IQOS 2.4 System Holder and Charger, Marlboro Amber HeatSticks,[1] Marlboro Green Menthol HeatSticks [2] and Marlboro Blue Menthol HeatSticks,[3] products that previously received authorization under section 911(g)(2) of the FD&C Act [4] to be marketed as modified risk tobacco products with reduced exposure claims. For purposes of premarket review, FDA has identified these tobacco products as HTPs. HTPs meet the definition of a cigarette, but the tobacco is heated and not combusted (products that do not exceed 350 °C). The applicant is including information from the previous MRTPAs by cross-reference.

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the application are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of information in the MRTPA that has not already been available for public comment as part of the previously authorized MRTPAs for the IQOS system.

FDA will notify the public about the availability of additional application documents and comment period closing date via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. To receive email alerts, visit FDA's email subscription service management website (*https://www.fda.gov/about-fda/contact-fda/get-email-updates*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Update'', and click ''Submit''. FDA does not intend to issue additional notices in the **Federal Register** regarding the availability of additional application documents, including amendments, or the comment period for this MRTPA. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

[1] Product name was previously Marlboro Heatsticks.

[2] Product name was previously Marlboro Smooth Menthol Heatsticks.

[3] Product name was previously Marlboro Fresh Menthol Heatsticks.

[4] The notice of availability for the IQOS MRTPAs that received modified risk granted orders appeared in the **Federal Register** of June 15, 2017 (82 FR 27487), and the docket containing notices and public comments, FDA–2017–D–3001, is accessible at: *https://www.regulations.gov/docket/FDA-2017-D-3001.*

II. Electronic Access

Persons with access to the internet may obtain the document(s) *https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications.*

Dated: May 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10054 Filed 5–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3741]

Remanufacturing of Medical Devices; Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Remanufacturing of Medical Devices.'' This final guidance is intended to help clarify whether activities performed on devices are likely ''remanufacturing.'' This final guidance also clarifies existing regulatory requirements for remanufacturers and includes recommendations for information that should be included in labeling to help assure the continued quality, safety, and effectiveness of devices that are intended to be serviced over their useful life.

DATES: The announcement of the guidance is published in the **Federal Register** on May 10, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3741 for ''Remanufacturing of Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Remanufacturing of Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Katelyn Bittleman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4250, Silver Spring, MD 20993–0002, 240–402–1478; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Many devices are reusable and need preventive maintenance and repair during their useful life. For these devices, proper servicing is critical to their continued safe and effective use. However, there is a lack of clarity regarding the distinction between ''servicing'' and ''remanufacturing'' activities. FDA has been working to promote clarity on the distinction between ''servicing'' and ''remanufacturing.''

FDA opened a docket for public comment (81 FR 11477) and held a public workshop (81 FR 46694) in 2016. The Food and Drug Administration Reauthorization Act (FDARA) became law on August 18, 2017. Section 710 of FDARA charged the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing. In May 2018, FDA published on its website the report entitled ''FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices'' (*https://www.fda.gov/media/113431/download*). One conclusion of the report stated ''a majority of comments, complaints, and adverse event reports alleging that inadequate 'servicing' caused or contributed to clinical adverse events and deaths actually pertain to 'remanufacturing' and not 'servicing,' '' and FDA committed to issue guidance that clarifies the difference between servicing and remanufacturing activities. In December 2018, FDA issued a white paper entitled ''Evaluating Whether Activities are Servicing or Remanufacturing'' (*https://www.fda.gov/media/117238/download*), opened a public docket (FDA–2018–N–3741), and held a public workshop (*https://wayback.archive-it.org/7993/20201222125933/https:/www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-device-servicing-and-remanufacturing-activities-december-10-11-2018-12102018*) to facilitate public discussion on the distinction between servicing and remanufacturing. The white paper described FDA's initial thoughts about guiding principles, provided a flowchart with accompanying text for understanding the distinctions, and contained a complementary approach for software, as well as considerations for labeling and examples utilizing the flowchart. FDA also included targeted questions throughout the white paper on which the Agency sought feedback. FDA

considered the comments from the public docket and discussions during the public workshop in developing the draft guidance. A notice of availability of the draft guidance appeared in the **Federal Register** of June 24, 2021 (86 FR 33305).

FDA focuses this guidance on activities that are likely remanufacturing—processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use (see 21 CFR 820.3(w)). The determination of whether the activities an entity performs are remanufacturing affects the applicability and enforcement of regulatory requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations. FDA has consistently enforced requirements under the FD&C Act and its implementing regulations on entities engaged in remanufacturing, including but not limited to registration and listing, adverse event reporting, the Quality System regulation, and marketing submissions.

FDA considered comments received and revised the guidance as appropriate. In this final guidance, FDA provided additional contextual examples of activities throughout Section VI.B to provide further clarity when determining whether activities remanufacture a device. FDA clarified the applicability of the guidance to original equipment manufacturers (OEMs) and external entities on behalf of OEMs. FDA also added Section VIII ''Regulatory Requirements and Considerations for Remanufacturers'' to the guidance clarifying and outlining certain existing regulatory requirements that apply to remanufacturers.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Remanufacturing of Medical Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Remanufacturing of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00017048 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or FDA form	Topic	OMB control No.
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910–0485
803	Medical Device Reporting	0910–0437
Form FDA 3670	Adverse event reports/MedSun program	0910–0471
806	Medical Devices; Reports of Corrections and Removals	0910–0359
810	Medical Device Recall Authority	0910–0432
820	Current Good Manufacturing Practice; Quality System Regulation	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
860, subpart D	De Novo classification process	0910–0844
812	Investigational Device Exemption	0910–0078
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
1000 through 1040	Electronic Products Requirements	0910–0025

Dated: May 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10230 Filed 5–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3455–FN]

Medicare and Medicaid Programs: Application From The Compliance Team (TCT) for Continued Approval of Its Rural Health Clinic (RHC) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Compliance Team (TCT) for continued recognition as a national accrediting organization (AO) for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this final notice is effective July 17, 2024, to July 17, 2028.

FOR FURTHER INFORMATION CONTACT:
Joy Webb (410) 786–1667.
Shonte Carter (410) 786–3532.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Rural Health Clinic (RHC) provided certain requirements are met by the RHC. Sections 1861(aa)(1) and (2) and 1905(l)(1) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488, subpart A. The regulations at 42 CFR part 491, subpart A, specify the conditions that an RHC must meet to participate in the Medicare program. The scope of covered services and the conditions for Medicare payment for RHCs are set forth at 42 CFR part 405, subpart X.

Generally, to enter into an agreement, an RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 491 of CMS regulations. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by State survey agencies. Section 1865(a)(1) of the Act provides that if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for CMS approval of their accreditation program under 42 CFR part 488, subpart A must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

The Compliance Team (TCT) has requested CMS approval for its RHC program. CMS has reviewed TCT's application as described in the following section and is hereby announcing TCT's term of approval for a period of four years.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning the review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Provisions of the Proposed Notice

On December 21, 2023, CMS published a proposed notice in the **Federal Register** (88 FR 88393), announcing TCT's request for approval of its Medicare Rural Health Clinic (RHC) accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5 and § 488.8(h), we conducted a review of TCT's RHC application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An administrative review of TCT's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its RHC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited RHCs; and (5) survey review and decision-making process for accreditation.
- A review of TCT's survey processes to confirm that a provider or supplier, under TCT's RHC deeming accreditation program, would meet or exceed the Medicare program requirements.
- A documentation review of TCT's survey process to do the following:

++ Determine the composition of the survey team, surveyor qualifications, and TCT's ability to provide continuing surveyor training.

++ Compare TCT's processes to those we require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against TCT-accredited RHCs.

++ Evaluate TCT's procedures for monitoring an accredited RHC it has found to be out of compliance with TCT's program requirements. (This pertains only to monitoring procedures when TCT identifies non-compliance. If a SA identifies non-compliance through a validation survey, the SA monitors corrections as specified at § 488.9(c)).

++ Assess TCT's ability to report deficiencies to the surveyed RHC and respond to the RHC's plan of correction in a timely manner.

++ Establish TCT's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TCT's staff and other resources.

++ Confirm TCT's ability to provide adequate funding for performing required surveys.

++ Confirm TCT's policies with respect to surveys being unannounced.

++ Confirm TCT's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain TCT's agreement to provide CMS with a copy of the most current accreditation survey, together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the December 21, 2023, proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare Conditions for Certification (CfCs) for RHCs. CMS did not receive any public comments.

V. Provisions of the Final Notice

A. Differences Between TCT's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TCT's RHC accreditation requirements and survey process with the Medicare conditions set forth at 42 CFR part 491, subpart A, the survey and certification process requirements of parts 488 and 489, and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TCT's RHC application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TCT has completed revising its standards and certification processes in order to—

- Meet the Medicare CfC requirements for all of the following regulations:

++ Section 488.5(a)(4)(ii), to provide documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting federal Medicare surveys for the same provider or supplier type to ensure levels of triaging will not negatively impact patient care and outcomes.

++ Section 488.5(a)(12) to specify a triage process for responding to and investigating complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

++ Section 488.26(b) to ensure citation level of deficiencies are cited appropriately, by conducting additional review of standards and RHC Medicare CfCs, provide a process for ensuring a thorough understanding of manner and degree of deficiency, and surveyor training.

++ Section 491.5(a)(1) to explicitly demonstrate RHC is located in a rural area, through policies and procedures, ensure surveyor's documentation exhibits the RHC physical name and address where services are provided.

++ SOM Chapter 2, Section 2700A to establish a policy and procedure to protect the integrity and intent of unannounced surveys when surveys are conducted at multiple locations and in close proximity.

++ SOM Chapter 2, Section 2728B, is to clarify an acceptable plan of correction that includes the RHC completing the organizational plan of correction template and documentation implementing the plan for future compliance and monitoring.

++ SOM Chapter 5 Section 5075, to ensure the administrative review and offsite investigation that are generally not permitted is consistent with the compliant policies found in Chapter 5.

++ Provide a revised plan of correction policy comparable to Chapter 2 of the SOM.

In addition to the standards review, CMS reviewed TCT's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, TCT has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Removing TCT's policies to allow patient and staff identifiers to be kept together. Such identifiers need to be kept separately from the surveyor's notes and findings to keep patients and staff private.

++ Revising language prohibiting Protected Health Information from being taken from the clinic. TCT language is inconsistent with CMS policy, which allows surveyors to photocopy documents needed to support deficient findings.

++ Clarifying TCT's policy that gives surveyors the discretion to conduct interviews privately. This policy is inconsistent with CMS policy governing private interviews with patients, staff, and visitors; it is a requirement and not discretionary unless the interviewee refuses.

++ Specifying TCT's policy to allow facilities to audio tape exit conferences, require facilities to provide two tapes and tape recorders and a recording of the meeting simultaneously, and then permitting the surveying team to select one of the tapes at the conclusion of the exit conference.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve TCT as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective July 17, 2024, to July 17, 2028 (4 years).

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–10250 Filed 5–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: NIEHS Support for Conferences and Scientific Meeting R13.

Date: June 11, 2024.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, 530 Davis Drive, Keystone Building, Durham, NC 27713 (Virtual Meeting).

Contact Person: Murali Ganesan, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, Room 3097, Research Triangle Park, NC 27713, (984) 287–4674, *murali.ganesan@nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Career Development in K Applications.

Date: June 20–21, 2024.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, 530 Davis Drive, Keystone Building, Durham, NC 27713 (Virtual Meeting).

Contact Person: Beverly W. Duncan, Ph.D., Scientific Review Officer, Keystone Building, 530 Davis Drive, Room 3130, Durham, NC 27713, (240) 353–6598, *beverly.duncan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 6, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10200 Filed 5–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Antibody-Drug Conjugates (ADCs) for Targeting CD56-Positive Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to McSAF Inside Oncology SAS (''McSAF Inside Oncology'') located in Tours, France.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before May 28, 2024 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Rose Freel, Ph.D., Unit Supervisor, NCI Technology Transfer Center, Telephone: (301) 624–1257; Email: *rose.freel@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/199,707 filed July 31, 2015, entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–US–01];

2. International Patent Application No. PCT/US2016/044777 filed July 29, 2016, entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–PCT–02]; and

3. United States Patent No. 10,548,987 issued February 02, 2020 (corresponding to United States Patent Application No. 15/747,620 filed January 25, 2018), entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–US–03].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

''The use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of Merkel cell carcinoma, wherein the ADC utilizes any technology for attachment of the cytotoxic payload and has:

(1) The CDR sequences of the m906 antibody; and

(2) a cytotoxic payload.''

and

''The use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of CD56-positive cancers except glioblastoma, wherein the ADC:

(1) has the CDR sequences of the m906 antibody;

(2) has a cytotoxic payload; and

(3) utilizes solely McSAF Inside Oncology's proprietary or exclusively in-licensed bioconjugation technologies for attachment of the linker-payload(s) to the m906 antibody.

The E–221–2015 patent family is directed to ADCs utilizing the CD56-specific monoclonal antibody known as m906 and conjugated to a drug. The technology is intended to be used as a therapeutic for CD56-positive cancers such as neuroblastoma, multiple myeloma, ovarian cancer, acute myeloid leukemia, and small cell lung cancer. The exclusive field of use which may be granted to McSAF Inside Oncology applies to only ADCs which either (1) treat Merkel Cell Carcinoma; or (2) use McSAF Inside Oncology's proprietary bioconjugation platform for attachment of the antibody to the linker-payload. Accordingly, the proposed scope of rights which may be conveyed under the license covers only a portion of the total scope of the E–221–2015 patent family and only a subset of the possible ADCs that incorporate the m906 antibody as well as the possible therapeutic applications of the ADCs.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 6, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–10198 Filed 5–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Fellowships in Diabetes Endocrinology and Metabolic Diseases.

Date: June 12, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7021, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–3993, *tathamt@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 6, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10197 Filed 5–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group; Transition to Independence Study Section (I).

Date: June 5–6, 2024.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Hotel Rockville, 1 Helen Heneghan Way, Rockville, Maryland 20850 (In-Person and Virtual Meeting).

Contact Person: Delia Tang, M.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W602, Rockville, Maryland 20850, 240–276–6456, *tangd@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Biospecimens Collection and Processing Methods.

Date: June 20, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240–276–5856, *nadeem.khan@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP–F.

Date: July 1, 2024.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Mukesh Kumar, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Rockville, Maryland 20850, 240–276–6611, *mukesh.kumar3@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Innovative Technologies for Cancer Research.

Date: July 11–12, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850, 240–276–6371, *decluej@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 7, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10229 Filed 5–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel: AMSC/AMS Member Conflict Review.

Date: June 17, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis,

Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: May 6, 2024

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10201 Filed 5–9–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2011–0008]

Request for Applicants for Appointment to the Aviation Security Advisory Committee

AGENCY: Transportation Security Administration, Department of Homeland Security.

ACTION: Committee management; request for applicants.

SUMMARY: The Transportation Security Administration (TSA) requests that qualified individuals interested in serving on the Aviation Security Advisory Committee (ASAC) apply for appointment as identified in this notice. All applicants must represent one of the constituencies specified below in order to be eligible for appointment. ASAC's mission is to provide advice and recommendations to the TSA Administrator on improving aviation security matters, including developing, refining, and implementing policies, programs, rulemakings, and security directives pertaining to aviation security, while adhering to sensitive security guidelines.

DATES: Applications for membership must be submitted to TSA, using one of the methods identified in the **ADDRESSES** section below, on or before May 31, 2024.

ADDRESSES: Applications must be submitted by one of the following means:

- *Email: ASAC@tsa.dhs.gov.*
- *Mail:* Tamika McCree Elhilali, ASAC Designated Federal Officer, Transportation Security Administration (TSA–28), 6595 Springfield Center Drive, Springfield, VA 20598–6028.

The ASAC will send you an email that confirms receipt of your application and will notify you of the final status of your application once TSA selects members.

FOR FURTHER INFORMATION CONTACT: Tamika McCree Elhilali, ASAC Designated Federal Officer, Transportation Security Administration (TSA–28), 6595 Springfield Center Drive, Springfield, VA 20598–6028, *ASAC@tsa.dhs.gov,* 202–595–4802.

SUPPLEMENTARY INFORMATION: The ASAC is an advisory committee established pursuant to 49 U.S.C. 44946. The committee is composed of individual members representing 19 key constituencies affected by aviation security requirements, as defined at 49 U.S.C. 44946(c)(1)(C).

This request for applications is limited to specific membership categories. Consistent with applicable law, TSA is committed to pursuing opportunities to appoint a committee that reflects the diversity of the United States. The following list provides the key constituencies and identifies with an asterisk (*) the constituencies for whom the current representative's term is expiring:

1. Air carriers.
2. All-cargo air transportation.*
3. Labor organizations representing air carrier employees (3 vacancies).*
4. Aircraft manufacturers.*
5. Airport operators.*
6. General aviation.*
7. Travel industry.*
8. Victims of terrorist acts against aviation.*
9. Law enforcement and security experts.
10. Indirect air carriers.*
11. Aviation security technology industry (including screening technology and biometrics).
12. Airport-based businesses.*
13. Passenger advocacy groups.
14. Airport authorities and businesses that conduct security operations at airports.*
15. Labor organizations representing transportation security officers.*
16. Airport construction and maintenance contractors.*
17. Labor organizations representing employees of airport construction and maintenance contractors.
18. Privacy organizations.
19. Aeronautical repair stations.

Unless otherwise noted, the ASAC does not have a specific number of members allocated to any membership category and the number of members in a category may change to fit the needs of the Committee. As required by the statute, however, individuals selected on the ASAC may not represent more than 34 member organizations.

Appointees will be designated as Representative members. Representative members speak for the key constituency group they represent. Membership on ASAC is personal to the appointee and a member may not send an alternate to a Committee meeting. Pursuant to 49 U.S.C. 44946(c)(3), members shall not receive pay, allowances, or benefits from the Government by reason of their service on ASAC.

Committee Meetings

The ASAC typically convenes four times per year. Additional meetings may be held with the approval of the Designated Federal Official. While at least one meeting per year is open to the public, the other meetings are typically closed to the public due to the sensitive nature of the material discussed. In addition, members are expected to participate on ASAC subcommittees that typically meet more frequently to deliberate and discuss specific aviation matters.

Committee Membership

Committee members are appointed by, and serve at the pleasure of, the TSA Administrator for a 2-year term or until a successor is appointed. Members who are currently serving on the Committee are eligible to reapply for membership (a new application is required).

Committee Membership Vetting

All applicants that are presented to the TSA Administrator for appointment to ASAC must successfully complete a Security Threat Assessment (STA) by TSA, as access to sensitive security information will be necessary. U.S. citizens and those meeting residency requirements will be vetted using TSA's Universal Enrollment Services (UES), which includes the collection of biographic and biometric information to allow TSA to perform the STA in regards to criminal history, intelligence, and citizenship. Selected applicants will be offered a no-cost authorization code to complete the three-step UES process; which includes online pre-enrollment, coordinating a visit to an enrollment center, and the in-person visit to the enrollment center.

Non-U.S. applicants presented for appointment to ASAC will be required to complete additional vetting. This vetting will include the completion and submission of TSA Form 2816B form, which must be submitted at least 30 days before visiting TSA spaces.

Application for Advisory Committee Appointment

TSA is seeking applications for the membership categories which are marked with an asterisk in the Supplementary Information section above. Any person wishing to be

considered for appointment to ASAC must provide the following:

- Complete professional resume.
- Statement of interest and reasons for application, including the membership category and how you represent a significant portion of that constituency and also provide a brief explanation of how you can contribute to one or more TSA strategic initiatives, based on your prior experience with TSA, or your review of current TSA strategic documents that can be found at *www.tsa.gov/about/strategy.*
- If there are aspects of diversity that you wish to describe or emphasize in support of your candidacy, please do so within your statement of interest application.
- Home and work addresses, telephone number, and email address.

Please submit your application to the Responsible TSA Official in the **ADDRESSES** section noted above by May 31, 2024.

Dated May 6, 2024.

Eddie D. Mayenschein,

Assistant Administrator, Policy, Plans, and Engagement.

[FR Doc. 2024–10203 Filed 5–9–24; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0028]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Petition To Classify Orphan as an Immediate Relative; Application for Advance Processing of an Orphan Petition; Supplement 1, Listing of an Adult Member of the Household; Supplement 2, Consent To Disclose Information; and Supplement 3, Request for Action on Approved Form I–600A/I–600

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until June 10, 2024.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0020. All submissions received must include the OMB Control Number 1615–0028 in the body of the letter, the agency name and Docket ID USCIS–2008–0020.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on October 26, 2023, at 88 FR 73614, allowing for a 60-day public comment period. USCIS received no comments in connection with the 60-day notice.

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2008–0020 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition to Classify Orphan as an Immediate Relative; Application for Advance Processing of an Orphan Petition; Supplement 1, Listing of an Adult Member of the Household; Supplement 2, Consent to Disclose Information; and Supplement 3, Request for Action on Approved Form I–600A/I–600.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–600; I–600A; I–600/I–600A Supplement 1; I–600/I–600A Supplement 2; I–600/I–600A Supplement 3; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. A U.S. adoptive parent may file a petition to classify an orphan as an immediate relative through Form I–600 under section 101(b)(1)(F) of the INA. A U.S. prospective adoptive parent may file Form I–600A in advance of the Form I–600 filing and USCIS will determine the prospective adoptive parent's eligibility to file Form I–600 and their suitability and eligibility to properly parent an orphan. If a U.S. prospective/adoptive parent has an

adult member of their household, as defined at 8 CFR 204.301, the prospective/adoptive parent must include the Supplement 1 when filing both Form I–600A and Form I–600. A U.S. prospective/adoptive parent files Supplement 2 to authorize USCIS to disclose case-related information to adoption service providers that would otherwise be protected under the Privacy Act, 5 U.S.C. 552a. Authorized disclosures will assist USCIS in the adjudication of Forms I–600A and I–600. A U.S. prospective/adoptive parent files Supplement 3 to request action such as an extended or updated suitability determination based upon a significant change in their circumstances or change in the number or characteristics of the children they intend to adopt, a change in their intended country of adoption, or a request for a duplicate notice of their approved Form I–600A suitability determination.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form I–600 is 1,200 and the estimated hour burden per response is .82 hours; the estimated total number of respondents for the information collection Form I–600A is 2,000 and the estimated hour burden per response is .82 hours; the estimated total number of respondents for the information collection Form I–600A Supplement 1 is 301 and the estimated hour burden per response is .82 hours; the estimated total number of respondents for the information collection Form I–600A Supplement 2 is 1,260 and the estimated hour burden per response is 0.25 hours; the estimated total number of respondents for the information collection Form I–600A Supplement 3 is 1,286 and the estimated hour burden per response is .82 hours; the estimated total number of respondents for the Home Study information collection is 2,500 and the estimated hour burden per response is 25 hours; the estimated total number of respondents for the biometrics submission is 2,520 and the estimated hour burden per response is 1.17 hours; and the estimated total number of respondents for the Biometrics—DNA information collection is 2 and the estimated hour burden per response is 6 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 69,701 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $7,759,932.

Dated: May 6, 2024

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2024–10219 Filed 5–9–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0113]

Agency Information Collection Activities; Revision of a Currently Approved Collection: MyAppointment

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until July 9, 2024.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0113 in the body of the letter, the agency name and Docket ID USCIS–2009–0024. Comments must be submitted in English, or an English translation must be provided. Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0024.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov*, or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0024 in the search box. Comments must be submitted in English, or an English translation must be provided. All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov*, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* MyAppointment.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and Households. The MyAppointment system allows respondents to access the appointment scheduling system on the USCIS main web page via the ''Make an Appointment'' link. Respondents may also contact USCIS via phone or chat to provide information that will be collected in evaluating the request for appointment.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection MyAppointment (electronic/Online) is 350,000 and the estimated hour burden per response is .1 hours, the estimated total number of respondents for the information collection MyAppointment (phone) is 80,000 and the estimated hour burden per response is .15 hours, and the estimated total number of respondents for the information collection MyAppointment (web/chat) is 10,000 and the estimated hour burden per response is .22 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 49,200 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* There is no estimated total annual cost burden associated with this collection of information, all costs are captured in the information collections that require an appointment.

Dated: May 6, 2024.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2024–10244 Filed 5–9–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6462–N–01]

Section 8 Housing Assistance Payments Program—Fiscal Year (FY) 2024 Inflation Factors for Public Housing Agency (PHA) Renewal Funding

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This notice establishes Renewal Funding Inflation Factors (RFIFs) to adjust Fiscal Year (FY) 2024 renewal funding for the Housing Choice Voucher (HCV) Program of each public housing agency (PHA), as required by the Consolidated Appropriations Act, 2024. The notice apportions the expected percent change in national Per Unit Cost (PUC) for the HCV program, 7.38 percent, to each PHA based on the change in Fair Market Rents (FMRs) for their operating area to produce the FY 2024 RFIFs. HUD's FY 2024 methodology differs in part from that used in FY 2023. HUD has refined the national PUC forecast by changing the gross rent component in a manner that weights projected recent mover rents as measured by the FMR with an independent forecast of all-mover rents as measured by the Consumer Price Index (CPI).

DATES: *Applicability Date:* May 10, 2024.

FOR FURTHER INFORMATION CONTACT: Miguel A. Fontanez, Director, Housing Voucher Financial Division, Office of Public Housing and Voucher Programs, Office of Public and Indian Housing, Room 4222, U.S. Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 422–0278 (this is not a toll-free number). Adam Bibler, Program Parameters and Research Division, Office of Policy Development and Research, Room 8208, U.S. Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 402–6057 (this is not a toll-free number), for technical information regarding the development of the schedules for specific areas or the methods used for calculating the inflation factors. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

Division F, Title II of the Consolidated Appropriations Act, 2024 requires that the HUD Secretary, for the calendar year 2024 funding cycle, provide renewal funding for each public housing agency (PHA) based on validated voucher management system (VMS) leasing and cost data for the prior calendar year and by applying an inflation factor as established by the Secretary, by notice published in the **Federal Register**. This notice announces the availability of the FY 2024 inflation factors and describes the methodology for calculating them. Tables in PDF and Microsoft Excel formats showing Renewal Funding Inflation Factors (RFIFs) by HUD Fair Market Rent Area are available electronically from the HUD data information page at: *https://www.huduser.gov/portal/datasets/rfif/rfif.html.*

II. Methodology

RFIFs are used to adjust the allocation of Housing Choice Voucher (HCV) program funds to PHAs for local changes in rents, utility costs, and tenant incomes. To calculate the RFIFs, HUD first forecasts a national inflation factor, which is the annual change in the national average Per Unit Cost (PUC). HUD then calculates individual area inflation factors, which are based on the annual changes in the two-bedroom Fair Market Rent (FMR) for each area. Finally, HUD adjusts the individual area inflation factors to be consistent with the national inflation factor.

Since FY 2017, HUD's method of projecting the national average PUC has been based on independent forecasts of gross rent and tenant income. Each forecast is produced using historical and forecasted macroeconomic data as independent variables, where the forecasts are consistent with the Economic Assumptions of the Administration's FY Budget. The forecast for gross rent is itself based on forecasts of the Consumer Price Index (CPI) Rent of Primary Residence Index and the CPI Fuels and Utilities Index. Forecasted values of gross rent series were then applied to the relevant FY national average two-bedroom FMR to produce a CY value. Finally, a ''notional'' PUC is then calculated as the difference between gross rent value and 30 percent of tenant income (the standard for tenant rent contribution in the voucher program). HUD uses a notional PUC as opposed to the actual

PUC to project costs that are consistent with PHAs leasing the same number and quality of units.

For FY 2024, HUD is continuing its overall methodology of forecasting notional PUC based on a combination of expected gross rent increases and tenant income increases. However, HUD has modified how it calculates the gross rent increase based on recent dynamics in rental markets. As previously mentioned, HUD has historically used the CPI Rent of Primary Residence series as its measure of shelter rent inflation. The CPI is constructed based on a survey of rents paid in a fixed sample of units over time. Recent research has shown that since 2020, rents paid for newly leased units have increased at a significantly faster rate than overall rents. HUD attempted to address this dynamic in its calculation of FY 2024 FMRs by replacing the use of the CPI in part with rates of rental inflation as captured by private sector rent data. This was done as the FMR is required by regulation to reflect rents paid by ''recent movers.'' However, for purposes of forecasting Per Unit Costs, the gross rent component should represent all types of tenants in the Housing Choice Voucher program, including new admissions and recent movers, as well as those staying in place. Using both a baseline and projected CY FMR as the gross rent component of PUC as in prior years risks overstating program gross rents in a manner that only reflects rents paid by recent movers. HUD's analysis of tenant administrative data has found that the vast majority of HUD assisted households remain in place from year to year, and experience slower rates of rent inflation on average. Using an FMR-only rent, especially in times of large recent mover rent growth, would likely overstate per unit costs. In contrast, using a PUC based solely on an all-mover CPI Forecast would further risk underestimating per unit costs when PHA's are implementing large recent mover rent increases. Therefore, for FY 2024, HUD is calculating the gross rent component of PUC based on a weighted average of the expected change in national FMR (to represent recent movers) and the expected national change in Rent of Primary Residence CPI (to represent in-place tenants).

For the reasons outlined above, HUD is considering two different approaches for weighting the FMR and CPI. Under the first approach, HUD develops a gross rent inflation factor using a weighted average of the established CY FMR projection and independent CY CPI gross rent index forecast methodology, where the FMR is weighted at approximately 56.7 percent and the CPI gross rent inflation index measure is weighted at approximately 43.3 percent. HUD determined the weights empirically in a manner that best predicts the historical average voucher tenant gross rents.[1] The change between the forecasted CY 2024 notional PUC and the CY 2023 notional PUC is the expected national change in PUC, or 9.54 percent. The strengths of this approach are that by considering the time series of actual rents, these weights are likely capturing important dynamics of the real-world dynamics of the voucher program. The weaknesses are that there is no guarantee that these past trends will continue and, given that there was historically little difference between rates of recent mover and all mover inflation, the weights assigned to each component may be arbitrary.

Under the second approach, HUD takes a weighted average of the CY FMR projection and independent CY CPI gross rent index forecast, where the FMR is weighted at approximately 15 percent and the CPI gross rent index is weighted at approximately 85 percent. HUD determined these weights based on the historical composition of new admissions and recent movers based on HUD administrative data. The change between the forecasted CY 2024 notional PUC and the CY 2023 notional PUC for this approach is 5.22 percent. The strength of this approach is that weights based on the actual number of new leases in the program is a better theoretical approach to assigning recent mover rates of inflation than simply following past trends. However, there is also evidence to suggest that even non-movers in the voucher program may experience higher rates of rent inflation, such as existing tenants having rents exceeding payment standards or landlords pricing units based on FMR regardless of unit turnover.

Given these uncertainties, HUD takes the average of the two factors produced by these approaches and gets a final CY2024 PUC estimate of 7.38 percent. HUD's forecasts of the Consumer Price Index (CPI) Rent of Primary Residence Index, CPI Fuels and Utilities Index and HUD tenant incomes remain consistent with the Economic Assumptions of the Administration's FY 2025 Budget. For more information on HUD's forecast methodology, see 82 FR 26710 (June 8, 2017).

[1] Specifically, HUD attempted to predict each year's tenant gross rent using a weighted average of FMR and CPI change, then compared the predicted gross rent to the actual historical gross rent. HUD then generated an error measure as the difference between the predicted and actual rent. HUD then solved for the weights that minimize the root mean squared error of the predicted and actual rents.

The inflation factor for an individual geographic area is based on the annualized change in the area's FMR between FY 2023 and FY 2024. These changes in FMRs are then scaled such that the voucher-weighted average of all individual area inflation factors is equal to the national inflation factor, *i.e.,* the expected annual change in national PUC from CY 2023 to CY 2024, and such that no area has a factor less than one. For PHAs operating in multiple FMR areas, HUD calculates a voucher-weighted average inflation factor based on the count of vouchers in each FMR area administered by the PHA as captured in HUD administrative data as of December 31, 2023.

III. The Use of Inflation Factors

HUD subsequently applies the calculated individual area inflation factors to eligible renewal funding for each PHA based on VMS leasing and cost data for the prior calendar year.

IV. Geographic Areas and Area Definitions

As explained above, inflation factors based on area FMR changes are produced for all FMR areas and applied to eligible renewal funding for each PHA. The tables showing the RFIFs, available electronically from the HUD data information page, list the inflation factors for each FMR area on a state-by-state basis. The inflation factors use the same OMB metropolitan area definitions, as revised by HUD, that are used in the FY 2024 FMRs. PHAs should refer to the Area Definitions Table on the following web page to make certain that they are referencing the correct inflation factors: *http://www.huduser.org/portal/datasets/rfif/FY20234/FY2024_RFIF_FMR_AREA_REPORT.pdf.* The Area Definitions Table lists areas in alphabetical order by state, and the counties associated with each area. In the six New England states, the listings are for counties or parts of counties as defined by towns or cities. HUD is also releasing the data in Microsoft Excel format to assist users who may wish to use these data in other calculations. The Excel file is available at *https://www.huduser.gov/portal/datasets/rfif/rfif.html.* Note that, as described earlier, the actual renewal funding inflation factor applied to agency funding will be the voucher-weighted average of the FMR area factors when the PHA operates in multiple areas.

V. Environmental Impact

This notice involves a statutorily required establishment of a rate or cost determination which does not constitute

a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Solomon Greene,

Principal Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2024–10212 Filed 5–9–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[245D0102DM. DS62400000. DLSN00000.000000. DX62401; OMB Control Number 1084–0034]

Agency Information Collection Activities; Documenting, Managing, and Preserving Department of the Interior Museum Collections Housed in Non-Federal Repositories

AGENCY: Office of Acquisition and Property Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Acquisition and Property Management, Office of the Secretary, Department of the Interior are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before July 9, 2024.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Rochelle Bennett, Office of Acquisition and Property Management, U.S. Department of the Interior, 1849 C Street NW, MS 4262–MIB, Washington, DC 20240; or by email to *Rochelle_Bennett@ios.doi.gov*. Please reference OMB Control Number 1084–0034 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Rochelle Bennett by email at *Rochelle_Bennett@ios.doi.gov,* or by telephone at 202–513–7564. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside of the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Department of the Interior (DOI) manages an estimated 75 million museum objects and over 92 thousand linear feet of archives in trust for the American public. This diverse collection consists of archaeological artifacts, archives, biological specimens, ethnographic objects, fine arts, geological specimens, historic objects, and paleontological specimens owned and managed by DOI bureaus and offices (bureaus). Although the majority of DOI museum collections are housed in DOI bureau facilities, at least 10 percent are located at more than 1,000 non-Federal repositories, primarily state and tribal institutions, museums, and university departments. Most of DOI museum collections housed in non-Federal repositories resulted from projects on Federal lands, and include objects from the disciplines of archaeology, biology, geology, and paleontology, as well as associated project documentation (archives or associated records).This information collection request is directed to these non-Federal repositories that house DOI museum collections.

DOI museum collections cared for in non-Federal repositories are established as Federal property under Federal law. Permits and other agreements for the collection of artifacts and specimens from public lands managed by DOI further affirm Federal ownership. Federal regulations and DOI policy require that all permittees (authorized individuals) conducting research or performing compliance activities on DOI-managed lands must ensure that any retained museum objects and archives collected or generated during a project are: (1) accessioned and cataloged according to DOI standards in the Interior Collection Management System (ICMS), its successor the Museum Collection Management System (MCMS), or another collection management system from which the necessary data can be imported into ICMS or MCMS; and (2) housed in an appropriate museum repository that meets professional and DOI museum standards. These requirements help to establish and maintain accountability, as well as ensure the collections' long-term preservation, protection, and availability for access and use.

Upon request by DOI bureaus, voluntary submittal of the information identified below from non-Federal repositories supports DOI's management of its museum collections, as well as compliance with the Native American Graves Protection and Repatriation Act (NAGPRA) where applicable.DOI bureaus may request information within the following categories:

(1) Museum records created to manage DOI museum collections, such as accession, catalog, inventory, loan, and deaccession records, and backups of collection management systems or other software/programs. (REVISED)

(2) Associated records/archives generated by the activity of collecting and analyzing DOI museum collections. (NEW)

(3) Access and use of DOI museum collections, such as use requests, analyses, physical and virtual exhibits, online catalogs and finding aids, presentations, and publications resulting from use. (NEW)

(4) Objects newly identified as under DOI ownership and possible Native American Graves Protection and Repatriation Act (NAGPRA) human remains or cultural items in DOI museum collections. (NEW)

(5) Improved management and care recommendations, including considerations for Duty of Care requirements consistent with NAGPRA. (NEW)

(6) Reports of damaged, deteriorated, missing, or stolen objects. (NEW)

(7) Core management and planning documents, such as scope of collection statement, emergency management, integrated pest management, security, and housekeeping plans. (NEW)

(8) Partnerships, funding, or commercial sponsorships that may involve DOI museum collections. (NEW)

(9) *Facility Checklist for Spaces Housing DOI Museum Property (Checklist)* to capture current environmental, security, and other management controls in place to document and safeguard DOI museum collections and provide recommendations for improvements. (EXISTING)

(10) *Input on Collections from Lands Administered by the U.S. Department of the Interior that are Located at Non-Federal Facilities (Input Form)* to query a limited range of information about the repository, scope and types of DOI museum collections in the repository, DOI bureaus with which the collections are associated, status of documentation and NAGPRA compliance, and availability of objects and archives for research and other uses. (EXISTING)

The expanded categories of information identified above provide a more accurate representation of the information that DOI bureaus may ask non-Federal repositories to voluntarily provide on DOI museum collections. The proposed changes in this information collection request also include elimination of the three instruction sheets for accession, catalog, and inventory information included in previous iterations, as that information is captured in a revised category identified above.

Title of Collection: Documenting, Managing, and Preserving Department of the Interior Museum Collections Housed in Non-Federal Repositories.

OMB Control Number: 1084–0034.

Form Number: None.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Museums; academic, cultural, and research institutions; and state, tribal, and local agencies and institutions.

Total Estimated Number of Annual Respondents: 900.

Total Estimated Number of Annual Responses: 900.

Estimated Completion Time per Response: Varies from less than 1 hour to 80 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 12,550.

Respondent's Obligation: Voluntary.

Frequency of Collection: Maximum of once per year per collection instrument, and likely less frequently.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Megan Olsen,

Director, Office of Acquisition and Property Management.

[FR Doc. 2024–10215 Filed 5–9–24; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO4500179595]

Public Meeting for the Wyoming Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Wyoming Resource Advisory Council (Council) will meet as follows.

DATES: The Council will participate in a business meeting on June 12, 2024, and a field tour on June 13, 2024, to the North Lander Herd Management Area (HMA) Complex. A virtual participation option will also be available for the June 12, 2024, business meeting. The business meeting and field tour will start at 9 a.m. Mountain Time (MT) and conclude at 4 p.m. MT. The meeting and field tour are open to the public.

ADDRESSES: The June 12, 2024, business meeting will be held at the Holiday Inn Express and Suites at 1002 11th Street, Lander, WY 82520. The field tour will commence and conclude at the Holiday Inn and include a visit to the North Lander HMA Complex. Individuals that prefer to participate virtually in the meeting must register in advance. Registration information will be posted two weeks in advance of the meeting on the Council's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/wyoming.*

FOR FURTHER INFORMATION CONTACT: Azure Hall, BLM Wyoming State Office, telephone: (307) 775–6208, email: *ahall@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Council provides recommendations to the Secretary of the Interior concerning the planning and management of the public land resources located within the State of Wyoming. Agenda topics for June 12, 2024, may include updates and discussions on statewide planning efforts, energy trends, district and field manager updates, State Director comments, and other resource management issues the Council may raise. The final agenda will be posted on the Council's web page two weeks in advance of the meeting. The Council will participate in a field tour on June 13, 2024, to the North Lander HMA Complex. Members of the public are welcome on field tours but must provide their own transportation and meals.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least 7 business days prior to the meeting to give the BLM sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

A 30-minute public comment period will be offered June 12, 2024, at 2:25 p.m. MT. Depending on the number of persons wishing to speak and the time

available, the amount of time for oral comments may be limited. Written comments for the Council may be sent electronically in advance of the scheduled meeting to Public Affairs Specialist Azure Hall at *ahall@blm.gov,* or in writing to BLM Wyoming/Public Affairs, 5353 Yellowstone Rd., Cheyenne, WY 82009. All comments received will be provided to the Council. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. While the business meeting and field tour are scheduled from 9 a.m. to 4 p.m. MT, they may end earlier or later depending on the needs of group members. Therefore, members of the public interested in a specific agenda item or discussion at the June 12, 2024, meeting should schedule their arrival accordingly.

Detailed minutes for Council meetings will be maintained in the BLM Wyoming State Office. Minutes will also be posted to the Council's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/wyoming.*

(Authority: 43 CFR 1784.4–2)

Andrew Archuleta,

BLM Wyoming State Director.

[FR Doc. 2024–10236 Filed 5–9–24; 8:45 am]

BILLING CODE 4331–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_CO_FRN_MO4500174287; COC 028580]

Public Land Order No. 7941; Partial Withdrawal Revocation, Power Site Reserve No. 244; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order partially revokes a withdrawal created by Executive Order dated February 17, 1912, which established Power Site Reserve (PSR) No. 244, insofar as it affects 7.55 acres and releases these acres from applicability of section 24 of the Federal Power Act. This order opens the lands to sale under section 203 of the Federal Land Policy and Management Act of 1976, as amended (FLPMA), subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

DATES: This public land order takes effect on May 10, 2024.

ADDRESSES: Comments and meeting requests should be sent to State Director, Bureau of Land Management, Colorado State Office, P.O. Box 151029, Lakewood, Colorado 80215. Information regarding the proposed withdrawal, including environmental and other reviews, will be available at the Colorado State Office.

FOR FURTHER INFORMATION CONTACT: Jennifer Jardine, Senior Realty Specialist, BLM Colorado State Office, telephone: (970) 385–1224; email: *jjardine@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Jardine. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management (BLM) requested partial revocation affecting portions of PSR No. 244, classified for potential power site development. The BLM, in consultation with the Federal Energy Regulatory Commission, determined that the interests of the United States will not be injured by conveyance of the land out of Federal ownership, without reservation. This order opens the lands described within PSR No. 244 to sale under section 203 of FLPMA.

Order

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, and pursuant to the determination by the Federal Energy Regulatory Commission, it is ordered as follows:

1. The withdrawal created by Executive order dated February 17, 1912, which established PSR No. 244, is hereby revoked in part as to the following described lands:

6th Principal Meridian, Colorado

T. 4 S., R. 86 W.,
Sec. 9, lots 18 and 28.

The area described contains 7.55 acres.

2. The provisions of section 24 of the Federal Power Act no longer apply to the land described in paragraph 1.

3. At 9 a.m. on May 10, 2024, the lands described in Paragraph 1 are opened to sale under section 203 of the Federal Land Policy and Management Act of 1976, as amended (43 U.S.C. 1713), subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2024–10213 Filed 5–9–24; 8:45 am]

BILLING CODE 4331–16–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Fish and Wildlife Service

[BLM_FRN_MO4500175331]

Notice of Availability of the Draft Supplemental Environmental Impact Statement To Reconsider a Highway Right-of-Way Application and Associated Amendment of an Incidental Take Permit, Washington County, Utah

AGENCY: Bureau of Land Management, Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), the Federal Land Policy and Management Act of 1976, as amended (FLPMA), and the Endangered Species Act of 1973, as amended (ESA), the Bureau of Land Management (BLM) and the Fish and Wildlife Service (FWS), as co-lead agencies, announce the availability of the Draft Supplemental Environmental Impact Statement (SEIS) for the Northern Corridor Project (a proposed highway) as well as a potential amendment to the Incidental Take Permit (ITP) issued to Washington County, Utah, under section 10(a)(1)(B) of the ESA.

DATES: To afford the BLM and FWS the opportunity to consider comments in the Final SEIS, please ensure the agencies receive your comments within 45 days following the date the Environmental Protection Agency (EPA) publishes its Notice of Availability (NOA) of the Draft SEIS in the **Federal Register**. The EPA usually publishes its NOAs on Fridays.

ADDRESSES: The Draft SEIS is available for review on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2026562/510.* Click the Documents link on the left

side of the screen to find the electronic versions of these materials. Written comments related to the highway right-of-way (ROW) and associated potential amendment of an ITP can be submitted by either of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2026562/510.*
- *Mail:* Bureau of Land Management, Attn: Northern Corridor SEIS, 345 East Riverside Drive, St. George, UT 84790.

FOR FURTHER INFORMATION CONTACT: Dawna Ferris-Rowley, NCA Manager, Red Cliffs and Beaver Dam Wash NCAs, telephone (435) 688–3200; address 345 East Riverside Drive, St. George, UT 84790; email *BLM_UT_NorthernCorridor@blm.gov.* Contact Ms. Ferris-Rowley to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Ms. Ferris-Rowley. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Replies are provided during normal business hours. If you would like to request to view a hard copy, please call the St. George Field Office for more information at (435) 688–3200, Monday through Friday, except holidays.

SUPPLEMENTARY INFORMATION: The BLM and FWS are issuing this NOA pursuant to NEPA, 42 United States Code (U.S.C.) 4321 *et seq.;* the Council on Environmental Quality regulations for implementing NEPA, 40 Code of Federal Regulations (CFR) parts 1500–1508; and the Department of the Interior's NEPA regulations, 43 CFR part 46.

The Draft SEIS has been prepared to supplement the analysis contained in the 2020 Final EIS (FEIS) by BLM and FWS. (The entire FEIS can be found at: *https://eplanning.blm.gov/eplanning-ui/project/1502103/570.*)

On September 4, 2018, the Utah Department of Transportation (UDOT) applied for a ROW grant for the Northern Corridor Project north of the City of St. George, Utah, on BLM-managed and non-Federal lands within the Red Cliffs National Conservation Area (NCA) and Red Cliffs Desert Reserve. To consider the application, the BLM needed to also consider amending the St. George Field Office and Red Cliffs NCA Resource Management Plans (RMPs). The Red Cliffs NCA was established through the passage of the Omnibus Public Land Management Act of 2009 (16 U.S.C. 460www). Prior to the NCA's designation, the Red Cliffs Desert Reserve was established for the protection of the Mojave desert tortoise as part of the 1995 Washington County Habitat Conservation Plan (HCP). In 2015, pursuant to section 10(a)(1)(B) of the ESA, Washington County applied to renew and amend the HCP and associated ITP. The restated and amended HCP described the Northern Corridor highway as a potential changed circumstance, which would be partially offset with the addition of a new sixth zone to the Red Cliffs Desert Reserve (Reserve Zone 6) as the primary conservation strategy.

In 2019–2020, in accordance with NEPA, the BLM and FWS prepared an EIS to analyze the environmental impacts associated with the proposed action and reasonable alternatives. The BLM also consulted with the FWS to meet the requirements in section 7(a)(2) of the ESA. The FWS issued a biological opinion to the BLM that determined the ROW and the amendments to the RMPs were not likely to jeopardize the continued existence of the Mojave desert tortoise or destroy or adversely modify designated critical habitat for the Mojave desert tortoise. In addition, the FWS issued an intra-agency biological opinion which determined that the ITP is not likely to jeopardize the continued existence of the Mojave desert tortoise, Holmgren milkvetch, Shivwits milkvetch, dwarf bear-poppy, Siler pincushion cactus, Gierisch mallow, and Fickeisen plains cactus or result in the adverse modification of critical habitat for any of the above listed species.

On January 13, 2021, the Secretary of the Interior signed a Record of Decision that approved the Northern Corridor ROW application and approved the amendments to the RMPs. The decision approving the ROW was effective immediately. The BLM then signed and issued the ROW grant to UDOT on the same day. Also on January 13, 2021, the FWS Regional Director for Interior Regions 5 and 7 signed a Record of Decision approving the issuance of an ITP to Washington County, and the FWS issued the ITP to Washington County. Because BLM approved the UDOT ROW application, the changed circumstance was triggered, and Zone 6 was formally added to the Reserve.

On June 3, 2021, seven conservation organizations (collectively, Plaintiffs) filed a complaint in the United States District Court for the District of Columbia, Case No. 1:21–cv–01506. Among other claims, Plaintiffs alleged the BLM's ROW decision violated both NEPA and the National Historic Preservation Act (NHPA). The Plaintiffs stated, in part, that the FEIS did not fully address the changed circumstances of wildfire in the region and the impacts it may have on the Mojave desert tortoise, desert tortoise habitat, and the spread of invasive annual grasses. The Plaintiffs also alleged that the BLM failed to comply with the consultation requirements under section 106 of the NHPA. On July 27, 2021, Plaintiffs amended their complaint to include the FWS and additional claims related to NEPA and the ESA.

During the litigation, the United States and Plaintiffs reached a settlement agreement that was signed on August 30, 2023. Prior to executing that agreement, the United States moved for the remand and partial vacatur of BLM's and FWS's 2021 decisions. In the motion, the United States acknowledged that the BLM did not comply with the NHPA and that the agencies had substantial and legitimate concerns that the FEIS may lack sufficient analysis of certain resource effects, including the effects of the construction and use of the Northern Corridor Project in the context of the following: (1) the trend in the increasing frequency and extent of wildfires in the Mojave Desert; (2) the rise of non-native/exotic and invasive vegetation in post-burn areas; and (3) the impacts increased fire and new non-native/exotic and invasive vegetation have on desert tortoise. On September 1, 2023, the Plaintiffs filed a response in support of the United States' motion. On November 16, 2023, the United States District Court for the District of Columbia issued an Order that granted the remand of all decisions associated with the January 2021 Records of Decision issued by the BLM and FWS.

Purpose and Need for the Proposed Action

The BLM's purpose and need for this action is to reconsider the 2018 UDOT ROW application to determine whether the BLM will affirm, affirm with modifications, or terminate the ROW grant. The FWS's purpose and need for this action is to consider whether to amend Washington County's ITP so that it reflects the BLM's reconsideration of UDOT's ROW.

Proposed Action and Alternatives

The Draft SEIS considers six alternatives that include both a specific ROW alignment and the corresponding action required of the FWS regarding the Washington County ITP. The six ROW alternatives analyzed in detail in the Draft SEIS are similar to those included in the FEIS published in November 2020. No new highway

alignments that meet UDOT's stated purpose and need for the Northern Corridor highway were identified by the public during the scoping period.

- *UDOT ROW Alignment alternative (No Action, or No Change):* the BLM would affirm the ROW grant issued to UDOT in 2021 following an alignment that is approximately 4.5 miles long, 1.9 miles of which would be across BLM-managed lands. This alternative would have a similar analysis of effects as the ''UDOT Application Alignment for the Northern Corridor'' alternative described in the 2020 Final EIS. In this case, the FWS would affirm Washington County's ITP. The changed circumstance related to the construction of the Northern Corridor across the Reserve described in the HCP would remain triggered, and Zone 6 would remain in the Reserve.
- *T-Bone Mesa Alignment alternative:* the BLM would modify UDOT's ROW grant across public lands in the NCA. This alignment would connect Green Springs Drive on the east to Red Hills Parkway on the west just north of the Pioneer Hills trailhead parking area. Under this alternative, the Northern Corridor would skirt the southern edge of T-Bone Mesa. The Northern Corridor would be approximately 4.2 miles long, 2.2 miles of which would be across BLM-administered lands. In this case, the FWS would affirm Washington County's ITP. The changed circumstance related to the construction of the Northern Corridor across the Reserve described in the HCP would remain triggered, and Zone 6 would remain in the Reserve.
- *Southern Alignment alternative:* the BLM would modify UDOT's ROW grant across public lands in the NCA. This alignment would skirt the southern border of the NCA, connecting Green Springs Drive on the east to Red Hills Parkway on the west just south of, and slightly encroaching onto, the Pioneer Hills trailhead parking area. The Northern Corridor would be approximately 5.5 miles long, approximately 1.5 miles of which would be across BLM-administered lands. In this case, the FWS would affirm Washington County's ITP. The changed circumstance related to the construction of the Northern Corridor across the Reserve described in the HCP would remain triggered, and Zone 6 would remain in the Reserve.
- *Red Hills Parkway Expressway alternative:* This alternative would convert Red Hills Parkway into a grade-separated expressway between I–15 and Bluff Street. Under this alternative, UDOT would no longer hold the ROW grant for the Northern Corridor across the NCA. The BLM may need to grant necessary ROW amendments to the City of St. George's existing FLPMA Title V ROW for the Red Hills Parkway if the planned improvements exceed the boundaries of the existing ROW. Under this alternative, the FWS would amend Washington County's ITP because it could no longer assume the Northern Corridor changed circumstance is occurring.
- *St. George Boulevard/100 South One-Way Couplet alternative:* Under this alternative, UDOT would no longer hold the ROW grant for the Northern Corridor across the NCA. This alternative would include modifications to St. George Boulevard and 100 South to convert the two roadways into a one-way couplet system between I–15 and Bluff Street, wherein St. George Boulevard would only accommodate westbound traffic and 100 South would only accommodate eastbound traffic. While this alternative meets the purpose and need of the project, it would have to be implemented by the City of St. George because it does not cross any BLM-administered lands. Under this alternative, the FWS would amend Washington County's ITP because it could no longer assume the Northern Corridor changed circumstance is occurring.
- *Terminate UDOT's ROW alternative:* Under this alternative, UDOT would no longer hold the ROW grant for the Northern Corridor across the NCA. This alternative would have a similar analysis of effects as, and represents an equivalency with, the ''no action'' alternative in the 2020 Final EIS. Under this alternative, the FWS would amend Washington County's ITP because it could no longer assume the Northern Corridor changed circumstance is occurring.

Under the Red Hills Parkway Expressway, St. George Boulevard/100 South One-Way Couplet, and Terminate UDOT's ROW alternatives, the 6,812-acre mitigation area in the southwest area of St. George, known as Reserve Zone 6, would be removed from the Red Cliffs Desert Reserve. However, the 3,471 acres managed by the BLM within Zone 6 would continue to be managed with the protections put in place under the 2021 St. George Field Office RMP amendments. The remaining 3,341 acres of land, which are either privately owned or managed by the Utah Trust Lands Administration, would no longer be afforded special protections by Washington County and would be subject to development under the amended ITP.

The Draft SEIS does not reconsider any amendments to the BLM's RMPs or to Washington County's amended HCP.

Anticipated Permits and Authorizations

The BLM will decide whether to affirm, affirm with modifications, or terminate UDOT's ROW grant. The FWS will determine whether to amend Washington County's ITP for the Mojave desert tortoise consistent with the BLM's reconsideration of UDOT's ROW grant.

Schedule for the Decision-Making Process

The Final SEIS is anticipated to be released in fall 2024 with Records of Decision in November 2024.

Public Involvement Process

A public scoping period for the Draft SEIS was offered between November 16, 2023, and December 28, 2023, having been extended at the request of Washington County and the State of Utah. The scoping period included a public open house held in St. George, Utah on December 6, 2023, with over 200 attendees. A total of 8,993 comment submissions were received, of which 8,145 were form letters, 793 were unique comments, and 55 did not include a comment or were comments not relevant to scoping for the Draft SEIS. The BLM and FWS considered all comments received during the scoping period in preparation of the Draft SEIS. A scoping report is available for public review on the BLM ePlanning project website (see **ADDRESSES**).

This NOA initiates the Draft SEIS public review process. The BLM and FWS will hold one in-person public meeting during the public comment period. The BLM and FWS will announce the date and time for this meeting at least 15 days prior to the event. Announcements will be made through media releases and posting on the BLM ePlanning project website (see **ADDRESSES**).

Public review of the Draft SEIS allows the public an opportunity to provide substantive comments on the alternatives and analysis in the Draft SEIS. Public comments often identify factual errors, data gaps, relevant methods, or scientific studies. The BLM and FWS will respond to substantive comments and make appropriate revisions in development of the Final SEIS or explain why a comment did not warrant a change. Non-substantive comments may not receive a response from the BLM and FWS.

Lead and Cooperating Agencies

The BLM and FWS are co-lead agencies. Cooperating agencies consist of the State of Utah Public Lands Policy Coordinating Office, State of Utah Department of Environmental Quality, State of Utah Trust Lands Administration, Washington City, Dixie Metropolitan Planning Organization, City of St. George, City of Ivins, Santa Clara City, City of Hurricane, the Paiute Indian Tribe of Utah, and the Shivwits Band of the Paiute Indian Tribe of Utah.

Additional Information

There may be changes to the Draft SEIS based on information received during the public comment period and the gathering of additional data and analyses. The BLM and FWS invite and encourage detailed comments on all alternatives, alignments, actions, and analyses provided in the Draft SEIS.

The BLM and FWS will continue to consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM Manual Section 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can include in your comment a request to withhold your personal identifying information from public review, the agencies cannot guarantee that they will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10)

Gregory Sheehan,

State Director.

Anna Munoz,

Deputy Regional Director.

[FR Doc. 2024–10078 Filed 5–9–24; 8:45 am]

BILLING CODE 4331–25–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–24–019]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: May 17, 2024 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. A*gendas for future meetings:* none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. Inv. Nos. 701–TA–716–719 and 731–TA–1683–1687 (Preliminary) (Epoxy Resins from China, India, South Korea, Taiwan, and Thailand). The Commission currently is scheduled to complete and file its determinations on May 20, 2024; views of the Commission currently are scheduled to be completed and filed on May 28, 2024.
5. Commission vote on Inv. Nos. 701–TA–710–711 and 731–TA–1673–1674 (Preliminary)(2,4-Dichlorophenoxyacetic Acid (2,4–D) from China and India). The Commission currently is scheduled to complete and file its determinations on May 20, 2024; views of the Commission currently are scheduled to be completed and filed on May 28, 2024.
6. *Outstanding action jackets:* none.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: May 8, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–10389 Filed 5–8–24; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; National Agricultural Workers Survey

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed revision for the authority to conduct the information collection request (ICR) titled, ''National Agricultural Workers Survey.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by July 9, 2024.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Mr. Daniel Carroll by telephone at 202–693–2795 (this is not a toll-free number) or by email at *carroll.daniel.j@dol.gov.* For persons with a hearing or speech disability who need assistance to use the telephone system, please dial 711 to access telecommunications relay services.

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Policy Development and Research, Room N–5641, 200 Constitution Ave. NW, Washington, DC 20210; by email: *carroll.daniel.j@dol.gov;* or by Fax 202–693–2766.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Gordon by telephone at 202–693–3179 (this is not a toll-free number) or by email at *gordon.wayne@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The National Agricultural Workers Survey (NAWS) is an employment-based, annual survey of the demographic, employment, and health characteristics of hired crop workers, including those who employers hire indirectly through labor contractors. The survey began in 1988. It is distinct from other farm labor information sources, such as the United States Department of Agriculture's Farm Labor Survey, in that it collects information directly from crop workers. Each year the NAWS contractor interviews between 1,500 and 3,500 crop workers. The contractor interviews crop workers

three times per year to account for the seasonality of agricultural employment. ETA uses NAWS data to estimate each state's share of crop workers who are eligible for employment and training services through ETA's National Farmworker Jobs Program. Other Federal agencies similarly use the survey's data to estimate the number and characteristics of crop workers and their dependents who qualify to participate in or receive services from various migrant and seasonal farmworker programs. The United States Department of Agriculture periodically uses NAWS data, along with other data, to estimate changes in agricultural productivity.

ETA is seeking approval to modify a currently approved collection. This request is to include H–2A crop workers in the survey population, combine separate questions on race and ethnicity into one question, in conformance with the new OMB Standard for race and ethnicity, and add new questions to the survey on foodborne illness, heat illness, and precision agriculture.

In reference to the job site, questions on foodborne illness will gather information on:

- Food safety training and practices
- Use and type of food storage vessels
- Provision of toilets and hand-cleaning facilities
- Occurrence of discharge in the field/open air

Questions on heat-related illness will gather information on:

- The prevalence and incidence of heat stress
- The prevalence of reporting severe symptoms to the employer
- Heat stress interventions at the job site
- Employer provision of heat-related safety training
- Employer provision of an acclimatization period during extremely high temperatures

A question on precision agriculture will ask about the types of technology that crop workers use or interact with at the work site while performing agricultural tasks (*e.g.,* GPS-enabled devices, internet-enabled devices, task automation).

The Wagner-Peyser Act, as amended (29 U.S.C. 49f(d) and 49l–2(a)) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. To receive consideration, you must provide written comments, which DOL will summarize and include in the request for OMB approval of the final ICR. To help ensure appropriate consideration, comments should mention OMB Control No. 1205–0453.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: National Agricultural Workers Survey.

Form: Primary Questionnaire.

OMB Control Number: 1205–0453.

Affected Public: Individuals and Households, Private Sector.

Estimated Number of Respondents: 3,594.

Frequency: Annual.

Total Estimated Annual Responses: 3,594.

Estimated Average Time per Response: 41 minutes.

Estimated Total Annual Burden Hours: 1,289 hours.

Total Estimated Annual Other Cost Burden: $0.

José Javier Rodríguez,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2024–10228 Filed 5–9–24; 8:45 am]

BILLING CODE 4510–FM–P

DEPARTMENT OF LABOR

Labor Advisory Committee for Trade Negotiations and Trade Policy

AGENCY: The Bureau of International Labor Affairs, Department of Labor.

ACTION: Notice; intent to renew charter.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), as amended, the Secretary of Labor and the United States Trade Representative have determined that renewal of the Labor Advisory Committee for Trade Negotiations and Trade Policy is necessary and in the public interest.

DATES: The Department will renew the Labor Advisory Committee for Trade Negotiations and Trade Policy charter on or before May 20, 2024, before the current charter expires.

FOR FURTHER INFORMATION CONTACT: Anne M. Zollner, Designated Federal Officer and Division Chief, Preference Program Enforcement, Office of Trade and Labor Affairs, Bureau of International Labor Affairs, Department of Labor, Frances Perkins Building, Room S–5317, 200 Constitution Ave. NW, Washington, DC 20210, telephone (202) 693–4890, *zollner.anne@dol.gov*.

SUPPLEMENTARY INFORMATION: The Committee will be chartered pursuant to section 135(c)(1) and (2) of the Trade Act of 1974, 19 U.S.C. 2155(c) (1) and (2), as amended and Executive Order 11846 of March 27, 1975, 3 CFR 1971–1975 Comp., p. 971 (which delegates certain Presidential responsibilities conferred in section 135 of the Trade Act of 1974 to the United States Trade Representative).

The Labor Advisory Committee for Trade Negotiations and Trade Policy consults with and makes recommendations to the Secretary of Labor and the United States Trade Representative on general policy matters concerning labor and trade negotiations, operations of any trade agreement once entered into, and other matters arising in connection with the administration of the trade policy of the United States.

The current charter expires on May 20, 2024. The renewal of the charter of the Labor Advisory Committee for Trade Negotiations and Trade Policy is necessary and in the public interest, as

the Committee will provide information that cannot be obtained from other sources. The Committee will provide its views to the Secretary of Labor and the Unites States Trade Representative through the Bureau of International Labor Affairs of the U.S. Department of Labor. The Committee is to be comprised of no more than 30 members representing the labor community.

The Committee will meet at irregular intervals at the call of the Secretary of Labor and the United States Trade Representative.

Signed at Washington, DC.

Thea M. Lee,

Deputy Undersecretary, Bureau of International Labor Affairs.

[FR Doc. 2024–10247 Filed 5–9–24; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

[Agency Docket Number DOL–2023–0003]

Notice of Initial Determination To Remove Shrimp From Thailand and Garments From Vietnam From the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor Pursuant to Executive Order 13126

AGENCY: The Bureau of International Labor Affairs, Department of Labor.

ACTION: Notice of initial determination; request for comments.

SUMMARY: This initial determination proposes to revise the list required by Executive Order No. 13126 (''Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor'') (E.O. List) in accordance with the Department of Labor's (DOL) ''Procedural Guidelines for the Maintenance of the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor'' (the Procedural Guidelines). The E.O. List identifies a list of products, by their country of origin, that DOL, in consultation and cooperation with the Department of State and the Department of Homeland Security (hereinafter ''the three Departments''), has a reasonable basis to believe might have been mined, produced, or manufactured by forced or indentured child labor. Federal contracting officers must check the E.O. List when issuing a solicitation for supplies expected to exceed the micro-purchase threshold and take certain steps if the solicited product appears on the list. This notice proposes to remove shrimp from Thailand and garments from Vietnam because the three Departments have preliminarily determined that the use of forced or indentured child labor in the production of these products has been significantly reduced. The Department of Labor invites public comment on this initial determination. The three Departments will consider all public comments prior to publishing a final determination revising the E.O. List.

DATES: Comments should be submitted to the Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) via one of the methods described below and must be received by no later than 5 p.m. ET, June 10, 2024, to guarantee consideration.

ADDRESSES: Information submitted to the Department of Labor should be submitted directly to OCFT, Bureau of International Labor Affairs, U.S. Department of Labor. Comments, identified as ''Docket No. DOL–2004–0003,'' may be submitted by any of the following methods:

Federal eRulemaking Portal: The portal includes instructions for submitting comments. Parties submitting responses electronically are encouraged not to submit paper copies.

Facsimile (fax): OCFT at 202–693–4830.

Mail, Express Delivery, Hand Delivery, and Messenger Service (1 copy): Ryan Olden at U.S. Department of Labor, ILAB/Office of Child Labor, Forced Labor, and Human Trafficking, 200 Constitution Ave. NW, Room S–5317, Washington, DC 20210.

Email: Email submissions should be addressed to Ryan Olden. Email: *eo13126@dol.gov.*

Digital Accessability: The United States Department of Labor (DOL) is required to ensure that all its digital information is accessible to people with disabilities, including those who use assistive technology such as screen readers. Therefore, DOL requests that your submissions through the portal be as accessible as possible. If you are able to conform to the current Web Content Accessibility Guidelines (WCAG), then please do so. Otherwise, DOL requests that submissions be made in a Microsoft Word document, using the built-in Styles for document formatting, including descriptive Alt Text on embedded images and graphics, and using the built-in Word Accessibility Checker for additional accessibility improvements. Although permissible, please avoid submitting scanned images, screen shots, or PDFs whenever possible.

FOR FURTHER INFORMATION CONTACT: Ryan Olden. Phone: (202) 693–4867. *eo13126@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL is requesting public comment on the revisions to the E.O. List proposed below, as well as any other issue related to the fair and effective implementation of E.O. 13126. This notice is a general solicitation of comments from the public. All submitted comments will be made a part of the public record and will be available for inspection on *http://www.regulations.gov.*

In conducting research for this initial determination, the three Departments considered a wide variety of materials based on their own research, and materials from other U.S. Government agencies, foreign governments, international organizations, non-governmental organizations (NGOs), U.S. Government-funded technical assistance and field research projects, academic and other independent research, media, and other sources. The Department of State and U.S. embassies and consulates abroad also provided important information by gathering data from contacts, conducting site visits, and reviewing local media sources. In developing the proposed revision to the E.O. List, the three Departments' review focused on information concerning the use of forced or indentured child labor that was available from the above sources.

As outlined in the Procedural Guidelines, several factors were weighed in determining whether a product should be placed, or remain on, the revised E.O. List: the nature of the information describing the use of forced or indentured child labor; the source of the information; the date of the information; the extent of corroboration of the information by appropriate sources; whether the information involved more than an isolated incident; and whether recent and credible efforts are being made to address forced or indentured child labor in a particular country and industry (66 FR 5351).

This notice constitutes an initial determination to revise the E.O. List. Based on available information from various sources, the three Departments have preliminarily concluded that there is no longer a reasonable basis to believe that there is use of forced or indentured child labor in the production of the following products, identified by their countries of origin:

Product: Shrimp
Country: Thailand

DOL has received recent, credible, and corroborated information from various sources on the use of forced or indentured child labor in shrimp production in Thailand. This information indicates that while

children previously worked under forced labor conditions in the production of shrimp, the use of forced child labor appears to have been significantly reduced. Therefore, the three Departments have preliminarily concluded that there is no longer a reasonable basis to believe that shrimp from Thailand is produced by forced or indentured child labor, except in a few isolated instances, and therefore it should not continue to be on the E.O. List.

DOL placed shrimp from Thailand on the E.O. List in 2009, and to date, the listing cites 11 sources dating from 2006 to 2015. Sources indicated that children in Thailand—primarily migrant children—were peeling shrimp in small, unregulated ''shrimp sheds.'' In more than isolated incidents, these migrant children were engaged in forced child labor. Following international attention and action on labor exploitation in Thailand's seafood industry, the Royal Thai Government (RTG) and other stakeholders made a series of concerted significant efforts to address child labor and forced child labor throughout the seafood industry, including in the shrimp peeling sector.

The RTG acceded to the ILO's Maritime Labor Convention and the ILO's Work in Fishing Convention and passed the Ministerial Regulation Prohibiting Children in Seafood Processing. The RTG also enacted the Royal Ordinance on Fisheries, which enhanced traceability systems of aquatic resources in Thailand, inclusive of shrimp processing, and strengthened migrant worker recruitment regulations through revisions in the Labor Protection Act of 1998 and the Royal Ordinance on Foreign Worker Management (No. 2). Additionally, the RTG collaborated with international nongovernmental organizations to implement projects focused on eliminating forced child labor and child labor in the seafood processing sector, including the *Combatting Unacceptable Forms of Work in the Thai Fishing and Seafood Industry* program funded by the ILO and the European Union; the *FAIR Fish* program funded by DOL; and the *Ship to Shore* project funded by the EU. Private sector entities also acted against forced child labor by formalizing their supply chains, eliminating nearly all unregulated ''shrimp sheds'' in which child labor and forced child labor were previously documented. In 2023, Thai government officials, an industry trade group, workers' associations, international organizations, and nongovernmental organizations reported that incidents of forced child labor in shrimp processing had been reduced to no more than isolated cases. DOL's review of available information corroborated that forced child labor in the production of shrimp had been significantly reduced to isolated incidents.

Product: Garments
Country: Vietnam

DOL has also received recent, credible, and corroborated information from various sources on the use of forced or indentured child labor in garment production in Vietnam. This information indicates that while children previously worked under forced labor conditions in the production of garments, the use of forced child labor appears to have been significantly reduced. Therefore, the three Departments have preliminarily concluded that there is no longer a reasonable basis to believe that garments from Vietnam are produced by forced or indentured child labor, except in a few isolated instances, and therefore it should not continue to be on the E.O. List.

DOL placed garments from Vietnam on the E.O. List in 2012, and to date, the listing cites 18 sources dating from 2008 to 2015. Sources indicated that children in Vietnam—primarily children from rural areas—were being trafficked from their homes to Ho Chi Minh City, where they were coerced to work, and often live, in garment factories. Reports indicated that children working in the sector were underpaid, forced to work long hours, and in many cases were found living in the workshops. Between 2010 and 2014 there were between 20 and 64 children trafficked for these purposes each year, after which the number of children dropped rapidly. Reporting that exposed this trafficking pipeline was led by data from Blue Dragon Children's Foundation (BDCF)—a local NGO which functions as a key partner to the Vietnamese police. According to the U.S. Embassy in Hanoi and its contacts, all forced child labor cases in Vietnamese garment factories go through BDCF for intervention, removal of children from the trafficking situations, and victim services.

Research indicates that following reports of forced child labor in the sector, the police worked quickly and effectively to identify both victims and perpetrators of this trafficking pipeline. The police shut down all responsible criminal enterprises. According to a 2021 BDCF report, BDCF rescue operations for victims of trafficking have not uncovered a child in sweatshop labor since 2017.

Since the addition of garments to the E.O. List in 2012, Vietnam has made efforts in its legal framework, partnerships, and enforcement efforts to eradicate and prevent forced child labor in this sector. Vietnam enacted a Labor Code in 2012 prohibiting unlawful, underage, or forced labor of children, and included regulations on the employment of minors including working hours, working times of day, and types of work allowed for minors. Vietnam specifically prohibited minors from operating fabric and yarn-starching machines, as well as dyeing and dry-cleaning fabric and yarn, criminalized child trafficking, and affirmed the right of children to be protected from labor exploitation. Additionally, Vietnam has conducted two national programs on the reduction of child labor and has conducted a national survey on child labor. The government continues to work with Blue Dragon, as well as other INGOs and NGOs like the ILO, Fair Wear Foundation, and Better Work. Vietnam actively collaborates with stakeholders on programs like ENHANCE, which aims to build governmental capacity to address and prevent child labor; and Fear Wear's programming, which brings together key stakeholders to enhance the rights of garment workers. Reports also indicate that grievance mechanisms exist and are accessible for garment workers.

DOL invites public comment on whether these products (and/or other products, regardless of whether they are mentioned in this notice) should be included in or removed from the revised E.O. List. To the extent possible, comments provided should address the criteria for inclusion of a product on the E.O. List contained in the Procedural Guidelines discussed above.

Following receipt and consideration of comments, the three Departments will issue a final determination in the **Federal Register**. The three Departments intend to continue to revise the E.O. List periodically to add or remove products as warranted by the receipt of new and credible information.

Background

E.O. 13126 was signed on June 12, 1999, and published in the **Federal Register** on June 16, 1999 (64 FR 32383). E.O. 13126 declared that it was ''the policy of the United States Government . . . that executive agencies shall take appropriate actions to enforce the laws prohibiting the manufacture or importation of goods, wares, articles, and merchandise mined, produced or manufactured wholly or in part by forced or indentured child labor.'' The E.O. defines ''forced or indentured child labor'' as ''all work or service (1) exacted from any person under the age

of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or (2) performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.''

Pursuant to E.O. 13126, and following public notice and comment, the Department of Labor published in the January 18, 2001 **Federal Register** the first E.O. List of products, along with their respective countries of origin, that DOL, in consultation and cooperation with the Department of State and the Department of the Treasury (whose relevant responsibilities are now within the Department of Homeland Security), had a reasonable basis to believe might have been mined, produced or manufactured with forced or indentured child labor (66 FR 5353). This list included 11 goods produced in 12 countries. DOL also published the Procedural Guidelines on January 18, 2001, which provide procedures for the maintenance, review, and, as appropriate, revision of the E.O. List (66 FR 5351).

The Procedural Guidelines provide that the E.O. List may be revised through consideration of submissions by individuals and on the three Departments' own initiative. When proposing a revision to the E.O. List, DOL must publish in the **Federal Register** a notice of initial determination, which includes any proposed alteration to the E.O. List. The three Departments will consider all public comments prior to the publication of a final determination of a revised E.O. List.

On January 18, 2001, pursuant to Section 3 of E.O. 13126, the Federal Acquisition Regulatory Council published a final rule to implement specific provisions of E.O. 13126 that require, among other things, that Federal contractors who supply products that appear on the list certify to the contracting officer that the contractor, or, in the case of an incorporated contractor, a responsible official of the contractor, has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any product furnished under the contract and that, on the basis of those efforts, the contractor is unaware of any such use of forced or indentured child labor (48 CFR subpart 22.15).

On September 11, 2009, the Department of Labor published an initial determination in the **Federal Register** proposing to revise the E.O. List to include 29 products from 21 countries. The Notice requested public comments for a period of 90 days. Public comments were received and reviewed by all relevant agencies and a final determination was issued on July 20, 2010. Following the same process, the E.O. List was revised again in 2011, 2012, 2013, 2014, 2019, and 2022. The most recent E.O. List, finalized on July 13, 2022, includes 34 products from 26 countries.

The current E.O. List and the Procedural Guidelines can be accessed at *https://www.dol.gov/agencies/ilab/reports/child-labor/list-of-products* or can be obtained from: OCFT, Bureau of International Labor Affairs, Room S–5313, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–4843; fax (202) 693–4830.

(Authority: E.O. 13126, 64 FR 32383)

Signed at Washington, DC.

Thea Mei Lee,

Deputy Undersecretary for International Affairs.

[FR Doc. 2024–10249 Filed 5–9–24; 8:45 am]

BILLING CODE 4510–28–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings

TIME AND DATE: The Legal Services Corporation Board of Directors will meet virtually on May 17, 2024. The meeting will commence at 10:30 a.m. Eastern Time and will continue until the conclusion of the Board's agenda.

PLACE: Public Notice of Virtual Meetings.

LSC will conduct the May 17, 2024, meeting via Zoom videoconference.

Public Observation: Unless otherwise noted herein, the LSC Board of Directors meeting will be open to public observation via Zoom. Members of the public who wish to participate remotely in the public proceedings may do so by following the directions provided below.

Directions for Open Session:

May 17, 2024

To join the Zoom meeting by computer, please use this link.

- *https://lsc-gov.zoom.us/j/81388912215?pwd=QXIffPVaC4zhNT1JSIhiqRplFodKof.1&from=addon*
- *Meeting ID:* 813 8891 2215
- *Passcode:* 51724

To join the Zoom meeting with one tap from your mobile phone, please click dial:

- +13017158592,,81526341918# US
- +13126266799,,81526341918# US

To join the Zoom meeting by telephone, please dial one of the following numbers:

- +1 669 900 6833 (San Jose)
- +1 253 215 8782 (Tacoma)
- +1 346 248 7799 (Houston)
- +1 408 638 0968 (San Jose)
- +1 646 876 9923 (New York)
- +1 301 715 8592 (Washington, DC)
- +1 312 626 6799 (Chicago)
- *Meeting ID:* 813 8891 2215
- *Passcode:* 51724

Once connected to Zoom, please immediately mute your computer or telephone. Members of the public are asked to keep their computers or telephones muted to eliminate background noise. To avoid disrupting the meetings, please refrain from placing the call on hold if doing so will trigger recorded music or other sound.

From time to time, the Board Chair may solicit comments from the public. To participate in the meeting during public comment, use the 'raise your hand' or 'chat' functions in Zoom and wait to be recognized by the Chair before stating your questions and/or comments.

STATUS: Open, except that, upon a vote of the Board of Directors, a portion of the meeting may be closed to the public to receive a briefing from LSC Management and to consider and act on as a list of prospective Leaders Council and Emerging Leaders Council members.

MATTERS TO BE CONSIDERED: The LSC Board of Directors' Transmittal Letter to Accompany the Inspector General's Semiannual Report to Congress, for the Period of Oct. 1, 2023 through March 31, 2024.

CONTACT PERSON FOR MORE INFORMATION: Jessica Wechter, Special Assistant to the President, at (202) 295–1621. Questions may also be sent by electronic mail to *wechterj@lsc.gov.*

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *https://www.lsc.gov/about-lsc/board-meeting-materials.*

(Authority: 5 U.S.C. 552b.)

Dated: May 8, 2024.

Stefanie Davis,

Deputy General Counsel, Legal Services Corporation.

[FR Doc. 2024–10437 Filed 5–8–24; 4:15 pm]

BILLING CODE 7050–01–P

LIBRARY OF CONGRESS

[Docket No. 2024–1]

Announcement Reauthorizing Copyright Public Modernization Committee

AGENCY: Library of Congress.

ACTION: Notice of reauthorizing IT modernization public stakeholder committee.

SUMMARY: The Library of Congress is reauthorizing a public committee to provide a forum for the technology-related aspects of the U.S. Copyright Office's modernization initiative. Given the success of the previous Copyright Public Modernization Committee (CPMC) and the value and insights provided by CPMC members, the Library wants to renew the committee for an additional term. Therefore, the Library will accept applications from qualified members of the public to serve on this committee. Membership will be on a volunteer basis, with the expectation of participation in at least two virtual or hybrid open forums a year at the member's own expense.

DATES: Applications must be submitted on or before June 18, 2024.

ADDRESSES: Applications may be submitted electronically to the CPMC's dedicated email inbox at *cpmc@loc.gov*.

FOR FURTHER INFORMATION CONTACT: Neil D. Bernstein, Program Analyst, Office of the Chief Information Officer, by telephone at 202–707–9319 or by email at *cpmc@loc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Library of Congress will reauthorize and form a public committee on Copyright Office information technology (IT) modernization. The committee will be managed by the Office of the Chief Information Officer (OCIO), with support from the U.S. Copyright Office and from other Library offices as necessary. The goal of the committee will be to expand and enhance communication with external stakeholders on IT modernization of Copyright Office systems and to provide an ongoing public forum for sharing information and answering questions related to this initiative. The scope of contributions made by the committee are limited to the specific topics set forth in this notice.

II. Public Stakeholder Committee Subjects of Discussion

Members of the Copyright Public Modernization Committee will provide feedback to the Library on the technology-related aspects of the Copyright Office's modernization initiative, including both Copyright Office IT systems and broader Library IT systems that interface with and/or support Copyright Office operations.

III. Public Stakeholder Committee Application Process

Members of the public who seek to participate in the Copyright Public Modernization Committee should submit a current curriculum vitae and a statement of interest of no more than 1000 words addressing the questions identified below no later than June 18, 2024. Members who served on the previous Committee are eligible to reapply for membership but must submit a new application. Applications can be submitted via email at *cpmc@loc.gov*. If you are unable to access a computer or the internet, please contact the Library using the contact information above for special instructions. Individuals selected for participation will be notified directly by the Library not later than September 6, 2024. In order to accommodate the expected level of interest, the Library expects to assign no more than one representative per organization to the committee.

The public stakeholder committee will have a limited number of seats, and the application and selection process are expected to be competitive. The Library will seek to select a membership that is representative of the broad and diverse Copyright Office stakeholder community. The areas of relevant expertise for membership include skill in communicating on complex technical issues; the ability to work collaboratively; and familiarity with technology relevant to Copyright Office services.

IV. Questions for Statement of Interest

For the Statement of Interest, the applicant need not address every subject identified below, but the Library requests that applicants clearly identify and separately address each numbered subject for which a response is submitted. Answers will be evaluated by the Library to select a committee with members that represent the broadest possible cross-section of Copyright Office stakeholders.

1. An important skill for members of the CPMC is the ability to communicate, whether orally or in writing, on complex technological issues, including describing their impact on the needs or interests of Copyright Office stakeholders. Please identify any relevant experience you have working and communicating on technological issues with these or any other relevant parties:

(a) Individual creators and copyright owners;

(b) Large corporate creators and companies that own or manage copyrights;

(c) Small-to-medium size enterprises that own or manage copyrights;

(d) Creators, copyright owners, or copyright users from the following sectors: photography, motion picture, musical works, sound recordings, graphic arts, publishing, software, and information technology;

(e) users of Copyright Office services, including but not limited to individuals or entities that register their works with the Office, record copyright-related documents with the Office, or benefit from or pay into the licensing systems administered by the Copyright Office;

(f) user interest groups, including researchers, universities, archives, and libraries; and

(g) representatives of the public and public interest groups (including organizations involved in issues related to open government, public government data and APIs, and government use of technology).

2. Another important skill for members of the CPMC is the ability to work collaboratively with others, including diverse stakeholders. Please describe any relevant past experience developing and maintaining relationships with a variety of individuals; communicating effectively about topics involving inter-dependencies, competing priorities, and diverse audiences/user groups; or reaching a consensus among diverse stakeholders with conflicting interests.

3. A key skill that the Library is seeking in members of the CPMC is familiarity with the technology relevant to the Copyright Office and the Office's recent IT initiatives. Please describe any relevant experience in the following sectors: government innovation and/or technology, copyright law and Copyright Office services, rights management, and the development and use of IT systems in library, cultural heritage, museum, creative industry or other settings.

4. Please describe your knowledge of user-centered strategies and design methods, including any experience applying iterative design principles to solving complex problems.

5. If your application is endorsed by other stakeholders or associations, please identify them.

Dated: May 7, 2024.

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2024–10243 Filed 5–9–24; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Grantee Reporting Requirements for the Engineering Research Centers

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission may be obtained by calling 703–292–7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Title of Collection: Grantee Reporting Requirements for the Engineering Research Centers.

OMB Number: 3145–0220.

Type of Request: Extension without revision of an information collection.

Type of Request: Intent to seek approval to renew an information collection.

Abstract: The Engineering Research Centers (ERC) program supports an integrated, interdisciplinary research environment to advance fundamental engineering knowledge and engineered systems; educate a globally competitive and diverse engineering workforce from K–12 on; and join academe and industry in partnership to achieve these goals. ERCs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. New knowledge thus created is meaningfully linked to society.

ERCs conduct world-class research with an engineered systems perspective that integrates materials, devices, processes, components, control algorithms and/or other enabling elements to perform a well-defined function. These systems provide a unique academic research and education experience that involves integrative complexity and technological realization. The complexity of the systems perspective includes the factors associated with its use in industry, society/environment, or the human body.

ERCs enable and foster excellent education, integrate research and education, speed knowledge/technology transfer through partnerships between academe and industry, and prepare a more competitive future workforce. ERCs capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

Centers are required to submit annual reports on progress and plans, which will be used as a basis for performance review and determining the level of continued funding. To support this review and the management of a Center, ERCs also are required to submit management and performance indicators annually to NSF via a data collection website that is managed by a technical assistance contractor. These indicators are both quantitative and descriptive and may include, for example, the characteristics of center personnel and students; sources of cash and in-kind support; expenditures by operational component; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students involved in Center activities; descriptions of significant advances and other outcomes of the ERC effort. Such reporting requirements will be included in the cooperative agreement which is binding between the academic institution and the NSF.

Each Center's annual report will address the following categories of activities: (1) vision and impact, (2) strategic plan, (3) research program, (4) innovation ecosystem and industrial collaboration, (5) education, (6) infrastructure (leadership, management, facilities, diversity) and (7) budget issues.

For each of the categories the report will describe overall objectives for the year, progress toward center goals, problems the Center has encountered in making progress towards goals and how they were overcome, plans for the future and anticipated research and other barriers to overcome in the following year, and specific outputs and outcomes.

Use of the Information: The data collected will be used for NSF internal reports, historical data, performance review by peer site visit teams, program level studies and evaluations, and for securing future funding for continued ERC program maintenance and growth.

Estimate of Burden: 150 hours per center for 17 centers for a total of 2550 hours.

Respondents: Academic institutions.

Estimated Number of Responses per Report: One from each of the 17 ERCs.

Dated: May 7, 2024.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–10268 Filed 5–9–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

716th Meeting of the Advisory Committee on Reactor Safeguards (ACRS)

In accordance with the purposes of sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232(b)), the Advisory Committee on Reactor Safeguards (ACRS) will hold meetings on June 5–7, 2024. The Committee will be conducting meetings that will include some Members being physically present at the NRC while other Members

participate remotely. Interested members of the public are encouraged to participate remotely in any open sessions via MS Teams or via phone at 301–576–2978, passcode 893169154#. A more detailed agenda including the MSTeams link may be found at the ACRS public website at *https://www.nrc.gov/reading-rm/doc-collections/acrs/agenda/index.html.* If you would like the MSTeams link forwarded to you, please contact the Designated Federal Officer as follows: *Quynh.Nguyen@nrc.gov,* or *Lawrence.Burkhart@nrc.gov*

Wednesday, June 5, 2024

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chair (Open)—The ACRS Chair will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–11:30 a.m.: Terrapower Natrium Topical Reports on Principal Design Criteria and Fuel and Control Assembly Qualification Plan/Commission Meeting Preparations (Open/Closed)—The Committee will have presentations and discussion with the licensee representatives and NRC staff regarding the subject topic.

[*Note:* Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

11:30 a.m.–2:00 p.m.: Committee Deliberation on Terrapower Natrium Topical Reports on Principal Design Criteria and Fuel and Control Assembly Qualification Plan/Commission Meeting Preparations (Open/Closed)—The Committee will deliberate with the NRC staff regarding the subject topic.

[*Note:* Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

2:00 p.m.–6:00 p.m.: Preparation of Reports/Commission Meeting Preparations (Open/Closed)—The Committee will proceed to preparation of reports and preparation of Commission Meeting.

[*Note:* Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Thursday, June 6, 2024

8:30 a.m.–6:00 p.m.: Planning and Procedures Session/Future ACRS Activities/Reconciliation of ACRS Comments and Recommendations/Preparation of Reports/Commission Meeting Preparations (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings, and/or proceed to preparation of reports and preparation of Commission Meeting as determined by the Chair.

[*Note:* Pursuant to 5 U.S.C. 552b(c)(2), a portion of this meeting may be closed to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS.]

[*Note*: Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Friday, June 7, 2024

1:00 p.m.–6:00 p.m.: Committee Deliberation/Preparation of Reports (Open/Closed)—The Committee will deliberate with the NRC staff regarding the subject topic and proceed to preparation of reports.

[*Note:* Pursuant to 5 U.S.C. 552b(c)(4), a portion of this session may be closed in order to discuss and protect information designated as proprietary.]

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on June 13, 2019 (84 FR 27662). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff and the DFO (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), 5 days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chair as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the cognizant ACRS staff if such rescheduling would result in major inconvenience.

An electronic copy of each presentation should be emailed to the cognizant ACRS staff at least one day before the meeting.

In accordance with subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chair. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room (PDR) at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System component of NRC's Agencywide Documents Access and Management System, which is accessible from the NRC website at *https://www.nrc.gov/reading-rm/adams.html* or *https://www.nrc.gov/reading-rm/doc-collections/#ACRS/.*

Dated: May 6, 2024.

Russell E. Chazell,

Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2024–10180 Filed 5–9–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of May 13, 20, 27, and June 3, 10, 17, 2024. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public and closed.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of May 13, 2024

Thursday, May 16, 2024

10:00 a.m. Executive Branch Briefing on NRC International Activities (Closed Ex. 1 & 9)

Week of May 20, 2024—Tentative

There are no meetings scheduled for the week of May 20, 2024.

Week of May 27, 2024—Tentative

There are no meetings scheduled for the week of May 27, 2024.

Week of June 3, 2024—Tentative

Tuesday, June 4, 2024

10:00 a.m. Briefing on Human Capital and Equal Employment Opportunity (Public Meeting) (Contact: Angie Randall: 301–415–6806)

Additional Information: The meeting will be held in the Commissioners' Hearing Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Friday, June 7, 2024

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public Meeting) (Contact: Robert Krsek: 301–415–1766)

Additional Information: The meeting will be held in the Commissioners' Hearing Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of June 10, 2024—Tentative

There are no meetings scheduled for the week of June 10, 2024.

Week of June 17, 2024—Tentative

There are no meetings scheduled for the week of June 17, 2024.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: May 8, 2024.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2024–10424 Filed 5–8–24; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–272 and CP2024–278; MC2024–273 and CP2024–279; MC2024–274 and CP2024–280; MC2024–275 and CP2024–281; MC2024–276 and CP2024–282]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 14, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–272 and CP2024–278; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 245 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* May 14, 2024.

2. *Docket No(s).:* MC2024–273 and CP2024–279; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 64 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Cristopher C. Mohr; *Comments Due:* May 14, 2024.

3. *Docket No(s).:* MC2024–274 and CP2024–280; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 246 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 14, 2024.

4. *Docket No(s).:* MC2024–275 and CP2024–281; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 247 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 6, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 14, 2024.

5. *Docket No(s).:* MC2024–276 and CP2024–282; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 65 to Competitive Product List and Notice of Filing Materials Under

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Seal; *Filing Acceptance Date:* May 6, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* May 14, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–10259 Filed 5–9–24; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100065; File No. SR–CboeBZX–2023–087]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of the Invesco Galaxy Ethereum ETF Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

May 6, 2024.

On October 20, 2023, Cboe BZX Exchange, Inc. (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Invesco Galaxy Ethereum ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on November 8, 2023.[3]

On December 13, 2023, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On February 6, 2024, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7]

Section 19(b)(2) of the Act [8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on November 8, 2023.[9] The 180th day after publication of the proposed rule change is May 6, 2024. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates July 5, 2024, as the date by which the

Commission shall either approve or disapprove the proposed rule change (File No. SR–CboeBZX–2023–087).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–10191 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–151, OMB Control No. 3235–0291]

Submission for OMB Review; Comment Request; Extension: Rules 17Ad–6 and 17Ad–7

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad–6 (17 CFR 240.17Ad–6) and Rule 17Ad–7 (17 CFR 240.17Ad–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'').

Rule 17Ad–6 under the Exchange Act requires every registered transfer agent to make and keep current records about a variety of information, such as: (1) specific operational data regarding the time taken to perform transfer agent activities (to ensure compliance with the minimum performance standards in Rule 17Ad–2 (17 CFR 240.17Ad–2)); (2) written inquiries and requests by shareholders and broker-dealers and response time thereto; (3) resolutions, contracts, or other supporting documents concerning the appointment or termination of the transfer agent; (4) stop orders or notices of adverse claims to the securities; and (5) all canceled registered securities certificates.

Rule 17Ad–7 under the Exchange Act requires each registered transfer agent to retain the records specified in Rule 17Ad–6 in an easily accessible place for a period of six months to six years, depending on the type of record or document. Rule 17Ad–7 also specifies the manner in which records may be maintained using electronic, microfilm, and microfiche storage methods.

These recordkeeping requirements are designed to ensure that all registered transfer agents are maintaining the records necessary for transfer agents to monitor and keep control over their own performance and for the Commission to adequately examine registered transfer agents on an historical basis for compliance with applicable rules.

The Commission estimates that approximately 315 registered transfer agents will spend a total of 157,500 hours per year complying with Rules 17Ad–6 and 17Ad–7 (500 hours per year per transfer agent).

The retention period under Rule 17Ad–7 for the recordkeeping requirements under Rule 17Ad–6 is six months to six years, depending on the particular record or document. The recordkeeping and retention requirements under Rules 17Ad–6 and 17Ad–7 are mandatory to assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rules.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 98846 (Nov. 2, 2023), 88 FR 77116. Comments on the proposed rule change are available at: *https://www.sec.gov/comments/sr-cboebzx-2023-087/srcboebzx2023087.htm*.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 99151, 88 FR 87822 (Dec. 19, 2023).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 99479, 89 FR 9880 (Feb. 12, 2024).

[8] 15 U.S.C. 78s(b)(2).

[9] *See supra* note 3 and accompanying text.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

These rules do not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by June 10, 2024 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov*.

Dated: May 6, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–10206 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100062; File No. SR–CboeBYX–2024–013]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Introduce a New Connectivity Offering Through Dedicated Cores

May 6, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 24, 2024, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') proposes to introduce a new connectivity offering.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/byx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to introduce a new connectivity offering relating to the use of Dedicated Cores. By way of background, all Central Processing Units (''CPU Cores'') have historically been shared by logical order entry ports (*i.e.,* multiple logical ports from multiple firms may connect to a single CPU Core). Starting May 6, 2024, the Exchange will allow Users[5] to assign a single Binary Order Entry (''BOE'') logical order entry port[6] to a single dedicated CPU Core (''Dedicated Core'').[7] Use of Dedicated Cores can provide reduced latency, enhanced throughput, and improved performance since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core instead of sharing that power with other firms. This offering is completely voluntary and will be available to all Users.[8] Users will also continue to have the option to utilize BOE logical order entry ports on shared CPU Cores as they do today, either in lieu of, or in addition to, their use of Dedicated Core(s). As such, Users will be able to operate across a mix of shared and dedicated CPU Cores which the Exchange believes provides additional risk and capacity management, especially during times of market volatility and high message traffic. Further, Dedicated Cores are not required nor necessary to participate on the Exchange and as such Users may opt not to use Dedicated Cores at all.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposal would provide Users the option to assign a single BOE logical entry port to a single Dedicated Core. As described above, CPU Cores have historically been shared by logical order entry ports (*i.e.,* multiple logical ports from multiple

[5] A User may be either a Member or Sponsored Participant. The term ''Member'' shall mean any registered broker or dealer that has been admitted to membership in the Exchange. limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange. A Sponsored Participant may be a Member or non-Member of the Exchange whose direct electronic access to the Exchange is authorized by a Sponsoring Member subject to certain conditions. See Exchange Rule 11.3.

[6] Users may currently connect to the Exchange using a logical port available through an application programming interface (''API''), such as the Binary Order Entry (''BOE'') protocol. A BOE logical order entry port is used for order entry.

[7] The Exchange notes that firms will not have physical access to their Dedicated Core and thus cannot make any modifications to the Dedicated Core or server. All Dedicated Cores (including servers used for this service) are owned and operated by the Exchange.

[8] The Exchange intends to submit a separate rule filing to adopt monthly fees related to the use of Dedicated Cores.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

firms may connect to a single CPU Core). Use of Dedicated Cores can provide reduced latency, enhanced throughput, and improved performance since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core instead of sharing that power with other firms. The Exchange also emphasizes that the use of Dedicated Cores is not necessary for trading and as noted above, is entirely optional. Indeed, Users can continue to access the Exchange through shared CPU Cores at no additional cost. Depending on a firm's specific business needs, the proposal enables Users to choose to use Dedicated Cores in lieu of, or in addition to, shared CPU Cores (or as noted, not use Dedicated Cores at all). The Exchange believes the proposal to operate across a mix of shared and dedicated CPU Cores may further provide additional risk and capacity management. The Exchange also notes that its affiliated exchange, Cboe EDGA Exchange, Inc, recently introduced Dedicated Cores and that another Exchange [sic] also provides a similar connectivity offering.[12]

Furthermore, this service is optional and is available to all Users. In this regard, some Users may determine it does not want or need Dedicated Cores and may continue their use of the shared CPU Cores, unchanged. The Exchange has no current plans to eliminate shared Cores nor require subscription to the dedicated offering.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the Exchange believes the proposed rule change does not impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act because Dedicated Cores will be available to all Users. While the Exchange believes that the proposed Dedicated Cores provide a valuable service, Users can choose to purchase, or not purchase, Dedicated Cores based on their own determination of the value and their business needs. Indeed, no User is required or under any regulatory obligation to use Dedicated Cores.

Additionally, nothing in the proposal imposes any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which exchanges offer various connectivity services as a means to facilitate the trading and other market activities of those market participants and at least one other exchange has an offering comparable to Dedicated Cores.[13]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that its affiliated exchange, Cboe EDGA Exchange, Inc., recently introduced Dedicated Cores and another exchange has a connectivity offering comparable to Dedicated Cores.[18] The Commission believes that the proposed rule change presents no novel legal or regulatory issues, and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeBYX–2024–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBYX–2024–013. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[12] *See* Securities Exchange Act Release No. 99818 (March 21, 2024), 89 FR 21294 (March 27, 2024) (SR–CboeEDGA–2024–008). *See also* The Nasdaq Stock Market, Equity 7 Pricing Schedule, Section 115(g)(3), Dedicated Ouch Port Infrastructure.

[13] *See* Securities Exchange Act Release No. 99818 (March 21, 2024), 89 FR 21294 (March 27, 2024) (SR–CboeEDGA–2024–008). *See also* The Nasdaq Stock Market, Equity 7 Pricing Schedule, Section 115(g)(3), Dedicated Ouch Port Infrastructure.

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] *See supra* note 12.

[19] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78s(b)(2)(B).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–013 and should be submitted on or before May 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–10190 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–770, OMB Control No. 3235–0750]

Submission for OMB Review; Comment Request; Extension: Rule 18a–8

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Exchange Act Rule 18a–8 (17 CFR 240.18a–8) specifies the circumstances under which stand-alone security-based swap dealers (''SBSDs''), stand-alone major security-based swap participants (''MSBSPs''), bank SBSDs, and bank MSBSPs must notify the Commission about their financial or operational condition, as well as the form that the notice must take.

The Commission estimates that the total hour burden under Rule 18a–8 is approximately 5 burden hours per year, and the total cost burden is approximately $0 per year. There has been no change in the estimated total hour and cost burdens since the last approval of this information collection.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by June 10, 2024 to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: May 6, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–10205 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–446, OMB Control No. 3235–0503]

Proposed Collection; Comment Request; Extension: Form N–6

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

The title for the collection of information is ''Form N–6 (17 CFR 239.17c and 274.11d) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) and under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) registration statement of separate accounts organized as unit investment trusts that offer variable life insurance policies.'' Form N–6 is the form used by insurance company separate accounts organized as unit investment trusts that offer variable life insurance contracts to register as investment companies under the Investment Company Act of 1940 and/or to register their securities under the Securities Act of 1933. The primary purpose of the registration process is to provide disclosure of financial and other information to investors and potential investors for the purpose of evaluating an investment in a security. Form N–6 also requires separate accounts organized as unit investment trusts that offer variable life insurance policies to provide investors with a prospectus and a statement of additional information (''SAI'') covering essential information about the separate account when it makes an initial or additional offering of its securities.

The Commission estimates that approximately 448 registration statements (20 initial registration statements plus 428 post-effective amendments) are filed on Form N–6 annually. The estimated hour burden per portfolio for preparing and filing an initial registration statement on Form N–6 is 772.25 hours. The estimated annual hour burden for preparing and filing initial registration statements is 15,445 hours (20 initial registration statements annually times 772.25 hours per registration statement). The Commission estimates that the hour burden for preparing and filing a post-effective amendment on Form N–6 is 154.25 hours. The total annual hour burden for preparing and filing post-effective amendments is 66,019 hours (428 post-effective amendments annually times 154.25 hours per amendment). The frequency of response is annual. The total annual hour burden for Form N–6, therefore, is estimated to be 81,464 hours (15,445 hours for initial registration statements plus 66,019 hours for post-effective amendments).

The Commission estimates that the cost burden for preparing an initial Form N–6 filing is $40,000 per filing and the current cost burden for preparing a post-effective amendment to a previously effective registration statement is $20,000 per filing. Thus, the total cost burden allocated to Form N–6 would be $9,360,000 (20 initial filings times $40,000 and 428 post-effective amendment filings times $20,000).

The information collection requirements imposed by Form N–6 are mandatory. Responses to the collection of information will not be kept

[21] 17 CFR 200.30–3(a)(12), (59).

confidential. Estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by July 9, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov*.

Dated: May 7, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10252 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100067; File No. SR–FINRA–2024–006]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 1240.01 To Reopen the Period by Which Certain Participants in the Maintaining Qualifications Program May Complete Their Prescribed Continuing Education Content

May 6, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 30, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 1240.01 (Eligibility of Other Persons to Participate in the Continuing Education Program Specified in Paragraph (c) of this Rule) to reopen the period by which certain participants in the Maintaining Qualifications Program (''MQP'') will be able to complete their prescribed 2022 and 2023 continuing education (''CE'') content.

Below is the text of the proposed rule change. Proposed new language is italicized; proposed deletions are in brackets.

* * * * *

1200. REGISTRATION AND QUALIFICATION

* * * * *

1240. Continuing Education

This Rule prescribes requirements regarding the continuing education of registered persons. The requirements shall consist of a Regulatory Element and a Firm Element as set forth below. This Rule also sets forth continuing education programs through which specified persons may maintain their qualification in a representative or principal registration category following the termination of that registration category.

(a) through (c) No Change.

• • • Supplementary Material:————

.01 Eligibility of Other Persons to Participate in the Continuing Education Program Specified in Paragraph (c) of this Rule. A person registered in a representative or principal registration category with FINRA within two years immediately preceding March 15, 2022 shall be eligible to participate in the continuing education program under paragraph (c) of this Rule, provided that he or she satisfies the conditions set forth in paragraphs (c)(1) and (c)(3) through (c)(6) of this Rule. In addition, a person participating in the Financial Services Affiliate Waiver Program under Rule 1210.09 immediately preceding March 15, 2022 shall be eligible to participate in the continuing education program under paragraph (c) of this Rule, provided that he or she satisfies the conditions set forth in paragraphs (c)(3), (c)(5) and (c)(6) of this Rule. Persons eligible under this Supplementary Material .01 shall make their election to participate in the continuing education program under paragraph (c) of this Rule either (1) between January 31, 2022, and March 15, 2022; or (2) between March 15, 2023, and December 31, 2023. If such persons elect to participate in the continuing education program, their participation period shall also be for a period of five years following the termination of their registration categories, as with other participants under paragraph (c) of this Rule. [In addition, eligible persons who elect to participate in the continuing education program between March 15, 2023, and December 31, 2023, must complete any prescribed 2022 and 2023 continuing education content by March 31, 2024.] *Individuals enrolled in the continuing education program under this Supplementary Material .01 in both 2022 and 2023 who did not complete their prescribed 2022 and 2023 continuing education content as of March 31, 2024, shall be able to complete such content between May 22, 2024, and July 1, 2024, to be eligible to continue their participation in the continuing education program. In addition, any such individuals who will have completed their prescribed 2022 and 2023 continuing education content between March 31, 2024, and May 22, 2024, shall be deemed to have completed such content by July 1, 2024, for purposes of this Supplementary Material .01.*

.02 No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Rule 1240.01 extended the option to participate in the MQP to individuals who: (1) were registered as a representative or principal within two years immediately prior to March 15, 2022 (the implementation date of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

MQP); and (2) individuals who were participating in the Financial Services Affiliate Waiver Program (''FSAWP'') under FINRA Rule 1210.09 (Waiver of Examinations for Individuals Working for a Financial Services Industry Affiliate of a Member) immediately prior to March 15, 2022 (collectively, ''Look-Back Individuals'').[4] The rule provided two open enrollment periods for Look-Back Individuals to participate in the MQP.[5] FINRA provided all Look-Back Individuals who had enrolled in the MQP until March 31, 2024, to complete any prescribed 2022 and 2023 CE content.[6] Look-Back Individuals who are enrolled in the MQP, similar to other MQP participants, are able to complete any prescribed CE and renew their annual MQP participation through their FINRA Financial Professional Gateway (''FinPro'') accounts.

On March 16, 2024, FINRA sent an email to Look-Back Individuals who had enrolled in the MQP but had not completed their prescribed CE to remind them of the March 31, 2024, deadline.[7] In the week leading up to the deadline, however, FINRA noticed that several thousand of those individuals were renewing their participation in the MQP for 2024 instead of completing their prescribed CE.[8] FINRA believes that some of those individuals may have been confused by the layout of their FinPro accounts. Specifically, if they selected the 2024 renewal banner, which was prominently displayed on their FinPro accounts, and completed the renewal process, they would not have been automatically redirected to complete any prescribed CE. Therefore, individuals may have inadvertently assumed that completion of the renewal process alone would have satisfied all of the necessary requirements to continue their participation in the MQP.[9]

For these reasons, FINRA is proposing to amend Rule 1240.01 to provide Look-Back Individuals enrolled in the MQP in both 2022 and 2023 who did not complete their prescribed 2022 and 2023 CE content as of March 31, 2024, the opportunity to complete such content between May 22, 2024, and July 1, 2024, to be eligible to continue their participation in the MQP.[10] FINRA is also proposing to amend the rule to provide that any such individuals who will have completed their prescribed 2022 and 2023 CE content between March 31, 2024, and May 22, 2024, will be deemed to have completed such content by July 1, 2024, for purposes of the rule. FINRA plans to reach out to all impacted individuals and inform them of the new CE completion period. FINRA has made changes, and is also considering future changes, to the layout of FinPro to more effectively communicate the necessary steps that individuals must take to satisfy their MQP obligations.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing. The operative date will be the date of filing of the proposed rule change, if the SEC grants the waiver.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[11] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that reopening the period by which Look-Back Individuals will be able to complete their prescribed 2022 and 2023 CE content is appropriate under the circumstances. FINRA believes that Look-Back Individuals who had enrolled in the MQP in 2022 and 2023 but had not completed their prescribed 2022 and 2023 CE content by the March 31, 2024, deadline may have been confused, as described above. FINRA continues to believe that participation in the MQP reduces unnecessary impediments to requalification without diminishing investor protection.[12] In addition, the MQP promotes other goals, such as diversity and inclusion in the securities industry by attracting and retaining a broader and diverse group of professionals. The MQP also allows the industry to retain expertise from skilled individuals, providing investors with the advantage of greater experience among the individuals working in the industry. FINRA believes that reopening the CE completion period, as proposed, will further these goals and objectives.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Further, FINRA provided an extensive economic impact assessment relating to the MQP as part of the rule filing that proposed the adoption of the MQP.[13]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time

[4] The FSAWP is a waiver program for eligible individuals who have left a member firm to work for a foreign or domestic financial services affiliate of a member firm. FINRA stopped accepting new participants for the FSAWP beginning on March 15, 2022; however, individuals who were already participating in the FSAWP prior to that date had the option of continuing in the FSAWP.

[5] In March 2023, FINRA amended Rule 1240.01 to provide Look-Back Individuals with a second opportunity to participate in the MQP. *See* Securities Exchange Act Release No. 97184 (March 22, 2023), 88 FR 18359 (March 28, 2023) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2023–005).

[6] FINRA determined to treat the individuals who enrolled during the first period (between January 31, 2022, and March 15, 2022) the same as those who enrolled during the second period (between March 15, 2023, and December 31, 2023) for purposes of the March 31, 2024, deadline for completion of prescribed 2022 and 2023 CE content. This is because those who had enrolled in the MQP during the first period satisfied all of the eligibility criteria for enrollment during the second period and would have been able to complete their prescribed CE content by March 31, 2024, had they chosen to enroll during the second period instead of enrolling during the first period.

[7] FINRA had sent multiple reminders prior to March 16, 2024, but the March 16, 2024, email was the last reminder that was sent prior to the March 31, 2024, deadline for completion of any prescribed 2022 and 2023 CE content.

[8] Look-Back Individuals who enrolled in the MQP have until December 31, 2024, to renew their participation in the MQP for 2024, provided that they complete their prescribed CE by the stated deadline.

[9] A number of these individuals contacted FINRA to confirm whether they were required to satisfy any additional requirements other than completing the 2024 renewal. To provide FINRA with additional time to assess the situation, FINRA temporarily changed the March 31, 2024, due date for CE completion in its systems. This may have compounded the confusion because any Look-Back Individual who may have logged into their FinPro account during this time would have seen an interim CE completion date and would have been able to complete their prescribed CE content based on that interim CE completion date.

[10] This would include any Look-Back Individuals who were still in the process of completing their prescribed CE content as of March 31, 2024.

[11] 15 U.S.C. 78*o*–3(b)(6).

[12] As of April 15, 2024, approximately 31,000 individuals, including approximately 20,000 Look-Back Individuals, have enrolled in the MQP, of which approximately 1,400 individuals have used the MQP to return to the industry without having to go through requalification.

[13] *See* Securities Exchange Act Release No. 92183 (June 15, 2021), 86 FR 33427 (June 24, 2021) (Notice of Filing of File No. SR–FINRA–2021–015).

as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b-4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. As outlined above, FINRA states that it plans to reach out to all impacted individuals and inform them of the new CE completion period established by this rule change. FINRA has indicated that the immediate operation of the proposed rule change is appropriate so that FINRA can communicate the rule change to impacted individuals promptly. FINRA also believes that immediate operation of the proposed rule change is appropriate because it would provide clarity to impacted individuals without unnecessary delay. For these reasons, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2024–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2024–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–FINRA–2024–006 and should be submitted on or before May 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–10196 Filed 5–9–24; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. FINRA has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission Investor Advisory Committee will hold a public meeting on Thursday, June 6, 2024. The meeting will begin at 10:00 a.m. (ET) and will be open to the public.

PLACE: The meeting will be conducted by remote means. Members of the public may watch the webcast of the meeting on the Commission's website at *www.sec.gov.*

STATUS: This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

PUBLIC COMMENT: The public is invited to submit written statements to the Committee. Written statements should be received on or before June 5, 2024.

Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's internet submission form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email message to *rules-comments@sec.gov.* Please include File No. 265–28 on the subject line; or

Paper Statements

- Send paper statements to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. 265–28. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method.

The Commission will post all statements on the Commission's website. Statements also will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Room 1503, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Operating conditions may limit access to the

Commission's Public Reference Room. Do not include personal information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright.

MATTERS TO BE CONSIDERED: The agenda for the meeting includes: welcome and opening remarks; approval of previous meeting minutes; a panel discussion examining the new frontier for investment advice; a panel discussion regarding AI regulation: embracing the future; a discussion of a recommendation regarding the protection of self-directed investors when trading complex products and utilizing complex strategies; a discussion of a recommendation on financial literacy and investor education; subcommittee and working group reports; and a non-public administrative session.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: May 8, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–10355 Filed 5–8–24; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20303 and #20304; OKLAHOMA Disaster Number OK–20001]

Presidential Declaration Amendment of a Major Disaster for the State of Oklahoma

AGENCY: Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4776–DR), dated 04/30/2024.

Incident: Severe Storms, Straight-line Winds, Tornadoes, and Flooding.

Incident Period: 04/25/2024 and continuing.

DATES: Issued on 05/03/2024.

Physical Loan Application Deadline Date: 07/01/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 01/30/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the State of Oklahoma, dated 04/30/2024, is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Carter.

Contiguous Counties (Economic Injury Loans Only):

Oklahoma: Stephens

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Francisco Sánchez, Jr.,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–10258 Filed 5–9–24; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2024–0009]

Maximum Dollar Limit in the Fee Agreement Process

AGENCY: Social Security Administration.

ACTION: Notice.

SUMMARY: We are increasing the maximum dollar amount limit for fee agreements approved under the Social Security Act (the Act) to $9,200. Effective November 30, 2024, we may approve fee agreements up to the new dollar limit, provided that the fee agreement otherwise meets the statutory conditions of the agreement process.

DATES: We will apply this notice beginning on November 30, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Quatroche, Office of Vocational, Evaluation, and Process Policy in the Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–4794.

For information on eligibility or filing for benefits, call the Social Security Administration's (SSA) national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit SSA's internet site, Social Security Online at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: The Act provides a streamlined process for a representative to obtain approval of the fee the representative wishes to charge for representing a claimant before us.[1] To use that fee agreement process, the representative(s) and the claimant must agree, in a signed writing, to a fee that does not exceed the limit set by the statute, which is the lesser of 25 percent of past due benefits or a prescribed dollar amount. Section 5106 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, Public Law 101–508, set the initial fee amount at $4,000 and gave the Commissioner the authority to increase it periodically, provided that the cumulative rate of increase did not at any time exceed the rate of increase in the primary insurance amount (PIA) since January 1, 1991. The law further provided that notice of any increased amount shall be published in the **Federal Register**. On June 30, 2022, we published a notice raising the maximum fee to $7,200, effective November 30, 2022, which is the current maximum dollar amount for fee agreements.[2]

With this notice, we announce that the maximum dollar amount under the fee agreement process, will increase to $9,200, effective November 30, 2024. This increase does not exceed the rate of increase provided in the OBRA of 1990. We expect that this increase will compensate representatives for their services while ensuring claimants are protected from excessive fees. In setting the new cap, we considered a number of factors, including: data about fees authorized under the current fee cap, data about case backlogs, COLA, PIAs, feedback we received about the current fee cap, increases in disability benefits, and the effects on our claimants.

Beginning November 30, 2024, decision makers may approve a fee agreement up to the new dollar limit if the fee agreement meets the statutory conditions for approval, no exceptions to the fee agreement process exist, and the favorable determination or decision is issued on or after this date. We are setting this date to ensure that there is adequate time to provide training and guidance to our employees and to make the necessary changes in our information technology infrastructure.

Starting in January 2026, along with our announcements of other cost of living adjustments (COLA) (*e.g.,* for title II benefits, title XVI payments, or the appointed representative fee assessment), we will annually address the maximum dollar amount for fee agreements and provide a rationale for either increasing or not increasing the maximum dollar amount based upon the annual COLA for the prior year. Future increases will not exceed the rate of increase provided in the OBRA of 1990. We expect that future increases will compensate representatives for

[1] 42 U.S.C. 406(a) and 1383(d)(2)(A).

[2] 87 FR 39157 (2022).

their services while ensuring claimants are protected from excessive fees.

The Commissioner of the Social Security Administration, Martin O'Malley, having reviewed and approved this document, is delegating the authority to electronically sign this document to Jennifer L. Dulski, who is a Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Jennifer L. Dulski,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

[FR Doc. 2024–10248 Filed 5–9–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 12405]

Notice of Public Meeting in Preparation for International Maritime Organization NCSR 11th Meeting

The Department of State will conduct a public meeting at 11:00 a.m. on Wednesday, May 29, 2024, both in-person at Coast Guard Headquarters in Washington, DC, and via teleconference. The primary purpose of the meeting is to prepare for the 11th session of the International Maritime Organization's (IMO) Sub-Committee on Navigation, Communication and Search and Rescue (NCSR 11) to be held in London, United Kingdom from Tuesday, June 4, 2024 to Thursday, June 13, 2024.

Members of the public may participate up to the capacity of the teleconference line, which will handle 500 participants, or up to the seating capacity of the room if attending in-person. The meeting location will be the United States Coast Guard Headquarters, and the teleconference line will be provided to those who RSVP. To RSVP, participants should contact the meeting coordinator, Mr. John Stone, by email at *John.M.Stone@uscg.mil.* Mr. Stone will provide access information for in-person and virtual attendance.

The agenda items to be considered include:

—Adoption of the agenda
—Decisions of other IMO bodies
—Routing measures and mandatory ship reporting systems
—Updates to the LRIT system
—Developments in GMDSS services, including guidelines on maritime safety information (MSI)
—Response to matters related to the ITU–R Study Groups and ITU World Radiocommunication Conference
—Development of global maritime SAR services, including harmonization of maritime and aeronautical procedures and amendments to the IAMSAR Manual
—Development of performance standards for a digital navigational data system (NAVDAT)
—Development of amendments to SOLAS chapters IV and V and performance standards and guidelines to introduce VHF Data Exchange System (VDES)
—Review of the appropriateness and effectiveness of SOLAS regulation IV/5 (Provision of radiocommunication services)
—Revision of the Criteria for the provision of mobile satellite communication services in the Global Maritime Distress and Safety System (GMDSS) (Resolution A. 1001(25))
—Development of guidelines for the use of electronic nautical publications (ENP)
—Revision of SOLAS regulation V/23 and associated instruments to improve the safety of pilot transfer arrangements
—Identification of measures to improve the security and integrity aspects of AIS
—Unified interpretation of provision of IMO safety, security, environment, facilitation, liability and compensation-related conventions.
—Biennial status report and provisional agenda for NCSR 12
—Election of Chair and Vice-Chair for 2025
—Any other business
—Report to the Maritime Safety Committee

Please note: The IMO may, on short notice, adjust the NCSR 11 agenda to accommodate any constraints associated with the meeting. Although no changes to the agenda are anticipated, if any are necessary, they will be provided to those who RSVP.

Those who plan to participate should contact the meeting coordinator, Mr. John Stone at *John.M.Stone@uscg.mil,* by phone at (206) 815–1335, or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7418, Washington, DC 20593–7418 not later than May 15, 2024, 14 days prior to the meeting. Requests made after May 15, 2024 might not be able to be accommodated. The meeting coordinator will provide the teleconference information, facilitate the building security process, and requests for reasonable accommodation. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's. This building is accessible by taxi, public transportation, and privately owned conveyance (upon advanced request).

Additional information regarding this and other IMO public meetings may be found at: *https://www.dco.uscg.mil/IMO.*

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552)

Leslie W. Hunt,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2024–10183 Filed 5–9–24; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 12404]

Notice of Charter Renewal for the Cultural Property Advisory Committee

SUMMARY: The Charter of the Department of State's Cultural Property Advisory Committee has been renewed for an additional two years.

FOR FURTHER INFORMATION CONTACT: Allison Davis, Cultural Heritage Center, U.S. Department of State, Bureau of Educational and Cultural Affairs, 2200 C Street NW, Washington, DC 20522. Telephone: (771) 204–4765; Email *culprop@state.gov.*

SUPPLEMENTARY INFORMATION: The Department of State has renewed the Charter of the Cultural Property Advisory Committee. The Committee was established by the Convention on Cultural Property Implementation Act of 1983, 19 U.S.C. 2601 *et seq.,* to provide recommendations regarding requests for assistance from foreign governments under the UNESCO 1970 Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property. The Presidentially appointed members include individuals representing the interests of museums; experts in the fields of archaeology, anthropology, or related areas; experts in the international sale of archaeological, ethnological, and other cultural property; and individuals who represent the interests of the general public. The renewed Charter was filed with Congress on April 4, 2024.

Allison R. Davis Lehmann,

Executive Director, Cultural Property Advisory Committee, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–10184 Filed 5–9–24; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36771]

Merrimack & Grafton Railroad Corporation—Change in Operator Exemption—in Grafton and Coos Counties, N.H., and Essex County, Vt.

Merrimack & Grafton Railroad Corporation (MGRC), a Class III rail carrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to assume operations over the following railroad lines (the Lines), totaling approximately 52 route miles, owned by the State of New Hampshire through the New Hampshire Department of Transportation (NHDOT): (1) from milepost P 131.93 at North Stratford, N.H., to milepost P 145.21 at Colebrook, N.H.; (2) from milepost C 119.86 east of Wing Road in Bethlehem, N.H., to milepost C 130.7/P 101.9 at Hazen Road in Whitefield, N.H.; (3) from milepost C 130.7/P 101.9 at Hazen Road in Whitefield to milepost P 112.46/C 137.42 at Lancaster, N.H.; (4) from milepost P 112.46/C 137.42 at Lancaster to milepost C 145.76 (proximate to the Whistle Post located south of the West Street crossing at the connection with the St. Lawrence & Atlantic Railroad Company) at Groveton, N.H.; and (5) from milepost P 100.91 at Whitefield to milepost P 111.57 at Lunenburg, Vt. The verified notice states that the Lines are currently operated by New Hampshire Central Railroad, Inc. (NHCR).

According to the verified notice, MGRC, a subsidiary of Trans Rail Holding Company, has entered into an operating agreement with NHDOT to assume common carrier operations over the Lines. Upon consummation of the proposed transaction, MGRC will replace NHCR as the exclusive common carrier operator over the Lines.

MGRC certifies that the documents governing the proposed transaction do not include terms that would limit future interchange with a third-party connecting carrier. MGRC also certifies that its projected annual revenues resulting from the transaction will not result in the creation of a Class I or II rail carrier and are not expected to exceed $5 million.

Under 49 CFR 1150.42(b), a change in operator requires that notice be given to shippers. MGRC certifies that it has provided a copy of its verified notice to all customers on the Lines.

The transaction may be consummated on or after May 26, 2024, the effective date of the exemption (30 days after the verified notice was filed). If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 17, 2024 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36771, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on MGRC's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606–3208.

According to MGRC, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: May 7, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2024–10285 Filed 5–9–24; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability, Notice of Public Comment Period, Notice of Public Meeting, and Request for Comment on the Draft Programmatic Environmental Assessment for Drone Package Delivery in North Carolina

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability; notice of public meeting; request for comments.

SUMMARY: The Federal Aviation Administration (FAA) announces the availability of the Draft Programmatic Environmental Assessment (PEA) for Drone Package Delivery in North Carolina for public review and comment.

DATES: Send comments on or before May 30, 2024. The FAA will hold a virtual public meeting on Tuesday, May 21, 2024, from 6:00–8:00 p.m. Eastern Time.

ADDRESSES: Email comments to *9-FAA-Drone-Environmental@faa.gov* or by mail to Federal Aviation Administration, Suite 802W, C/O AVS Environmental, 800 Independence Ave. SW, Washington, DC 20591. Members of the public may view the virtual meeting via Zoom at *https://us06web.zoom.us/j/84319168260.*

Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: For questions concerning this action, contact Nicholas Baker, Environmental Protection Specialist, Unmanned Aircraft Systems Integration Office, Safety & Integration Division, Strategic Programs Branch, AUS–430; telephone 1–202–267–4714; email *9-FAA-Drone-Environmental@faa.gov.*

SUPPLEMENTARY INFORMATION: The Draft PEA evaluates the potential environmental impacts of Unmanned Aircraft Systems (UAS) package delivery operations in the state of North Carolina. The proposed action analyzed in the PEA is UAS operators conducting commercial drone package deliveries under 14 Code of Federal Regulations (CFR) part 135 in North Carolina. The North Carolina Department of Transportation is the project proponent.

The Draft PEA is submitted for review pursuant to the National Environmental Policy Act (NEPA) (42 United States Code [U.S.C.] 4321 *et seq.*), the Council on Environmental Quality NEPA Implementing Regulations (40 CFR parts 1500–1508), FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* section 4(f) of the Department of Transportation Act (49 U.S.C. 303), and section 106 of the National Historic Preservation Act (16 U.S.C. 470). The draft PEA is available to view and download electronically at *https://www.faa.gov/uas/advanced_operations/nepa_and_drones/.* The Draft PEA is available from any internet access, including from computers freely available at public libraries.

Based on the analysis in the Draft PEA, including any mitigation measures that may be used to prevent significant noise impacts, the FAA has preliminarily determined there will not be significant impacts to the human environment. As a result, an Environmental Impact Statement has not been initiated. The FAA intends for this PEA to create efficiencies by establishing a framework that can be used for ''tiering,'' when appropriate, to

project-specific actions that require additional analysis. As decisions on specific applications are made, to the extent additional NEPA analysis is required, environmental review will be conducted to supplement the analysis set forth in this PEA.

Public Meeting

The FAA will provide an overview of the project and potential environmental impacts at a virtual public meeting on May 21, 2024. There will be a question-and-answer session where the public will have the opportunity to ask questions about the project after the presentation. Following the question-and-answer session, the public will have the opportunity to provide oral comments on the Draft PEA. The opportunity to provide oral comment will be given in the order that the requests are received. Comments should be limited to three minutes and must be reserved to the topic of the Draft PEA. Commenters who may need longer than three minutes are strongly encouraged to submit a written comment. The FAA will accept written comments until May 30, 2024. The FAA will not respond to oral comments during the virtual public meeting, but will review and respond to oral comments in the same fashion as written comments in preparing the Final PEA.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Comments Invited

The FAA invites interested stakeholders to submit comments on the Draft PEA, as specified in the **ADDRESSES** section of this Notice. The most helpful comments reference a specific recommendation, explain the reason for any recommended change, and include supporting information. The FAA will consider all comments received or post-marked on or before the closing date. The FAA will also consider late filed comments if it is possible to do so without incurring expense or delay.

Issued in Washington, DC, on May 7, 2024.

Derek W. Hufty,

Manager, General Aviation and Commercial Branch, Emerging Technologies Division, Office of Safety Standards, Flight Standards Service.

[FR Doc. 2024–10232 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Office of Commercial Space Transportation; Notice of Intent To Prepare an Environmental Impact Statement (EIS), Open a Public Scoping Period, and Hold Public Scoping Meetings

AGENCY: The Federal Aviation Administration (FAA), National Aeronautics and Space Administration (NASA), Fish and Wildlife Service (USFWS), National Park Service (NPS), Coast Guard (USCG), and Department of the Air Force (DAF).

ACTION: Notice of Intent to prepare an EIS, open a public scoping period, and hold public scoping meetings.

SUMMARY: This Notice provides information to Federal, State, and local agencies; Native American tribes; and other interested persons regarding the FAA's intent to prepare an EIS to evaluate the potential environmental impacts of issuing a commercial launch Vehicle Operator License to SpaceX for the Starship-Super Heavy launch vehicle at Launch Complex 39A (LC–39A) at Kennedy Space Center (KSC), Florida. SpaceX proposes to construct launch, landing, and other associated infrastructure at and in proximity to LC–39A. The proposal would also include Starship-Super Heavy launches at LC–39A; recoverable Super Heavy booster and Starship landings at LC–39A or on a droneship; and expendable Super Heavy booster and Starship landings in the ocean. The FAA will prepare the EIS in accordance with the National Environmental Policy Act of 1969, the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA, and FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* as part of its licensing process. Additional information is available online at: *https://www.faa.gov/space/stakeholder_engagement/spacex_starship_ksc.*

DATES: The FAA invites interested agencies, organizations, Native American Tribes, and members of the public to submit comments to inform the FAA on the significant issues to be analyzed in depth in the EIS (*e.g.,* range of actions, alternatives, environmental impacts). The public scoping period starts with the publication of this Notice in the **Federal Register**. To ensure sufficient time to consider issues identified during the public scoping period, comments should be submitted by one of the methods listed under **ADDRESSES** no later than June 24, 2024. All comments will receive the same attention and consideration in the preparation of the EIS.

ADDRESSES: Comments, statements, or questions concerning scoping issues must be identified with the Docket Number FAA–2024–1395 and may be provided to the FAA as follows:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Retrieve the docket by conducting a search for ''FAA–2024–1395'' and follow the online instructions for submitting comments. Please note that the FAA will post all comments on the internet without changes, including any personal information provided.
- By U.S. mail to Ms. Eva Long, FAA Environmental Protection Specialist, c/o Leidos, 2877 Guardian Lane, Virginia Beach, VA 23452.

We encourage you to submit comments electronically through the Federal E-Rulemaking Portal. If you submit your comments electronically, it is not necessary to also submit a hard copy. All comments received will be posted without change to *http://www.regulations.gov.* Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including any personal identifying information you provide—may be publicly available at any time. While you can request in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

SUPPLEMENTARY INFORMATION:

Background

When fully operational, SpaceX proposes that the Starship-Super Heavy launch vehicle will offer a heavy lift platform that expands the company's ability to execute the totality of its current and expected future customers' requirements. By providing a reusable launch vehicle, SpaceX proposes that the Starship-Super Heavy would deliver efficient access to space and enable cost-effective delivery of cargo and people to the moon and Mars. Currently, SpaceX is conducting flight tests of the Starship-Super Heavy at Starbase in Boca Chica, Texas, an exclusive use launch site that serves as SpaceX's primary research, development, and flight test launch facility for the vehicle.

In September 2019, NASA completed the *Final Environmental Assessment for the SpaceX Starship and Super Heavy Launch Vehicle at Kennedy Space Center (KSC)* (''2019 EA'') to evaluate the potential environmental impacts

resulting from construction and operations associated with utilization of LC–39A for the SpaceX Starship-Super Heavy launch vehicle in practical applications. LC–39A is a SpaceX-leased launch site located on northern KSC property, approximately 3 miles east of NASA's Vehicle Assembly Building. LC–39A currently supports SpaceX Falcon 9 and Falcon Heavy launches.

The 2019 EA established the purpose and need for Starship-Super Heavy at KSC and LC–39A, which was to develop and implement formal agreements with SpaceX for use of NASA assets and to provide services and commodities to enable Starship-Super Heavy launches. Commercial use of KSC real property supports NASA's mandate to encourage the fullest commercial use of space, supports the goals of the National Aeronautics and Space Act, and advances the National Space Policy that Federal agencies shall ensure that United States (U.S.) Government space technology and infrastructure is made available for commercial use on a reimbursable, noninterference, and equitable basis. The need for Starship-Super Heavy at KSC aligns with NASA's Commercial Space Launch Act, as amended, which is to support the U.S. goal of encouraging activities by the private sector to strengthen and expand U.S. space transportation infrastructure.

NASA is seeking the support of the Starship-Super Heavy at KSC in its continued mission to expand commercial uses of space and the space industry by facilitating SpaceX efforts to strengthen U.S. space transportation and launch infrastructure and providing greater mission capability to NASA and SpaceX by continuing the development of ever evolving next generation launch vehicles and spacecraft. Additionally, NASA is seeking the support of the Starship-Super Heavy in meeting the U.S. goal of near-term lunar exploration, such as the NASA Artemis and Human Landing System (HLS) programs.

SpaceX proposes that the Starship-Super Heavy at KSC serves to increase the company's operational portfolio diversity (*i.e.,* the ability to support multiple customer missions at different locations) and capabilities through multiple Starship-Super Heavy launch sites, reduce space transportation costs (including within the Artemis and HLS programs), enhance exploration, support national leadership in space, and make space access more affordable.

Within the context of the 2019 EA, the scope of the Proposed Action was defined as infrastructure development and Starship-Super Heavy operations. Infrastructure development included construction of a launch mount for the Starship and Super Heavy Booster, a liquid methane farm, transport road leading from the pad entrance gate to the launch mount, high-pressure gaseous commodity lines, a deluge water system, and a landing zone (including pad). The 2019 EA assessed approximately 24 Starship-Super Heavy launches per year, including lunar and Mars missions, satellite payload missions, and human spaceflight. Starship design at the time of the 2019 EA consisted of seven raptor engines, while the Super Heavy booster consisted of 31 Raptor engines. Starship landing locations included Landing Zone 1 at Cape Canaveral Space Force Station (CCSFS), downrange on a droneship (converted barge), and a new landing pad at LC–39A. Landings for Super Heavy, the first stage booster, were proposed to occur downrange on a droneship. Super Heavy booster returns to LC–39A were not considered in the 2019 EA. NASA's resultant Finding of No Significant Impact (FONSI) issued on September 19, 2019, concluded that the environmental impacts associated with Starship-Super Heavy infrastructure development and operations, within the scope of the 2019 EA, would not individually or cumulatively have a significant impact on the quality of the biological or physical environment.

Since 2019, SpaceX has undertaken infrastructure improvements at LC–39A (*e.g.,* construction of a launch mount) consistent with the scope of the 2019 EA. However, while the purpose and need for Starship-Super Heavy at LC–39A have not changed, the Starship-Super Heavy concept of operations has evolved from the original 2019 EA scope. SpaceX now proposes to construct additional launch infrastructure not previously contemplated in the 2019 EA: a Super Heavy booster catch tower, a natural gas liquefaction system and air separation unit for propellant generation, and stormwater/deluge ponds. SpaceX also proposes to launch an advanced design of the Starship and Super Heavy vehicle (up to nine raptor engines for Starship and up to 35 raptor engines for the Super Heavy booster), operate at a projected higher launch tempo (up to 44 launches per year), and land the Super Heavy booster at LC–39A in support of its reusability concept. Starship landings are no longer proposed to occur at Landing Zone 1 at CCSFS.

In order to conduct Starship-Super Heavy launch and landing operations from LC–39A, SpaceX must obtain a Vehicle Operator License from the FAA. Issuing a Vehicle Operator License and approving associated airspace closures is considered a major Federal action under NEPA. In consideration of SpaceX's revised proposal, NASA, as the land management agency, and FAA, as the licensing agency, have determined that an EIS is the appropriate level of NEPA analysis to address the adjusted scope of Starship-Super Heavy at LC–39A. SpaceX will prepare this EIS under the supervision of the FAA which will serve as the lead agency at NASA's request (see 40 CFR 1506.5).

The EIS will consider the potential environmental impacts of the Proposed Action and the No Action Alternative. The successful completion of the environmental review process does not guarantee that the FAA would issue a Vehicle Operator License. The project must also meet all FAA safety, risk, and indemnification requirements for the appropriate license.

Proposed Action

The FAA's Federal Action would include (1) issuing a Vehicle Operator License to SpaceX, as well as potential future renewals or modifications to the Vehicle Operator License for operations that would be within the scope analyzed in the EIS; and (2) developing one or more formal agreements with SpaceX to outline notification procedures prior to, during, and after an operation including Notice to Air Missions (NOTAM), as well as issuing temporary airspace closures to ensure public safety in accordance with FAA Order 7400.2M, *Procedures for Handling Airspace Matters.*

SpaceX's Proposed Action within the context of this EIS consists of the totality of Starship-Super Heavy infrastructure improvements and operations, to include those identified in the 2019 EA, as well as those adjusted scope elements described previously. This includes up to 44 Starship-Super Heavy launches per year. Launches may occur during the day or at night. Each Starship-Super Heavy orbital launch would include either landing the Super Heavy booster at LC–39A or downrange in the Atlantic Ocean on a droneship or expending the booster in the Atlantic Ocean, no closer than approximately 5 nautical miles off the coast. Starship could also land at LC–39A or on a droneship or be expended in the high seas between 55 degrees south latitude and 55 degrees north latitudes. SpaceX would continue to launch Falcon 9 and Falcon Heavy missions at LC–39A while Starship-Super Heavy is operational.

While infrastructure improvements consistent with the 2019 EA are already

underway, additional infrastructure improvements at LC–39A associated with the evolved Starship-Super Heavy program to be addressed in this EIS include, but are not limited to, a Super-Heavy catch tower; onsite facilities for propellant generation and propellant storage (*e.g.,* natural gas pretreatment system and methane liquefier); cooling tower; air separation unit; and deluge system.

The potential environmental impacts of all proposed construction and operational activities, including those from launch and landing, will be analyzed in the EIS. The EIS will evaluate the potential environmental impacts associated with air quality; biological resources (including fish, wildlife, and plants); climate; coastal resources; Department of Transportation Act, Section 4(f); farmlands; hazardous materials, solid waste, and pollution prevention; historical, architectural, archeological and cultural resources; land use; natural resources and energy supply; noise and noise-compatible land use; socioeconomics, environmental justice, and children's health and safety risks; visual effects; and water resources (including wetlands, floodplains, surface waters, groundwater, and wild and scenic rivers). This analysis will consist of an evaluation of potential direct and indirect impacts and will account for cumulative impacts from other relevant activities in the vicinity of the action.

Concurrent with the NEPA process, the FAA is initiating National Historic Preservation Act section 106 Consultation to determine the potential effects of the Proposed Action on historic properties. Additionally, the FAA is consulting with the USFWS under section 7 of the Endangered Species Act (ESA) regarding potential impacts on federally listed threatened and endangered species. The FAA is also consulting with the National Marine Fisheries Service under section 7 of the ESA and the Marine Mammal Protection Act for potential impacts on protected marine species. Pursuant to the U.S. Department of Transportation Act of 1966, this EIS will comply with the requirements of section 4(f) of the Act, as applicable.

Alternatives

The Council on Environmental Quality defines ''reasonable alternatives'' as those ''that are technically and economically feasible and meet the purpose and need for the proposed action.'' (40 CFR 1508.1(z)). Through an alternative screening process based on Starship-Super Heavy requirements and the purpose and need, the 2019 EA established LC–39A as the approved location for Starship-Super Heavy operations, and infrastructure development based on NASA's 2019 FONSI is already underway. LC–39A could provide time-critical mission capability to NASA and commercial pursuits via the Starship-Super Heavy. In addition to existing launch infrastructure, LC–39A could provide launch site diversity for Starship-Super Heavy to meet the purpose and need for near-term lunar exploration under the NASA Artemis and HLS programs.

Given the above, the only alternative to the Proposed Action as described in this EIS is the No Action Alternative. Under the No Action Alternative, FAA would not issue a Vehicle Operator License for Starship-Super Heavy operations at LC–39A. SpaceX would not implement further improvements or launch Starship-Super Heavy from LC–39A. Potential impacts associated with the No Action Alternative will be analyzed in this EIS.

Scoping Meetings

FAA will hold three IN-PERSON scoping meetings and one VIRTUAL public scoping meeting. The meetings will allow the public to receive information on the Proposed Action, meet lead and cooperating agency representatives, and provide comments to the record.

The IN-PERSON meetings will be held on June 12, 2024, and June 13, 2024. The June 12, 2024, meetings will be held from 2 p.m.–4 p.m. and 6 p.m.–8 p.m. (Eastern) at the Radisson Cape Canaveral, 8701 Astronaut Blvd., Cape Canaveral, Florida 32920. The June 13, 2024, meeting will be held from 6 p.m.–8 p.m. (Eastern) at the Kennedy Space Center Visitor Complex, Space Commerce Way, Merritt Island, Florida 32953. All meetings will consist of an open house information-station format wherein the FAA will provide information describing the purpose of the scoping meetings, project schedule, opportunities for public involvement, Proposed Action and alternatives summary, and environmental resource area summary. Fact sheets will be made available containing similar information. At any time during the meetings, the public will have the opportunity to provide verbal comments to a court reporter or written comments via a written comment form at one of several commenting stations. English-Spanish translation services will be provided at the in-person meetings.

The VIRTUAL meeting will be held on June 17, 2024; 6 p.m.–8 p.m. (Eastern); the URL and call-in number for the meeting will be provided in advance on the FAA's project website *https://www.faa.gov/space/stakeholder_engagement/spacex_starship_ksc.* The virtual meeting will consist of a closed-captioned auto-run presentation describing the purpose of the scoping meetings, project schedule, opportunities for public involvement, Proposed Action and alternatives summary, and environmental resource area summary. Presentations will be run at the beginning of each hour. Members of the public may provide written comments via the chat function during the presentation and for the remainder of each hour. Verbal comments up to three minutes can be given after the completion of each presentation. A moderator will facilitate verbal comments. English-Spanish translation services for verbal comments will be provided. Both English and Spanish versions of the presentation will be made available to the public on FAA's project website.

More information regarding the scoping meetings, along with any published scoping materials, is available on FAA's project website at *https://www.faa.gov/space/stakeholder_engagement/spacex_starship_ksc.*

Issued in Washington, DC.

Daniel P. Murray,

Executive Director, Office of Operational Safety.

[FR Doc. 2024–10149 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0038]

Agency Information Collection Activities: Notice of Request for Reinstatement of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for reinstatement of a previously approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for reinstatement of an existing information collection that is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by July 9, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0038 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Foundoukis, (785) 273–2655, Department of Transportation, Federal Highway Administration, Highway Systems Performance (HPPI–20), Office of Highway Policy Information, Office of Policy & Governmental Affairs, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Highway Performance Monitoring System (HPMS).

OMB Control: 2125–0028.

Background: The HPMS data that is collected is used for management decisions that affect transportation, including estimates of the Nation's future highway needs and assessments of highway system performance. The information is used by the FHWA to develop and implement legislation and by State and Federal transportation officials to adequately plan, design, and administer effective, safe, and efficient transportation systems. This data is essential to the FHWA and Congress in evaluating the effectiveness of the Federal-aid highway program. The HPMS also provides mile and lane-mile components of the Federal-Aid Highway Fund apportionment formulae. The data that is required by the HPMS is continually reassessed and streamlined by the FHWA. The process has recently been updated to enable the transactional submission of many data items, thereby reducing the need to submit redundant data each year.

Respondents: State governments of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

Frequency: Annually.

Estimated Average Burden per Response: The estimated average burden per response for the annual collection and processing of the HPMS data is 2,000 hours for each State, the District of Columbia, and the Commonwealth of Puerto Rico.

Estimated Total Annual Burden Hours: The estimated total annual burden for all respondents is 104,000 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: May 7, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–10227 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0243]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Gemini Motor Transport LP, USDOT# 913300

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; grant of exemption.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant Gemini Motor Transport LP's, USDOT No. 913300, (Gemini) application for an exemption to allow it to operate commercial motor vehicles (CMVs) equipped with a module manufactured by Intellistop, Inc. (Intellistop). The Intellistop module is designed to pulse the required rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds when the brakes are applied and then return the lights to a steady-burning state while the brakes remain engaged. The Agency has determined that granting the exemption to Gemini, an individual, easily identifiable motor carrier operating a finite number of CMVs, would likely achieve a level of safety equivalent to, or greater than, the level of safety achieved by the regulation.

DATES: This exemption is effective May 10, 2024 and ending May 12, 2029.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–9209, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001; *MCPSV@dot.gov.*

I. Viewing Comments and Documents

To view comments, go to *www.regulations.gov,* insert the docket number ''FMCSA–2022–0243'' in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.''

To view documents mentioned in this notice as being available in the docket, go to *www.regulations.gov,* insert the docket number ''FMCSA–2022–0243'' in the keyword box, click ''Search,'' and choose the document to review.

If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from certain parts of the FMCSRs if it ''finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption.'' FMCSA must publish a notice of each exemption request in the **Federal Register** and provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis, and an opportunity for public comment on the request (49 U.S.C. 31315(b)(6)(A); 49 CFR 381.315(a).

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level

of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. Granted exemptions may be renewed (49 CFR 381.300(b)).

III. Background

A. Current Regulatory Requirements

Section 393.25(e) of the Federal Motor Carrier Safety Regulations (FMCSRs) requires all exterior lamps (both required lamps and any additional lamps) to be steady-burning, with certain exceptions not relevant here. Two other provisions of the FMCSRs—section 393.11(a) and section 393.25(c)—mandate that required lamps on CMVs meet the requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 108 in effect at the time of manufacture. FMVSS No. 108, issued by the U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA), includes a requirement that installed brake lamps, whether original or replacement equipment, be steady burning.

B. Applicant's Request

Gemini applied for an exemption from 49 CFR 393.25(e) to allow it to operate CMVs, equipped with Intellistop's module. When the brakes are applied, the Intellistop module is designed to pulse the rear clearance, identification, and brake lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds and then maintain the original equipment manufacturer's (OEM) level of illumination for those lamps until the brakes are released and reapplied. Intellistop asserts that its module is designed to ensure that if the module ever fails, the clearance, identification, and brake lamps will default to normal OEM function and illumination.

Gemini's application followed the Agency's October 7, 2022 (87 FR 61133), denial of Intellistop's application for an industry-wide exemption to allow all interstate motor carriers to operate CMVs equipped with the Intellistop module. While the Agency determined that the scope of the exemption Intellistop sought was too broad to ensure that an equivalent level of safety would be achieved, the Agency explained that individual motor carrier applications for exemption may be more closely aligned with FMCSA authorities. Exemptions more limited in scope would allow the Agency to ensure compliance with all relevant FMCSA regulations because the individual exemptee would be easily identifiable and its compliance with applicable regulations could be monitored, thus providing a level of safety equivalent to compliance with 49 CFR 393.25(e).

Gemini stated that previous research demonstrated that the use of pulsating brake-activated lamps increases the visibility of vehicles and should lead to a significant decrease in rear-end crashes. In support of its application, Gemini submitted several reports of research conducted by the National Highway Traffic Safety Administration (NHTSA), another agency in the U.S. Department of Transportation, on the issues of rear-end crashes, distracted driving, and braking signals.[1] [2] [3] This same body of research was also referenced in Intellistop's industry-wide exemption application. Relying on these studies, Gemini stated that the addition of brake-activated pulsating lamp(s) will not have an adverse impact on safety and would likely maintain a level of safety equivalent to or greater than the level of safety achieved without the exemption.

A copy of the application is included in the docket referenced at the beginning of this notice.

IV. Comments

FMCSA published a notice of the application in the **Federal Register** on February 1, 2023, and asked for public comment (88 FR 6805). The Agency received 26 comments from the American Trucking Associations (ATA); Intellistop, Inc.; the National Truck Equipment Association (NTEA); the Transportation Safety Equipment Institute (TSEI); and 22 other commenters. Twenty-five of the commenters favored the exemption application, while TSEI expressed concerns.

TSEI reiterated comments it had previously made in support of the safety benefits of brake-activated warning lamps when used in conjunction with steady burning red brake lamps as well as its prior support of the exemption requests from Groendyke, NTTC, and Grote. Despite these previous expressions of support for the potential benefits of some brake warning lamp configurations, TSEI stated that it is concerned about any exemption permitting the pulsing of lamps that are currently required to be steady burning without a thorough consideration of safety data and research. TSEI stated that the aim of future rulemaking should be to ensure consistent application across all vehicles equipped with such pulsating lamps and recommended that the Agency engage in a formal rulemaking to amend Part 393 to allow for pulsating brake lamps.

ATA supported Gemini's request and stated that enhanced rear signaling (ERS) can provide functionality beyond what traditional CMV lighting and reflective devices offer, including drawing attention to CMVs stopped ahead; increasing awareness of roadside breakdowns; notification of emergency braking; and improving driver confidence from both vehicles. ATA also stated that, in addition to these safety benefits, ERS performance is superior to that of steady-burning brake lamps in conditions of severe weather, taillight glare, and around infrastructure obstacles. Specifically, ATA noted that this ''request by Gemini presents another opportunity for the DOT to learn about the performance of ERS in real world applications.'' Further, ATA stated that ''[it] believes the exemption process is well-suited for these kinds of situations, where the DOT can monitor small, controlled deployments to learn about benefits and costs and gather important data to make sound judgments on a broader industry exemption or change in regulations.''

ATA recommended the Agency provide clear guidance in the terms and conditions of the exemption grant to aid the Agency in monitoring the exemption for unintended consequences and aid the Applicant in understanding expectations for potential renewal of the exemption application. ATA further commented that FMCSA should work with industry to develop research efforts that examine the performance of ERS to supplement future DOT decisions on ERS technologies. and aid the Applicant

[1] See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf*; As part of the General Findings the NHTSA study report concluded that ''rear lighting continues to look promising as a means of reducing the number and severity of rear-end crashes.''

[2] See also NHTSA Study—Enhanced Rear Lighting and Signaling Systems *https://tinyurl.com/y2romx76* or *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/task_3_results_0.pdf*; As part of the conclusions NHTSA found that enhanced, flashing brake lighting ''demonstrated improvements in brake response times and other related performance measures.''

[3] See also NHTSA—Traffic Safety Facts *https://tinyurl.com/yxglsdax* or *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/tsf811128.pdf*; which concluded that flashing brake lights were a promising signal for improving attention-getting during brake applications.

in understanding expectations for potential renewal of the exemption application. ATA further commented that FMCSA should work with industry to develop research efforts that examine the performance of ERS to supplement future DOT decisions on ERS technologies.

The NTEA supported the Agency's authority to grant a temporary exemption. The NTEA, however, expressed concern that some of its members who are manufacturers and alterers of motor vehicles may receive requests from fleet operators to install brake-activated pulsating warning lamps on certain new vehicles they construct or modify. As manufacturers of new motor vehicles, NTEA members are required to certify these vehicles to applicable NHTSA Federal Motor Vehicle Safety Standards (FMVSS). NTEA noted that FMCSA does not have the authority to exempt CMV manufacturers from their obligation to certify FMVSS compliance. It recommended the Agency clarify in the terms and conditions of the exemption the responsibilities of carriers, manufacturers, and repair facilities, and the limitations and the conditions under which modifications may be made. NTEA specifically requested that FMCSA ''make clear that [this] exemption does not currently change any NHTSA regulations applying to the certification of federal motor vehicle safety standards,'' if it grants the exemption.

Intellistop supported the Applicant's request for exemption. It commented that for over 20 years, multiple States have allowed pulsing or flashing of brake lamps. Intellistop also asserted many State driver training schools recommend tapping brakes to warn other drivers when a CMV is slowing or stopping. Intellistop stated that it is unlikely that other motorists would confuse the use of their module with the recommendation to tap brakes when a CMV is slowing or stopping, as ''[s]eeing brake lights flash is a commonly communicated method to alert other drivers that a vehicle is slowing down or stopping.''

Twenty-one additional comments were submitted in support of granting the exemption. These commenters believe that any technology that has been shown to reduce rear-end crashes should be allowed and cited various benefits of brake activated pulsating lamps, including (1) enhanced awareness that the vehicle is making a stop, especially at railroad crossings, and (2) increased visibility in severe weather conditions. Several commenters noted that 37 States currently allow brake lamps to flash. In addition, three commenters noted that the guidelines developed by the American Driver and Traffic Safety Education Association advise driving instructors to teach new drivers to pulse brake lamps when stopping to improve visibility.

V. FMCSA Equivalent Level of Safety Analysis

Gemini petitions FMCSA to grant an exemption from 49 CFR 393.25(e)—requiring certain exterior lamps to be steady burning—to allow it to operate CMVs equipped with Intellistop's module. FMCSA has determined that in order for Gemini to operate vehicles in compliance with the FMCSRs, an exemption from 49 CFR 393.25(e) must be accompanied by limited exemptions from 49 CFR 393.11(a) and 393.25(c), both of which mandate that required lamps on CMVs operated in interstate commerce must, ''at a minimum, meet the applicable requirements of 49 CFR 571.108 (FMVSS No. 108) in effect at the time of manufacture of the vehicle.'' FMCSA grants exemptions only when it determines ''such exemption[s] would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent the exemption[s].''

Rear-end crashes generally account for approximately 30 percent of all crashes. They often result from a failure to respond (or delays in responding) to a stopped or decelerating lead vehicle. Data on crashes that occurred between 2010 and 2016 show that large trucks are consistently three times more likely than other vehicles to be struck in the rear in two-vehicle fatal crashes.[4] [5] FMCSA is deeply interested in the development and deployment of technologies that can reduce the frequency, severity, and risk of rear-end crashes.

Both FMCSA and NHTSA have examined alternative rear-signaling systems to reduce the incidence of rear-end crashes. While research efforts concluded that improvements in the incidence of rear-end crashes could be realized through certain rear-lighting systems that flash,[6] the FMCSRs do not currently permit the use of pulsating, brake-activated lamps on the rear of CMVs. FMCSA believes that the two agencies' previous research programs demonstrate that rear-signaling systems may be able to ''improve attention getting'' to reduce the frequency and severity of rear-end crashes. Any possible benefit must be balanced against a possible risk of increased driver distraction and confusion. In balancing these interests, the Agency was compelled to deny the Intellistop application for exemption because the industry-wide scope of the request was too broad for the Agency to effectively monitor for the potential risk of driver distraction or confusion.

The Agency acknowledges the limitations of the research studies completed to date and the overall data deficiencies in this area. Nonetheless, as noted in its Intellistop decision, the Agency recognizes that existing data do suggest a potential safety value in the use of alternative rear-signaling systems, generally. Specifically, FMCSA considered NHTSA's research concerning the development and evaluation of rear-signaling applications designed to reduce the frequency and severity of rear-end crashes via enhancements to rear-brake lighting. The study examined enhancements for (1) redirecting drivers' visual attention to the forward roadway (for cases involving a distracted driver) and (2) increasing the saliency or meaningfulness of the brake signal (for inattentive drivers).[7] The research considered the attention-getting capability and discomfort glare of a set of candidate rear brake lighting configurations using driver judgments and eye-drawing metrics. The results of this research served to narrow the set of candidate lighting configurations to those that would most likely be carried forward for additional on-road study. Based on subjective participant responses, this research indicates some form of flashing or variation in brake light brightness may be more than two times more attention-getting than the baseline, steady-burning brake lights for distracted drivers.[8]

[4] U.S. Department of Transportation, National Highway Traffic Safety Administration (2012), Traffic Safety Facts—2010 Data; Large Trucks, Report No. DOT HS 811 628, Washington, DC (June 2012), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/811628.*

[5] U.S. Department of Transportation, National Highway Traffic Safety Administration (2018), Traffic Safety Facts—2016 Data; Large Trucks, Report No. DOT HS 812 497, Washington, DC (May 2018), *available at: https://crashstats.nhtsa.dot.gov/Api/Public/Publication/812497.*

[6] Expanded Research and Development of an Enhanced Rear Signaling System for Commercial Motor Vehicles: Final Report, William A. Schaudt *et al.* (Apr. 2014) (Report No. FMCSA–RRT–13–009).

[7] See NHTSA Study—Evaluation of Enhanced Brake Lights Using Surrogate Safety Metrics *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/811127.pdf.*

[8] Ibid. While data demonstrated that brighter flashing lights were the most attention-getting combination for distracted drivers in this study, flashing lights with no increase in brightness were still more effective at capturing a distracted driver's attention than the baseline steady-burning brake

Continued

While some of the data collected in the study may not be statistically significant, the study results nonetheless indicate that additional efforts to get drivers' attention when they are approaching the rear of a CMV that is stopping may be helpful to reduce driver distraction and, ultimately, rear-end crashes. This was among several reasons why researchers concluded that the promising nature of enhanced brake lighting systems warranted additional work and research. FMCSA believes the acquisition of relevant data through real-world monitoring is of critical importance as the Agency continues to seek new and innovative options for reducing crashes. This is particularly true given the data limitations noted in previous studies.

Despite finding a potential safety value in the use of alternative rear-signaling technology, in the Intellistop decision the Agency determined that the data presently available did not justify an exemption to allow all interstate motor carriers to alter the performance of an FMVSS-required lighting device (*i.e.,* stop lamps) on any CMV. In contrast, however, Gemini's application requests an exemption from the steady-burning brake lamp requirement for CMV operations by only one interstate motor carrier. As FMCSA noted in its denial of Intellistop's industry-wide exemption application, individual motor carrier exemption requests more closely align with FMCSA and NHTSA authorities to ensure compliance with all other applicable regulations and with the safety performance of the smaller population of affected motor carriers. With an individual motor carrier exemption, the Agency can also more easily monitor compliance with terms and conditions intended to ensure operations conducted under the exemption do in fact provide an equivalent level of safety. Gemini's application demonstrates why this is particularly true, since the vehicles operated by Gemini under the exemption would be easily identifiable, and compliance with NHTSA's ''make inoperative'' prohibition and other related regulations could be readily checked.

The Agency's decision to grant this exemption is based on the data suggesting enhanced rear signal systems, such as pulsing brake lights, may help reduce the frequency and severity of rear-end crashes, as well as on the limited number of vehicles operating under the exemption. Gemini currently operates a nationwide fleet of approximately 1,200 vehicles, primarily fuel haulers. The installation of the module on a finite number of CMVs operated by a single motor carrier provides the opportunity for the Agency to collect data on the effects of pulsing brake lights in real-world conditions. The terms and conditions FMCSA imposes through this exemption will ensure appropriate Federal oversight in the use of these devices on a finite number of CMVs utilizing a phased in approach.

Initially restricting the application of this exemption to a limited portion of Gemini's fleet will allow for a comparison between the crash involvement of Gemini CMVs equipped with the Intellistop device, those without the device, and the overall crash involvement of CMVs operated by similarly sized motor carriers with similar operations and overall safety performance. Data collected through this exemption and any other similar exemptions the Agency may grant in the future will allow for an evaluation of how the Intellistop module may improve following vehicle driver responses to CMV braking. Consideration of the scope of any particular carrier's operation and the number and types of vehicles the carrier operates are critical to ensuring FMCSA gathers the most relevant data as the Agency considers safety benefits gained by the deployment of these rear brake lamp systems in CMV operations. The Agency's incremental approach in granting this limited exemption will also allow FMCSA to investigate and respond as appropriate to any incidents of alleged driver confusion attributable to use of the brake lamp systems in CMV operations, which some commenters have raised as a potential concern.

FMCSA acknowledges that all other pulsating rear lamp exemptions the Agency previously granted involved the addition of non-mandatory auxiliary lights while the Intellistop module that Gemini seeks to install alters the functionality of original equipment manufacturers' lamps. Nonetheless, those previous exemptions are instructive, most notably Groendyke.

The Groendyke exemption involved auxiliary lamps rather than required lighting, but, like the Intellistop module, the modulation of the auxiliary lamps in the Groendyke exemption occurs during braking. More importantly, Groendyke also involved a technology with limited supporting data being installed on a finite number of CMVs of a single motor carrier, which allowed the Agency more realistically to monitor the exemptee's compliance with other applicable regulations. When granting the exemption, FMCSA found Groendyke's experience with brake-activated pulsating warning lamps, which resulted in a 33.7 percent reduction in rear-end crashes, to be compelling. Through the granting of the Groendyke exemption, the Agency was able to collect additional valuable real-world data about the operation of the module at issue. Similarly, limited exemptions with narrowly tailored terms and conditions permitting the use of the Intellistop module will allow the Agency to collect data about the reliability and safety benefits of an integrated alternative rear-signaling system.

FMCSA notes that Gemini failed to provide any evidence beyond what is publicly available about the integration of the Intellistop module with its CMVs' existing systems or to support the claim that a malfunction of the device would result in the brake lights returning to OEM functionality. Nonetheless, based on the Agency's understanding of the device's design and assertions made in publicly available materials, FMCSA believes concerns about both the reliability and integration of the device are sufficiently alleviated in this instance because of the narrow scope of the exemption and the stringent requirements imposed by the Agency in the terms and conditions. Any evidence that module failure results in anything less than a return to brake light OEM functionality will result in revocation of the exemption.

Likewise, granting this exemption to an easily identifiable carrier alleviates concerns the Agency previously articulated about its inability to monitor compliance with NHTSA's ''make inoperative'' prohibition. FMCSA can monitor compliance with this exemption and ensure that only Gemini installs the module on its own CMVs.

Notwithstanding the promise the Agency sees in this technology, exemptions are warranted only if the applicant can demonstrate that an equivalent level of safety likely will be maintained. For this reason, the Agency believes it is important to consider the safety record of the applicant motor carrier. Gemini's existing on-road safety performance record warrants granting this exemption, to collect safety performance data in a limited set of operations. Gemini's out-of-service rate is well below the national average, with a vehicle out-of-service rate of only 3.0 percent (national average—21.4

lamps. Both look-up (eye drawing) data and interview data supported the hypothesis that simultaneous flashing of all rear lighting combined with increased brightness would be effective in redirecting the driver's eyes to the lead vehicle when the driver is looking away with tasks that involve visual load.

percent), a driver out-of-service rate of only 0.4 percent (national average—6 percent), and hazardous material out-of-service rate of 0.2 percent (national average—4.5 percent). Gemini maintains a Satisfactory safety rating.

FMCSA has authority to grant temporary exemptions to the FMCSRs only to motor carriers and not to CMV manufacturers or vehicle alterers. FMCSA acknowledges that the research described above did not fully address all of the implications of allowing pulsating stop lamps, especially by automobiles where stop lamp design is stylized and often brand-specific, and that it remains unclear whether deviation from the uniform brake-light patterns of CMVs may cause confusion among highway users when the lamps are pulsated during braking. When Intellistop sought an industry-wide exemption, FMCSA concluded that the potential risks of widespread adoption outweighed the potential benefits. But FMCSA reaches a different conclusion here, where any risks will be more limited and easier to monitor. FMCSA notes, moreover, that the research suggests that the use of rear-signaling systems may be a means to reduce the frequency and severity of rear-end crashes involving CMVs, as do the reductions in rear-end crashes reported by Groendyke (84 FR 17910, April 26, 2019) utilizing an auxiliary flashing rear-signaling system. These facts and the specific safety record of the applicant motor carrier support the conclusion that permitting the use of Intellistop's pulsating-lamp module among a finite number of vehicles of a single motor carrier, subject to terms and conditions for monitoring, is likely to achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

VII. Exemption Decision

a. Grant of Exemption

FMCSA has evaluated Gemini's exemption application and the comments received. The Agency believes that granting a temporary exemption to 393.25(e), and temporary limited exemptions to the requirements of 49 CFR 393.11(a) and 393.25(c) to allow Gemini to operate a defined and limited number of CMVs equipped with Intellistop's pulsating-brake module will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

This exemption is restricted to a finite number of vehicles in Gemini's fleet and provides relief from the steady burning requirement for rear clearance, identification, and brake lamp activation for 2 seconds following brake activation. All other FMVSS No. 108 requirements cross-referenced or incorporated within the FMCSRs remain in effect, with a limited exception to the requirement exempted here in 393.11(a) and 393.25(c) for only the first two seconds of brake engagement. In addition, through the terms and conditions, FMCSA will be able to monitor to performance of these CMVs to determine whether they were involved in a crash and whether they appear to be overrepresented in crashes compared to a control group (Gemini vehicles that are not equipped with the Intellistop unit but are operating on similar routes with similar schedules, etc.).

The Agency has evaluated the application and hereby grants the exemption for a 5-year period, beginning May 10, 2024 and ending May 12, 2029. During the temporary exemption period, Gemini (Applicant) may operate CMVs, equipped with Intellistop's module that pulses the rear brake, clearance, and identification lamps from a lower-level lighting intensity to a higher-level lighting intensity 4 times in 2 seconds. This grant applies only to the ''steady-burning'' requirement as specified in FMVSS 108 S7.3, and Tables I–a, I–b, and I–c. All other photometric and requirements for stop lamps specified in FMVSS 108 must still be met.

b. Terms and Conditions of the Exemption

(i) Installation of the Intellistop Module

The Applicant is responsible for installing the Intellistop module and assumes any liability for installation of the module. This exemption applies only to CMVs owned and operated by the Applicant. THE PRODUCT MUST BE INSTALLED BY THE OWNER OF THE VEHICLE ONLY. IN ACCORDANCE WITH FEDERAL LAW (49 U.S.C. 30112(a)(1) AND 49 U.S.C. 30122), THE PRODUCT MAY NOT BE INSTALLED BY ANY MANUFACTURER, DISTRIBUTOR, DEALER, RENTAL COMPANY, OR MOTOR VEHICLE REPAIR BUSINESS.

The Applicant may not install the Intellistop module on more than 25% of its power units, and 25% of its trailers during the first year of operation under the exemption, or on more than 50% of its power units, and 50% of its trailers during the second year. The Applicant shall provide the vehicle identification numbers for the power units and trailers that will be operating under the exemption.

The Applicant must maintain a control group of equal size to portion of its power units and trailers equipped with the Intellistop unit during the first 2 years of the exemption. And the CMVs in the control group would operate on routes with schedules that are similar to those of the Intellistop vehicles.

Installed modules may only be used to modulate rear clearance, identification, and stop lamps.

Within 30 business days of its first installation of the Intellistop module, the Applicant must notify the FMCSA via email at *MCPSV@dot.gov* of the number and type of CMVs it is operating, or intends to operate, with the Intellistop module installed; the module type and/or sub-type; and any trouble-shooting, repair, or other use of an Intellistop module covered by this exemption. Amended installation information, including CMVs on which the device is installed or uninstalled, may then be submitted via the quarterly submission specified in sub-paragraph (iv) *Recurring Reporting Requirements* below.

If the Applicant sells or transfers ownership of any CMV equipped with an Intellistop module under this exemption, or if the exemption is terminated for any reason, the Applicant must remove the module and restore the CMV to full compliance with the FMCSRs and FMVSSs prior to the transfer of ownership, or upon termination of the exemption. The Applicant must also certify in writing to the purchaser/transferee and FMCSA that the CMV has been restored to compliance with the FMCSRs and FMVSSs.

(ii) Driver Pre-Trip Vehicle Inspections

The Applicant must ensure that each driver of an Intellistop-equipped CMV performs a pre-trip inspection to confirm that the Intellistop module operates only for 2 seconds and does not interfere with the normal operation of lamps after 2 seconds. If the lamps are not steady burning after 2 seconds, the CMV must not be dispatched until repairs are made. At the end of each workshift, drivers must note any problems observed by or reported to the driver concerning the Intellistop module on a driver vehicle inspection report (see 49 CFR 396.11), and the motor carrier must correct the problem before the vehicle is dispatched again.

(iii) Safety Notification to FMCSA

The Applicant will notify FMCSA within 5 business days after it becomes aware, or otherwise determines, that the continued use of a module or entire type or subtype of module covered by this

exemption is no longer likely to maintain a level of safety that is at least equivalent to the level that would be achieved absent this exemption. Notification will be made by sending an email to FMCSA at *MCPSD@dot.gov.*

(iv) Recurring Reporting Requirements

During the exemption period, the Applicant will provide quarterly submissions to FMCSA of the data described below. The Applicant's first quarterly submission is due on August 12, 2024, and thereafter will be due every 3 months, on the first business day of the month. The first quarterly submission will include the required data beginning 60 days prior to the date of module installation. All quarterly submissions will include data through at least the 14th day (inclusive) of the month immediately preceding the submission. Unless otherwise agreed to by FMCSA, quarterly submissions will be sent via email to FMCSA at *MCPSD@dot.gov.* If the Applicant does not have one or more categories of information described below, it will, within 20 days of the effective date of this exemption, discuss with FMCSA other available information. If the Agency accepts such alternative information, the Applicant will submit that data in lieu of the information specified below.

In the quarterly submission, the Applicant must provide FMCSA the following information known to the Applicant regarding all crashes and other incidents (''crash or incident'') involving a CMV equipped with an Intellistop module covered by this exemption where the Intellistop module is potentially implicated. Crashes involving a CMV equipped with an Intellistop module that are ''head-on'' or otherwise involve only the front of the Intellistop-equipped CMV impacting some other object (such that the Intellistop module, without question, could not be implicated) are not subject to this condition. For the first quarterly submission, data must include any crash or incident occurring in the 60 days prior to installation of the Intellistop module that would have been contained in this reporting category had the module been installed at the time of the crash or incident. The Applicant's knowledge includes, but is not limited to: (1) outreach from a consumer, lawyer, or any other person or organization (via letter, email, fax, telephone call, social media, or any other medium); (2) lawsuits to which the Applicant is a party, or otherwise knows exist where an Intellistop module covered by this exemption is an issue in the litigation; and (3) insurance claims against the Applicant related to use of the Intellistop module. When in the Applicant's possession, information provided to FMCSA shall include:

1. The date of first contact regarding, or the Applicant's first awareness of, the crash or incident;
2. The date of the most recent follow-up contact, if any, between the Applicant and the other party;
3. The date, time, and location of the crash or incident;
4. A brief description of the crash or incident; and
5. The Intellistop module type and/or subtype(s) involved in the crash or incident.
6. Information, if any, indicating that the Intellistop module is, or was, not working as intended, or caused confusion or a roadway hazard for either the consumer or other motorists.

Annual data. At the end of each 12-month period this exemption is in effect, the Applicant shall, within 60 days, submit a report detailing all information in its possession regarding crash rates and vehicle miles traveled by CMVs equipped with a module covered by this exemption. Additionally, the report will specify the number and type of CMVs the Applicant is operating under the exemption, the module type or sub-type installed on each CMV, the affected lamps (rear clearance, identification, and/or brake lamps), the number of covered vehicles sold or transferred in ownership during the 12-month reporting period, and a statement certifying that any sold/transferred vehicle(s) have been restored to compliance with applicable FMVSSs and FMCSRs.

Meetings. The Applicant shall, at FMCSA's request, meet with FMCSA to answer questions regarding data and information provided by the Applicant under this exemption.

(v) Early Termination

The exemption will be valid for 5 years from the date of issuance unless rescinded earlier by FMCSA. FMCSA will terminate the exemption if: (1) the Applicant fails to comply with its terms and conditions; (2) the exemption results in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

(vi) Notification From the Public

Interested parties possessing information that would demonstrate that Gemini's CMVs equipped with Intellistop's pulsating rear-light module may not be achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

(vii) Non-Endorsement

This limited and conditional exemption does not constitute an endorsement of the Intellistop product by FMCSA, NHTSA, the U.S. DOT, or any of their components, or by any of these agencies' employees or agents. As a condition of the continued effectiveness of this exemption, Intellistop is expressly prohibited from describing its product as approved by, endorsed by, or otherwise authorized by FMCSA, NHTSA, or U.S. DOT, or as compliant with Federal safety regulations.

VIII. Preemption

In accordance with 49 U.S.C. 31313(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Sue Lawless,

Acting Deputy Administrator.

[FR Doc. 2024–10270 Filed 5–9–24; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2024–0008]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) summarized below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On February 21, 2024, FRA published a notice providing a 60-

day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before June 10, 2024.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the particular ICR by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Arlette Mussington, Information Collection Clearance Officer, at email: *arlette.mussington@dot.gov* or telephone: (571) 609–1285 or Ms. Joanne Swafford, Information Collection Clearance Officer, at email: *joanne.swafford@dot.gov* or telephone: (757) 897–9908.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On February 21, 2024, FRA published a 60-day notice in the **Federal Register** soliciting public comment on the ICR for which it is now seeking OMB approval. *See* 89 FR 13142. FRA has received no comments related to the proposed collection of information.

Before OMB decides whether to approve this proposed collection of information, it must provide 30-days' notice for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *See also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Metrics and Minimum Standards for Intercity Passenger Rail Service.

OMB Control Number: 2130–0632.

Abstract: In November 2020, in connection with a Congressional mandate, FRA published a final rule titled Metrics and Minimum Standards for Intercity Passenger Train Operations. (49 CFR part 273). The final rule established metrics and a minimum standard for measuring the performance and service quality of intercity passenger train operations, including cost recovery, on-time performance and minutes of delay, ridership, on-board services, stations, facilities, equipment, and other services.[1]

Type of Request: Extension without change (with changes in estimates) of a currently approved collection.

Affected Public: Amtrak.

Form(s): N/A.

Respondent Universe: Amtrak and Host Railroad(s).

Frequency of Submission: Varied.

Total Estimated Annual Responses: 93.

Total Estimated Annual Burden: 141 hours.

FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Christopher S. Van Nostrand,

Deputy Chief Counsel.

[FR Doc. 2024–10214 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–06–P

[1] See 85 FR 72971.

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2024–0056 (Notice No. 2024–08)]

Hazardous Materials: Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, PHMSA invites comments on three Office of Management and Budget (OMB) control numbers pertaining to hazardous materials transportation. PHMSA intends to request renewal and extension for these three control numbers from OMB.

DATES: Interested persons are invited to submit comments on or before July 9, 2024.

ADDRESSES: You may submit comments identified by the Docket Number PHMSA–2024–0056 (Notice No. 2024–08) by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* To the Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and Docket Number (PHMSA–2024–0056) for this notice at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS) and will include any personal information you provide.

Requests for a copy of an information collection should be directed to Steven Andrews or Nina Vore, Standards and Rulemaking Division, (202) 366–8553, *ohmspra@dot.gov,* Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey

Avenue SE, Washington, DC 20590–0001.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Steven Andrews or Nina Vore, Standards and Rulemaking Division, and addressed to the Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or *ohmspra@dot.gov.* Comments received by PHMSA which are not specifically designated as ''CBI'' will be placed in the public docket for this notice.

FOR FURTHER INFORMATION CONTACT: Steven Andrews or Nina Vore, Standards and Rulemaking Division, (202) 366–8553, *ohmspra@dot.gov,* Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: Section 1320.8(d), title 5, Code of Federal Regulations (CFR) requires the Pipeline and Hazardous Materials Safety Administration (PHMSA) to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collection requests PHMSA will be submitting to OMB for renewal and extension. These information collections are contained in 49 CFR 171.6 of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). PHMSA has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in proposed or final rules published since the information collections were last approved. The following information is provided for each information collection: (1) title of the information collection, including former title if a change is being made; (2) OMB control number; (3) summary of the information collection activity; (4) description of affected public; (5) estimate of total annual reporting and recordkeeping burden; and (6) frequency of collection. PHMSA will request a 3-year term of approval for each information collection activity and will publish a notice in the **Federal Register** upon OMB's approval. PHMSA requests comments on the following information collections:

Title: Flammable Cryogenic Liquids.

OMB Control Number: 2137–0542.

Summary: Provisions in § 177.840(a)(2) specify certain safety procedures and documentation requirements for drivers of motor vehicles transporting flammable cryogenic liquids. This information allows the driver to take appropriate remedial actions to prevent a catastrophic release of the flammable cryogenics should the temperature of the material begin to rise excessively or if the travel time will exceed the safe travel time. These requirements are intended to ensure a high level of safety when transporting flammable cryogenics due to their extreme flammability and high compression ratio when in a liquid state. The following information collections and their burdens are associated with this OMB Control Number.

Information collection	Respondents	Total annual responses	Time per response	Total annual burden hours
Flammable Cryogenic Liquids—Reporting	175	18,200	3.5 minutes	1,062
Flammable Cryogenic Liquids—Recordkeeping	175	18,200	30 seconds	152

Affected Public: Carriers of cryogenic materials.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 350.

Total Annual Responses: 36,400.

Total Annual Burden Hours: 1,214.

Frequency of Collection: On occasion.

Title: Response Plans for Shipments of Oil.

OMB Control Number: 2137–0591.

Summary: Under authority of the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990 (33 U.S.C. 1251 *et seq.*), PHMSA issued regulations in 49 CFR part 130 that require preparation of written spill response plans. The following information collections and their burdens are associated with this OMB Control Number.

Information collection	Respondents	Total annual responses	Time per response (hours)	Total annual burden hours
Basic Written Response Plan—New Plans	80	80	33	2,640
Basic Written Response Plan—Updating Plans	7,920	7,920	1	7,920

Affected Public: Carriers that transport oil in bulk, by motor vehicle or rail.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 8,000.

Total Annual Responses: 8,000.

Total Annual Burden Hours: 10,560.

Frequency of Collection: On occasion.

Title: Requirements for United Nations (UN) Cylinders.

OMB Control Number: 2137–0621.

Summary: This information collection and recordkeeping burden is the result of efforts to amend the HMR to adopt standards for the design, construction, maintenance, and use of cylinders and multiple-element gas containers (MEGCs) based on the standards contained in the UN Recommendations on the Transport of Dangerous Goods. Aligning the HMR with the UN Recommendations promotes flexibility, permits the use of technological advances for the manufacture of the pressure receptacles, provides for a broader selection of pressure receptacles, reduces the need for special permits, and facilitates international commerce in the transportation of compressed gases. Information collection requirements address domestic and international manufacturers of cylinders that request approval by the approval agency for cylinder design types. The approval process for each cylinder design type includes review, filing, and recordkeeping of the approval application. The approval agency is required to maintain a set of the approved drawings and calculations for each design it reviews and a copy of each initial design type approval certificate approved by the Associate Administrator for the Office of Hazardous Materials Safety for not less than 20 years. The following information collections and their burdens are associated with this OMB Control Number.

Information collection	Respondents	Total annual responses	Time per response	Total annual burden hours
UN Pressure Receptacle Approval—New Request	35	35	6 hours	210
UN Pressure Receptacle Approval—Modified Request	100	100	6 hours	600
UN Pressure Receptacle Approval—Recordkeeping	75	75	6 minutes	8

Affected Public: Fillers, owners, users, and retesters of UN cylinders.

Annual Reporting and Recordkeeping Burden:

Number of Respondents: 210.

Total Annual Responses: 210.

Total Annual Burden Hours: 818.

Frequency of Collection: On occasion.

Issued in Washington, DC, on May 7, 2024, under authority delegated in 49 CFR 1.97.

Steven W. Andrews Jr.,

Acting Chief, Regulatory Review and Reinvention Branch, Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2024–10241 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket ID Number: DOT–OST–2018–0068]

Notice of Submission of Proposed Information Collection to OMB; Agency Request for Reinstatement of Previously Approved Collections: Traveling by Air With Service Animals—U.S. Department of Transportation Service Animal Air Transportation Form and U.S. Department of Transportation Service Animal Relief Attestation Form

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Notice; addendum.

SUMMARY: The U.S. Department of Transportation (Department or DOT) published a notice for comment that confirms the Department's intention to renew Office of Management and Budget (OMB) Control Number 2105–0576, concerning Traveling by Air with Service Animals—U.S. Department of Transportation Service Animal Air Transportation Form, and U.S. Department of Transportation Service Animal Relief Attestation Form. The purpose of this addendum is to notify the public that an accessible version of the notice is available for view on DOT's Office of Aviation Consumer Protection website.

DATES: This addendum is effective May 10, 2024.

FOR FURTHER INFORMATION CONTACT: Maegan Johnson or Livaughn Chapman, Jr., Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone number (202) 366–9342 (voice), (202) 366–7152 (fax); *maegan.johnson@dot.gov* or *livaughn.chapman@dot.gov* (email). Arrangements to receive this document in an alternative format may be made by contacting the above-named individuals.

SUPPLEMENTARY INFORMATION: DOT published a **Federal Register** notice with a 30-day comment period soliciting comments on the information collections on April 29, 2024 (89 FR 33443). The notice was also submitted to OMB for review and approval on April 29, 2024. DOT's Office of Aviation Consumer Protection has posted accessible PDF and Word versions of this Notice on its website on its website, *www.transportation.gov/airconsumer* on its What's New Page, *www.transportation.gov/airconsumer/latest-news.*

* * * * *

Issued in Washington, DC.

Maegan Lea Johnson,

Senior Attorney, Office of Aviation Consumer Protection.

[FR Doc. 2024–10199 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket: DOT–OST–2014–0031 BTS Paperwork Reduction Notice]

Agency Information Collection; Activity Under OMB Review; Reporting Required for International Civil Aviation Organization (ICAO)

AGENCY: Office of the Assistant Secretary for Research and Technology (OST–R), Bureau of Transportation Statistics (BTS), Department of Transportation.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 19, 2024. No comments were received.

DATES: Written comments should be submitted by June 10, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number DOT–OST–2014–0031 OMB Approval

No. 2138–0039 by any of the following methods:

Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Services: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

Hand Delivery or Courier: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Fax: 202–366–3383.

Instructions: Identify docket number, DOT–OST–2014–0031, at the beginning of your comments, and send two copies. To receive confirmation that DOT received your comments, include a self-addressed stamped postcard. Internet users may access all comments received by DOT at *http://www.regulations.gov*. All comments are posted electronically without charge or edits, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*. or the street address listed above. Follow the online instructions for accessing the dockets.

Electronic Access

An electronic copy of this rule, a copy of the notice of proposed rulemaking, and copies of the comments may be downloaded at *http://www.regulations.gov,* by searching docket DOT–OST–2014–0031.

FOR FURTHER INFORMATION CONTACT: James Bouse, *james.bouse@dot.gov,* 202–366–3000, Office of Airline Information, RTS–42, Room E34, OST–R, 1200 New Jersey Avenue Street SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

OMB Approval No. 2138–0039.

Title: Reporting Required for International Civil Aviation Organization (ICAO).

Form No.: BTS Form EF.

Type Of Review: Extension of a currently approved collection.

Respondents: Large certificated air carriers.

Number of Respondents: 34.

Number of Responses: 34.

Total Annual Burden: 23 hours.

Needs and Uses: As a party to the Convention on International Civil Aviation (Treaty), the United States is obligated to provide ICAO with financial and statistical data on operations of U.S. carriers. Over 99% of the data filled with ICAO is extracted from the air carriers' Form 41 submissions to BTS. BTS Form EF is the means by which BTS supplies the remaining 1% of the air carrier data to ICAO.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501 note), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Issued Washington, DC, May 7, 2024.

William Chadwick, Jr.,

Director, Office of Airline Information, Bureau of Transportation Statistics.

[FR Doc. 2024–10265 Filed 5–9–24; 8:45 am]

BILLING CODE 4910–9X–P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: May 15, 2024, 10:30 a.m. to 1:30 p.m., Eastern time.

PLACE: This meeting will take place at the National Press Building 529 14th Street NW, Suite 1280, Washington, DC 20045. This meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 948 4051 5537, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJAlc-mtrz4vGdONsaXbTwLuoDAYqBiSoE42.*

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Industry Advisory Subcommittee (the ''Subcommittee'') will conduct a meeting to continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Call to Order—UCR Industry Advisory Subcommittee Chair

The Industry Advisory Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Industry Advisory Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Subcommittee Agenda- UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Subcommittee Action

The proposed Agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on agenda.

IV. Review and Approval of Minutes From the February 28, 2024 Meeting—UCR Industry Advisory Subcommittee Chair

For Discussion and Possible Subcommittee Action

Draft minutes from the February 28, 2024 Industry Advisory Subcommittee meeting via teleconference will be reviewed. The UCR Industry Advisory Subcommittee will consider action to approve.

V. 2024 Priorities and Project Development for the Subcommittee—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will provide an update on current and planned initiatives, to include the development of a video series intended to increase participation in the UCR focused on brokers, motor carriers, and bus operators.

VI. Industry Update on Compliance—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair UCR will provide an update on compliance numbers for all the industry stakeholders. Demonstrating current numbers and how those compare to the last few years, current compliance strategies being utilized, and the goal for 2024.

VII. Industry Update on Truck Parking—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will provide an information update on trucking parking initiatives.

VIII. Other Items—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

IX. Adjournment—UCR Industry Advisory Subcommittee Chair

The UCR Industry Advisory Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, May 8, 2024 at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024–10360 Filed 5–8–24; 11:15 am]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0399]

Agency Information Collection Activity: Student Beneficiary Report—REPS (Restored Entitlement Program for Survivors)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a previously approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 9, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0399'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.*

Please refer to ''OMB Control No. 2900–0399'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 42 U.S.C. 402.

Title: Student Beneficiary Report—REPS (Restored Entitlement Program for Survivors).

OMB Control Number: 2900–0399.

Type of Review: Extension of a previously approved collection.

Abstract: VA Form 21P–8938–1 is primarily used to verify that a surviving child who is receiving REPS benefits based on school-child status is in fact enrolled full-time in an approved school and is otherwise eligible for continued benefits. VA Form 21P–8938–1 is generated by VA's central computer system each March and sent to all student beneficiaries. If the completed form is not received by the end of May, the beneficiary is sent a system-generated due process letter with another VA Form 21P–8938–1. No changes have been made to this form. The respondent burden has remained the same.

Affected Public: Individuals and households.

Estimated Annual Burden: 300 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 1,200.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–10235 Filed 5–9–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0889]

Agency Information Collection Activity Under OMB Review: COVID–19 Veterans Assistance Partial Claim Payment Program

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by clicking on the following link *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0889.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0889'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: U.S. Code 38 3720, U.S. Code 38 3732.

Title: COVID–19 Veterans Assistance Partial Claim Payment Program.

OMB Control Number: 2900–0889.

Type of Review: Revision of a currently approved collection.

Abstract: This collection is necessary for VA to accept resubmissions for the COVID–19 Veterans Assistance Partial Claim Payment program (VAPCP) and continue to accept COVID–19 Refund Modifications added under this authority. The COVID–19 Refund Modification submission date was extended through May 31, 2024, and coincides with the foreclosure moratorium which also ends May 31, 2024.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at, 89 FR 16817 on March 8, 2024, page 16817.

Affected Public: Individuals and households.

Estimated Annual Burden: 11,670 hours.

Estimated Average Burden per Respondent: 45 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 15,560.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–10231 Filed 5–9–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Friday,

No. 92 May 10, 2024

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, et al.

Medicaid Program; Ensuring Access to Medicaid Services; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, and 447

[CMS–2442–F]

RIN 0938–AU68

Medicaid Program; Ensuring Access to Medicaid Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule takes a comprehensive approach to improving access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across fee-for-service (FFS), managed care delivery systems, and in home and community-based services (HCBS) programs. These improvements increase transparency and accountability, standardize data and monitoring, and create opportunities for States to promote active beneficiary engagement in their Medicaid programs, with the goal of improving access to care.

DATES: These regulations are effective on July 9, 2024.

FOR FURTHER INFORMATION CONTACT:

Karen LLanos, (410) 786–9071, for Medicaid Advisory Committee.

Jennifer Bowdoin, (410) 786–8551, for Home and Community-Based Services.

Jeremy Silanskis, (410) 786–1592, for Fee-for-Service Payment.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

Title XIX of the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals, including many with low incomes. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures must establish eligibility standards, benefits packages, and payment rates, and undertake program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid ''State plan'' and, as applicable, related authorities, such as demonstration projects and waivers of State plan requirements. Among other responsibilities, CMS approves State plans, State plan amendments (SPAs), demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act; and reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access to ensure that all applicable Federal requirements are met.

The Medicaid program provides essential health coverage to tens of millions of people, covering a broad array of health benefits and services critical to underserved populations,[1] including low-income adults, children, parents, pregnant individuals, older adults, and people with disabilities. For example, Medicaid pays for approximately 41 percent of all births in the U.S.[2] and is the largest payer of long-term services and supports (LTSS),[3] the largest, single payer of services to treat substance use disorders,[4] and services to prevent and treat the Human Immunodeficiency Virus.[5]

On January 28, 2021, the President signed Executive Order (E.O.) 14009,[6] ''Strengthening Medicaid and the Affordable Care Act,'' which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American. The E.O. also directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April 5, 2022, E.O. 14070,[7] ''Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,'' directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Consistent with CMS' authorities under the Act, this final rule implements E.O.s 14009 and 14070 by helping States to strengthen Medicaid and improve access to and quality of care provided.

Ensuring that beneficiaries can access covered services is necessary to the basic operation of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems (for example, FFS, fully-capitated managed care, partially capitated managed care, etc.), including through demonstrations and waiver programs. The volume of Medicaid beneficiaries enrolled in a managed care program in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021, with 74.6 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations.[8] [9] The remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

Current access regulations are neither comprehensive nor consistent across delivery systems or coverage authority (for example, State plan and demonstration authority). For example, regulations at 42 CFR 447.203 and 447.204 relating to access to care, service payment rates, and Medicaid provider participation in rate setting apply only to Medicaid FFS delivery systems and focus on ensuring that payment rates are consistent with the statutory requirements in section 1902(a)(30)(A) of the Act. The regulations do not apply to services

[1] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[2] National Center for Health Statistics. Key Birth Statistics. Accessed at *https://www.cdc.gov/nchs/nvss/births.htm*.

[3] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated September 2023. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343*.

[4] Soni, Anita. Health Care Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019. Statistical Brief #539, pg 12. February 2022. Agency for Healthcare Research and Quality, Rockville, MD. Accessed at *https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf*.

[5] Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at *https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/*.

[6] Executive Order 14009: *https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act*.

[7] Executive Order 14070: *https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage*.

[8] Medicaid Managed Care Enrollment Report. *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html*.

[9] Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

delivered under managed care. These regulations are also largely procedural in nature and rely heavily on States to form an analysis and reach conclusions on the sufficiency of their own payment rates.

With a program as large and complex as Medicaid, access regulations need to be multi-factorial to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In the spring of 2022, we released a request for information (RFI) [10] to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and Children's Health Insurance Program (CHIP) payments are sufficient to enlist enough providers.

Some of the most common feedback we received through the RFI related to ways that we can promote health equity through cultural competency. Commenters shared the importance that cultural competency plays in how beneficiaries access health care and in the quality of health services received by beneficiaries. The RFI respondents shared examples of actions that we could take, including collecting and analyzing health outcomes data by sociodemographic categories; establishing minimum standards for how States serve communities in ways that address cultural competency and language preferences; and reducing barriers to enrollment and retention for racial and ethnic minority groups.

In addition to the topic of cultural competency, commenters also commonly shared that they viewed reimbursement rates as a key driver of provider participation in Medicaid and CHIP programs. Further, commenters noted that aligning payment approaches and setting minimum standards for payment regulations and compliance across Medicaid and CHIP delivery systems, services, and benefits could help ensure that beneficiaries' access to services is as similar as possible across beneficiary groups, delivery systems, and programs.

As mentioned previously in this final rule, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage but have become eligible for other health coverage programs. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and Renewal Processes* to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP) (87 FR 54760). This proposed rule was finalized in two parts, the *Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment Final Rule* (88 FR 65230) and the *Streamlining Eligibility & Enrollment final rule* (89 FR 22780).

The third dimension, which is the focus of this final rule, is access to services and supports. This rule addresses additional critical elements of access: (1) potential access, which refers to a beneficiary's access to providers and services, whether or not the providers or services are used; (2) beneficiary utilization, which refers to beneficiaries' actual use of the providers and services available to them; and (3) beneficiaries' perceptions and experiences with the care they did or were not able to receive. These terms and definitions build upon previous efforts to examine how best to monitor access.[11]

We completed an array of regulatory activities, including three rules: the aforementioned Streamlining Eligibility & Enrollment final rules and a final rule entitled Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (as published elsewhere in this issue of the **Federal Register**, Managed Care final rule), on managed care including matters of access, and this final rule on access. Additionally, we are taking non-regulatory actions to improve beneficiary access to care (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems.

As noted earlier, we issued the Streamlining Eligibility & Enrollment final rules to address the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through those final rules, we streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants/enrollees toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals.

The Managed Care final rule improves access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in managed care by: creating standards for timely access to care and States' monitoring and enforcement efforts; reducing burden for some State directed payments and certain quality reporting requirements; adding new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization, and specifying the scope and nature of ILOS; specifying medical loss ratio (MLR) requirements, and establishing a quality rating system for Medicaid and CHIP managed care plans.

Through the Managed Care final rule and this final rule (Ensuring Access to Medicaid Services), we finalize additional requirements to address the third dimension of the health care access continuum: access to services. The requirements outlined later in this section focus on improving access to services in Medicaid by utilizing tools such as FFS rate transparency,

[10] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[11] Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. ''Proposed Medicaid Access Measurement and Monitoring Plan.'' Washington, DC: The Urban Institute. August 2016. Accessed at *https://www.urban.org/sites/default/files/publication/88081/2001143-medicaid-access-measurement-and-monitoring-plan_0.pdf.*

standardized reporting for HCBS, and improving the process for interested parties, especially Medicaid beneficiaries, to provide feedback to State Medicaid agencies and for Medicaid agencies to respond to the feedback (also known as a feedback loop).

Through a combination of these four final rules, we address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems. FFP will be available for expenditures that are necessary to implement the activities States will need to undertake to comply with the provisions of these final rules.

Finally, we also believe it is important to acknowledge the role of health equity within this final rule. Medicaid plays a disproportionately large role in covering health care for people from underserved communities in this country.[12] Consistent with E.O. 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),'' [13] which calls for advancing equity for underserved populations, we are working to ensure our programs consistently provide high-quality care to all beneficiaries, and thus advance health equity, consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022–2032 [14] and the HHS Equity Action Plan.[15] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable coverage and care.

We recognize that each State faces a unique set of challenges related to the resumption of its normal program activities after the end of the COVID–19 public health emergency (PHE). More specifically, the expiration of the Medicaid continuous enrollment condition authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, States were required to maintain enrollment of nearly all Medicaid enrollees. This continuous enrollment condition expired on March 31, 2023, after which States began completing renewals for all individuals enrolled in Medicaid, CHIP, and the BHP. Additionally, many other temporary authorities adopted by States during the COVID–19 PHE expired at the end of the PHE, and States are returning to regular operations across their programs. The resumption of normal Medicaid operations is generally referred to as ''unwinding'' and the period for States to initiate all outstanding eligibility actions that were delayed because of the FFCRA continuous enrollment condition is called the ''unwinding period.'' We considered States' unwinding responsibilities when finalizing the dates for States to begin complying with the requirements being finalized in this rule, but, as noted in the Ensuring Access to Medicaid Services proposed rule, we solicited State feedback on whether our proposals struck the correct balance.

We considered adopting an effective date of 60 days following publication of this final rule and separate compliance dates for various provisions, which we note where relevant in our discussion of specific proposals in this final rule. We solicited comment on whether an effective date of 60 days following publication would be appropriate when combined with later dates for compliance for some provisions.

We also solicited comment on the timeframe that would be most achievable and appropriate for compliance with each proposed provision and whether the compliance date should vary by provision.

B. Medical Care Advisory Committees (MCAC)

We obtained feedback during various public engagement activities conducted with States and other interested parties, which supports research findings that the beneficiary perspective and lived Medicaid experience [16] should be considered when making policy decisions related to Medicaid programs.[17] [18] A 2022 report from the HHS Assistant Secretary of Planning and Evaluation (ASPE) noted that including people with lived experience in the policy-making process can lead to a deeper understanding of the conditions affecting certain populations, facilitate identification of possible solutions, and avoid unintended consequences of potential policy or program changes that could negatively impact the people the program aims to serve.[19] We have concluded that beneficiary perspectives need to be central to operating a high-quality health coverage program that consistently meets the needs of all its beneficiaries.

However, effective community engagement is not as simple as planning a meeting and requesting feedback. To create opportunities that facilitate true engagement, it is important to understand and honor strengths and assets that exist within communities; recognize and solicit the inclusion of diverse voices; dedicate resources to ensuring that engagement is done in culturally meaningful ways; ensure timelines, planning processes, and resources that support equitable participation; and follow up with communities to let them know how their input was utilized. Ensuring optimal health outcomes for all beneficiaries served by a program through the design, implementation, and operationalization of policies and programs requires intentional and continuous effort to engage people who have historically been excluded from the process.

Section 1902(a)(4) of the Act is a longstanding statutory provision that, as implemented in part in regulations currently codified at 42 CFR 431.12,[20] requires States to have a Medical Care

[12] Guth, M and Artiga, S. Medicaid and Racial Health Equity March 2022. Accessed at *https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/*.

[13] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[14] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

[15] HHS Equity Action Plan. April 2022. Accessed at *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf*.

[16] Lived experience refers to ''representation and understanding of an individual's human experiences, choices, and options and how those factors influence one's perception of knowledge'' based on one's own life. In this context, we refer to people who have been enrolled in Medicaid currently or in the past. Accessed at *https://aspe.hhs.gov/lived-experience#:~:text=In%20the%20context%20of%20ASPE%E2%80%99s%20research%2C%20people%20with,programs%20that%20aim%20to%20address%20the%20issue%20%28s%29*.

[17] Zhu JM, Rowland R, Gunn R, Gollust S, Grande DT. Engaging Consumers in Medicaid Program Design: Strategies from the States. Milbank Q. 2021 Mar;99(1):99–125. doi: 10.1111/1468–0009.12492. Epub 2020 Dec 15. PMID: 33320389; PMCID: PMC7984666. Accessed at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984666/*.

[18] Key Findings from the Medicaid MCO Learning Hub Discussion Group Series and Roundtable—Focus on Member Engagement and the Consumer Voice. NORC at the University of Chicago. Jan 2021. Accessed at *https://www.norc.org/PDFs/Medicaid%20Managed%20Care%20Organization%20Learning%20Hub/MMCOLearningHub_MemberEngagement.pdf*.

[19] Syreeta Skelton-Wilson et al., ''Methods and Emerging Strategies to Engage People with Lived Experience,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, January 4, 2022, *https://aspe.hhs.gov/reports/lived-experience-brief*.

[20] The regulatory provision was originally established in 36 FR 3793 at 3870.

Advisory Committee (MCAC) in place to advise the State Medicaid agency about health and medical care services. Under section 1903(a)(7) of the Act, expenditures made by the State agency to operate the MCAC are eligible for Federal administrative match.

The current MCAC regulations at § 431.12 require States to establish such a committee and describe high-level requirements related to the composition of the committee, the scope of topics to be discussed, and the support the Committee can receive from the State in its administration. Due to the lack of specificity in the current regulations, these regulations have not been consistently implemented across States. For example, there is no mention of how States should approach meeting periodicity or meeting structure in ways that are conducive to including a variety of Medicaid interested parties. There is also no mention in the regulations about how States can build accountability through transparency with their interested parties by publicly sharing meeting dates, membership lists, and the outcomes of these meetings. The regulations also limit the required MCAC discussions to topics about health and medical care services—which in turn limits the benefits of using the MCAC as a vehicle that can provide States with varied ideas, suggestions, and experiences on a range of issues related to the effective administration of the Medicaid program.

As such, we have determined the requirements governing MCACs need to be more robust to ensure all States are using these committees optimally to realize a more effective and efficient Medicaid program that is informed by the experiences of beneficiaries, their caretakers, and other interested parties. The current regulations have been in place without change for over 40 years.[21] Over the last four decades, we have learned that the current MCAC requirements are insufficient in ensuring that the beneficiary perspective is meaningfully represented on the MCAC. Recent research regarding soliciting input from individuals with lived experience, including our recent discussions with States about their MCAC, provide a unique opportunity to re-examine the purpose of this committee and update the policies to reflect four decades of program experience.

In 2022, we gathered feedback from various public engagement activities conducted with States, other interested parties, and directly from a subset of State Medicaid agencies that described a wide variation in how States are operating MCACs today. The feedback suggested that some MCACs operate simply to meet the broad Federal requirements. As discussed previously in this section, we have discovered that our current regulations do not further the statutory goal of meaningfully engaging Medicaid beneficiaries and other low-income people in matters related to the operation of the Medicaid program. Meaningful engagement can help develop relationships and establish trust between the communities served and the Medicaid agency to ensure States receive important information concerning how to best provide health coverage to their beneficiary populations. The current MCAC regulations establish the importance of broad feedback from interested parties, but they lack the specificity that can ensure States use MCACs in ways that facilitate that feedback.

The current regulations require that MCACs must include Medicaid beneficiaries as committee members. However, the regulations do not mention or account for the reality that other interested parties can stifle beneficiary contribution in a group setting. For example, when there are a small number of beneficiary representatives in large committees with providers, health plans, and professional advocates, it can be uncomfortable and intimidating for beneficiaries to share their perspective and experience. Based on these reasons, several States already use beneficiary-only groups that feed into larger MCACs.

Improvements to the MCACs are critical to ensuring a robust and accurate understanding of beneficiaries' challenges to health care access. The current regulations value State Medicaid agencies having a way to get feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care, and to assist States in understanding and better addressing those challenges. These committees also represent unique opportunities for States to include representation by members that reflect the demographics of their Medicaid program to ensure that the program is best serving the needs of all beneficiaries, but not all States are utilizing that opportunity.

This final rule strikes a balance that reflects how States currently use advisory committees (such as MCACs or standalone beneficiary groups). We know that some States approach these committees as a way to meet a Federal requirement while other States are using them in much more innovative ways. As a middle ground, this final rule seeks to: (1) address the gaps in the current regulations described previously in this section; and (2) establish requirements to implement more effective advisory committees. States will select members in a way that reflects a wide range of Medicaid interested parties (covering a diverse set of populations and interests relevant to the Medicaid program), place a special emphasis on the inclusion of the beneficiary perspective, and create a meeting environment where each voice is empowered to participate equally.

The changes we are making in this rule are rooted in best practices learned from States' experiences implementing the existing MCAC provisions and from other State examples of community engagement that support getting the type of feedback and experiences from beneficiaries, their caretakers, providers, and other interested parties that can then be used to positively impact care delivered through the Medicaid program.

Accordingly, this final rule includes changes that will support the implementation of the principles of bi-directional feedback, transparency, and accountability. We are making changes to the features of the new committee that can most effectively ensure member engagement, including the staff and logistical support that is required for beneficiaries and individuals representing beneficiaries to meaningfully participate in these committees. We are also making changes to expand the scope of topics to be addressed by the committee, address committee membership composition, prescribe the features of administration of the committee, establish requirements of an annual report, and underscore the importance of beneficiary engagement through the addition of a related beneficiary-only group.

C. Home and Community-Based Services (HCBS)

While Medicaid programs are required to provide medically necessary nursing facility services for most eligible individuals age 21 or older, coverage for

[21] 43 FR 45091 at 45189.

HCBS is a State option.[22] As a result of this ''institutional bias'' in the statute, Medicaid reimbursement for LTSS was primarily spent on institutional care, historically, with very little spending for HCBS.[23] However, over the past several decades, States have used several Medicaid authorities,[24] as well as CMS-funded grant programs,[25] to develop a broad range of HCBS to provide alternatives to institutionalization for eligible Medicaid beneficiaries and to advance person-centered care. Consistent with many beneficiaries' preferences for where they would like to receive their care, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people with disabilities that spans efforts across the Federal government. In fact, total Medicaid HCBS expenditures surpassed the long-standing benchmark of 50 percent of LTSS expenditures in FY 2013 and has remained higher than 50 percent since then, reaching 55.4 percent in FY 2017 and 62.5 percent in FY 2020.[26] A total of 35 States spent at least 50 percent of Medicaid LTSS expenditures on HCBS in FY 2020.

Furthermore, HCBS play an important role in States' efforts to achieve compliance with Title II of the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973 (section 504),[27] section 1557 of the Affordable Care Act, and the Supreme Court's decision in *Olmstead* v. *L.C.,*[28] in which the Court held that unjustified segregation of persons with disabilities is a form of unlawful discrimination under the ADA [29] and States must ensure that persons with disabilities are served in the most integrated setting appropriate to their needs.[30] Section 9817 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) recently made a historic investment in Medicaid HCBS by providing qualifying States with a temporary 10 percentage point increase to the FMAP for certain Medicaid expenditures for HCBS that States must use to implement or supplement the implementation of one or more activities to enhance, expand, or strengthen HCBS under the Medicaid program.[31]

Medicaid coverage of HCBS varies by State and can include a combination of medical and non-medical services, such as case management, homemaker, personal care, adult day health, habilitation (both day and residential), and respite care services. HCBS programs serve a variety of targeted population groups, such as older adults, and children and adults with intellectual or developmental disabilities, physical disabilities, mental health/substance use disorders, and complex medical needs. HCBS programs provide opportunities for Medicaid beneficiaries to receive services in their own homes and communities rather than in institutions.

CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across and within services, but instead vary depending on the authorities under which States are delivering services. Additionally, States have flexibility to determine the quality measures they use in their HCBS programs. While we support State flexibility, a lack of standardization has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different populations.

In addition, although there are differences in rates of disability among demographic groups, there are very limited data currently available to assess disparities in HCBS access, utilization, quality, and outcomes. Few States have the data infrastructure to systematically or routinely report data that can be used to assess whether disparities exist in HCBS programs. This lack of available data also prevents CMS and States from implementing interventions to make improvements in HCBS programs designed to consistently meet the needs of all beneficiaries. Compounding these concerns have been notable and high-profile instances of abuse and neglect in recent years, which have been shown to result from poor quality care and inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [32] (''Joint Report''), which was jointly developed by the U.S. Department of Health Human Services' Administration for Community Living (ACL), Office for Civil Rights (OCR), and the Office of

[22] Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019.'' Chicago, IL: Mathematica, December 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf*.

[23] Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf*.

[24] These authorities include Medicaid State plan personal care services and Social Security Act (the Act) section 1915(c) waivers, section 1915(i) State plan HCBS, section 1915(j) self-directed personal assistant services, and section 1915(k) Community First Choice. See *https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html* for more information on these authorities. Some States also use demonstration authority under section 1115(a) of the Act to cover and test home and community-based service strategies. See *https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html* for more information.

[25] Federally funded grant programs include the Money Follows the Person (MFP) demonstration program, which was initially authorized by the Deficit Reduction Act of 2005 (Pub. L. 109–171). The MFP program was recently extended under the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which allowed new States to join the demonstration and made statutory changes affecting MFP participant eligibility criteria, allowing grantees to provide community transition services under MFP earlier in an eligible individual's inpatient stay.

[26] Murray, Caitlin, Michelle Eckstein, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2020.'' Chicago, IL: Mathematica, December 9, 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2020.pdf*.

[27] HHS interprets section 504 and Title II of the ADA similarly regarding the integration mandate and the Department of Justice generally interprets the requirements under section 504 consistently with those under Title II of the ADA.

[28] 527 U.S. 581 (1999).

[29] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688*.

[30] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688*.

[31] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html*.

[32] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf*.

Inspector General (OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm. In addition, while existing regulations provide safeguards for all Medicaid beneficiaries in the event of a denial of Medicaid eligibility or an adverse benefit determination by the State Medicaid agency and, where applicable, by the beneficiary's managed care plan, there are no safeguards related to other issues that HCBS beneficiaries may experience, such as the failure of a provider to comply with the HCBS settings requirements or difficulty accessing the services in the person-centered service plan unless the individual is receiving those services through a Medicaid managed care arrangement.

Finally, through our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we observed that all these interested parties routinely cite a shortage of direct care workers and high rates of turnover in direct care workers among the greatest challenges in ensuring access to high-quality, cost-effective HCBS for people with disabilities and older adults. Some States have also indicated that a lack of direct care workers is preventing them from transitioning individuals from institutions to home and community-based settings. While workforce shortages have existed for years, they have been exacerbated by the COVID–19 pandemic, which has resulted in higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in types of retail and other jobs that tend to draw from the same pool of workers.[33] [34] [35]

To address the list of challenges outlined in this section, we proposed Federal requirements to improve access to care, quality of care, and health and quality of life outcomes; promote health equity for people receiving Medicaid-covered HCBS; and ensure that there are safeguards in place for beneficiaries who receive HCBS through FFS delivery systems. We solicited comment on other areas for rulemaking consideration. The requirements we are finalizing in this rule are intended, individually and as a whole, to promote public transparency related to the administration of Medicaid HCBS programs.

D. Fee-For-Service (FFS) Payment

Section 1902(a)(30)(A) of the Act requires States to ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Regulations at § 447.203 require States to develop and submit to CMS an access monitoring review plan (AMRP) for a core set of services. Currently, the regulations rely on available State data to support a determination that the State's payment rates are sufficient to ensure access to care in Medicaid FFS that is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required under section 1902(a)(30)(A) of the Act.

In the May 6, 2011, **Federal Register**, we published the Medicaid Program; Methods for Assuring Access to Covered Medicaid Services proposed rule (76 FR 26341; hereinafter ''2011 proposed rule''), which outlined a data-driven process for States with Medicaid services paid through a State plan under FFS to follow in order to document their compliance with section 1902(a)(30)(A) of the Act. We finalized the 2011 proposed rule in the November 2, 2015, **Federal Register** when we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services'' final rule with comment period (80 FR 67576; hereinafter ''2015 final rule with comment period''). Among other requirements, the 2015 final rule with comment period required States to develop and submit to CMS an AMRP for certain Medicaid services that is updated at least every 3 years. Additionally, the rule required that when States submit a SPA to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care. We published the ''Medicaid Program; Deadline for Access Monitoring Review Plan Submissions'' final rule in the April 12, 2016 **Federal Register** (81 FR 21479; hereinafter ''2016 final rule'') with a revised deadline for States' AMRPs to be submitted to us.

Following the implementation of the AMRP process, numerous States have expressed concern regarding the administrative burden associated with the 2015 final rule with comment period requirements, especially those States with high rates of beneficiary enrollment in managed care. In an attempt to address some of the States' concerns regarding unnecessary administrative burden, we issued a State Medicaid Director letter (SMDL) on November 16, 2017 (SMDL #17–004), which clarified the circumstances in which provider payment reductions or restructurings would likely not result in diminished access to care, and therefore, would not require additional analysis and monitoring procedures described in the 2015 final rule with comment period.[36] Subsequently, in the March 23, 2018 **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold'' proposed rule (83 FR 12696; hereinafter ''2018 proposed rule''), which would have exempted States from requirements to analyze certain data or monitor access when the vast majority of their covered beneficiaries receive services through managed care plans. That proposed rule, if it had been finalized, would have provided similar flexibility to all States when they make nominal rate reductions or restructurings to FFS payment rates. Based on the responses received during the public comment period, we decided not to finalize the proposed exemptions.

In the July 15, 2019, **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission'' proposed rule (84 FR 33722; hereinafter ''2019 proposed rule'') to rescind the regulatory access requirements at §§ 447.203(b) and 447.204, and

[33] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[34] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[35] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[36] State Medicaid Director Letter #17–0004 Re: Medicaid Access to Care Implementation Guidance. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf* (November 2017).

concurrently issued a CMCS Informational Bulletin (CIB) [37] stating the agency's intention to establish a new access strategy. Based on the responses we received during the public comment period, we decided not to finalize the 2019 proposed rule, and instead continue our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program.

States have continued to question whether the AMRP process is the most effective or accurate reflection of access to care in a State's Medicaid program, and requested we provide additional clarity on the data necessary to support compliance with section 1902(a)(30)(A) of the Act. In reviewing the information that States presented through the AMRPs, we also have questioned whether the data and analysis consistently address the primary access-related question posed by section 1902(a)(30)(A) of the Act—namely, whether rates are sufficient to ensure access to care at least as great as that enjoyed by the general population in geographic areas. The unstandardized nature of the AMRPs, which largely defer to States to determine appropriate data measures to review and monitor when documenting access to care, have made it difficult to assess whether any single State's analysis demonstrates compliance with section 1902(a)(30)(A) of the Act.

While the AMRPs were intended to be a useful guide to States in the overall process to monitor beneficiary access, they are generally limited to access in FFS delivery systems and focus on targeted payment rate changes rather than the availability of care more generally or population health outcomes (which may be indicative of the population's ability to access care). Moreover, the AMRP processes are largely procedural in nature and not targeted to specific services for which access may be of particular concern, requiring States to engage in triennial reviews of access to care for certain broad categories of Medicaid services—primary care services, physician specialist services, behavioral health services, pre- and post-natal obstetric services, and home health services. Although the 2016 final rule discussed that the selected service categories were intended to be indicators for available access in the overall Medicaid FFS system, these categories do not directly translate to the services authorized under section 1905(a) of the Act, granting States deference as to how broadly or narrowly to apply the AMRP analysis to services within their programs. For example, the category ''primary care services'' could encompass several of the Medicaid service categories described within section 1905(a) of the Act and, without clear guidance on which section 1905(a) services categories, qualified providers, or procedures we intended States to include within the AMRP analyses, States were left to make their own interpretations in analyzing access to care under the 2016 final rule.

Similarly, a number of the AMRP data elements, both required and suggested within the 2016 final rule, may be overly broad, subject to interpretation, or difficult to obtain. Specifically, under the 2016 final rule provisions, States are required to review: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Although service utilization and provider participation are relatively easy measures to source and track using existing Medicaid program data, an analysis of whether beneficiary needs are fully met is at least somewhat subjective and could require States to engage in a survey process to complete. Additionally, while most Medicaid services have some level of equivalent payment data that can be compared to other available public payer data, such as Medicare, private payer information may be proprietary and difficult to obtain. Therefore, many States struggled to meet the regulatory requirement to compare Medicaid program rates to private payer rates because of their inability to obtain private payer data.

Due to these issues, States produced varied AMRPs through the triennial process that were, as a whole, difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. In isolation, a State's specific AMRP most often presented data that could be meaningful as a benchmark against changes within a State's Medicaid program, but did not present a case for Medicaid access consistent with the general population in geographic areas. Frequently, the data and information within the AMRPs were presented without a formal determination or attestation from the State that the information presented established compliance with section 1902(a)(30)(A) of the Act. Because the States' AMRPs generally varied to such a great degree, there was also little to glean in making State-to-State comparisons of performance on access measures, even for States with geographic and demographic similarities.

Based on results of the triennial AMRPs, we were uncertain of how to make use of the information presented within them other than to make them publicly available. We published the AMRPs on Medicaid.gov but had little engagement with States on the content or results of the AMRPs since much of the information within the plans could not meaningfully answer whether access in Medicaid programs satisfied the requirements of section 1902(a)(30)(A) of the Act. Additionally, we received little feedback from providers, beneficiaries, or advocates on whether or how interested parties made use of the triennial AMRPs. However, portions of the 2016 final rule related to public awareness and feedback on changes to Medicaid payment rates and the analysis that we received from individual States proposing to make rate changes was of great benefit in determining approvals of State payment change proposals. Specifically, the portion of the AMRP process where States update their plans to describe data and measures to serve as a baseline against which they monitor after reducing or restructuring Medicaid payments allows States to document consistency with section 1902(a)(30)(A) of the Act at the time of SPA submission, usually as an assessment of how closely rates align with Medicare rates, and to understand the impact of reductions through data monitoring after SPA approval.

Under this final rule, we balance elimination of unnecessary Federal and State administrative burden with robust implementation of the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act. The provisions of this final rule, as discussed in more detail later, will better achieve this balance through improved transparency of Medicaid FFS payment rates, through publication of a comparative payment rate analysis to Medicare and payment rate disclosures,

[37] CMCS Informational Bulletin: Comprehensive Strategy for Monitoring Access in Medicaid, Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf* (July 2019).

and through a more targeted and defined approach to evaluating data and information when States propose to reduce or restructure their Medicaid payment rates. Payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. In addition, payment rate transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes discussed within this final rule. Along with improved payment rate transparency and disclosures as well as comparative payment rate analyses, we are finalizing a more efficient process for States to undertake when submitting rate reduction or restructuring SPAs to CMS for review. As we move toward aligning our Medicaid access to care strategy across FFS and managed care delivery systems, we will consider additional rulemaking to help ensure that Medicaid payment rate information is appropriately transparent and rates are fully consistent with broad access to care across delivery systems, so that interested parties have a more complete understanding of Medicaid payment rate levels and resulting access to care for beneficiaries.

II. Summary of the Proposed Provisions and Analysis of and Responses to the Public Comments

We received 2,123 public comments from individuals and organizations, including, but not limited to, individuals, State government agencies, non-profit health care organizations, advocacy groups, associations, law firms, managed care plans, academic groups, and tribal organizations. We thank and appreciate the commenters for their consideration of the proposed requirements for ensuring access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across FFS and managed care delivery systems, and in HCBS programs. In general, commenters supported the proposed rule. In this section, arranged by subject area, we summarize the proposed provisions, the public comments received, and our responses. For a complete and full description of the proposed requirements, see the 2023 proposed rule, ''Medicaid Program; Ensuring Access to Medicaid Services'' (88 FR 27960, May 5, 2023) hereafter referred to as the ''proposed rule.''

We also received a number of out-of-scope comments that are not addressed in this final rule. In addition, we received some comments which were s solely applicable to the Managed Care proposed rule. Please see the Managed Care final rule for a for a summary of the comments CMS received pertaining to that proposed rule.

We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. If any provision is held to be invalid or unenforceable, the remaining provisions which could function independently, should take effect and be given the maximum effect permitted by law. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Finally, we note that we are finalizing with modification several of the dates for when we expect States to begin complying with the requirements being finalized in this rule, instead of what we proposed. Generally, we are finalizing that this rule, including the proposals being finalized herein, will be effective 60 days after publication of this final rule. However, we are finalizing that States are not required to begin compliance with most requirements being finalized in this rule until a specified applicability date, which we have specified for each such individual proposal being finalized. We discuss in detail the applicability date we are finalizing for each proposal being finalized in this rule in the respective section of this preamble. We encourage States, providers, and interested parties to confirm the applicability dates indicated in this final rule for any changes from the proposed. To assist, we are including Table 1 with the provisions and relevant timing information and dates.

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TABLE 1: Provisions and Relevant Timing Information and Dates*

Regulation Section(s) in Title 42 of the CFR	Applicability Dates**
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	*Establishment of MAC and BAC*: 1 year after the effective date of the final rule.
	BAC crossover on MAC: For the period from the effective date of the final rule through 1 year after the effective date, 10 percent; for the period from year 1 plus one day through year 2 after the effective date of the final rule, 20 percent; and thereafter, 25 percent of committee members must be from the BAC
	Annual report: States have 2 years from the effective date of the final rule to finalize the first annual report. After the report has been finalized, States will have 30 days to post the annual report.
Person-Centered Service Plans §§ 441.301(c)(1) and (3), 441.450(c), 441.540(c), and 441.725(c)	Beginning 3 years after the effective date of the final rule***
Grievance Systems §§ 441.301(c)(7), 441.464(d)(5), 441.555(e), and 441.745(a)(1)(iii)	Beginning 2 years after the effective date of the final rule
Incident Management System §§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v), and (b)(1)(i)	Beginning 3 years after the effective date of the final rule***; except for the requirement at § 441.302(a)(6)(i)(B) (electronic incident management system), which begins 5 years after the effective date of the final rule***
HCBS Payment Adequacy §§ 441.302(k), 441.464(f), 441.570(f), and 441.745(a)(1)(vi)	Beginning 6 years after the effective date of the final rule***
Reporting Requirements §§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii)	Beginning 3 years after the effective date of the final rule*** for § 441.311(b) (compliance reporting) and § 441.311(d) (access reporting) Beginning 4 years after the effective date of the final rule*** for § 441.311(c) (reporting on the HCBS Quality Measure Set) and (e) (HCBS payment adequacy reporting)
HCBS Quality Measure Set §§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)	HHS Secretary begins identifying quality measures no later than December 31, 2026, and no more frequently than every other year. HHS Secretary shall make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate.
Website Transparency §§ 441.313, 441.486, 441.595, and 441.750	Beginning 3 years after the effective date of the final rule***
Payment Rate Transparency Publication § 447.203(b)(1)	July 1, 2026, then updated within 30 days of a payment rate change.
Comparative Payment Rate Analysis Publication § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Payment Rate Disclosure § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Interested Parties Advisory Group § 447.203(b)(6)	The first meeting must be held within 2 years after effective date of the final rule (then at least every 2 years).
Rate Reduction and Restructuring SPA procedures § 447.203(c)(1) and (2)	Effective date of the final rule

* Regulatory provisions in this table are applicable at the time this rule becomes effective.

** In this final rule, including the regulations being finalized herein, we use the term "applicability date" to indicate when a new regulatory requirement will be applicable and when States must begin compliance with the requirements as specified in that regulation.

*** In the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the managed care organization's (MCO), prepaid inpatient health plan's (PIHP), or prepaid ambulatory health plan's (PAHP) contract, the applicability date is the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the applicability date specified in the chart.

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A. Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The current regulations at § 431.12 require States to have a Medical Care Advisory Committee (MCAC) to advise the State Medicaid agency about health and medical care services. The regulations are intended to ensure that State Medicaid agencies had a way to receive feedback regarding health and medical care services from interested parties. However, these regulations lacked specificity related to how these committees can be used to ensure the proper and efficient administration of the Medicaid program more expressly by more fully promoting beneficiary perspectives.

Under the authority of section 1902(a)(4) of the Act, section 1902(a)(19) of the Act, and our general rulemaking authority in section 1102 of the Act, we are finalizing proposals to § 431.12 to replace the current MCAC requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program and to better ensure that services under the Medicaid program will be provided in a manner consistent with the best interests of the beneficiaries. States will be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Council (BAC). Please note that in the proposed rule, the BAC was referred to as the Beneficiary Advisory Group, or BAG. The MAC and its corresponding BAC will serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program as determined by the State and MAC. With the changes in this final rule FFP, or Federal match, for Medicaid administrative activities will remain available to States for expenditures related to MAC and BAC activities in the same manner as the former MCAC.

The proposed and finalized requirements of the MAC amend previous and add new Federal requirements to: (1) expand the scope and use of States' MACs; (2) rename the Medicaid Advisory Committee, which will advise the State on a range of issues including medical and non-medical services; (3) require States to establish a BAC; (4) establish minimum requirements for Medicaid beneficiary representation on the MAC, membership, meetings materials, and attendance; and (5) promote transparency and accountability between the State and interested parties by making information on the MAC and BAC activities publicly available. The finalized requirements aimed at promoting transparency and accountability also include a requirement for States to create and publicly post an annual report summarizing the MAC and BAC activities.

We note that some commenters expressed general support for all of the provisions in section II.A. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule, we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.A. of this final rule are intended to present a comprehensive approach to implementing Medicaid Advisory Committees and Beneficiary Advisory Councils, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.B. (Home and Community-Based Services) and II.C.(Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.A is distinct and severable from other final policies and regulations being finalized in this section or in sections II.B. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the State Plan requirement (section II.A.2 of this final rule) are distinct and severable from the policies and regulations we are finalizing related to the MAC Membership and Composition requirement and the Annual Report requirement (sections II.A.4 and II.A.9 of this final rule, which we further intend are severable from each other).

1. Basis and Purpose (§ 431.12(a))

Under § 431.12 of the current regulation, paragraph (a) Basis and Purpose, sets forth a State plan requirement for the establishment of a committee (Medical Care Advisory Committee) to advise the Medicaid agency about health and medical care services. In the proposed rule, we proposed to amend the title of § 431.12 and paragraph (a) to update the name of the existing MCAC to the Medicaid Advisory Committee (MAC), and to add the requirement for States to establish and operate a dedicated advisory council comprised of Medicaid beneficiaries, the Beneficiary Advisory Group. In this final rule, we are changing the name from the Beneficiary Advisory Group to the Beneficiary Advisory Committee (BAC).

In the proposed rule, we stated that our goal was for the committee and its corresponding advisory council to serve in an advisory role to the State on issues related to health and medical services, as the MCAC did, as well as on other matters related to policy development and to the effective administration of the Medicaid program consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.[38] The Medicaid program covers medical services and is increasingly also covering services designed to address beneficiaries' social determinants of health and their health-related social needs more generally. Therefore, we believe that the MAC should discuss topics directly related to covered services as well as the potential need for the coverage of additional services that may be necessary to ensure that beneficiaries are able to meaningfully access these services. Expanding the scope of the current committee is necessary in order to align with the expanding scope of the Medicaid program. These changes are consistent with section 1902(a)(4)(B) of the Act because the MAC creates a formalized way for interested parties and beneficiary representatives to provide feedback to the State about issues related to the Medicaid program and the services it covers. The feedback from the MAC and BAC will be used by the State to ensure that the program operates efficiently and as it was designed to operate.

We received public comments on these proposals. The following is a

[38] Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27967).

summary of the comments we received and our responses.

Comment: We received a large number of comments in support of the proposed changes to the MCAC regulation and structure as proposed in § 431.12(a). The commenters expressed broad support for creation of the dual structure of the MAC and BAC. They noted that the creation of the BAC was a positive and welcome step to better capturing the lived experiences of people enrolled in Medicaid. Commenters also noted that having the BAC advise the MAC on policy development was a way to prioritize beneficiaries' perspectives. Commenters noted that the improvements proposed to the existing MCAC structure had the potential to be transformative and make the State more attuned to the needs and priorities of Medicaid beneficiaries.

Response: We thank commenters for their support of our overhaul of the MCAC. We are finalizing as proposed, with minor technical changes, the creation of the MAC and BAC.

Comment: We also received comments in opposition to the creation of a BAC. Generally, opposing commenters wanted CMS to be less prescriptive and allow States to engage Medicaid beneficiaries in other ways (for example, using existing State committees to serve as the BAC, conducting focus groups, and fielding surveys). Other commenters noted that States would need resources to implement the BAC, citing the additional administrative burden and layering of meetings for certain members.

Response: We encourage States to engage with their Medicaid beneficiaries in a variety of ways, and we understand that many States may already operate groups or committees comprised of Medicaid beneficiaries. However, having a formalized structure to work directly with Medicaid beneficiaries will help to ensure a level and manner of engagement across all State programs. For the commenters concerned with the BAC adding administrative burden, we acknowledge that implementing these changes will create administrative burden. We discuss administrative burden to States in the Regulatory Impact Analysis section of this rule. However, in an effort to minimize administrative burden for States, we note that existing committees can be used to fulfill the BAC requirement as long as the committees meet the membership requirements specified in § 431.12(e). Later in this section, we also note that States do not have to use the same BAC members to join all MAC meetings. While it may not be an ideal way to create long-term consistency of the MAC membership, States could, in an effort to lessen the time commitment of BAC members, choose to rotate which members attend the quarterly MAC meetings.

Comment: We received several comments asking for the BAG name to be changed. The commenters cited potentially negative connotations that could be associated with the acronym BAG. Additionally, a few commenters requested that States with existing beneficiary groups be able to maintain their names.

Response: We have changed the name of the BAG to the BAC, as noted earlier in this final rule. For commenters concerned with duplicative efforts, we noted in the proposed rule that States with existing BAC-like committees can use those committees to fulfil the BAC requirement as long as they meet the membership requirements specified § 431.12(e). States are not required to change their existing group names to match the BAC name as long as interested parties understand what existing group or committee is being used to fulfill regulatory requirement of the BAC. To clarify this for interested parties, States must note in their publicly posted by-laws (§ 431.12 (f)(1)) that the group is being used to fulfill the regulatory requirements of § 431.12.

Comment: Several commenters asked CMS to clarify the role of the MAC and BAC, citing that in the proposals, the language varies from ''advisory'' to ''providing feedback.'' Other commenters expressed that they do not want the MAC and BACs to be approval bodies that lack the ability to make decisions.

Response: The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. It is our intention that the MAC and BAC serve in an advisory capacity to the State. However, serving in an advisory capacity does not preclude the MAC and BAC members from sharing experiential feedback. We did not propose to give the MAC or BAC a decision-making role because we want to allow States the freedom to administer their Medicaid programs in the manner they see fit, but be guided by these two entities' recommendations and experiences with the Medicaid program.

Comment: We received a comment asking CMS to require that the MAC and BAC not be used to take the place of a State's tribal consultation requirements.

Response: We do not anticipate that the MAC or BAC could be used to fulfill tribal consultation requirements under section 1902(a)(73) of the Act. For States with one or more Indian Health Programs or Urban Indian Organizations that furnish health care services, the State must consult with such Programs and Organizations on a regular, ongoing basis. While the statute specifically permits representatives of such Programs and Organizations to be included on the MCAC [now known as the MAC], this alone would not meet the requirement to consult on any State plan amendments (SPAs), waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations prior to submission.

Comment: We received a few comments requesting that CMS conduct a study to assess which States already have MCACs or BACs to ensure they are no duplicative efforts. Another commenter asked CMS to solicit feedback from existing MCAC members to see how it can be improved before making beneficiary groups a requirement.

Response: We clarify that MCACs are currently required of all States so conducting an assessment to see which States already have MCACs would not necessarily result in a lot of new information. However, we agree that understanding which States already have BAC-like committees in place would be helpful. In fact, when developing the proposed rule, we engaged with interested parties, both from State Medicaid agencies and the wider Medicaid community, to determine what improvements were needed to the MCACs to allow States and beneficiaries to obtain the most benefit from their work. For commenters concerned with duplicative BAC activities, we note again that States with an existing beneficiary group or beneficiary committee that meets the requirement of the BAC, as finalized in this rule at § 431.12(e), do not need to set up a second beneficiary committee.

Comment: We received a few comments asking CMS to require the MAC and BAC to coordinate with other State advisory committees.

Response: States will vary in how they run their advisory committees. Some States may choose to coordinate across their different advisory committees, while other States may have reasons for keeping their advisory committees and their processes separate. We do not want to add more administrative burden by adding a requirement to § 431.12 for States to coordinate across State advisory committees. However, if coordinating

across these committees in some manner would be advantageous for the Medicaid program, then we encourage the State to do so.

After consideration of public comments, we are finalizing § 431.12(a) as proposed with the following change:

Language modifications to reflect the new name of the ''Beneficiary Advisory Council (BAC).''

2. State Plan Requirement (§ 431.12(b))

Under § 431.12 of the current regulation, paragraph (b) State Plan Requirement, calls for a State plan to provide for a MCAC to advise the Medicaid agency director about health and medical care services.

We proposed conforming updates to paragraph (b) regarding the State plan requirements, to reflect the addition of the BAC and the expanded scope.

The Interested Parties Advisory Group, described in a later section of this final rule (Interested Parties Advisory Group § 447.203(b)(6)), is designed to advise States on rate setting and other matters for certain HCBS and is not related to the MAC or BAC specified here. In section II.C.2.c. of this final rule, under § 447.203(b)(6), we explain that States will have the option to use its MAC and BAC to provide recommendations for payment rates, thereby satisfying the requirements of § 447.203(b)(6). However, the MAC and BAC requirements finalized here are wholly separate from the Interested Parties Advisory Group.

We did not receive public comments on § 431.12(b). However, we are making one conforming edit to this paragraph based on a language change identified in § 431.12(c) to replace the term State Medicaid Director. We are finalizing as proposed with the following changes:

- Language modifications to reflect the new name of the ''Beneficiary Advisory Council (BAC).''
- Replacing the term Medicaid Agency Director with the term, ''director of the single State Agency for the Medicaid program.''

3. Selection of Members (§ 431.12(c))

Under § 431.12 of the current regulation, paragraph (c) Appointment of members, the agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

We proposed to revise paragraph (c) to specify that the members of the MAC and BAC must be appointed by the agency director or a higher State authority on a rotating and continuous basis. We also proposed to require the State to create a process for the recruitment and appointment of members of the MAC and BAC. Additionally, we proposed to require the State to post this information on the State's website. As discussed in the proposed rule,[39] the website page where this information is located would be required to be easily accessible by the public. These proposed updates align with how some States' existing MCACs are already run, which will facilitate the transition of these MCACs into MAC/BACs. Additionally, the proposed changes are designed to provide additional details to support States' operation of the MAC and BAC. Further, we believe these proposed updates will facilitate transparency, improving the current regulations, which did not mention nor promote transparency of information related to the MCAC with the public. We also believe that transparency of information can lead to enhanced accountability on the part of the State in making its MAC and BAC as effective as possible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments regarding the terms used to describe who should be given the authority to appoint members to the MAC and BAC. Many commenters supported the proposal of having the State Medicaid Director appoint the members. A few commenters suggested that we make clarifications to the proposed regulation language so that only the State Medicaid Director and not ''a higher State authority'' is referenced, since the work of the MAC and BAC is to advise the State Medicaid Director. Others noted that the correct term to use in the regulation when referring to the State Medicaid Director is the director of the single State agency for the Medicaid program. There was another category of commenters that did not believe the authority to select MAC and BAC members should sit with either the State Medicaid Director or a higher State Authority. These commenters instead stated it would be more equitable if prospective MAC and BAC members were selected by an outside company, a computer, at random, or by a lottery system. They noted that in their experiences sometimes parents or family members are excluded from selection processes. Finally, other commenters noted that the term ''appointed'' implied that the State did not use any kind of a ''selection process'' to choose its MAC and BAC members. These commenters may have felt that the term ''appoint'' means that the State can simply pick whomever it wants to serve as a member rather than ''selecting'' members from a pool of people who submitted applications to serve as MAC or BAC members.

Response: We appreciate the comments provided on this section and acknowledge the complicated work that comes with selecting MAC and BAC members. Since the MAC and BAC serve in an advisory role to the Medicaid program, we believe strongly that the authority to select should lie with the director of the State Medicaid agency. We know that Medicaid agencies' names may vary from State to State, and thus, agree that language in the regulation can be changed to more clearly reflect a more commonly used term for the Medicaid agency (that is, the single State Agency for the Medicaid Program). For commenters that expressed concern that parents or family members are excluded from the selection processes, we note that the BAC regulations require both Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries, such as family members to be selected. Finally, we agree that the word ''appoint'' in the proposed rule does not accurately reflect the intention of the regulation and could be misinterpreted to mean that the State did not use a selection process where interested parties submit an application and then the State reviews those applications before selecting its MAC and BAC members. Based on the comments we received, we now understand that the term ''appoint'' can be taken to mean that a selection process did not occur. We want to avoid any confusion that the requirements are asking the State to appoint members without using a selection process, which was not our intention. For clarity, we are also amending the regulatory language in § 431.12(c) to now state that the ''director of the single State Agency for the Medicaid program,'' must ''select'' members for the MAC and BAC.

Comment: We received comments on the proposed changes to § 431.12(c) related to term limits of the MAC and BAC members. The commenters were generally divided across wanting CMS to require States to have set term limits for members, not wanting any term limits, and not wanting short term limits. Commenters who expressed support for set term limits noted that setting term limits ensured that new perspectives would be added on a regular basis while others noted that setting term limits allowed members to

[39] Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27968).

share recommendations or constructive criticism without fear of retaliation. The commenters who opposed term limits noted that finding people with Medicaid expertise may be difficult in some geographic areas and, as a result, the State would benefit from having the same members serve without term limits. Other commenters noted that it takes time for members to build their expertise and understanding of the Medicaid program and setting short term limits may not take into account the time needed to accumulate enough knowledge to contribute fully to the MAC and BAC. These commenters suggested term limits with lengths ranging from 2 to 6 years.

Response: States have the ability to determine the tenure of members, as States are best situated to assess their members' ability to participate in and meaningfully contribute to the MAC and BAC and for what length of time. In the proposed rule, we described the requirement for States to determine the length of terms for committee and council members. For clarity, we are amending the regulatory language in § 431.12(c) to reflect this information as well, to now state ''. . . members to the MAC and BAC for a term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis.'' We proposed this type of term because we believe there is value in ensuring new voices and perspectives are introduced to the committee and council. We further clarify that once a MAC or BAC member's term has been completed, the State will select a new member, thus ensuring that MAC and BAC memberships rotate continuously. Setting memberships as continuously rotating means that the State must seek to recruit members to fill open seats on the MAC and BAC on an ongoing basis. States can also select members to serve multiple non-consecutive terms.

After consideration of public comments, we are finalizing § 431.12(c) with the following changes:

- Language modifications to reflect the new name of the BAC.
- Replacing the term agency director or higher authority with the term, ''director of the single State Agency for the Medicaid program.''
- Replacing the word ''appoint'' with ''select'' in various places.
- Adding language to the regulation to reflect that ''the term of length for MAC and BAC members will be term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis.''

4. MAC Membership and Composition (§ 431.12(d))

Under § 431.12 of the current regulation, paragraph (d), Committee Membership, States are required to select three types of committee members: (1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; (2) Members of consumers' groups, including Medicaid beneficiaries, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and (3) the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

In the proposed rule, paragraph (d) of § 431.12, MAC membership and composition, we proposed in (d)(1) to require that a minimum of 25 percent of the MAC must be individuals with lived Medicaid beneficiary experience from the BAC. The BAC, which is defined later in § 431.12(e), is comprised of people who: (1) are currently or have been Medicaid beneficiaries, and (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid).

We proposed 25 percent as the minimum threshold requirement for (d)(1) to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. We did not propose a higher percentage because we acknowledge that States will benefit from a MAC that includes representation from a diverse set of interested parties who work in areas related to Medicaid but are not beneficiaries, their family members, or their caregivers.

In terms of the required representation from the remaining MAC members, as specified in the proposed rule, paragraph (d)(2), we proposed that a State must include at least one from each category: (A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries; (B) clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care; (C) participating Medicaid managed care organizations or the State health plan association representing such organizations, as applicable; and (D) other State agencies serving Medicaid beneficiaries, as ex-officio members.

We believe that advisory committees and councils can be most effective when they represent a wide range of perspectives and experiences. Since we know that each State environment is different, we aimed to provide the State with discretion on how large the MAC and BAC should be. In the proposed changes we did, however, specify the types of categories of Committee members that can best reflect the needs of a Medicaid program. We believe that diversely populated MACs and BACs can provide States with access to a broad range of perspectives, and importantly, beneficiaries' perspective, which can positively impact the administration of the Medicaid program. This approach is consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. The changes in membership we proposed and are finalizing will support States to set up MACs that align with section 1902(a)(4)(B) since States will now have to select the membership composition to reflect the community members who represent the interests of Medicaid beneficiaries. The State also benefits from having a way to hear how the Medicaid program can be responsive to its beneficiaries' and the wider Medicaid community's needs.

We also noted in the proposed rule that we encourage States to take into consideration, as part of their member selection process, the demographics of the Medicaid population in their State. Keeping diverse representation in mind as a goal for the MAC membership can be a way for States to help ensure that specific populations and those receiving critically important services are appropriately represented on the MAC. For example, in making MAC membership selections, the State may want to balance the representation of the MAC according to geographic areas of the State with the demographics and health care needs of the Medicaid program of the State. The State will want to consider geographical diversity (for example, urban and rural areas) when making its membership selections. We noted in the proposed rule, that a State could also consider demographic representation of its membership by including members representing or serving Medicaid beneficiaries who receive services in the

following categories: (1) pediatric health care; (2) behavioral health services; (3) preventive care and reproductive health services; (4) health or service issues pertaining specifically to people over age 65; and (5) health or service issues pertaining specifically to people with disabilities. By offering these considerations, we seek to support States in their efforts to eliminate differences in health care access and outcomes experienced by diverse populations enrolled in Medicaid. We intend that the MAC and the BAC can support several of the priorities for operationalizing health equity across CMS programs as outlined in the CMS Framework for Health Equity (2022–2032) and the HHS Equity Action Plan which is consistent with E.O. 13985, which calls for advancing equity for underserved communities.

Rather than prescribing specific percentages for the other (non-BAC) categories in the proposed rule, we only required representation from each category as part of the MAC. The specific percentage of each of category (other than the BAC members) relative to the whole committee can be determined by each State. This approach will provide States with the flexibility to determine how to best represent the unique landscape of each State's Medicaid program. We solicited comment on what should be the minimum percentage requirement that MAC members be current/past Medicaid beneficiaries or individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers of those enrolled in Medicaid). In addition to hearing directly from beneficiaries, the State can gain insights into how to effectively administer its program from other members of the Medicaid community.

States will determine which types of providers to include under the clinical providers or administrators category, and we recommend they consider a wide range of providers or administrators that are experienced with the Medicaid program including, but not limited to: (1) primary care providers (internal or family medicine physicians or nurse practitioners or physician assistants that practice primary care); (2) behavioral health providers (that is, mental health and substance use disorder providers); (3) reproductive health service providers, including maternal health providers; (4) pediatric providers; (5) dental and oral health providers; (6) community health, rural health clinic or Federally Qualified Health Center (FQHC) administrators; (7) individuals providing long-term care services and supports; and (8) direct care workers [40] who can be individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers).

We have also identified managed care plans, including Primary Care Case Management (PCCM) entities and Primary Care Case Managers (PCCMs),[41] as an important contributor to the MAC, but we acknowledge that not all States have managed care delivery systems. We know many Medicaid managed care plans administer similar committees and thus allow for States to tailor managed care plan representation based on its delivery system and the experience and expertise of managed care plans in the State. For example, States, if applicable, can fulfill this category with only one or with multiple managed care plans operating in the State. In addition, we also give States the flexibility to meet the managed care plan representation requirements with either participating Medicaid managed care plans or a health plan association representing more than one such organization.

The language in paragraph (d)(2)(D) broadens the previous MCAC requirement to allow for additional types of representatives from other State agencies to be on the committee. Specifically, the previous MCAC regulation requires membership by ''the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.'' In the proposed rule, we expanded the requirement for external agency representation to be broader than the welfare or public health department, which would give States more flexibility in representing the Medicaid program's interests based on States' unique circumstances and organizational structure. States can work with sister State agencies to determine who should participate in the MAC (for example, foster care agency, mental health agency, department of public health). We also proposed that these representatives be part of the committee as ex-officio members, meaning that they hold the position because they work for the relevant State agency. In finalizing the proposals, we reviewed this requirement closer. While we believe it will be essential to have these State-interested parties present for program coordination and information-sharing, we intended to reflect in the proposed rule that the formal representation of the MAC should be comprised of beneficiaries, advocates, community organizations, and providers that serve Medicaid beneficiaries. Therefore, we clarify in this final rule that while these ex-officio members will sit on the MAC, they will not be voting members of the MAC. Therefore, on matters that the MAC decides by vote, including but not necessarily limited to finalizing the MAC's recommendations to the State, the ex-officio members will not participate in voting.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments about the proposed requirement of having some BAC members serving on the MAC. Commenters either agreed with the importance of having a subset of Medicaid beneficiaries serve on both the BAC and the MAC, or they noted that having a subset of BAC members on both committees could lead to undue burden for these members based on the number of meetings they would have to attend. One commenter suggested a phased-in approach where the BAC members meet only as the BAC for a time (for example, a year) and then transition to serving on the MAC only.

Response: We understand the concerns raised by the commenters about putting undue burden on a subset of BAC members. We believe it is vital for the success of both the BAC and MAC that there is a point of integration via the crossover membership requirement since this is the way to ensure that the Medicaid beneficiary perspective is included in both groups.

[40] As finalized in § 441.302(k) of this final rule, CMS defines as Direct care worker as any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model: (A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart; (B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; (C) A direct support professional; (D) A personal care attendant; (E) A home health aide; or (F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

[41] Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

We created this crossover requirement to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. For commenters that are concerned with undue burden of having a subset of BAC members also attend MAC meetings, in § 431.12(f)(3), we note that MACs and BACs are only required to meet once per quarter. While the regulation does not state that the subset of BAC members that join each MAC meeting has to be the same, we recognize that it would be more effective to have consistency in the BAC members that attend the MAC meetings in many cases. However, if States or the BAC are concerned with overburdening its BAC members, a potentially less efficient but workable alternative could be to rotate which BAC members attend the MAC in an effort to further reduce the number of meetings attended for a given BAC member. Nevertheless, the suggestion of having a member transition from solely being on the BAC to solely being on the MAC might not always promote the crossover concept we are seeking with the requirement that the MAC membership consist of 10 to 25 percent members from the BAC, since we are striving for inclusion of the Medicaid beneficiary perspective in both groups via the BAC members.

Comment: In response to our solicitation about having 25 percent as the minimum threshold of BAC membership crossover on the MAC, the majority of the commenters stated that a minimum 25 percent was the appropriate amount of crossover members. They noted that 25 percent crossover membership would help to center and amplify beneficiary voices on the MAC. A few commenters stated that the percentage should be lower (for example 10 or 15 percent). These commenters cited several reasons why having a lower threshold number would be better. Some commenters noted that having a smaller number of BAC members would allow States to better support or train their members so they could fully participate in the MAC. Other commenters stated that having a smaller number of BAC members could lessen the burden on States of finding and recruiting members to participate. Another group of commenters wanted the percentage of BAC crossover to be higher than 25 percent (for example 33, 50, 51, or 75 percent). These commenters sought a higher BAC crossover in order to: safeguard against marginalization of beneficiary members on the MAC; amplify diverse voices through a higher crossover number; and rectify any power imbalances that may exist. There were also a few commenters who noted that States should have the ability to determine their own percentages for the BAC crossover. Finally, we received comments asking CMS to consider allowing States to use a graduated approach to reach the 25 percent minimum requirement of BAC crossover on the MAC.

Response: We thank the commenters who agreed with our proposed threshold of the requirement for a minimum of 25 percent BAC crossover on the MAC. For commenters who thought the percentage should be lower, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC. To account for these challenges, we are extending the timeframe for implementation of this requirement in this final rule so that States have 2 years to achieve the 25 percent minimum threshold requirement of MAC members that come from the BAC. Instead of the 25 percent minimum threshold coming into effect right away, we are revising this final rule to provide in § 431.12(d)(1) that, for the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

For commenters who expressed the need for a percentage higher than 25 for the BAC member crossover, we note that the policy we proposed and are finalizing establishes a minimum percentage threshold for States to meet. If a State so chooses, it can select a percentage higher than the minimum of 25 percent, provided the MAC membership also satisfies the requirements of § 431.12(d)(2) of this final rule. For commenters who raised the issue of providing training for BAC members, we have a comment/response on this topic under § 431.12(h)(3).

Comment: The majority of comments received on § 431.12(d) were about § 431.12(d)(2), MAC composition categories. We received comments that fell into four groups. The first group of commenters shared their broad support for the MAC committee member categories that we proposed and also urged CMS to ensure that States select members that represented the Medicaid community and who were geographically as well as racially/ethnically diverse. The second group of commenters asked for the MAC to include representation from members who would qualify for the BAC (for example, Medicaid beneficiaries, their families, and caregivers). It is unclear from the comments if these commenters were asking for an additional group of Medicaid beneficiaries be added to the MAC (in addition to the 25 percent of MAC we proposed to require be from the BAC) or if they did not understand that the MAC composition already includes a category which accounts for this category of members. The third group of commenters asked that specific types of interested parties be required to be represented on the MAC categories (for example, specific provider types, unions, HCBS provider agencies, hospitals, protection and advocacy programs, legal professionals, and medical billing professionals). The fourth group of commenters suggested ideas for types of MAC members that States could use to meet categories specified in the proposed rule (for example add a State Ombudsman to the ex-officio category). We also received a few suggestions to add specific member categories (for example, a member category for FFS members, a member category for people with behavioral health conditions, and a youth member category).

Response: We appreciate the wide range of comments that were submitted about the MAC membership composition. We developed the MAC composition framework in the proposed rule by creating broad membership categories that captured a range of interested parties who are members of the Medicaid community while giving States as much flexibility as possible to build their MACs in ways that account for the unique features of the State's environment. All of the membership categories, as currently written, are broad enough to accommodate the types of members described by the commenters. For example, a State Ombudsman can be used to fulfil the State agency category; a State with both managed care and FFS could chose to select two members (one for each type of delivery system) for the MAC; a person with behavioral health condition(s) could be suitable for multiple categories depending on whether they are a Medicaid beneficiary (current or former) or represent a consumer advocacy or community-based organization. Finally, for the commenter asking for a specific youth member category, we will note that there are no Federal requirements or limitations concerning youth participation on the MAC or BAC, and this is in the State's discretion. The

State could select a youth member to fulfill a MAC or BAC member category as long as that person meets the requirements of that membership category.

We also want to clarify for commenters that Medicaid beneficiaries, their families, and caregivers have their own MAC category in the regulation, because the BAC is listed in the final regulation as one of the categories of MAC members at § 431.12(d)(1).

After consideration of public comments, for § 431.12(d), we are finalizing as proposed with:

- Language modifications to reflect the new name of the BAC;
- Replacing the language at § 431.12 (d)(1) to clarify the timeframe for States to reach 25 percent of MAC members coming from the BAC. The new sentence will now read, ''For the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 10, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.''
- Language modifications to § 431.12 (d)(2)(C) to replace ''managed care plan'' with ''MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2''; and
- Adding the word ''non-voting'' to ex-officio members at the end of § 431.12 (d)(2)(D).

5. Beneficiary Advisory Council (§ 431.12(e))

The current requirements governing MCACs require the presence of beneficiaries in committee membership but do little else to ensure their contributions are considered or their voices heard. For example, in the current regulations of § 431.12, paragraph (e) Committee participation, only briefly mentions the participation of beneficiary members. The current requirement provides little guidance about how to approach the participation of beneficiary members on the committee.

We proposed to add new paragraph § 431.12(e). The proposed rule noted that in the new paragraph, (e) Beneficiary Advisory Council, States would be required to create a BAC, a dedicated Beneficiary Advisory Council, that will meet separately from the MAC on a regular basis and in advance of each MAC meeting.

Specifically, at new paragraph (e)(1), we proposed to require that the MAC members described in paragraph (d)(1) must also be members of the BAC. This requirement will facilitate the bi-directional communication essential to effective beneficiary engagement and allow for meaningful representation of diverse voices across the MAC and BAC. In paragraph (e)(2), we proposed to require that the BAC meetings occur in advance of each MAC meeting to ensure BAC member preparation for each MAC discussion. BAC meetings will also be subject to requirements in paragraph (f)(5), described later in this section, that the BAC meetings must occur virtually, in-person, or through a hybrid option to maximize member attendance. We plan to expound on best practices for engaging beneficiary participation in committees like the MAC in a future toolkit.

We proposed the addition of the BAC because we believe that it will result in providing States with increased access to beneficiary perspectives. The creation of a separate beneficiary-only advisory council also aligns with what we have learned from multiple interviews with State Medicaid agencies and other Medicaid interested parties (for example, Medicaid researchers, former Medicaid officials) conducted over the course of 2022 on the operation of the existing MCACs. These interested parties described the importance of having a comfortable, supportive, and trusting environment that facilitates beneficiaries' ability to speak freely on matters most important to them. Further, we believe that the crossover structure for the MAC and BAC proposed in § 431.12(d) allows for the beneficiary-only group to meet separately while still having a formal connection to the broader, over-arching MAC. It is important the MAC members can directly engage with the beneficiaries and hear from their experience. We noted earlier that some States may already have highly effective BAC-type councils operating as part of their Medicaid program. These existing councils may represent specific constituencies such as children with complex medical needs or older adults or may be participants receiving services under a specific waiver. In these instances, States may use these councils to satisfy the requirements of this rule, as long as the pre-existing BAC-type council membership includes the type of members required in the proposed paragraph of § 431.12(e).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments in support of the BAC as specified in the newly proposed § 431.12(e). Commenters noted that the BAC would provide a necessary and less-intimidating venue where Medicaid beneficiaries along with their families and caregivers can share first-person experiences and feedback to the State. While many commenters stated the BAC was needed and a welcomed improvement, a few commenters cautioned that States would need more than just to set up a BAC; they will also need to invest in creating opportunities for meaningful engagement.

Response: We agree that the BAC must be supported and used by the State in ways that create opportunities for BAC members to be actively involved and have their contributions considered.

Comment: A few commenters asked CMS to clarify how existing community groups or advisory councils could be used to satisfy the requirements of the BAC. One commenter asked if the BAC would meet a State's inclusive Community First Choice (CFC) requirements.

Response: The proposed new paragraph (e) requires that States form a BAC, but notes that the State can use an existing beneficiary group. Prior to rulemaking, CMS spoke to several States and researchers to understand how States were implementing the MCAC requirements. From the information gathered, we know that many States already have active Medicaid beneficiary groups that could fill these requirements and can function as their BACs. In these instances, it is not our intention to ask a State to create a second Medicaid beneficiary group to meet the BAC requirements. If a State wants to use an existing group to satisfy the BAC requirements, they will need to ensure that the existing committee's membership meets the membership requirements of the BAC and that the existing committee's bylaws are developed or updated, and published, to explain that the committee functions to meet the BAC requirements.

Regarding the ability to use the BAC to meet CFC requirements of the State, CMS notes in the ''Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers'' final rule,[42] that States may utilize existing

[42] ''Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers *https://www.medicaid.gov/sites/default/files/2019-12/cfc-final-settings.pdf*,'' (79 FR 2948, 2982).

advisory bodies in the implementation of CFC, as long as the statutory requirements as specified in § 441.715 for the Development and Implementation Council are met. We acknowledge the benefits of the Implementation Council coordinating with related interested parties councils and commissions and encourage States to do so. States may also choose to leverage these councils and/or include members from these councils to meet the requirements for CFC.

Comment: The majority of the comments received related to the newly proposed § 431.12(e) were commenters providing recommendations on which groups of people should also be required to be included as BAC members. We received a range of suggestions such as: HCBS beneficiaries, individuals with specific chronic diseases and disabilities, individuals using long term care services and supports (LTSS), individuals who are receiving perinatal health services, individuals who have lived experience with behavioral health conditions, and Medicaid beneficiaries who are deaf, hard of hearing, or deaf blind. Commenters also requested that the BAC members represent a cross-section of Medicaid beneficiaries that can also be regarded as demographically and geographically diverse.

Response: We agree with commenters that the States should select the types of BAC members that can provide them with representative views of the experience of Medicaid beneficiaries in their State. The regulatory language provides States with the flexibility to make those determinations based on the characteristics of their individual State Medicaid program. It can be challenging to find beneficiaries available to serve on a council, particularly if the requirements of membership are very specific. By keeping our regulations broad for what types of beneficiaries should be selected for the BAC, we seek to ensure States are able to recruit members with fewer challenges.

Comment: A few commenters asked for CMS to clarify or further define a few terms used in newly proposed § 431.12(e). Specifically, a couple of commenters asked CMS to clarify the phrase ''individuals with direct care experience supporting Medicaid beneficiaries.'' Another commenter asked if CMS could define whether the term ''caregivers'' included paid caregivers.

Response: In the proposed and in this final rule, we have described individuals with direct experience supporting Medicaid beneficiaries as ''family members or caregivers of those enrolled in Medicaid.'' In the proposed rule's preamble,[43] we state that caregivers can be paid or unpaid caregivers. To better clarify these definitions, we are adding the words ''paid or unpaid'' before the word caregiver to the proposed regulatory language at new paragraph § 431.12(e) so that the phrase reads, ''. . . individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State. . . .''

Comment: As noted in an earlier section, several commenters asked CMS to clarify the role of the BAC, citing that in the proposals, the language varies from ''advisory'' to ''providing feedback.''

Response: The primary role of the BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. To better clarify the BAC's advisory role, we are removing from the proposed regulatory language at new paragraph § 431.12(e) the words and to ''provide input to.'' The phrase now reads ''. . . to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.''

Comment: A few commenters shared suggestions related to the BAC meetings described in new paragraph § 431.12(e)(2). One commenter asked CMS to encourage States to hold BAC and MAC meetings on the same day, with the BAC meeting occurring first in an effort to minimize travel. Other commenters asked CMS for additional meetings for the BAC to be required to attend (for example, meetings with the State Medicaid Director and meetings with CMS regional administrators).

Response: The meeting structure specified in the BAC proposal is focused on the interplay between the BAC and MAC meetings. In new paragraph § 431.12(e)(2), we are requiring that the BAC meetings be held separate from the MAC and in advance of the MAC, so that the BAC members have the opportunity to prepare and hold an internal discussion among themselves. Holding MAC and BAC meetings in the same day could be in line with the meeting requirements. States may wish to hold additional BAC meetings with other parties, as needed.

Comment: Some commenters asked CMS to create a Federal-level BAC to ensure consistency across States.

Response: A Federal-level BAC would not further the goal of providing States with beneficiary input into their programs because it would not focus on the particular features of each individual State's Medicaid program or beneficiary and provider communities. Such a group is beyond the scope of this rulemaking.

After consideration of public comments, we are finalizing new § 431.12(e) as proposed, with changes to:

- Language modifications to reflect the new name of the BAC;
- Adding language that caregivers on the BAC can be ''paid or unpaid.'' Section 431.12 (e) will now state, ''. . . individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid) . . . .''
- Deleting the phrase ''. . . and provide input to . . . .'' Section 431.12(e) will now state ''. . . to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.''

6. MAC and BAC Administration (§ 431.12(f))

We proposed to add new paragraph § 431.12(f), MAC and BAC administration, to provide an administrative framework for the MAC and BAC that ensures transparency and a meaningful feedback loop to the public and among the members of the committee and council.[44]

Specifically, in new paragraph (f)(1), we proposed that State agencies would be required to develop and post publicly on their website bylaws for governance of the MAC and BAC, current lists of MAC and BAC memberships, and past meeting minutes for both the committee and council. In paragraph (f)(2), we proposed that State agencies would be required to develop and post publicly a process for MAC and BAC member recruitment and selection along with a process for the selection of MAC and BAC leadership. In paragraph (f)(3), we proposed that State agencies would be required to develop, publicly post, and implement a regular meeting schedule for the MAC and BAC. The proposed

[43] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27968).

[44] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27920).

requirement specified that the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. In paragraph (f)(4), we proposed requiring that that at least two MAC meetings per year must be opened to the public. For the MAC meetings that are open to the public, the meeting agenda would be required to include a dedicated time for public comment to be heard by the MAC. None of the BAC meetings were required to be open to the public unless the State's BAC members decided otherwise. We also proposed that the State ensure that the public is provided adequate notice of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance. We solicited comment on this approach. In paragraph (f)(5), we proposed that States would be required to offer in-person, virtual, and hybrid attendance options including, at a minimum telephone dial-in options at the MAC and BAC meetings for its members to maximize member participation at MAC and BAC meetings. If the MAC or BAC meeting was deemed open to the public, then the State must offer at a minimum a telephone dial-in option for members of the public.

With respect to in-person meetings, we proposed in paragraph (f)(6) that States would be required to ensure that meeting times and locations for MAC and BAC meetings were selected to maximize participant attendance, which may vary by meeting. For example, States may determine, by consulting with their MAC and BAC members, that holding meetings in various locations throughout the State may result in better attendance. In addition, States may ask the committee and council members about which times and days may be more favorable than others and hold meetings at those times accordingly. We also proposed that States use the publicly posted meeting minutes, which lists attendance by members, as a way to gauge which meeting times and locations garner maximum participate attendance.

Finally, in paragraph (f)(7), we proposed that State agencies were required to facilitate participation of beneficiaries by ensuring that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, that communication with individuals with disabilities is as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

Interested parties' feedback and recent reports [45] [46] published on meaningful beneficiary engagement illuminate the need for more transparent and standardized processes across States to drive participation from key interested parties and to facilitate the opportunity for participation from a diverse set of members and the community. Further, we believe that in order for the State to comply with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan, it needs to be responsive to the needs of its beneficiaries. To be responsive to the needs of its beneficiaries, the State needs to be able to gather feedback from a variety of people that touch the Medicaid program, and the MAC and BAC will serve as a vehicle through which States can obtain this feedback.

We acknowledge that interested parties may face a range of technological and internet accessibility limitations, and proposed requiring that, at a minimum, States provide a telephone dial-in option for MAC and BAC meetings. While we understand that in-person interaction can sometimes assist in building trusted relationships, we also recognize that accommodations for members and the public to participate virtually is important, particularly since the beginning of the COVID–19 pandemic. We solicited comment on ways to best strike this balance.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing broad support of § 431.12(f)(1) proposals requiring States to post publicly information on the MAC and BAC (bylaws, meeting minutes). The commenters noted that transparency plays an important role in promoting multi-directional accountability and could also help ensure the success of the MAC and BAC. While commenters were supportive, they also recommended that States consider their Medicaid communities' communication access needs, including cultural competency and linguistic needs, when posting these materials to their websites.

Response: We agree with commenters that States should take steps to ensure that any publicly posted materials are accessible to the various interested parties that comprise their Medicaid community.

Comment: We received a few comments asking us to reconsider the requirement of having States to post their BAC membership list on their websites. Several commenters suggested that States should give BAC members the choice of being publicly identified.

Response: We thank commenters for raising this issue, as we want to avoid any situation where a Medicaid beneficiary, family member or caregiver, does not want to be publicly identified. In response to these comments, we are updating and finalizing the proposed regulations to permit BAC members to choose whether to be publicly identified in materials such as membership lists and meeting minutes. If BAC members choose not to be identified in public materials, they can be referred to as BAC member 1, BAC member 2 and so on. Specifically, we are updating and finalizing the proposed language under new paragraph § 431.12(f)(1) to state, ''Develop and publish by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members . . . States will give BAC members the option to include their names on the membership list and meeting minutes that will be posted publicly.''

Comment: We received comments supporting the § 431.12(f)(2) requirement of having States publicly post their process for recruitment and selection. Commenters emphasized that these processes must be inclusive and reflect the diversity of their State's Medicaid community and beneficiaries. Other commenters asked for CMS to provide guidance or best practices on how to recruit members, as well as marketing best practices and the preferred format for print and audio materials.

Response: We agree that States should develop recruitment strategies that will result in identifying members that are

[45] Resources for Integrated Care and Community Catalyst, ''Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils'', 2019. Retrieved from *https://www.resourcesforintegratedcare.com/listening_to_voices_of_dually_eligible_beneficiaries/.*

[46] Centers for Medicare & Medicaid Services, Person & Family Engagement Strategy: Sharing with Our Partners. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategic-Plan-12-12-16.pdf#:~:text=person%E2%80%99s%20priorities%2C%20goals%2C%20needs%20and%20values.%E2%80%9D%20Using%20these,to%20guide%20all%20clinical%20decisions%20and%20drives%20genuine.*

representative of a State's Medicaid community and beneficiaries. However, we have kept the requirements flexible to be cognizant of the fact that States can experience challenges in recruiting Medicaid beneficiaries to serve on the BAC. We also encourage States to examine best practices from entities that specialize in marketing, recruitment, and the accessibility of published materials as outlined on *Digital.gov*.[47]

Comment: We received some comments asking that States have a process for identifying conflicts of interest when making member selections.

Response: We agree that avoiding conflicts of interest is important, and we encourage States to establish conflict of interest policies, to be documented in the MAC/BAC bylaws or other organizing documents that govern the membership and operations of the MAC/BAC, and to ensure these policies are respected when selecting MAC/BAC members. Since MAC and BAC membership represent a variety of backgrounds and interest relevant to Medicaid, we also believe that building in a time for conflict-of-interest disclosure into each meeting's agenda is important. Specifically, under new § 431.12(f)(3) we are now adding that each MAC and BAC meeting agenda should have time set aside for members to disclose any matters that are not incompatible with their participation on the MAC and/or BAC under the State's conflict of interest policy, but which nevertheless could give rise to a perceived or actual conflict of interest and therefore should be disclosed. We also believe our requirements for MAC and BAC meetings, including the posting of meeting minutes and membership lists, will provide the public and States with the transparency needed to know if a conflict of interest (perceived, apparent, or actual) occurred during a meeting.

Comment: We received comments regarding the requirement in § 431.12(f)(3) for both the MAC and BAC to each meet at a minimum of once quarterly. Commenters noted the number of meetings could pose a burden to the States and members. Several commenters suggested that CMS allow Medicaid agencies to hold meetings in a way that matches their administrative resources and goals.

Response: We selected a quarterly meeting versus a monthly meeting schedule for the MAC and BAC because we believe it will provide States with more flexibility in determining when to meet. For example, rather than having the MAC and BAC members meeting every month (12 times annually), we reduce the time commitment for members by having the State select which month per quarter works best for the MAC and BAC members (4 times annually). Further, the goal of the MAC and BAC is to advise the State on matters related to policy development and to the effective administration of the Medicaid program. We believe that holding a quarterly meeting, as a minimum, allows States to integrate their Medicaid community's voice into the effective administration of the Medicaid program in a way that is timely and meaningful. Further, we believe that holding quarterly meetings would result in the least amount of burden for States. Holding more meetings per year would likely result in additional strain of time and resources for the State and its members. Holding meetings less frequently than quarterly would not assist the timely integration of the community voice into the administration of the Medicaid program. We also strive to further reduce the burden to MAC and BAC members by structuring the meeting requirements in a way that allows States to select non-traditional meeting times and to use different telecommunications options (for example, online meetings) for its meetings which would eliminate members' commuting times to meetings.

Comment: We received several comments about new § 431.12(f)(4) in support of the requirement that each MAC meeting must have a public comment period, citing the importance of all interested parties to be able to share feedback. Additionally, a few commenters asked that States also have a process to accept input from interested parties while developing MAC agendas.

Response: States will have the flexibility to develop the MAC agendas in accordance with their own processes and procedures. We encourage commenters to work with their State regarding those processes.

Comment: A couple of commenters suggested that all MAC and BAC meetings be open to the public.

Response: We place great importance on meeting transparency, but we also believe that States may need the flexibility to keep closed some of their meetings each year. The proposed requirement in § 431.12(f)(4) related to BAC meetings notes that BAC meetings are not required to be open to the public unless the State and the BAC members decide otherwise. It is important for States to create a dedicated space for this group of Medicaid beneficiaries and people with lived Medicaid experience to share their interactions with and perceptions of the Medicaid program. Having a comfortable, supportive, and trusting environment will encourage members to speak freely on matters most important to them. We note that in order to support overall transparency, we proposed that the meeting minutes of the BAC meetings be required to be posted online and MAC members who are also on the BAC will share input from the BAC with the broader MAC.

Comment: We received comments in response to our request for comments about in-person and virtual attendance options for the MAC and BAC meetings. The comments emphasized the need for States to offer both in-person and virtual attendance options. One commenter questioned if the proposed requirement meant that offering an in-person attendance option was a requirement for each meeting.

Response: We thank commenters for responding to our request for comments. In response to those comments, we are updating new § 431.12(f)(5) to list the different types of meeting options. Specifically, § 431.12(f)(5) states, ''Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, a minimum, telephone dial-in option at the MAC and BAC meetings for its members.'' For the commenter who questioned if States had to always provide in-person attendance options, we are clarifying that if the meeting is designated as a virtual-only meeting, States do not need to have in-person attendance.

Comment: One commenter suggested we add a requirement for meetings to be held both during and after work hours.

Response: In new § 431.12(f)(6), we require that States ensure that the meeting times selected for MAC and BAC meetings maximize member attendance. We encourage States to consider working hours and the impact on their MAC and BAC membership, as appropriate.

Comment: Several commenters expressed broad support for the proposal to ensure that MAC and BAC meetings are accessible by people with disabilities and Limited English Proficiency (LEP). Commenters also provided suggestions to better ensure meaningful participation, such as making sure States have available: interpreter services, American Sign Language translation services, closed captioning for virtual meeting, and

[47] *https://digital.gov/resources/an-introduction-to-accessibility/?dg.*

making materials available in plain language.

Response: As reflected in § 431.12(f)(7), we agree that MAC and BAC members with disabilities and LEP should have access to the types of supports needed to meaningfully engage in meetings. We have updated the relevant Federal requirements for States to meet in this final rule.

Comment: One commenter requested that CMS clarify what is meant by the phrase, ''that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency . . . .''

Response: Title VI of the Civil Rights Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their programs or activities for individuals with Limited English Proficiency.[48] Section 1557 of the Affordable Care Act similarly requires recipients of Federal financial assistance to take reasonable steps to provide meaningful access to their health programs or activities for individuals with Limited English Proficiency, and the implementing regulation requires the provision of interpreting services and translations when it is a reasonable step to provide meaningful access.[49]

After consideration of public comments, we are finalizing § 431.12(f) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Updates to § 431.12(f)(1) to now state, ''States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.''
- Updates to § 431.12(f)(3) to state, ''Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.''
- Updates to § 431.12(f)(4) to move one sentence up to be the new second sentence and the deletion of a repetitive sentence so that third sentence now reads as, ''The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.''
- Updates to § 431.12(f)(5) to state, ''Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have at a minimum, telephone dial-in option at the MAC and BAC meetings for its members.''
- Updates to paragraph (f)(7) to reflect additional Federal requirements (adding reference to the Title VI of the Civil Rights Act of 1964). The sentence will now state, ''. . . that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.''

7. MAC and BAC Participation and Scope (§ 431.12(g))

We proposed to replace former paragraph (e) Committee participation, with new paragraph (g) MAC and BAC Participation and Scope. The original paragraph (e), Committee participation, required that the MCAC must have opportunity for participation in policy development and program administration, including furthering the participation of beneficiary members in the agency program.

In new paragraph § 431.12(g), we proposed and are finalizing the expansion of the types of topics which provide the MAC and BAC should advise to the State. The list of topics we proposed included at a minimum topics related to: (1) addition and changes to services; (2) coordination of care; (3) quality of services; (4) eligibility, enrollment, and renewal processes; (5) beneficiary and provider communications by State Medicaid agency and Medicaid managed care plans; (6) cultural competency, language access, health equity and disparities and biases in the Medicaid program; or (7) other issues that impact the provision or outcomes of health and medical services in the Medicaid program as identified by the MAC, BAC or State.

In researching States' MCACs, we know that some already use the MCACs advice on a variety of topics relating to the effective and efficient administration of the Medicaid program. With these changes, we aim to strike a balance that reflects some States' current practices without putting strict limitations on specific topics for discussion in a manner that would constrict flexibility for all States. Broadening the scope of the topics that the MAC and BAC discuss will benefit the State by giving greater insight into how it is currently delivering coverage and care for its beneficiaries and thereby assist in identifying ways to improve the way the Medicaid program is administered.

The State will use this engagement with the MAC and BAC to ensure that beneficiaries' and other interested parties' voices are considered and to allow the opportunity to adjust course based on the advice provided by the committee and council members. The State will base topics of discussion on State need and will determine the topics in collaboration with the MAC and BAC to address matters related to policy development and matters related to the effective administration of the Medicaid program. In finalizing the proposals, we reviewed the wording for this requirement closer. When listing the types of topics on which the MAC and BAC should advise to the State, we used the term ''or''. However, using the term ''or'' does not represent the intention behind the regulation. The MAC or BAC should not be limited to advising the State on one topic at a time. Our intent is that the MAC and BAC, in collaboration with the State, should be able to provide recommendations on all or any of the subset of the topics listed. We clarify this intention in this final rule by making a technical change to replace the word ''and'' with the word ''or'' in the list of the types of topics on which the MAC and BAC should advise the State.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: As noted in other sections, we received a few comments asking CMS to clarify the advisory authority of the MAC and BAC, noting that language fluctuated between advisory and experiential feedback.

Response: As discussed earlier with respect to § 431.12(a), the role of the MAC and BAC is to advise the State Medicaid agency. In reviewing the language proposed in § 431.12(g), we see similar opportunities where CMS can refine its wording to make clear the advisory roles that the MAC and BAC hold. The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on

[48] *Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students of Chinese origin with limited English proficiency to take affirmative steps to provide the students with a meaningful opportunity to participate in federally funded educational programs).

[49] 45 CFR 92.101; *see alsohttps://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.*

matters related to the effective administration of the Medicaid program. By replacing the wording in § 431.12(g) from ''provide recommendations'' to ''advise'' we are being consistent with the wording used in similar updates made in this final rule and also making clear that our intention is for the MAC and BAC to serve in an advisory capacity to the State.

Comment: All commenters who addressed § 431.12(g) supported the change in the MAC and BAC scope. The majority of those commenters also suggested additional topics for which the MAC and BAC should advise the State. These topics include getting feedback on Secret Shopper studies, external quality organization reports, consumer facing materials, enrollment materials, implementation of integrated programs for dually eligible individuals, rate reviews, and annual medical loss ratio report. We also received a comment noting the importance of access to services with a request that it be added it to the list of topics.

Response: We appreciate the support to the proposed changes. We clarify that the categories of topics we named in this section were selected as examples because they represented far-reaching parameters related to the effective administration of the Medicaid program. We believe that the proposal we are finalizing in this final rule allows for a broad interpretation of the topics that are within scope while leaving the ultimate decision on which topics the MAC and BAC will advise on to the MAC, BAC, and State. We encourage commenters to work with their States to define the topics that will be discussed at the MAC and BAC. Finally, we agree that specifically mentioning access to services is important, as it represents a key topic area of this regulation. Therefore, we are redesignating the proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), access to services.

After consideration of public comments, we are finalizing § 431.12(g) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Replacing the wording at § 431.12(g) ''to participate in and provide recommendations'' with ''advise'' so as to clarify the advisory role of the MAC and BAC.
- Conforming edits to replacing the term State Medicaid Director at § 431.12(g) with the term, ''director of the single State Agency for the Medicaid program.''

Language modifications to § 431.12(g)(5) to replace ''managed care plan'' with ''MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2.''

- Redesignating and finalizing proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), ''access to services.''
- Replacing the word ''or'' with the word ''and'' after 431.12(g)(7), access to services.

8. State Agency Staff Assistance, Participation, and Financial Help (§ 431.12(h))

Under § 431.12 of the current regulation, paragraph (f) Committee staff assistance and financial help, the State was required to provide the committee with—(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and (2) Financial arrangements, if necessary, to make possible the participation of beneficiary members.

In the proposed rule, we proposed to redesignate previous paragraph § 431.12(f) to new paragraph (h) and expand upon existing State responsibilities for managing the MAC and BAC regarding staff assistance, participation, and financial support. The changes we proposed and are finalizing to new paragraph (h) are for the State to provide staff to support planning and execution of the MAC and the BAC to include: (1) Recruitment of MAC and BAC members; (2) Planning and execution of all MAC and BAC meetings; and (3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include: (i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement; (ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and (iii) Attendance by at least one staff member from the State agency's executive staff at all MAC and BAC meetings.

The overlap of the current regulation with our proposed changes will mean much of the work to implement is already occurring. We are not changing the existing financial support requirements. We understand from States and other interested parties that many States already provide staffing and financial support to their MCACs in ways that meet or go beyond what we require through our updated requirements. We believe that expanding upon the current standards regarding State responsibility for planning and executing the functions of the MAC and BAC will ensure consistent and ongoing standards to further beneficiaries' and other interested parties' engagement. For example, we know that when any kind of interested parties council meets, all members of that council need to fully understand the topics being discussed in order to meaningfully engage in that discussion. This is particularly relevant when the topics of discussion are complex or based in specific terminology as Medicaid related issues often can be.

We believe that when States provide their MACs and BACs with additional staffing support that can explain, provide background materials, and meet with the members in preparation for the larger discussions, the members have a greater chance to provide more meaningful feedback and be adequately prepared to engage in these discussions. The proposed changes to the existing requirements seek to create environments that support meaningful engagement by the members of the MAC and the BAC, whose feedback can then be used by States to support the efficient administration of their Medicaid program. We anticipate providing additional guidance on model practices, recruitment strategies, and ways to facilitate beneficiary participation, and we solicited comments on effective strategies to ensure meaningful interested parties' engagement that in turn can facilitate full beneficiary participation.

Further, the proposed changes to the requirement for beneficiary support, including financial support, are similar to the original MCAC requirements. For example, using dedicated staff to support beneficiary attendance at both the MAC and BAC meetings and providing financial assistance to facilitate meeting attendance by beneficiary members are similar to the current regulations. Staff may support beneficiary attendance through outreach to the Medicaid beneficiary MAC and BAC members throughout the membership period to provide information and answer questions; identify barriers and supports needed to facilitate attendance at MAC and BAC meetings; and facilitate access to those supports.

In the proposed rule, we proposed to add a new requirement that at least one member of the State agency's executive staff attend all MAC and BAC meetings to provide an opportunity for beneficiaries and representatives of the State's leadership to interact directly.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: Many commenters supported the modifications proposed at § 431.12(h), but they emphasized the importance of requiring States to appropriately compensate members that are beneficiaries for their participation. The comments noted that there should be financial compensation to beneficiary members for the time spent on BAC activities, as well as financial reimbursement for any travel, lodging, meals, and childcare associated with their participation in the BAC and/or MAC. Commenters also asked CMS to exclude the value of any financial compensation paid to members for their participation in the MAC and/or BAC from consideration in determining eligibility for Medicaid. A few commenters expressed that the term ''if necessary'' should be dropped from the regulatory language, noting that States should offer reimbursement to all participating Medicaid beneficiaries.

Response: Under the policies we are finalizing at § 431.12(h)(3)(ii), States will have the ability to reimburse all beneficiaries to facilitate Medicaid beneficiary engagement in the MAC and the BAC. This can include, at the State's discretion, reimbursement for travel, lodging, meals, and childcare. We did not remove the words ''if necessary'' to account for Medicaid beneficiaries who may not need financial support to engage in the MAC and BAC activities.

We are also clarifying the circumstances in which compensation provided to beneficiary members would be considered income for Medicaid eligibility purposes. For both MAGI and non-MAGI methodologies, reimbursements (such as for meals eaten away from home, mileage, and lodging) do not count as income, but other compensation (such as a daily stipend) for participating in an advisory council is countable income under applicable financial methodologies. For non-MAGI methodologies, the State could submit a SPA to CMS to disregard such stipends or other countable income under section 1902(r)(2) of the Act. Other means tested programs may have other rules for counting income, and we encourage States to assess those rules and advise Medicaid beneficiary members of the MAC and BAC accordingly.

Comment: Many commenters in support of the proposed requirements in § 431.12(h)(3) noted how critical it will be for States to provide appropriate technical support and preparation to MAC and BAC members who are also Medicaid beneficiaries in order to ensure their full and active participation in discussions. Commenters shared a variety of suggestions for the type of support that can help prepare these members to feel comfortable fully and meaningfully engaging in the process. The suggestions made by the commenters included specific areas to be addressed in the trainings and materials that the State agency staff provides, such as providing background materials in plain language, implementing techniques to empower members to participate successfully and equally in MAC and BAC discussions, supporting health literacy needs, and training members on digital access to meetings/technology. Additionally, some commenters suggested that States be required to provide MAC and BAC members with a mentor and training on the Medicaid program throughout the length of their membership term. Several commenters suggested that States be required to select an independent (outside of the Medicaid agency) policy advisor or technical expert to provide BAC members with support in understanding Medicaid topics and policy.

Response: We appreciate the support for our proposals and understand the interest in ensuring support for beneficiary members of the MAC and BAC. The underpinning of meaningful member engagement is that members have a substantial understanding of the topics to be discussed. We agree with commenters' suggestions in general, but given the differences in States' structures and resources, we believe there is a benefit in leaving the decision of how best to provide training and support to the MAC and BAC members to the States. As we noted earlier in the preamble, CMS will post publicly a MAC best practices toolkit.

Comment: We received a couple of comments asking CMS to clarify the role of the State Medicaid agency staff attending the MAC and BAC meetings.

Response: The purpose of requiring a member from the State Medicaid agency's executive staff to attend MAC and BAC meetings is to provide an opportunity for beneficiaries and representatives of the State's Medicaid agency leadership to interact directly. The role of the executive staff person is not to be a MAC/BAC co-chair, nor to facilitate these meetings. The executive staff person's role is to hear directly from and interact with Medicaid beneficiaries and with the wider Medicaid community in that State. The person attending generally will be expected to share take-aways from these meetings with State's Medicaid agency leadership.

After consideration of public comments, we are finalizing § 431.12(h) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Conforming edits to replace the word ''State Agency'' with the ''single State agency for the Medicaid program'' in several places across § 431.12(h).

Language modifications to § 431.12(h)(3) to state, ''. . . MAC and BAC members who are Medicaid beneficiaries . . .''

9. Annual Report (§ 431.12(i)).

In the spirit of transparency and to ensure compliance with the updated regulations, we added in the proposed rule[50] and are finalizing new paragraph § 431.12(i) to require that the MAC, with support from the State and in accordance with the requirements updated at this section, must submit an annual report to the State. The State must review the report and include responses to the recommended actions. The State must also: (1) provide MAC members with final review of the report; (2) ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and (3) post the report to the State's website. In the proposed rule, we noted that States had one year to implement the annual report requirement and we sought comment on that timeline. In finalizing the proposals, we reviewed these requirements closer. It is our intention that the MAC is required to submit an annual report to the State. We clarify this intention in this final rule by making a technical change to add the word ''must'' which was unintentionally omitted in the proposed rule.

The proposed requirements of this paragraph seek to ensure transparency while also facilitating a feedback loop and view into the impact of the MAC and BAC's recommendations. We solicited comment on additional ways to ensure that the State can create a feedback loop with the MAC and BAC.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements in new § 431.12(i), of having States submit an annual report that describes activities of the MAC and BAC, including the topics discussed and their

[50] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27971).

recommendations. Commenters noted that requiring these reports is critical to building trust as well as ensuring transparency and accountability among the State, MAC, and BAC members. In addition, several commenters agreed with the annual report requirement, but they also wanted CMS to stipulate the contents of the annual report. One commenter suggested that States' annual reports include results from anonymous surveys of MAC and BAC members indicating whether these members felt they have been listened to and if they felt the State used members' feedback.

Response: We appreciate the support for the proposed regulations. We carefully considered the benefits of national uniformity of the contents of an annual report. However, due to the differences in how States may approach setting priorities, creating their MAC and BACs, and the varying level of resources, we believe that States should have the flexibility to adopt an approach to the content of the annual report that works best within their State.

Comment: A few commenters asked CMS to either further require that the BAC issue its own set of reports and recommendations independently or as part of the MAC report.

Response: While we fully understand and agree with the importance of the BAC and ensuring that their voices are heard, we believe that requiring States to create a second BAC-only annual report would add administrative burden. The proposed regulatory language requires that States create an annual report that reflects the activities of both the MAC and BAC. Since the annual report is required to contain the priorities and activities of both the MAC and BAC, there is no need for a separate BAC-only report.

Comment: There were a handful of commenters that wanted CMS to reconsider the report requirement because they thought the resource burden was too great to develop an annual report, the reporting requirement lacked meaning, or they wanted CMS to allow Medicaid agencies to set their own cadence to the reports.

Response: We understand the concerns of the commenters, but we have written the annual report requirement broadly to ensure maximal flexibility for States to meet this requirement. It is critical that States document the work and key outcomes of the MAC and BAC. Further, we believe the annual report requirement supports the implementation of the principles of bi-directional feedback, transparency, and accountability on the part of the State, MAC, and BAC. In response to comments about burden to States, we have adjusted the proposed applicability date for this requirement of 1 year and are now finalizing it as, States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

Comment: A few commenters asked CMS to require States to conduct additional activities related to monitoring the MAC and BAC, in addition to the annual report. The commenters' suggestions included: implementing a corrective action plan for States that failed to meet the MAC requirements; requiring process evaluations on the experiences of the MAC and BAC members be conducted and the findings be made public; and requiring States to engage in program improvement activities in response to the recommendations made by the MAC that appear in the annual report.

Response: We carefully considered the benefits of requiring additional studies and activities to be captured by States and included in the annual report. However, we want to keep the parameters of our expectations on the content of a State's annual report to be as broad as possible to give each State the ability to create a report that will help them best document the interested parties' engagement with the MAC and the BAC and serve as a tool for helping advance programmatic goals over time.

Comment: A couple of commenters requested CMS publish the annual reports on its website.

Response: We thank the commenters for this suggestion. Currently, we believe each respective State Medicaid agency's website to be the most appropriate place for the annual reports to be published. However, we will consider whether the needs of interested parties would be better served with CMS collecting and publishing annual reports as well.

Comment: A few commenters inquired about how CMS would provide oversight on compliance with activities such as the annual report and number of meetings requirements.

Response: We thank commenters for these questions. We are currently assessing the most effective strategies with which to provide oversight. As these requirements implement State plan requirements in section 1902(a)(4) and (a)(19) of the Act, noncompliance with the provisions of this final rule could result in a State plan compliance action in accordance with § 430.35.

After consideration of public comments, we are finalizing § 431.12(i) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Additional sentences at the end of § 431.12(i)(3), ''States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.''

10. Federal Financial Participation (§ 431.12(j))

In the current regulation, paragraph (g) Federal financial participation, noted that FFP is available at 50 percent in expenditures for the committee's activities. As noted in the proposed rule, we are not making changes to, and thus are maintaining, the current regulatory language on FFP from previous paragraph (g) to support committee activities, to appear in new paragraph (j) with conforming edits for the new MAC and BAC names.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments about the newly proposed § 431.12(j), encouraging CMS to offer a higher FFP than 50 percent. One commenter suggested that 90 percent FFP would be ideal.

Response: For Medicaid, all States receive a statutory 50 percent Federal matching rate for general administrative activities. States may also receive higher Federal matching rates for certain administrative activities, such as design, development, installation, and operation of certain qualifying systems. Federal matching rates are established by Congress, and CMS does not have the authority to change or increase them.

After consideration of public comments, we are finalizing new paragraph § 431.12(j) as proposed with:

- Language modifications to reflect the new name of the BAC.

11. Applicability Dates § 431.12(k)

For this final rule, we are adding new paragraph § 431.12 (k) *Applicability dates.* In the proposed rule, we noted that the requirements of § 431.12 would be effective 60 days after the publication date of the final rule, although we established different applicability dates by which States must implement certain provisions. We then solicited comment on whether 1 year was too much or not enough time for States to implement the updates in this regulation in an effective manner. We understand that States may need to modify their existing MCACs to reflect the finalized requirements for MACs and may also need to create the BAC and recruit members to participate

if they do not already have a similar entity already in place.

We received public comments on proposed implementation timeline. The following is a summary of the comments we received and our responses.

Comment: We received several comments related to the implementation timeframes specified in the MAC and BAC provisions of the proposed rule. The majority of comments fell into two categories: commenters who noted that 1 year should be sufficient to implement the required changes; and commenters who suggested that CMS provide at least 2 years for implementation. Other commenters suggested that CMS consider a graduated approach that would allow States to demonstrate compliance with the minimum 25 percent BAC crossover requirement over a period of time. The commenters who requested additional time shared concerns about States' many other ongoing priorities, workforce shortages, the amount of time and resources it would take to set up the MAC and BAC, and having enough time to submit budget requests to their legislature so they can get the resources to support the required activities.

Response: We have carefully considered the comments received and acknowledge that additional time for implementation of the requirements could be beneficial for States given competing priorities, budgeting and other challenges States may encounter. Additionally, we weighed the request for a graduated approach to demonstrate compliance with a 25 percent BAC crossover requirement, and we agree that a graduated approach will allow States a longer ramp-up time to modify their current MCACs, as well as to set up the BAC and recruit members to participate.

In the proposed rule, we proposed that States have 1 year from the effective date of the final rule to recruit members, set up their MAC and BAC, hold meetings, and submit their first annual report. Based on public comment, we understand that 1 year is not enough time to complete all of these activities. As a result, we are adding and finalizing in this final rule a second implementation year. Based on these changes, States would now recruit members and set up their MACs and BACs during the first year implementation year. In the second implementation year, States would hold the required MAC and BAC meetings. At the end of that second implementation year, States would summarize the information from the MAC and BAC activities and use that information to complete an annual report. States would then fulfill the annual report requirement by finalizing the report and posting the annual report to their websites. This annual report would need to be posted by States within 30 days of the report being completed.

Additionally, as noted in section II.A.4., and in response to public comment asking for States to have a more graduated approach to reach the requirement of having 25 percent of MAC members be from the BAC, we are finalizing in this rule an extended implementation timeline for this requirement. The finalized provision at § 431.12(d)(1) will require that, for the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC. We developed this approach based on the comments we received about competing State priorities and the time and resources that a State would need to meet the new requirements. Additionally, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC.

Based on the comments received, we are changing two applicability dates. We note in this new paragraph *Applicability dates* § 431.12(k), that except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) are applicable July 9, 2025.

B. Home and Community-Based Services (HCBS)

To address several challenges that we described in the proposed rule (88 FR 27964 and 27965), we proposed both to amend and add new Federal HCBS requirements to improve access to care, quality of care, and beneficiary health and quality of life outcomes, while consistently meeting the needs of all beneficiaries receiving Medicaid-covered HCBS. The preamble of the proposed rule (88 FR 27971 through 27996) outlined our proposed changes in the context of current law.

As we noted in the proposed rule (88 FR 27971), we have previously received questions from States about the applicability of HCBS regulatory requirements to demonstration projects approved under section 1115 of the Act that include HCBS. As a result, we proposed that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in the proposed rule would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project.

We proposed not to apply the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services that we proposed in the proposed rule to the Program of All-Inclusive Care of the Elderly (PACE) authorized under sections 1894 and 1934 of the Act, as the existing requirements for PACE either already address or exceed the requirements outlined in the proposed rule, or are substantially different from those for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services.

We received public comments on these proposals for HCBS under the Medicaid program. The following is a summary of the comments we received and our responses. We discuss the comments we received related to specific proposals, and our responses, in further detail throughout the sections in this portion of the final rule (section II.B.).

Comment: Many commenters expressed general support for our efforts to increase transparency and accountability in HCBS programs, and ultimately improve access to Medicaid services. Commenters in particular noted general support for our proposed provisions in this section that are designed to support HCBS delivery systems through improvements in data collection around waiting lists and service delivery, enhancements to person-centered planning, standardization of critical incident investigation and grievance process requirements, and establishment of defined quality measures. While overall reaction to the payment adequacy minimum performance level (discussed in section II.B.5. of the proposed rule and this final rule) was mixed, many commenters agreed that HCBS programs are facing shortages of direct care workers that pose obstacles to beneficiaries' access to high-quality HCBS.

Commenters also shared several ideas for ways we could improve beneficiaries' access to, or the overall quality of, HCBS beyond the provisions presented in the proposed rule.

Some commenters expressed concerns that the HCBS provisions we proposed, when taken together, could present significant administrative costs to States and, in some cases, to providers.

Response: We thank commenters for their support. Comments on specific provisions that we proposed are summarized below, along with our responses. We also appreciate the many thoughtful suggestions made by commenters for other ways they believe HCBS could be improved beyond what we proposed in the proposed rule. While comments that are outside the scope of what we proposed in the proposed rule and not relevant are not summarized in this final rule, we will take these recommendations under consideration for potential future rulemaking.

We recognize that we must balance our desire to stimulate ongoing improvements in HCBS programs with the need to give States, managed care plans, and providers sufficient time to make adjustments and allocate resources in support of these changes. After consideration of comments we received, we are finalizing many of our proposals, some with modifications. These modifications are discussed in this section (section II.B.) of the final rule.

We also note that some commenters expressed general support for all of the provisions in section II.B. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.B related to HCBS), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.B. of this final rule are intended to present a comprehensive approach to improving HCBS and complement the goals expressed and policies and regulations being finalized in sections II.A. (Medicaid Advisory Committee and Beneficiary Advisory Group) and II.C. (Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.B is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to person-centered planning and related reporting requirements (sections II.B.1 and II.B.7. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to grievance system (section II.B.2. of this final rule), and incident management system and related reporting requirements (sections II.B.3 and II.B.7. of this final rule). The standalone nature of the finalized provisions is further discussed in their respective sections in this rule.

Comment: Several commenters addressed the relationship between the proposed HCBS requirements and HCBS authorized under a section 1115 demonstration project. A few commenters requested clarification about the application of the proposed HCBS requirements in this section to services delivered under section 1115 authority. A few commenters expressed concern about what they perceived was the exclusion of services provided through a managed care delivery system under section 1115 demonstration authority. One commenter recommended only applying the finalized rules to new section 1115 demonstration programs; in the alternative, if applying the finalized requirements to current section 1115 demonstration programs, the commenter recommended that States develop transition plans and be given a reasonable timeframe for bringing their programs into compliance. A few commenters recommended that we add a specific reference to section 1115 demonstration authority of the Act in our proposed HCBS requirements (if finalized), including at § 438.72(b) (applying various finalized requirements to managed care programs) and § 441.302(k) (applying new payment adequacy requirements to section 1915(c) waiver programs).

Response: We are confirming that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project. Further, we have not identified a compelling reason to treat States operating section 1115 demonstration projects differently from States operating other HCBS programs in terms of implementation, such as by requiring States with section 1115 demonstration programs to develop transition plans (as was recommended by one commenter). We also believe that the timeframes that are finalized in this rule are reasonable and sufficient to allow all States operating programs under all relevant authorities to come into compliance. If States have specific questions or concerns regarding compliance with the finalized requirements, we will provide assistance as needed.

We note that we have already included references to managed care delivery systems implemented under section 1115(a) of the Act in the implementation requirements at §§ 441.301(c)(3)(iii) (implementing the person-centered planning process minimum performance requirements), 441.302(a)(6)(iii) (implementing the critical incident management system minimum performance requirements), 441.302(k)(8) (implementing the payment adequacy minimum performance requirement), 441.311(f) (implementing reporting requirements), and 441.313(c) (implementing the website transparency provision). We decline commenters' recommendations that we include additional references to section 1115 of the Act, as we believe doing so would be duplicative. We will ensure that the approved standard terms and conditions of States' section 1115 demonstration projects are clear that the States must comply with all applicable HCBS requirements that we are finalizing in this rule.

We did not receive any comments on our proposal not to extend HCBS requirements that we are finalizing in this rule to PACE. We are finalizing our proposal to not apply the requirements we are finalizing in this rule for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services to PACE authorized under sections 1894 and 1934 of the Act.

1. Person-Centered Service Plans (§§ 441.301(c), 441.450(c), 441.540(c), and 441.725(c))

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as person-centered service plans or service plans). Existing Federal regulations at § 441.301(c) address the person-centered planning process and

include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised, upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [51] (hereinafter the 2014 guidance) that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in 42 CFR part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. We refer readers to section II.B.1. of the proposed rule (88 FR 27972) for a detailed discussion of the six assurances identified in the 2014 guidance.

In the proposed rule (88 FR 27972 through 27975), we proposed a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in 42 CFR part 441, subpart G, including the requirements regarding assurances around service plans. We proposed this approach based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through a request for information (RFI) [52] we released in the spring of 2022. Through this feedback, many States and interested parties expressed, and we identified, that there is a need to standardize reporting and set minimum standards for HCBS. We proposed HCBS requirements to establish a new strategy for oversight, monitoring, quality assurance, and quality improvement for section 1915(c) waiver programs, including minimum performance requirements and reporting requirements for section 1915(c) waiver programs. Further, as is discussed later in this section (section II.B.1. of the rule), to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services, as appropriate.

As support for our proposals, we noted that under section 1902(a)(19) of the Act, States must provide safeguards to assure that eligibility for Medicaid-covered care and services are determined and provided in a manner that is consistent with simplicity of administration and that is in the best interest of Medicaid beneficiaries. While the needs of some individuals who receive HCBS may be relatively stable over some time periods, individuals who receive HCBS experience changes in their functional needs and individual circumstances, such as the availability of natural supports or a desire to choose a different provider, that necessitate revisions to the person-centered service plan to remain as independent as possible or to prevent adverse outcomes. Thus, the requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services change to meet the beneficiary's needs most appropriately as those needs change.

We also noted that effective State implementation of the person-centered planning process is integral to ensuring compliance with section 2402 of the of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, March 23, 2010). Section 2402 of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to facilitate the participant's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[53]

Finally, we noted that since the release of the 2014 guidance, we have received feedback from States, the HHS Office of Inspector General (OIG), Administration for Community Living (ACL), and Office for Civil Rights (OCR), and other interested parties on how crucial person-centered planning is in the delivery of care and the significance of the person-centered service plan for the assurance of health and welfare for section 1915(c) waiver program participants that underscored the need for the proposals.[54]

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed several changes to our person-centered service plan requirements in section II.B.1 of the proposed rule (88 FR 27972 through 27975), as discussed in more detail in this section of the final rule. First, we proposed revisions to § 401.301(c)(3)(i) to clarify that: (1) States are required to ensure person-centered service plans are reviewed and revised in compliance with requirements set forth therein; and (2) changes to the person-centered service plans are not required if the reassessment does not indicate a need for changes. Second, we proposed to establish a minimum performance level for States to demonstrate they meet the requirements at § 441.301(c)(3). Specifically, at § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. At § 441.301(c)(3)(ii)(B) we proposed to require that States demonstrate that they reviewed the person-centered service plan, and revised the plan as appropriate, based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. Finally, we proposed to apply the requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan

[51] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

[52] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[53] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

[54] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. U.S. Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf.*

services at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter questioned whether States would continue to be required to demonstrate compliance with the six assurances and the related subassurances, including those related to person-centered service plans described in the 2014 guidance, or whether the minimum performance requirements and reporting requirements that we proposed in the proposed rule for the section 1915(c) waiver program, if finalized in the final rule, supersede these six assurances and related subassurances.

Response: We noted in the proposed rule (88 FR 27972), and reiterate here, that States must demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around person-centered service plans.

We proposed new minimum performance requirements and new reporting requirements for section 1915(c) waiver programs that are intended to supersede and fully replace the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance. Further, to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services as appropriate.

We confirm that the section 1915(c) six assurances and the related subassurances,[55] including those related to person-centered service plans, continue to apply. The requirements proposed at § 441.301(c)(3)(ii)(A) and (B) (discussed in the next section, II.B.1.b. of this rule) assess State performance with the requirements at § 441.301(c)(3) and we did not intend to suggest that they would fully supersede the section 1915(c) six assurances and the related subassurances in the 2014 guidance. Further, as finalized later in this rule, States will be required to report on the minimum performance levels at § 441.301(c)(3)(ii)(A) and (B). To reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements, we plan to work with States to phase-out the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance as they implement these requirements in the final rule.

Comment: A commenter requested we clarify what the impacts would be to the existing section 1915(c) waiver reporting tools as defined in the Version 3.6 HCBS Waiver Application if we finalize our proposals.

Response: We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule. However, some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process.

a. Finalization of Amended Requirement for Review of the Person-Centered Service Plan (§ 441.301(c)(3)(i))

At § 441.301(c)(3), we proposed to revise the regulatory text so that it is clearer that the State is the required actor under § 441.301(c)(3), and that changes to the person-centered service plan are not required if the reassessment does not indicate a need for changes. In the proposed rule (88 FR 27973), we noted that, with this revision to the regulatory text, the State could, for instance, meet the requirement that the person-centered service plan was reviewed, and revised as appropriate, based on the results of the required reassessment of functional need by documenting that there were no changes in functional needs or the individual's circumstances upon reassessment that necessitated changes to the service plan. However, the State would still be expected to review the service plan to confirm that no revisions are needed, even if the reassessment identified no changes in functional needs or the individual's circumstances.

Specifically, we proposed to move the sentence at § 441.301(c)(3) beginning with ''The person-centered service plan must be reviewed. . .'' to a new paragraph at § 441.301(c)(3)(i) and reposition the regulatory text under the proposed title, *Requirement.* In addition, we proposed to revise the regulatory text at the renumbered paragraph to clarify that the person-centered service plan must be reviewed, and revised as appropriate, based on the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

We received public comment on this proposal. Below is the summary of the comment and our response.

Comment: Commenters did not raise specific concerns about the proposal at § 441.301(c)(3)(i). However, one commenter raised concerns about the impact the minimum performance requirement proposed at § 441.301(c)(3)(ii) (discussed in greater detail in the next section) would have on the requirement at § 441.301(c)(3)(i). The commenter expressed concern that States may interpret the 90 percent minimum performance levels proposed at § 441.301(c)(3)(ii)(A) and (B) as meaning they are only required to conduct the reassessments and updates to person-centered service plans as required by § 441.301(c)(3)(i) for 90 percent of beneficiaries, not for 100 percent of beneficiaries receiving HCBS. This commenter also suggested that CMS clarify that States should conduct functional assessments and person-centered plan updates for every individual to make sure that the requirement at § 441.301(c)(3)(i) is not open to interpretation.

Response: We intend that the 90 percent minimum performance requirements proposed at § 441.301(c)(3)(ii) would assess States' minimum performance of the requirements at § 441.301(c)(3)(i); we do not suggest that reassessments of functional need and reviews, and revisions as appropriate, of the person-centered service plan, based on the results of the required reassessment of functional need, are required for only 90 percent of individuals enrolled in the waiver program. The minimum performance requirements at § 441.301(c)(3)(ii) (and the associated reporting requirements at § 441.311(b)(3), discussed in section II.B.7. of this final rule), while important for aiding in our oversight and States' accountability for complying with § 441.301(c)(3)(i), are distinct and severable requirements from § 441.301(c)(3)(i). In other words, States would be expected to comply fully with § 441.301(c)(3)(i) even had we not also proposed the specific minimum performance requirement at § 441.301(c)(3)(ii). Thus, the minimum performance of 90 percent proposed in § 441.301(c)(3)(ii) notwithstanding, it is our intent to require at § 441.301(c)(3)(i) that States ensure that the person-

[55] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

centered service plan for every individual is reviewed, and revised as appropriate, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. To ensure that this expectation is clear in the requirement, we are finalizing § 441.301(c)(3)(i) with a modification to specify that the requirement at § 441.301(c)(3)(i) applies to every individual.

Upon further review, we also determined that retaining the reference to § 441.301(c)(3) in § 441.365(e), governing the frequency of functional assessments for section 1915(d) waiver programs, at the redesignated § 441.301(c)(3)(i), is both obsolete and unnecessary. Section 441.365(e) was a standard used by section 1915(d) waiver programs, which were time-limited programs that are no longer in effect, to establish the frequency of functional assessments. The requirements at § 441.301(c)(3) establish the frequency of functional assessments for section 1915(c) programs, thus referencing § 441.365(e), which is obsolete, is unnecessary.

Accordingly, we are finalizing § 441.301(c)(3)(i) with the previously noted modifications to specify that the requirement applies to every individual and removing reference to § 441.365(e), as well as a minor technical modification to remove an extraneous comma after the word ''revised.'' As finalized, § 441.301(c)(3)(i) specifies that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

b. Minimum Performance Level (§ 441.301(c)(3)(ii))

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3) (88 FR 27973).

Specifically, at new § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also proposed, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We intended that these proposed minimum performance levels would strengthen person-centered planning reporting requirements while taking into account that there may be legitimate reasons why assessment and care planning processes occasionally are not completed timely in all instances. We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we decided not to propose good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these minimum performance levels. Further, we noted that there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster (88 FR 27973).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals to codify at § 441.301(c)(3)(ii)(A) and (B) minimum performance levels for States to demonstrate that they meet the requirements at § 441.301(c)(3)(i). These commenters noted that, by CMS establishing minimum performance levels for the person-centered planning requirements, beneficiaries who receive HCBS may be more empowered to actively participate in decision-making processes related to their care and services.

Response: We appreciate the support for our proposals.

Comment: One commenter suggested we specify that a beneficiary's services should not be reduced, suspended, or terminated because the reassessment of functional need or person-centered service plan update did not occur within the specified timeframe.

Response: The proposed requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly, or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services are reassessed to ensure they continue meeting the beneficiary's needs most appropriately as those needs change. Any changes in the services and supports included in the person-centered service plan for beneficiaries should be based on changes in circumstances or needs or preferences of the individual; they should not result from a failure by the State or managed care plan to conduct required assessment and service planning processes timely. Further, States should not reduce, suspend, or terminate a beneficiary's services solely to reach the minimum performance level required at § 441.301(c)(3)(ii)(A) and (B).

Comment: A couple of commenters suggested we clarify whether States would be required to implement corrective action for noncompliance with the 90 percent performance level if the same beneficiaries do not receive timely reassessments or updated person-centered plans repeatedly. One commenter questioned whether a 90 percent performance level provides an acceptable margin of error (10 percent) and requested clarification on whether States will be expected to remediate through corrective action if this threshold is not met.

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States that are determined to not be compliant with the requirements at § 441.301(c)(3)(ii)(A) and (B). We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: One commenter stated that the person-centered planning requirements are essential to ensure choice and access to appropriate service and suggested that, although the proposed approach meets compliance oversight and monitoring objectives, a quality improvement strategy to address improving outcomes with the person-centered planning requirements is needed.

Response: We note that the proposed requirements at § 441.301(c)(3)(ii)(A) and (B) were intended to strengthen person-centered planning reporting requirements by codifying a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3). We encourage States to consider implementing quality

improvement processes to strengthen and improve person-centered planning in their HCBS programs. Further, as discussed in section II.B.8. of this final rule, we are finalizing the HCBS Quality Measure Set reporting requirements to include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set is distinct from the person-centered planning requirements being finalized at § 441.301(c)(3), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

Comment: A few commenters suggested CMS include a good cause exception for States that do not meet the minimum performance level to take into account certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges in rural areas, or for beneficiary-related events that could delay the ability to complete the assessment, such as medical emergencies/hospitalizations. Alternatively, a few commenters supported our proposal to not allow good cause exceptions to the performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We believe that the 90 percent minimum performance level proposed at § 441.301(c)(3)(ii)(A) and (B) sets a realistic and achievable threshold.

As we noted in the proposed rule (88 FR 27973), we decided to not propose any good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities, such as the waiver authority under section 1135 of the Act, that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. We decline to include good cause exceptions in the minimum performance level in this final rule.

After consideration of public comments, we are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met (since States typically have person-centered planning requirements carried out by entities such as case managers or providers, rather than directly by the State). We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to make the same punctuation correction as the modification finalized in § 441.301(c)(3)(i).

c. Application to Managed Care and Fee-for-Service (§ 441.301(c)(3))

To ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we proposed to add the requirements for services delivered under FFS at § 441.301(c)(3) to services delivered under managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. Therefore, we proposed that a State must ensure compliance with the requirements in § 441.301(c)(3) with respect to HCBS delivered both under FFS and managed care delivery systems.

We note that in the proposed rule at 88 FR 27974, we made the statement that to ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we propose to add the requirements at § 441.301(c)(3) to 42 CFR 438.208(c). This statement was published in error, and we did not intend to propose this specific regulation text include reference to § 438.208(c). We note that § 438.208(c)(3)(v) already requires that managed care plans comply with § 441.301(c)(3), generally, so we believe that referencing § 438.208(c) is not necessary. We also note that § 438.208(c)(3)(ii) requires compliance with the other person-centered planning requirements at § 441.301(c)(1) and (2). Thus, also referring to § 438.208(c) would be unnecessary.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the proposed requirements at § 441.301(c)(3) to be applied to managed care delivery systems as well, noting that States must ensure compliance with respect to HCBS delivered both in FFS and managed care delivery systems. Commenters also noted that the process of conducting reassessments and making updates to a person-centered service plan is agnostic to whether a provider is paid by a managed care plan or through a FFS delivery system.

Response: We appreciate the support for our proposal.

After consideration of public comments received, we are finalizing our proposed policy to require that the person-centered planning requirements at § 441.301(c)(3) finalized in this section are applied to HCBS delivered under both managed care and FFS delivery systems. As noted above, we are not finalizing a new reference to § 441.301(c)(3) at § 438.208(c), as § 438.208(c) already requires that managed care plans comply with § 441.301(c)(1) through (c)(3), which includes the requirements being finalized in this rule at § 441.301(c)(3)(i) and (ii). Additionally, as is discussed in section II.B.11. of this rule, we are finalizing our proposal at § 438.72(b) to direct States to comply with the requirements finalized in this final rule, including the revised person-centered centered planning requirements at § 441.301(c)(1) through (c)(3), for services authorized under HCBS authorities and provided under managed care delivery systems.

d. Person-Centered Planning—Definition of Individual (§ 441.301(c)(1))

We also proposed updates to existing language describing the person-centered planning process specific to section 1915(c) waivers. Current language describes the role of an individual's authorized representative as if every waiver participant will require an authorized representative, which is not the case. This language has been a source of confusion for States and providers. We proposed to amend the regulation text at § 441.301(c)(1) to better reflect that the individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term individual is used throughout this section, it includes the individual's authorized representative will lead the person-centered planning process if applicable. We note that, in the proposed rule, we described our proposal as removing extraneous language and not as an amendment of § 441.301(c)(1) (88 FR 27974). Upon further consideration, we believe characterizing this proposal as an amendment is more accurate. We intend that this proposed language as finalized will bring the section 1915(c) waiver regulatory text in line with person-centered planning process language in both the section 1915(j) and (k) State plan options.

We did not receive public comments on this proposal. However, after further

consideration of the proposed requirement, we are finalizing § 441.301(c)(1) with a technical modification to clarify that the language contained in § 441.301(c)(1), as finalized, applies to the person-centered planning requirements **throughout § 441.301(c)(1) through (3)**. (New language identified in bold.) This modification expresses our intent that § 441.301(c)(1) applies to the person-centered planning requirements in § 441.301(c)(1) through (3), rather than § 441.301(c) in its entirety.

e. Applicability Date (§ 441.301(c)(3)(iii))

We proposed at § 441.301(c)(3)(iii) to make the performance levels under § 441.301(c)(3)(ii) effective 3 years after the effective date of § 441.301(c)(3) (in other words, 3 years after the effective date of the final rule) in FFS delivery systems. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the managed care organization's (MCO's), prepaid inpatient health plan's (PIHP's), or prepaid ambulatory health plan's (PAHP's) contract, we proposed to provide States until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. We solicited comment on whether the timeframe to implement the proposed regulations is sufficient, whether we should require a shorter timeframe or longer timeframe to implement these provisions, and, if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the 3-year timeframe for the effective date as defined at § 441.301(c)(3)(iii). A few commenters expressed concerns about the overall burden they believe will be associated with the final rule, due to competing priorities, and the effect it may have on States' ability to implement the proposed person-centered planning provisions at § 441.301(c)(3)(ii) within 3 years following the effective date of the final rule. A few commenters expressed that the performance levels under § 441.301(c)(3)(ii) may require States to have a longer runway to implement and operationalize State regulation changes and processes, revise policies, and hire critical staff. A few commenters also requested we consider alternative effective dates for the person-centered planning minimum performance requirements, ranging from 18 months to 4 years.

Response: We noted, in the proposed rule (88 FR 27974), that we recognize many States may need time to implement the proposed HCBS requirements we are finalizing in the final rule. We acknowledge that States will have to expend resources in addressing the person-centered planning minimum performance requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these person-centered planning requirements.

We believe that 3 years for States to ensure compliance with the person-centered planning minimum performance requirements being finalized at § 441.301(c)(3)(ii) is realistic and achievable for States. We also note that the minimum performance requirements measure performance of the requirements at § 441.301(c)(3)(i), which substantively reflect activities States are currently expected to perform under existing § 441.301(c)(3). For States implementing a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the in the MCO's, PIHP's, or PAHP's contract, we similarly believe it is realistic and achievable to provide States with a date to comply that is until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of this final rule to implement these requirements. We will provide technical assistance to States as needed with meeting the timeframe for compliance.

After consideration of the comments received, we are finalizing the substance of §§ 441.301(c)(3)(iii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and to make technical modifications to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.301(c)(3)(iii) as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(3)(iii) to specify that **States must comply with** the requirements at § 441.301(c)(3)(ii) **beginning** 3 years from the effective date of this final rule (rather than stating that the performance levels described in § 441.301(c)(3)(ii) are effective 3 years after the date of enactment of the final rule); and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first **rating period *for contracts with the MCO, PIHP, or PAHP beginning*** on or after **the date that is** 3 years after the effective date of this **final rule**. (New language identified in bold.).

f. Application to Other Authorities

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act and because HCBS State plan options have similar person-centered planning and service plan requirements, we proposed to include the proposed requirements at § 441.301(c)(3) in section 1915(j), (k), and (i) State plan services, at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements under section 1902(a)(19) of the Act, which authorizes safeguards necessary to assure that eligibility for care and services under the Medicaid program will be determined, and such care and services will be provided, in a manner consistent with the best interest of beneficiaries. We believe these same reasons for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We considered whether to apply the proposed person-centered plan requirements at § 441.301(c)(3) to section 1905(a) ''medical assistance'' State plan personal care services, home health services, and case management services. However, we did not propose that these requirements apply to any section 1905(a) State plan services at this time. First, States do not have the same data collection and reporting capabilities for these services as they do for other HCBS at section 1915(c), (i), (j), and (k). Second, person-centered planning and service plan requirements are not required by Medicaid for section 1905(a) services, although we recommend that States implement person-centered planning processes for all HCBS. We note that the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS

nationally is delivered under section 1905(a) State plan authorities. However, the small overall percentage includes large numbers of people with mental health needs who receive case management.

We solicited comment on whether we should establish similar person-centered planning and service plan requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for applying the proposed person-centered planning and person-centered plan requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan services.

Response: We appreciate the support for our proposal. As noted earlier, we are finalizing modifications to § 441.301(c)(3)(i) to specify that the requirement applies to every individual and to make a technical correction to remove an extraneous comma. We are finalizing corresponding edits for section 1915(k) in § 441.540(c) and section 1915(i) in § 441.725(c). The revised language for both § 441.540(c) and § 441.725(c) will specify that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care services, home health services, and case management services. Several commenters supported that we decided not to propose to extend the person-centered plan requirements at § 441.301(c)(3) to section 1905(a) services. These commenters expressed concern that applying these requirements to these State plan benefits could pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for section 1905(a) services. A few commenters recommended that CMS apply the person-centered planning requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of other commenters suggested that mental health rehabilitative services are considered HCBS under the broader definition enacted by Congress in the American Rescue Plan Act of 2021 (Pub. L. 117–2, March 11, 2021), suggesting that CMS should consider including these services in the person-centered plan requirements at § 441.301(c)(3).

Response: At this time and as noted in the proposed rule (88 FR 27974 and 27975), we are not applying the person-centered service plan requirements at § 441.301(c)(3) to section 1905(a) services, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. For example, there are no statutory provisions in section 1905(a) of the Act that attach State-level reporting requirements to any section 1905(a) service. Relatedly, States do not have the same data collection and reporting capabilities for these services as they do for HCBS at section 1915(c), (i), (j), and (k).

Additionally, we note that section 1905(a) services do not have the same person-centered planning requirements at § 441.301(c)(1) through (6). Formal person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While service planning might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to implement effective person-centered planning processes that are based on individual preferences and personal goals and support full engagement in community for Medicaid beneficiaries receiving section 1905(a) State plan personal care services, home health services, case management services, and rehabilitative services. We thank commenters for their feedback on this request for comment, which we may consider in future rulemaking.

After consideration of public comments, we are finalizing the application of § 441.301(c)(3), as finalized in this rule, to section 1915(j), (k), and (i) State plan services by finalizing relevant requirements at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. We are finalizing §§ 441.450(c), 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively. We are finalizing the requirements at §§ 441.540(c) and 441.725(c) with minor modifications. To maintain consistency with modifications finalized in § 441.301(c)(3)(i), we are finalizing §§ 441.540(c) and 441.725(c) with modifications to specify that the requirements apply to every individual and to remove an extraneous comma.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at §§ 441.301(c)(1), 441.301(c)(3), 441.450(c), 441.540(c), and 441.725(c) as follows:

- We are finalizing the requirement at § 441.301(c)(1) with a technical modification to clarify that § 441.301(c)(1) applies to paragraphs (c)(1) through (3) of this section.
- We are finalizing § 441.301(c)(3)(i) with modifications to specify that the requirement applies to every individual and to remove the reference to § 441.365(e), as well as finalizing a minor technical change to remove an extraneous comma.
- We are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met. We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to correct the punctuation (consistent with the change finalized in § 441.301(c)(3)(i)).
- We are finalizing the applicability date requirement at § 441.301(c)(3)(iii), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.301(c)(3)(iii) to specify that States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.
- We are finalizing §§ 441.450(c), 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of

the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

- We are finalizing §§ 441.540(c) and 441.725(c), consistent with modifications finalized in § 441.301(c)(3)(i), with a modification to specify that the requirements apply to every individual, and with technical modification to correct the punctuation.

2. Grievance System (§ 441.301(c)(7); Proposed at § 441.464(d)(2)(v), Being Finalized at § 441.464(d)(5); Proposed at § 441.555(b)(2)(iv), Being Finalized at § 441.555(e); and § 441.745(a)(1)(iii))

a. Scope of Grievance System and Definitions (§ 441.301(c)(7)(i) and § 441.301(c)(7)(ii))

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[56] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. Further, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interest of Medicaid beneficiaries.

Federal regulations at 42 CFR part 431, subpart E, require States to provide Medicaid applicants and beneficiaries with an opportunity for a fair hearing before the State Medicaid agency in certain circumstances, including for a denial, termination, suspension, or reduction of Medicaid eligibility, or for a denial, termination, suspension, or reduction in benefits or services. These fair hearing rights apply to all Medicaid applicants and beneficiaries, including those receiving HCBS regardless of the delivery system. Under 42 CFR part 438, subpart F, Medicaid managed care plans must have in place an appeal system that allows a Medicaid managed care enrollee to request an appeal, which is a review by the Medicaid managed care plan of an adverse benefit determination issued by the plan; and a grievance system, which allows a Medicaid managed care enrollee to file an expression of dissatisfaction with the plan about any matter other than an adverse benefit determination. Currently, our regulations do not provide for a venue to raise concerns about issues that HCBS beneficiaries in an FFS delivery system may experience which are not subject to the fair hearing process, such as the failure of a provider to comply with the HCBS settings requirements at § 441.301(c)(4) (which are issues that a managed care enrollee could file a grievance with their plan).

Under our authority at section 1902(a)(19) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed to require that States establish grievance procedures for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Specifically, for section 1915(c) HCBS waivers, we proposed at § 441.301(c)(7) that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). This proposal was based on feedback obtained during various public engagement activities conducted with interested parties over the past several years about the need for beneficiary grievance processes in section 1915(c) waiver programs related to these requirements. We also proposed to apply this requirement to section 1915(i), (j) and (k) authorities, which are discussed below in section II.B.2.h. of this final rule.

To avoid duplication with the grievance requirements at part 438, subpart F, we proposed not to apply this requirement to establish a grievance procedure to managed care delivery systems. We note, though, that the requirements in this section are similar to requirements for managed care grievance requirements found at part 438, subpart F, with any differences reflecting changes appropriate for FFS delivery systems. The proposed requirements included at § 441.301(c)(7) in the proposed rule (88 FR 27975) were focused specifically on grievance systems and did not establish new fair hearing system requirements, as appeals of adverse eligibility, benefit, or service determinations are addressed by existing fair hearing requirements at 42 CFR part 431, subpart E. We solicited comments on any additional changes we should consider in this section with respect to a grievance system.

As discussed earlier in this section II.B.2. of this final rule, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. In addition, section 2402(a)(3)(A) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. As such, we believe the proposed requirement for States to establish grievance procedures for Medicaid beneficiaries receiving HCBS through a FFS delivery system is necessary to comply with the HCBS complaint system requirements at section 2402(a)(3)(B)(ii) of the Affordable Care Act and to ensure consistency in the administration of HCBS between managed care and FFS delivery systems. Further, in the absence of a grievance system requirement for FFS HCBS programs, States may not have established processes and systems for people receiving HCBS through FFS delivery systems to express dissatisfaction with or voice concerns related to States' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), as such concerns are not subject to the existing fair hearing process at 42 CFR part 431 subpart E. As a result, we believe the proposal for a grievance system for FFS HCBS programs is necessary to assure that care and services will be provided in a manner that is in the best interests of the beneficiaries, as required by section 1902(a)(19) of the Act.

We specifically focused our proposed grievance system requirement on States' and providers' compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) because of the critical role that person-centered planning and service plans play in appropriate care delivery for people receiving HCBS. Additionally, we focused the grievance system requirements on the HCBS settings requirements because of the importance of the HCBS settings requirements to ensuring that HCBS beneficiaries have full access to the benefits of community

[56] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

living and are able to receive services in the most integrated setting appropriate to their needs. Beneficiary advocates and other interested parties indicated to us that these are especially important areas for which to ensure that grievance processes are in place for all Medicaid beneficiaries receiving HCBS. Further, focusing the grievance systems requirements on the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) helps to ensure that the proposed grievance requirements do not duplicate or conflict with existing fair hearing requirements at part 431, subpart E, as HCBS settings requirements and person-centered planning requirements are outside the scope of the fair hearing requirements.

At § 441.301(c)(7)(ii), we proposed to define a grievance as an expression of dissatisfaction or complaint related to the State's or a provider's compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), regardless of whether the beneficiary requests that remedial action be taken to address the area of dissatisfaction or complaint. Also, at § 441.301(a)(7)(ii), we proposed to define the grievance system as the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for our proposal to require that States establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). In general, commenters believed that clear, transparent, and accessible grievance processes are critical to ensuring that beneficiaries can address violations of their rights, provide feedback on their experiences in HCBS, and more fully participate in HCBS programs. One commenter noted that a Federal requirement will help establish national best practices.

Some commenters connected a strong grievance process with improved safety and service quality in HCBS programs. For instance, one commenter noted that a grievance process can complement other quality mechanisms (such as performance measures) because a grievance system can address problems as they happen, thus preventing harm before it can occur. Another commenter suggested that preventing or remediating poor service delivery has the potential of improving the HCBS workforce by promoting professionalism and improving the public perception of HCBS providers, which could aid providers' worker recruitment and retention efforts; this commenter noted that a strong workforce would promote quality in HCBS.

Other commenters noted that a grievance system would allow beneficiaries to state their rights and provide a fair and unbiased review of beneficiaries' concerns. Several commenters were specifically supportive of the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

A few commenters also described frustrations with current State or provider grievance processes that they have found difficult to access, unresponsive, ineffective, or opaque. One commenter described our proposal as ''overdue,'' but also expressed concerns about whether providers will comply with requirements moving forward. In this vein, a few commenters suggested that CMS involvement and oversight may be critical to ensuring that existing or newly created grievance processes are effective. One commenter expressed the hope that beneficiaries would be able to contact CMS if they believe the State is not complying with grievance process obligations.

Response: We thank commenters for their support. We believe the personal experiences with grievance systems that commenters shared underscore the need for national standards. Additionally, while States will have a great deal of responsibility for developing and monitoring their own systems, having Federal requirements for grievance systems will facilitate our ability to engage in oversight. We note that members of the public are able to share concerns with us about their State's Medicaid activities, which would include the grievance system, once implemented.[57] We also note that in addition to the grievance process finalized under this rule, individuals who believe they have been discriminated against in HCBS programs, including the right to be served in the most integrated setting, may file a civil rights complaint with the HHS Office for Civil Rights at *https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

Comment: Several commenters expressed opposition to the proposal, suggesting that it was too prescriptive and would result in unnecessary information technology (IT) systems changes in States that already have grievance systems in place. Several commenters also noted concerns that the proposal would place administrative burdens on providers. Additionally, several commenters noted that this requirement could be administratively burdensome for States with a small percentage of their population enrolled in FFS. One commenter suggested that we provide an exceptions process in these circumstances.

Response: We address specific concerns from commenters—including concerns about potential duplication, burden, and provider involvement—in more detail in subsequent responses. As described below, we are seeking to balance State flexibility with the need for accountability and consistency among State systems. We also do not believe that this proposal should place excessive burdens on providers, as we are requiring that States, and not providers, bear the primary responsibility of managing the grievance system. Finally, as part of our goal of establishing national standards, we do not intend to exempt States from these requirements based on the size of their FFS populations.

Comment: One commenter requested clarification on whether the State or CMS is ''in charge'' of the grievance process.

Response: We have proposed and, as discussed further below, we are finalizing Federal requirements that States operate and maintain a grievance system. The State is responsible for this system. However, we will monitor the States' compliance with these requirements.

Comment: A few commenters raised concerns or expressed confusion about how the proposed grievance system requirement will affect dually eligible beneficiaries who are enrolled in managed care plans that already have grievance processes. One commenter raised concerns about the possibility of multiple investigations being conducted parallel to one another. Other commenters inquired if Medicare Advantage care navigators could be required to help beneficiaries file grievances, or if the proposed grievance system requirements can be made part of dual eligible special needs plan (D–

[57] Specific questions or concerns regarding the application or implementation of the regulations finalized in section II.B. of this rule may be directed to *HCBS_Access_Rule@cms.hhs.gov*.

SNP) contracts. One commenter noted that it is critical for dually eligible beneficiaries to have one place to file grievances about both Medicare and Medicaid services. Another commenter requested clarification on how the grievance systems should work for dually eligible beneficiaries who have, as described by the commenter, ''multiple, perhaps conflicting plans of care.''

Response: We plan to provide States with technical assistance to help address issues specific to dually eligible beneficiaries. We note that we proposed that the grievance system requirements at § 441.301(c)(7), and as finalized in this rule, apply only to beneficiaries receiving services under section 1915(c), (i), (j), and (k) authorities through FFS delivery systems, and to issues arising with these services. The new grievance system requirement would not affect, for instance, dually eligible beneficiaries who receive services under section 1915(c), (i), (j), or (k) authorities through fully integrated dual eligible special needs plans (FIDE SNP), highly integrated dual eligible special needs plans (HIDE SNP), or D–SNPs otherwise affiliated with MLTSS plans, as those beneficiaries receive their HCBS through managed care and not through FFS. We also note that some dually eligible beneficiaries may be enrolled in managed care plans known as applicable integrated plans (AIP), which are subject to the integrated grievance requirements at § 422.630. AIPs must resolve and notify enrollees within required timeframes for integrated grievances filed for Medicare and Medicaid services. We will provide technical assistance as needed regarding the application of the requirements finalized at § 441.301(c)(7) to beneficiaries in different categories of dual eligibility.

Comment: One commenter recommended continuity across grievance systems in FFS and managed care delivery systems to ensure consistent and equitable processes for addressing enrollee concerns.

Response: We agree that such continuity is important. In drafting the proposed requirements at § 441.301(c)(7) for FFS grievance systems, which we are finalizing as described in this section II.B.2 of the final rule, we attempted to mirror the requirements for managed care grievance processes in part 438, subpart F, as much as possible in order to promote consistency between the two systems.

Comment: A few commenters requested that we allow States to arrange for the operations of the grievance procedures to be performed by a vendor, local agencies, or other contracted entity. Conversely, a few other commenters raised concerns about the possibility of the grievance process being administered by providers. Some of these commenters expressed concerns that the requirement might be burdensome for local and regional entities to administer, and one commenter raised concerns that administration of the grievance process by local agencies might cause problems in terms of oversight and conflict of interest.

A few commenters also noted that, unlike in managed care where care is managed under one plan, some FFS delivery systems involve multiple State agencies or agency divisions operating different programs. The commenters requested more clarification about which agency or department is responsible for oversight of the system and coordination in these circumstances.

Response: The requirements proposed, and being finalized, in § 441.301(c)(7) are applied to the State, by which we refer (as we do in many of our regulations) to the single State agency as described in § 431.10(b). However, we believe that some States may find it more efficient or effective to have the operations of the grievance system performed by other government agencies or contractors, depending on how a State's systems are organized. Allowing such contracting may also help preserve existing State grievance processes; we address additional comments about preservation of existing grievance systems later in this section II.B.2. of the final rule. However, the single State agency must retain ultimate responsibility for ensuring compliance with the requirements set forth in § 441.301(c)(7). We expect that States are familiar with their local resources (including the capacity of local agencies) and would only have the operations of the grievance system performed by an entity that had the necessary infrastructure and resources to operate a system that would comply with the requirements in § 441.301(c)(7). To ensure that the responsibility of the single State agency is clear, we are finalizing § 441.301(c)(7)(i) with a modification to specify that the State may contract with contractors or other government entities to perform activities described in § 441.301(c)(7) provided however that the State retains responsibility for ensuring performance of and compliance with these provisions.

We also note that we intend that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance. While we do not intend to specify any additional restrictions on the entities operating the grievance system in this final rule, we believe that it would be difficult to envision scenarios in which it would be appropriate for the State to contract with a provider (or local agencies that act as providers) to operate the grievance system. For example, an employee of a provider who signed off on the provider's actions that gave rise to the grievance would be someone who was involved with making a decision about the grievance and thus neither that employee (nor their subordinates) would be appropriate decisionmakers in the grievance process. If a State believed it necessary to arrange for the operations of the grievance system to be performed by a local agency that also provided services, firewalls would have to be put in place to ensure that grievances were reviewed by a neutral decisionmaker within that agency.

Comment: Several commenters supported the definition of grievance we proposed at § 441.301(c)(7)(ii). Overall, these commenters supported the focus on compliance with the person-centered planning process and the HCBS settings rule. One of these commenters observed that issues with these requirements are often at the core of challenges experienced by beneficiaries. One commenter, however, questioned the inclusion of concerns about the HCBS settings requirements, noting that if a setting violates the HCBS settings requirements, the individual has the choice of moving to a different setting.

Response: We appreciate commenters' support for the definition of grievances. We specifically included noncompliance with the HCBS settings requirements as one of the bases for grievances so that beneficiaries do not have the burden of addressing violations of their rights by having to change providers, which could result in some circumstances in having to move out of their home. We do not believe that beneficiaries should have to choose between their rights or their homes. As a practical matter, switching residences can be disruptive, emotionally and physically demanding, costly, and time-intensive, not to mention particularly difficult in areas that lack plentiful affordable and accessible housing options. We also believe that requiring States to address these issues related to

compliance with HCBS settings requirements in the context of a grievance system may encourage States and providers to prevent similar issues from occurring with other beneficiaries.

Comment: One commenter stated that the definition of grievance was too broad and requested that CMS narrow the scope of allowable grievances. The commenter stated that although the proposed requirements limit the grievance system to person-centered planning, service plan requirements, and HCBS settings requirements, they would still allow a beneficiary to file a grievance on nearly every aspect of their HCBS experience, which would in turn create the potential for an unreasonably high volume of grievances to which States would be required to respond.

A few commenters stated that the definition of grievance was subjective, and asked for general clarification on what is meant by an ''expression of dissatisfaction.'' Conversely, a few commenters stated the definition of grievance was not broad enough. One commenter stated that the reference to §§ 441.301(c)(1) through (3) would only allow for the filing of grievances in relation to the person-centered planning process but would not allow for grievances in relation to beneficiaries' dissatisfaction with the delivery of the services in the plan. The commenter provided examples, such as a care provider handling an HCBS beneficiary roughly, failing to assist the beneficiary with certain activities of daily living or perform other services in the care plan, being slow to respond to the beneficiary's requests for assistance in residential settings, improper administration of chemical restraints, or general poor care that leads to injuries such as bed sores. The commenter recommended that the regulatory language be revised to include the right to file a grievance to protect beneficiary health and welfare.

One commenter suggested that we specify that grievances may include issues regarding timeliness, quality, and effectiveness of services, in addition to the HCBS setting, person-centered planning, and service plan requirements. The commenter noted that, in the commenter's State, beneficiaries have had to wait for long periods of time for the initiation of services after being approved for the services.

Finally, another commenter noted that they believed that the managed care regulations' grievance definition includes an expression of dissatisfaction about any matter other than an adverse benefit determination and recommended adding clarifying language to the definition of a grievance to ensure that beneficiaries do not mistakenly file grievances about issues that are adverse benefit decisions and that entitle them to a fair hearing.

Response: We disagree with commenters that the proposed definition is overly broad. The definition of grievance proposed at § 441.301(c)(7)(ii) was crafted to strike a balance between providing beneficiaries with broad, but not unlimited, bases for filing a grievance. We believe that the requirements in §§ 441.301(c)(1) through (6) provide a clear list of activities that the States and providers must perform to ensure that HCBS beneficiaries receive appropriate person-centered planning, receive the services described in the person-centered service plan to support the individual in the community, and have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs.[58] We note that some specific examples of when a beneficiary may express dissatisfaction by filing a grievance are discussed further in this section.

We also disagree that the scope of the definition is too narrow. We proposed that the definition of grievance include an expression of dissatisfaction or complaint related to the State's or provider's compliance with the person-centered service planning process, required in §§ 441.301(c)(1) through (3). We note that some issues regarding the timeliness, quality, or effectiveness of services may need to be addressed as part of the person-centered service planning process itself. For instance, if a beneficiary believes the service is not effective, the beneficiary may request revision to the person-centered service plan, as required at § 441.301(c)(3), to identify either a more effective service or a more effective provider; non-responsiveness on the part of the entity responsible for updating the service plan could be a reason to file a grievance.

Additionally, § 441.301(c)(4) requires that home and community-based settings must meet certain requirements enumerated therein, including (but not limited to): being integrated in and supporting full access of individuals to community life; ensuring that an individual has rights to privacy, dignity and respect, and freedom from coercion and restraint; optimizing an individual's initiative, autonomy, and independence in daily activities and the physical environment; and facilitating an individual's choice in services and supports, as well as who provides them. If, for instance, a beneficiary believes that a worker has not treated the beneficiary with respect, or the worker is chronically late, and the provider has failed to address the worker's behavior or provide a different worker at the beneficiary's request, it would be reasonable for a beneficiary to file a grievance, as the provider is not ensuring that all of the qualities of a home and community-based setting (as described by § 441.301(c)(4)) are being met. Accordingly, we believe that the activities set forth in §§ 441.301(c)(1) through (6) (both currently and as are being amended in this final rule) generally describe the actions of both providers and States that are necessary to uphold and promote high-quality service delivery that promotes respect for beneficiaries' rights.

While we believe the scope of grievances that may be considered under the grievance system that we proposed, and are finalizing, appropriately captures activities that promote delivery of quality HCBS and respect for beneficiaries' rights, we do believe further clarity is warranted. We believe it is more appropriate and precise to say grievances may be filed regarding the State's or a provider's performance of (rather than compliance with) the requirements described in §§ 441.301(c)(1) through (6). We note that the activities described in § 441.301(c)(1) through (6) must, as required at § 441.301(c), be included in a State's waiver application; we want to make it clear that grievances may be filed when a State or provider fails to perform these activities (not solely if the State fails to include these items in a waiver application). To clarify this point, we are finalizing the scope of grievances that may be filed under the grievance system we proposed to set forth at § 441.301(c)(7) with modification, by revising the language in § 441.301(c)(7)(i) to specify that beneficiaries may file grievances regarding a State's or provider's performance of (rather than compliance with) the activities described in §§ 441.301(c)(1) through (6). We are finalizing a conforming modification to the definition of grievance at § 441.301(c)(7)(ii).

We observe that most of the examples provided by commenters, as described above, included instances in which a beneficiary experienced abuse or harm during the performance (or lack thereof) of services in the person-centered service plan. These types of complaints

[58] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

may be more appropriately addressed under the critical incident system being finalized at § 441.302(a)(6). As discussed in II.B.3. of this rule, we believe the critical incident system proposed at § 441.302(a)(6) is the appropriate mechanism for investigating harms to beneficiaries' health and safety. As we discuss in II.B.3 of this rule, we proposed additional performance measures and reporting requirements for the critical incident system (beyond what is proposed for the grievance system) to ensure more formal oversight of the investigations and resolutions of threats to beneficiary health and safety. We do not believe a grievance system is an appropriate mechanism for investigating threats to the beneficiary's health and welfare. Therefore, we decline to broaden the definition of grievances that may be addressed under the grievance system we are finalizing at § 441.301(c)(7) in such a way that would suggest that the grievance system is intended for complaints regarding health and safety. We believe doing so would create duplicative system requirements for the grievance process and critical incident system and potentially cause States to resolve threats to health and safety in the grievance system that should have been investigated and addressed within the critical incident system.

We also disagree with the commenter that suggested we align the definition of grievance we proposed at § 441.301(c)(7)(ii) with the definition of grievance for managed care grievance processes at § 438.400(b). We believe that, for the purposes of a FFS grievance system intended to address specific concerns with HCBS, using the same or similar definition of grievance for managed care grievance processes would be overly broad and will not diminish confusion about whether an issue is appropriate to be filed as a grievance, a critical incident, or a fair hearing. We plan to provide technical assistance to States as needed on this topic.

We refer readers to section II.B.2.b. of this final rule where we also address more specific concerns related to ensuring matters are filed with the correct system in our discussion of § 441.301(c)(7)(iii).

Comment: One commenter suggested that we broaden the definition of grievance to specify that beneficiaries can file grievances when their rights are violated, and suggested that the following be included in the definition of rights:

- Right to work and fair pay;
- Right to control one's own money;
- Right of possessions and ownership;
- Right to privacy, dignity, and respect;
- Freedom of choice and decision-making;
- Right to leisure activities;
- Freedom to marry and have children;
- Right to food, shelter, and clothing;
- Freedom of movement;
- Freedom of religion;
- Freedom of speech and expression;
- Free association and assembly;
- Freedom from harm;
- Access to health care;
- Right to citizenship and right to vote;
- Right to equal education;
- Right to equal access; and
- Due process.

Response: We believe that some of the consumer rights listed by the commenter are addressed in or mirrored by components of the existing HCBS settings rule requirements at § 441.301(c)(4), such as: ensuring that the individuals have access to the greater community, including engagement in community life, opportunities for employment in competitive integrated settings, and control over personal resources (§ 441.301(c)(4)(i)); the right to privacy, dignity and respect, and freedom from coercion and restraint (§ 441.301(c)(4)(ii)); allowing for individuals to choose their activities and set their own schedules (§ 441.301(c)(4)(iv) and (vi)(C)); the ability to determine with whom the individual will interact, as well as to have visitors of the individual's choosing at any time (§ 441.301(c)(4)(iv) and (vi)(D)); and control over the individual's own physical environment, living and sleeping space, and access to food (§ 441.301(c)(4)(iv), (v)(B), and (vi)(C)).

We note that many of the other rights suggested by the commenter are either addressed by other systems (such as access to health care which, if related to an adverse benefit determination made by the State Medicaid agency, may be subject to the fair hearings process or are out of scope of the State Medicaid agency's authority) or by other authorities (such as fair wages, equal access to education, or violations of constitutional rights).

Comment: Several commenters requested that the grievance process include issues such as authorization disputes and the provision of services.

Response: We are not certain if the commenters are referring to using the grievance system to allow beneficiaries or providers to challenge denials of services. We are also uncertain if disputes over ''provision of services'' refers to the quantity or quality of services. We note that the fair hearings process at 42 CFR part 431, subpart E, sets out the parameters that allow beneficiaries to challenge an adverse action by the State Medicaid agency. For the purposes of a fair hearing, an ''action'' is defined at § 431.201 in part, as the termination, suspension of, or reduction in covered benefits or services, or a termination, suspension of, or reduction in Medicaid eligibility. A State must provide an individual the opportunity for a fair hearing in the circumstances described in § 431.220(a), which include when the Medicaid agency has denied eligibility, services, or benefits, and when the claim for medical assistance has not been acted on with reasonable promptness. In most circumstances, a refusal of a State Medicaid agency to authorize a particular service for a beneficiary, or to authorize the quantity of services the beneficiary believes is necessary, would be addressed in the fair hearings process. In contrast, the grievance process we have proposed is intended to allow beneficiaries to raise concerns about specific aspects of their services that have been authorized.

Comment: Several commenters who supported this proposal did so because they agreed that, currently, concerns regarding person-centered planning and HCBS settings requirements are not subject to the existing fair hearings process at 42 CFR part 431 subpart E. One commenter, however, suggested that, rather than create a grievance process to hear complaints about person-centered service plans and the HCBS settings requirements, we should require that concerns about person-centered service plans or the HCBS settings requirements be added to fair hearings processes. The commenter stated the belief that fair hearings permit an unbiased third-party Administrative Law Judge (ALJ) to consider the facts and render an objective decision. By contrast, the commenter believed that, in their State, the current State grievance process did not permit unbiased or effective review.

Response: We agree that it is important to provide beneficiaries with the opportunity to raise concerns about the person-centered service plans and planning process and the HCBS settings requirements. We do not, however, believe that these are necessarily appropriate matters for the fair hearings process. The authority for the fair hearings process comes from section 1902(a)(3) of the Act, which requires that States provide beneficiaries and

applicants an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance is denied or is not acted upon with reasonable promptness.

While beneficiaries can request a fair hearing to address concerns about service denials (including partial denials) and other concerns described under § 431.220(a), we believe that an individual's concerns about person-centered service plans, the planning process, and HCBS settings are outside the scope of issues for which the statute requires that a fair hearing be provided, and therefore we cannot require States to provide an opportunity for a fair hearing to address such issues. We note, however, that States have discretion to decide whether integrating their grievance processes with other State systems, including their fair hearings systems, is feasible and appropriate, and that the requirements for both systems may still be met.

Separate from the fair hearing requirement at section 1902(a)(3) of the Act, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires the development and monitoring of an HCBS complaint system. To address this statutory requirement, we proposed that the grievance system address matters that do not arise from a denial of Medicaid eligibility or denial of services, or failure to act upon the individual's claim for medical assistance with reasonable promptness, which are addressed separately under the required fair hearing process. We expect the grievance system will help beneficiaries resolve concerns about the quality of the services they are receiving. We also note that the purpose of our proposals in this section II.B.2. is to require that States create, implement, and maintain grievance systems that, while not necessarily as formal as a fair hearings process in all cases, will nevertheless result in unbiased and effective reviews of grievances.

We note that, while States may choose to use ALJs as hearing officers to conduct a Medicaid fair hearing, hearing officers are not required to be ALJs. Medicaid regulations at § 431.240(a)(3) require that all fair hearings be conducted by one or more impartial officials or other individuals who were not directly involved in the initial determination in question. We also note that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, are intended to promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance.

Comment: A few commenters expressed concerns that, in States that already have grievance systems, the proposed requirements could result in duplication of processes and confusion for beneficiaries about where and how to report grievances. Several of these commenters requested we allow States to use existing grievance systems to meet the Federal requirement. One commenter also suggested that if the State's existing system meets our proposed criteria, the State should be considered in compliance with the requirements. Another commenter suggested that providers or States with existing grievance systems should not have to modify their systems.

Commenters were especially concerned about the impact on States that already had multiple grievance systems for different programs, administered by different operating agencies. These commenters requested that we allow States flexibility to design grievance systems and processes to fit their unique program and systems structures and implement multiple grievance systems or processes tailored to their programs. One commenter raised specific concerns about having to consolidate current grievance systems into a single electronic system.

One commenter, however, requested that we require States to have a single grievance system; the commenter stated that having multiple grievance processes can be confusing and burdensome for beneficiaries.

Response: We acknowledge that many States already have grievance processes in place for HCBS, and it is not our intent for States to abandon these systems or create additional systems. We agree with the suggestion that, if a State already has a grievance process in place that meets the requirements that we are finalizing in this rule, that State will be considered in compliance with these requirements. However, we disagree that States with existing grievance systems should be allowed to maintain the system without modification where their systems do not meet Federal requirements. While we encourage States to economize by maintaining current systems as much as possible, we do expect that States will make any needed adjustments to bring their systems into compliance with the requirements we are finalizing in this rule. We believe that having Federal requirements for grievance systems will promote consistency and accountability across the country.

Additionally, we note that the definition of grievance system that we proposed referred to ''processes,'' suggesting that a grievance system may be made up of one or more processes (88 FR 28080). If a State wishes to maintain multiple grievance processes, and each of these processes comply with the Federal requirements we are finalizing in this rule, the State will be considered in compliance.

We did not propose a requirement for a State to maintain a single electronic system for their grievance system and, as discussed above, believe it would be acceptable to maintain multiple grievance processes. However, we also emphasize that part of the definition of grievance system we proposed, and are finalizing, in § 441.307(c)(7)(ii) is that the system allows States to collect and track information about grievances. If States choose to maintain separate systems, including separate electronic systems, they must develop ways to ensure that they are able to track trends across systems in meaningful ways. We refer readers to section II.B.2.f of this final rule, where we discuss our proposals related to recordkeeping requirements for the required grievance system.

Although not required, we encourage States to implement a single integrated system across their HCBS programs, as we echo one commenter's concerns that a single integrated system would likely reduce confusion for beneficiaries and facilitate their ability to access the system. We also believe that a single system would best permit States to track trends across their HCBS programs and use the data and information generated by the grievance system to address systemic issues in their HCBS programs. Additionally, a single integrated system may be more cost-effective for States to operate once implemented.

Comment: One commenter requested clarification on whether there is a difference between a complaint and a grievance, as well as what would elevate a complaint to the level of a grievance.

One commenter asked for clarification on the role of conflict-free case managers in the grievance system.

Response: While section 2402(a)(3)(B)(ii) requires that we promulgate regulations to ensure that all States develop service systems that include development and monitoring of a complaint system, the Affordable Care Act does not define the terms complaint or complaint system. In developing our proposal to implement this requirement from the Affordable Care Act, we have chosen to use the term grievance, instead of complaint, and proposed to define grievance and grievance system at § 441.301(c)(7)(ii). If a State has implemented a system it calls a

complaint system that meets the requirements we proposed, and are finalizing, at § 441.301(c)(7), it is possible that this system could satisfy the requirement for a State to have a grievance system.

We do not understand the specific nature of the comment regarding conflict-free case managers. We note, in general, that we will provide technical assistance to States to assist in adapting their HCBS programs and any associated existing grievance processes to comply with the requirements finalized at § 441.301(c)(7).

Comment: Several commenters observed that some States currently require providers to have policies and procedures in place related to service-delivery complaints. One commenter requested that we provide clarification, either in the final rule or subregulatory guidance, regarding the inclusion of the proposed grievance system requirements in existing provider-level complaint and grievance processes. Commenters stated that additional guidance is needed to help all interested parties understand when beneficiaries should file a grievance with their provider and when they should file with the State. One commenter recommended that beneficiaries be required to exhaust these processes at the provider level before a complaint is submitted to the State agency for investigation or intervention.

Response: Our goal for proposing uniform requirements for grievance systems applicable to all States providing HCBS under section 1915(c) waiver program authority, and other HCBS authorities as discussed in section II.B.2.h of this final rule, is to ensure consistent processes are available for Medicaid beneficiaries receiving such services. We decline to require in this final rule that beneficiaries exhaust their provider-level complaint process prior to accessing the State grievance system. We believe that such a Federal requirement would be inapplicable or confusing in States that do not have provider-level complaint process requirements, do not require all providers to have them, or do not require that providers have uniform complaint processes. We have attempted to provide States with as much flexibility as possible in the design of their grievance system. Additionally, we have concerns that such an exhaustion requirement would be a barrier, or would cause unnecessary delay, for beneficiaries where the relationship between the beneficiary and the provider is contentious, or where the provider does not have an effective or efficient complaint process.

Comment: Commenters requested that grievance processes be developed with input from providers, beneficiaries, families, and advocacy groups to create a grievance system that is accessible, practical, and sets realistic expectations for its users.

Response: We have attempted to provide States with as much flexibility as possible in the design of their grievance system and decline to add a specific requirement on this point in this final rule. We encourage States to include input from interested parties when developing their grievance system policies and procedures to comply with the requirements we are finalizing in this rule.

Comment: Several commenters suggested that the grievance system be integrated with the critical incident system. One commenter stated that States should be required to enter the grievance information and data into a State database with standardized fields that is either part of, or integrated with an incident management system, so that grievance data can be compared to data on relevant individuals, providers, and incidents (both reported and unreported). Similarly, a few commenters suggested that the grievance system should be integrated with the fair hearings system in States.

Response: While we agree that States may find it useful to have a single, integrated system for grievances, critical incidents, and fair hearings, we are not requiring in this final rule that States do so. We believe it is important for States to have flexibility in how they design their grievance systems so that they may expand on infrastructures and processes they already have in place and tailor the grievance systems to meet their programmatic and operational needs, even as they are held to standardized Federal grievance system requirements.

After consideration of the comments received, we are finalizing the language at § 441.301(c)(7)(i) and (ii) with modifications. For the reasons discussed above, we are modifying § 441.301(c)(7)(i) to include language specifying the State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions. Additionally, we are finalizing § 441.301(c)(7)(i) and the definition of grievance in § 441.301(c)(7)(ii) with the modification that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's *performance of* (rather than compliance with) the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). We are otherwise finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.

b. Grievance Process Requirements (§ 441.301(c)(7)(iii))

At § 441.301(c)(7)(iii)(A) through (C), we proposed new general requirements for States' grievance procedures for section 1915(c) HCBS waiver programs and other HCBS authorities as discussed in section II.B.2.h of this final rule. Specifically, at § 441.301(c)(7)(iii)(A), we proposed to require that a beneficiary or authorized representative be permitted to file a grievance under the section 1915(c) HCBS waiver program. As discussed below in section II.B.2.h. of this final rule, we also proposed to apply these same requirements to section 1915(i), (j) and (k) HCBS programs. Under the proposal, another individual or entity may file a grievance on a beneficiary's behalf, so long as the beneficiary or authorized representative provides written consent. We noted that our proposal would not permit a provider to file a grievance that would violate conflict of interest guidelines, which States are required to have in place under § 441.540(a)(5). At § 441.301(c)(7)(iii)(A), we also proposed to specify that all references to beneficiary in the regulatory text of this section includes the beneficiary's representative, if applicable.

At § 441.301(c)(7)(iii)(B)(1) through (7), we proposed to require States to:

- Have written policies and procedures for their grievance processes that at a minimum meet the requirements of this proposed section and serve as the basis for the State's grievance process;
- Provide beneficiaries with reasonable assistance in completing the forms and procedural steps related to grievances and to ensure that the grievance system is consistent with the availability and accessibility requirements at § 435.905(b);
- Ensure that punitive action is not threatened or taken against an individual filing a grievance;
- Accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries;
- Provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance

system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);

- Review grievance resolutions with which beneficiaries are dissatisfied; and
- Provide information on the grievance system to providers and subcontractors approved to deliver services under section 1915(c) of the Act.

At § 441.301(c)(7)(iii)(C)(1) through (6),[59] we proposed to require that the processes for handling grievances must:

- Allow beneficiaries to file a grievance either orally or in writing;
- Acknowledge receipt of each grievance;
- Ensure that decisions on grievances are not made by anyone previously involved in review or decision-making related to the problem or issue for which the beneficiary has filed a grievance or a subordinate of such an individual, are made by individuals with appropriate expertise, and are made by individuals who consider all of the information submitted by the beneficiary related to the grievance;
- Provide beneficiaries with a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance;
- Provide beneficiaries, free of charge and in advance of resolution timeframes, with their own case files and any new or additional evidence used or generated by the State related to the grievance; and
- Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal at § 441.301(c)(7)(iii)(A) to require that a beneficiary or the beneficiary's authorized representative be permitted to file a grievance, including allowing another individual or entity to file a grievance on a beneficiary's behalf, with written consent from the beneficiary or the beneficiary's authorized representative.

However, several commenters raised concerns about the proposed requirement that beneficiaries or their authorized representatives must provide written consent to another individual or entity to file a grievance on the beneficiary's behalf. A few commenters noted that some beneficiaries may not be able to give written consent, or that waiting for written consent to be obtained could create unnecessary delays in grievance filings and investigations. One commenter suggested that we either remove the word ''written'' or specify that consent may be verbal or written. Another commenter, using their State as an example, suggested that a grievance could be filed with verbal consent from the beneficiary or authorized representative, with written consent obtained later. One commenter suggested an agency could obtain a beneficiary or authorized representative's consent over the phone to allow another individual or entity to file a grievance on the beneficiary's behalf.

Response: As discussed further herein, we are finalizing the requirement that consent must be written as proposed. We modelled the proposed requirement and language at § 441.301(c)(7)(iii)(A) on requirements for the managed care grievance process at § 438.402(c)(1)(ii), which provides that, if State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of a managed care enrollee. Our general intent is to align the FFS grievance system and managed care grievance process to the greatest extent possible. We also believe it is important to ensure that there is some documentation demonstrating that beneficiaries or their authorized representatives have provided consent for a grievance to be filed on the beneficiary's behalf, especially as the investigation of a grievance may involve reviewing records pertaining to the beneficiary's care.

We note that written consent may be broadly interpreted to include electronic signatures, voice signatures, or other methods that provide reasonable accommodations to individuals who might face challenges providing traditional written signatures. States will have flexibility in determining how written consent is obtained and verified, so long as the system States develop ensures that the process presents as few administrative barriers as possible for a beneficiary or authorized representative to provide the necessary consent.

Comment: Several commenters recommended that we clarify that beneficiaries be able to choose who represents them throughout the grievance process. One commenter recommended that the grievance process should provide the beneficiary with the opportunity to indicate who they want to assist them in the process, and this should serve as a type of release.

Response: It was our intent that beneficiaries and their authorized representatives be able to involve other individuals or entities of their choosing to assist them throughout the grievance process, in addition to filing a grievance. We believe that it is logical to assume that if a beneficiary or their authorized representative needs assistance filing a grievance, they may also need assistance with other parts of the process (such as requesting and reviewing their case file, or presenting information to support their concerns at a hearing). We also note that while States are required at § 441.301(c)(7)(iii)(B)(*2*) to provide beneficiaries with reasonable assistance in completing forms and taking other procedural steps related to a grievance, beneficiaries may prefer to get this assistance from an individual or entity of their own choosing, particularly in situations where the beneficiary has filed a grievance against the State. To clarify this intent, we are finalizing § 441.301(c)(7)(iii)(A)(*1*) with a modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We note that we expect that, as part of ensuring the process is person-centered, beneficiaries or their authorized representatives will be able to withdraw consent for this third-party representation at any time, and that beneficiaries can generally terminate the grievance process at any time.

We are finalizing § 441.301(c)(7)(iii)(B)*(1)* with a modification to correct an erroneous reference to subchapter in the regulatory language and replace subchapter with paragraph (c)(7).

Comment: Several commenters requested clarifications or made suggestions regarding our proposal at § 441.301(c)(7)(iii)(B)(2) to require that States provide beneficiaries reasonable assistance in completing forms and taking other procedural steps related to a grievance. One commenter

[59] At 88 FR 27976, we incorrectly stated that we were proposing these requirements at § 441.301(c)(7)(iii)(C)(*1*) through (*5*), rather than (*1*) through (*6*). This typo has been corrected.

recommended that we set minimum criteria for reasonable assistance in filing a grievance, including but not limited to the State making someone available to meet with the beneficiary in person. Another commenter observed that many individuals who receive section 1915(c) waiver services, for example, have significant intellectual and developmental disabilities and as a result may need substantially more assistance than other beneficiaries to complete forms and procedural steps. The commenter requested clarification as to whether, in these circumstances, the reasonable threshold is determined by the needs of the beneficiary or the burden is on the State to determine how to provide reasonable assistance.

Response: We disagree that the term reasonable assistance that we proposed at § 441.301(c)(7)(iii)(B)(*2*) is unclear. We intentionally proposed language that would require States to determine, on a case-by-case basis, what constitutes reasonable assistance for beneficiaries utilizing the grievance system. Reasonable assistance may vary among beneficiaries and thus we intended to provide States with flexibility in determining what assistance is reasonable to provide. We decline to include additional formal definitions or criteria for the term reasonable assistance in this final rule lest we inadvertently set rigid standards that would, counterproductively, inhibit States from modifying processes for beneficiaries. For instance, if we were to require that States make someone available to meet with the beneficiary in person, we would not want this misinterpreted as a requirement that grievances may only be filed in person, which could pose significant barriers to individuals who lack transportation or live far from the physical locations in which grievances could be filed, even though we recognize that some beneficiaries may prefer to file a grievance in person.

We agree with the commenter that some beneficiaries may need more assistance, or different types of assistance, than other beneficiaries. We decline, however, to weigh in on what would be the threshold for determining reasonableness, as this appears to be a request for an opinion on hypothetical situations. We note that the concept of reasonableness is central to many areas of law and bodies of guidance regarding reasonableness are well-developed. We also note that the grievance system in general, by virtue of being administered by State Medicaid programs, will be subject to Title II of the Americans with Disabilities Act (ADA) of 1990, and section 504 of the Rehabilitation Act of 1973 (section 504), which may provide some specific guidance for what may be considered a reasonable modification in a government service.

Comment: A number of commenters advocated for the creation of a requirement for an HCBS Ombudsman program, similar to those required by the Older Americans Act. Many commenters noted an independent ombuds program could provide more effective assistance to individuals in filing grievances, helping them navigate the process, and representing them during the proceedings, rather than relying on assistance provided by the State.

Response: We thank commenters for their interest in this issue. As commenters noted, Title VII of the Older American Act authorizes and provides Federal funding for the national Long-Term Care Ombudsman Program, which is administered at the State level. These programs provide advocacy on behalf of residents of long-term care facilities. While there is no similar Federal statutory requirement for States to create an HCBS ombuds program, States may create such a program or similar programs at their own discretion to assist during grievance processes or to provide other advocacy supports.

Comment: Several commenters expressed concerns that it will be challenging for beneficiaries to understand when and how to file grievances. Several commenters noted the possibility that beneficiaries will be confused by the grievance and fair hearings processes and will file grievances or appeals with the wrong entities. One commenter suggested that beneficiaries enrolled in managed care for some medical services but receive FFS HCBS may be confused when presented with multiple grievance processes.

A number of commenters recommended that the grievance system should be set up with a ''no wrong door'' process so that, for example, a managed care plan receiving a grievance related to a FFS service would be responsible for forwarding the grievance to the appropriate entity. Similarly, another commenter suggested that if an enrollee mistakenly files a grievance about an adverse benefit determination, we require that this submission be treated as a fair hearing request unless the beneficiary objects. One commenter cautioned that, based on the commenter's experience, creating a ''no wrong door'' approach to grievances can be complicated and resource intensive. Another commenter requested that, if setting up a ''no wrong door'' approach, we ensure that the burden does not fall entirely on local entities, such as local Area Agencies on Aging.

One commenter requested clarification on whether appropriate referral of a grievance to the critical incident management process will count as a successful resolution of the grievance.

Response: We take very seriously the concerns raised by commenters regarding potential confusion among beneficiaries about which matters should be filed with which system. Our understanding of the commenters' suggestions is that such system should be coordinated for accepting grievances, fair hearing requests, and reports of critical incidents, among other engagements with beneficiaries, and ensure that each grievance, fair hearing request, or report of a critical incident is appropriately and seamlessly processed once it has been received by that system. However, we are not adding a formal ''no wrong door'' requirement in this final rule. Rather, we are finalizing the grievance system requirements we proposed with modifications as described below. We understand that, despite efforts to provide beneficiaries and interested parties with information and to make systems as user-friendly as possible, there will be instances in which beneficiaries attempt to access the ''wrong'' system. Additionally, there may be some matters where it is not immediately clear to the beneficiary if the problem, for instance, is a matter for the grievance system, critical incident investigation, or the fair hearings process. We also note that the beneficiary (or someone on their behalf) may report a critical incident (as defined at § 441.302(a)(6) of this final rule), or file an appeal under the fair hearings process that may not, as a whole, meet the definition of a grievance, but may contain elements that are more appropriate for consideration under the grievance system, while the remaining elements should still proceed as a critical incident investigation or in the fair hearing process. (We note that additional concerns about perceived overlap between grievances and critical incidents are addressed more fully later in this section.) Further, we agree that something akin to a ''no wrong door'' approach may be a good solution, to ensure that matters that are brought to the grievance system are not rejected because they are really a matter for a fair hearing or critical incident investigation. We encourage States to create a ''no wrong door'' policy and system or integrate grievance filings with existing ''no wrong door'' systems,

if feasible. We believe that such a system would help ensure that matters are filed correctly, which could reduce administrative burden on the grievance system.

However, we did not propose, nor are we requiring, that States create a ''no wrong door'' system. We note that some States may already have ''no wrong door'' systems that could be used to support beneficiary filings in the grievance system. While we encourage States that do not have such ''no wrong door'' systems to consider developing them, we recognize that there is variety among State systems and we do not wish to create a potentially rigid requirement that misaligns with States' existing infrastructures. We also want to ensure that the grievance process requirements finalized in this section focus on standardizing the grievance process itself, and are concerned that an attempt to further standardize ancillary processes would distract from this intention. We will take commenters' suggestions regarding ''no wrong door'' systems under consideration for potential future policy development or rulemaking.

While we are not requiring States develop a ''no wrong door'' system, we do take seriously commenters' concerns that beneficiaries may attempt to file grievances with other systems operated by the State. We proposed a requirement at § 441.301(c)(7)(iii)(B)(*2*) that States must provide reasonable assistance to beneficiaries both with filing grievances and completing other procedural steps; we believe it is logical to expect that if a beneficiary needs reasonable assistance from the State for the procedural steps, then they may need assistance with determining where to file their grievance in the first place. To better address the concern about potential beneficiary confusion about the grievance, incident management, fair hearings, and managed care grievance and appeal systems, we are modifying the language in § 441.301(c)(7)(iii)(B)(*2*) to indicate more clearly that States must provide reasonable assistance to ensure that grievances are appropriately filed with the grievance system (in other words, that States help beneficiaries identify whether their concern should be filed in the grievance system and, to the greatest extent possible, redirect grievances filed with other State systems to the grievance system).

Additionally, we note that the disposition of matters that are not grievances is outside the scope of the grievance process requirements at § 441.301(c)(7) finalized in this section regarding the grievance system; however, we strongly encourage States to ensure that grievances filed with the grievance system that contain matters that are appropriate for other systems, including the critical incident system (as finalized in section II.B.3. of this rule), the fair hearings system (as described in part 431, subpart E), or the managed care grievance or appeal system (as described in part 438, subpart F) are also considered filings with the appropriate system or systems in accordance with the requirements and timeframes for those systems.

We also remind States that States have the option under current regulations to assist beneficiaries with filing fair hearing requests (as described in part 431, subpart E). Section 431.221(c) provides that State Medicaid agencies may assist applicants or beneficiaries in submitting fair hearings requests and section 2901.3 of the State Medicaid Manual instructs States to make every effort to assist applicants and beneficiaries to exercise their appeal rights. Additionally, section 2902.1 of the State Medicaid Manual states that oral inquiries about the opportunity to appeal should be treated as an appeal for purposes of establishing the earliest possible date for an appeal. Thus, if a beneficiary submits a matter to the grievance system which the State recognizes as a matter more appropriate for a fair hearing, the State should treat this matter in accordance with the requirements of § 431.221(c) and the State Medicaid Manual by assisting the beneficiary with filing a fair hearing request and using the grievance submission date to establish the earliest possible submission date for the fair hearing requests. States also have the option to establish procedures that treat the request made to the grievance system as a submission of a fair hearing request described at § 431.221(a) when the matter raised in the grievance filing is more appropriate for a fair hearing.

Finally, we clarify that matters that are mistakenly filed with the grievance system but are appropriately referred to another system may be considered ''resolved grievances'' unless the State determines that the matter also contains separate grounds for a grievance review. We note that should a matter be resolved through referral to another system, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(*6*) (review of grievance resolutions with which the beneficiary is dissatisfied), which are being finalized in this section II.B.2. of the final rule.

Comment: A few commenters provided support for our proposal at § 441.301(c)(7)(iii)(B)(2) that the reasonable assistance provided by the State includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and individuals with Limited English Proficiency. These commenters noted the importance of providing accessible information to beneficiaries, to ensure beneficiaries have full participation in the process.

Some commenters suggested modifications or additions to the accessibility requirements, including:

- Replacing the term, interpreter services, with the term, linguistic accommodations, noting this would better capture the need for trans creative supports that addresses differences in cultural norms and understandings;
- Requiring plain language explanations of the grievance procedures; and
- Adding mention of the regulations implementing section 1557 of the Affordable Care Act, particularly to reflect §§ 92.201–92.205 of the 2022 Nondiscrimination in Health Programs and Activities proposed rule (87 FR 47824).

Response: As discussed further herein, we are not making modifications to § 441.301(c)(7)(iii)(B)(2) in response to these comments. While it may be a term of art used in some fields, there is no Federal guidance or definition of the term, linguistic accommodations. We retain the term, interpreter services, as defined at § 441.301(c)(7)(iii)(B)(*2*), in this final rule to remain consistent with other Federal requirements. We thank the commenter for bringing the term linguistic accommodations to our attention, and we will take it into consideration for future technical assistance related to this provision.

We note that the proposed requirement at § 441.301(c)(7)(iii)(B)(2) already included a mention of existing accessibility requirements at § 435.905(b). Section 435.905(b) includes a requirement that communications be provided in plain language. We believe it would be duplicative to add a specific requirement that information be provided in plain language.

We also decline to add specific reference to section 1557 of the Affordable Care Act or its implementing regulations, as we find such an addition to be unnecessary. State Medicaid agencies must comply with all relevant requirements in section 1557 in all aspects of their programs, including the grievance process.

Upon review, we are finalizing § 441.307(c)(7)(iii)(B)(*2*) with some modifications to better align the provision with other regulations. We are finalizing a modification to revise the term ''individuals who are limited English proficient'' to ''individuals with Limited English Proficiency.'' This modification conforms with the language being finalized in § 431.12(f)(7) (discussed in section II.A. of this final rule). We are finalizing a modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication (instead of upon request as originally proposed), which we believe better conforms to access standards such as those set forth in the ADA and section 504.

Comment: One commenter noted that the repeated references to the regulation at § 435.905(b) (in the proposed requirements at § 441.301(c)(7)(iii)(B)(*2*), (c)(7)(iii)(C)(*6*), and (c)(7)(vi)(A)) may suggest that these accessibility services are not necessary outside of the specific provisions for which they are listed. The commenter suggested we create a separate provision related to language and disability access under the general requirements for the grievance system and specify that it applies to all components of the grievance system.

Response: We disagree that a separate, standalone accessibility requirement would add clarity to States' accessibility requirements. We also do not believe that we have overlooked a part of the process that must be accessible and note that the entire grievance system is subject to other accessibility requirements, including the ADA and section 504, by virtue of being administered by government agencies. As discussed further herein, we are finalizing the references to § 435.905(b) included in the provisions in § 441.301(c)(7) as proposed, as we believe that it is helpful to reiterate the importance of compliance with § 435.905(b) in the various steps of the grievance process.

Comment: One commenter recommended that we mandate that States accept electronic grievances with fill-in forms that could be completed by someone using a smart phone. Another commenter also requested that we require that the grievance system be web-based. One commenter, however, expressed concerns about a grievance system that is only accessible electronically, noting that some people may not have access to or be able to use computers.

Another commenter suggested that we specify that States must maintain a toll-free number, a regularly monitored email address for receiving grievances from Medicaid HCBS beneficiaries, and multiple modes of submitting a grievance, including a request for assistance with articulating and submitting a grievance as a reasonable accommodation.

Response: We appreciate commenters' many thoughtful suggestions on how to ensure that the grievance process system is accessible and user-friendly. At this time, we are not making changes in this final rule at § 441.301(c)(7) to include specific regulatory requirements for exactly how States should implement an electronic system for filing grievances. We believe that the diversity of comments on this issue demonstrates that beneficiaries will likely need the ability to access the grievance filing process through multiple modalities. We encourage States to consider user access (in addition to legally required accessibility considerations) and engage the interested parties within the HCBS community regarding the construction of a user-friendly grievance filing process that accommodates beneficiaries' different communication and technology needs.

Comment: A few commenters expressed support for our proposal to prohibit punitive actions against individuals who file grievances. One commenter noted that, in their State, beneficiaries are reluctant to complain about care due to fear of retaliation. Another commenter requested that CMS clarify that the requirement applies to punitive actions taken by either the State or a provider. The commenter also requested that CMS clarify that States must investigate punitive actions from providers. One commenter requested that CMS clarify that punitive action includes implying that an individual or family might lose services if they access the grievance process. Another commenter stated that the State should provide operational definitions of punitive actions and provide easily understood guidance to providers and State entities as to what types of actions would be considered punitive.

Several commenters offered specific suggestions for revising the proposed requirement at § 441.301(c)(7)(iii)(B)(*3*). One commenter suggested we revise the language to read ''retaliatory action'' or ''retaliatory or punitive action.'' Another commenter suggested that we amend the proposed regulatory text to define such action as ''any negative action following a grievance, complaint, and appeal or reporting of any issue to any regulatory body.''

Response: We clarify that this requirement is intended to prohibit punitive actions from either the State or providers. We do expect that, as part of ensuring that beneficiaries (as well as authorized representatives or other individuals who have filed a grievance on the beneficiary's behalf) are protected from punitive action, States will have a system for both identifying and investigating allegations of punitive action. We agree with the commenter that verbal threats from a provider directed at the beneficiary, or the beneficiary's family, would be the type of punitive action contemplated by this provision that would merit investigation. We also agree that providing additional definitions and examples of punitive actions will be an important part of States' grievance system policies.

To better clarify who is protected from punitive actions (both beneficiaries and those filing grievances on their behalf), we are finalizing a modification to § 441.301(c)(7)(iii)(B)(*3*) to clarify that prohibited actions are neither threatened nor taken against an individual filing a grievance *or who has had a grievance filed on their behalf.* As discussed in this section (section II.B.2.b.), we are finalizing our proposal at § 441.301(c)(7)(iii)(A)(*1*) to allow beneficiaries to have another individual or entity file a grievance on their behalf with written consent. We intend to make it clear that punitive action may not be taken against a beneficiary, whether the beneficiary personally filed the grievance or received assistance filing the grievance. We also want to ensure that authorized representatives or other individuals (including family members or other beneficiaries) are protected from punitive action when helping beneficiaries file grievances.

We agree that amending the regulatory language to ''punitive or retaliatory actions'' would further clarify the intent of the requirement, as ''retaliation'' is a common term associated with prohibited behavior in other types of complaints systems. While there is overlap in the connotations of ''punitive'' and ''retaliatory'' actions, we also believe that some actions that could be taken against individuals in response to the filing of a grievance could be perceived as ''retaliatory'' rather than ''punitive.'' We believe that the word ''retaliatory'' may particularly capture threats or actions that could negatively affect a beneficiary's access to services, whether or not the threat or negative outcome actually materializes. For instance, if a provider noted negative things to other providers about a beneficiary or the beneficiary's authorized representative and discouraged other providers from accepting that beneficiary as client after a grievance was filed against the

provider, this action could be perceived as ''retaliatory'' rather than ''punitive,'' particularly if this did not ultimately result in a reduction or alteration of the beneficiary's services. Therefore, we are finalizing § 441.301(c)(7)(iii)(B)(*3*) with modification in this final rule to specify that States must ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf.

We decline to make the other modifications that commenters suggested. We believe the requirement we proposed at § 441.301(c)(7)(iii)(B)(*3*), as modified herein, is sufficiently broad and clear to address the essential concerns raised by commenters. We believe including language prohibiting ''any negative action'' may be ambiguous and overly broad. Additionally, we do not believe the grievance system regulations should be used to prohibit punitive or retaliatory actions in response to actions performed outside of the grievance process. However, we note that, if a beneficiary believes they are experiencing poor treatment from a provider because the beneficiary has filed a complaint about the provider in a system other than the grievance system, the beneficiary may have grounds to file a grievance on the basis of the poor treatment.

Comment: Several commenters recommended the addition of more specific provisions to protect against punitive or retaliatory action, including a post-grievance follow-up with the beneficiary and assessing fines or other penalties against a provider who has taken retaliatory action. One commenter also requested that CMS require States to make the results of investigations into allegations of punitive behavior available to the public.

Response: We decline to make modifications to § 441.301(c)(7)(iii)(B)(*3*) based on these commenters' suggestions because we believe that the proposed regulation text at § 441.301(c)(7)(iii)(B)(*3*), which we are finalizing with modification as discussed herein, is sufficient. To comply with the requirement that States ensure that punitive or retaliatory actions are neither threatened nor taken against individuals who have filed a grievance or have had a grievance filed on their behalf, we expect that States will develop a system for identifying, investigating, and deterring punitive or retaliatory actions. We believe creating more regulatory requirements as commenters suggested would not provide States with flexibility in how they comply with this requirement. Instead, States may develop processes in accordance with their grievance system's structure and other relevant considerations, such as provider agreements and State laws.

Comment: We received a few comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(*4*) that States must accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries. One commenter recommended that § 441.301(c)(7)(iii)(B)(*4*) be revised to specify that no ''magic language'' is needed to initiate the grievance process. The commenter noted that a ''demonstrated intent'' to obtain assistance with an HCBS-related problem should be accepted as a grievance.

Response: We are concerned that the language proposed by the commenter is overly broad. We agree that States should make filing a grievance as simple and accessible as possible for beneficiaries, their authorized representatives, and other individuals or entities filing on a beneficiary's behalf. For example, we believe that it would be inappropriate for a State to create a complex grievance filing form and then refuse to review a grievance because the form was not filled out completely or properly. We note that this scenario would also be a plausible illustration of a State's failure to provide reasonable assistance and accessibility as required at § 441.301(c)(7)(iii)(B)(*2*). We also believe it is critical that States make every effort to ensure that beneficiaries and their advocates know that a grievance system exists and how to access it. We do not, however, expect that every expression of dissatisfaction, in any context, must be treated as a presumptive grievance filing. We believe it is acceptable for States to develop a grievance filing process that requires a clear intent to file a grievance. Further, we do not want to encourage situations in which grievances are pursued on the beneficiary's behalf without the beneficiaries' knowledge or consent.

Comment: We received a number of comments regarding the requirement we proposed at § 441.301(c)(7)(iii)(B)(5) that States provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievances. One commenter expressed particular support for this requirement. Other commenters provided several suggestions for additional requirements to ensure that beneficiaries receive information regarding the grievance process, including:

- Requiring that States add an explanation of grievance rights in any HCBS-related communication from the State to the beneficiary;
- Requiring that providers include an explanation of grievance rights in the person-centered service planning process;
- Requiring that information on grievance procedures be posted in each group home or other provider owned or controlled residential setting, along with a toll-free number and email address for filing grievances; and
- Including common examples of grievances in the information given to beneficiaries, so that beneficiaries are better able to understand the potential utility of the process.

A few commenters noted that, regardless of where or how the information was shared, the information should be in accessible plain language and large print formats.

Response: We do not intend to add additional requirements in this final rule regarding how States must inform beneficiaries about the grievance system, as we believe it is important for States to retain flexibility in how they communicate with beneficiaries. We believe the ideas shared by commenters are great examples of what could be done. We note that there is a lot of diversity among beneficiaries receiving HCBS, States' existing communication pathways, and HCBS program design—all factors that will affect the methods of informing beneficiaries about the grievance process. Therefore, we believe it may be necessary for the information about the grievance system to be presented in multiple ways and through multiple modalities. We encourage States to engage with interested parties to determine the most effective ways to inform beneficiaries. We will also work with States to identify effective ways to inform beneficiaries about the State's grievance system.

We also highlight that our proposed text at § 441.301(c)(7)(iii)(B)(*5*) requires that information provided to beneficiaries must comply with § 435.905(b), which does require that materials use plain language. In addition, States generally must comply with the ADA and section 504, and their implementing regulations. We are finalizing § 441.301(c)(7)(iii)(B)(*5*) largely as proposed, although with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency, consistent with the change to § 441.301(c)(7)(iii)(B)(*2*) discussed previously in this section.

Comment: One commenter requested clarification whether States have an

ongoing obligation to provide this notice and information to beneficiaries, including to people who begin HCBS after the effective date of the grievance system requirements that we proposed at § 441.301(c)(7).

Response: We agree and clarify that States will have an ongoing responsibility to ensure that both new and current beneficiaries receive information about the grievance system to comply with § 441.301(c)(7)(iii)(B)(*5*), which we are finalizing as described in this section (section II.B.2. of the final rule).

Comment: One commenter noted that our proposal at § 441.301(c)(7)(iii)(B)(*6*), requiring the State to review any grievance resolution with which the beneficiary is dissatisfied, is too vague. This commenter suggested that the regulations should specify that the reviewer be someone not involved in the original determination, and the beneficiary should have a process to submit information as to why the original resolution was insufficient. The commenter also suggested that we specify that the beneficiary must request review, believing that otherwise the expectation appears to be that the State must decide whether the beneficiary is dissatisfied. Finally, the commenter suggested that the notice of the original resolution should inform the beneficiary of this review process and how to initiate it.

One commenter also requested clarification on how beneficiaries should express dissatisfaction with a resolution for the purpose of seeking review of a resolution under § 441.301(c)(7)(iii)(B)(6).

Response: We believe that the requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as described in this section II.B.2, address several of the commenter's concerns. We clarify that the requirements at § 441.301(c)(7)(ii)(C)(*3*) apply to initially filed grievances and review of grievances under § 441.301(c)(7)(iii)(B)(*6*). We note that § 441.301(c)(7)(iii)(C)(*3*)(*i*) requires that the individual making a decision on a grievance is an individual who was neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual. Section 441.301(c)(7)(iii)(C)(*3*)(*iii*) specifies that the individual must consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State.

We expect that beneficiaries would express dissatisfaction by affirmatively requesting review of a grievance resolution. We agree that beneficiaries have the responsibility of requesting the review, and expect that States will include, as part of their written policies, the method for how beneficiaries may request review and how beneficiaries will be notified of this right.

Comment: We did not receive comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(*7*) that States must provide information on the grievance system to providers and subcontractors. However, one commenter requested that we require States to give providers 14 days' notice if the provider is a party to the grievance.

Response: We believe that whether, and how, a State chooses to involve providers in individual grievances filed pursuant to § 441.301(c)(7) will vary on a case-by-case basis and, thus, a standardized notification requirement may not be appropriate. For instance, some grievances may be resolvable without the provider's involvement, and in some cases, the beneficiary may not want the provider to know the beneficiary's identity. If the beneficiary and the State believe it is necessary to have the provider involved in the investigation, including appearing at the resolution meeting, we expect that States will give the provider reasonable notice and ensure that the provider is able to participate in the process. Therefore, we intend to provide States with flexibility in determining their grievance system policies in this respect.

Comment: One commenter supported the requirement we proposed at § 441.301(c)(7)(iii)(C)(*1*) to allow beneficiaries to file grievances orally but recommended that we revise the requirement to specify that States must follow up with a written summary of the oral grievance so the beneficiary can ensure accuracy. Another commenter suggested that we revise the requirement at § 441.301(c)(7)(iii)(C)(*2*) to specify that acknowledgement of the receipt of a grievance must be in writing.

Response: We appreciate the comments and believe it is a best practice for States to provide a summary of the grievance to the beneficiary for accuracy. However, we decline to mandate that States provide a written summary, as we intend to allow flexibility for States to decide their own policies to operationalize this requirement. We believe that part of acknowledging the grievance, as required at § 441.301(c)(7)(iii)(C)(*2*), involves developing an appropriate system for providing beneficiaries with confirmation of their grievance.

Comment: One commenter requested that we specify whether all grievances filed must receive a full resolution or whether there are instances in which the acknowledgement of the grievance is sufficient. The commenter anticipated that because of the current direct care workforce crisis, many grievances may be filed related to provider shortages. While acknowledging that understaffing is a serious problem, the commenter believed that the grievance process is unlikely to be able to address the problem to the beneficiary's satisfaction.

Response: We note that the definition of grievance that we are finalizing at § 441.301(c)(7)(ii) indicates that a beneficiary may file a grievance regardless of whether remedial action is requested. We agree that, in instances in which the beneficiary does not wish to pursue remedial action and indicates they are not interested in presenting and debating their grievance as we proposed at § 441.301(c)(7)(iii)(C)(*4*), acknowledging the grievance may be considered resolving the complaint (rather than conducting additional inquiry). We note that should a matter be resolved with an acknowledgment, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(*6*) (review of grievance resolutions with which the beneficiary is dissatisfied).

Comment: A few commenters commented on our proposal at § 441.301(c)(7)(iii)(C)(*3*), establishing requirements for decisionmakers reviewing grievances considered under the grievance system. Several of these commenters supported our efforts to require a system that would provide a fair and unbiased review of beneficiaries' concerns. However, one commenter noted that the requirement at § 441.301(c)(7)(iii)(C)(*3*) would require a separate set of personnel to respond to and investigate grievances than the staff that is currently allocated for program management, administration, and support, and expressed concern that this would require additional resources.

Response: We note that the requirement we proposed at § 441.301(c)(7)(iii)(C)(*3*) requires that individuals reviewing and making decisions about grievances are not the same individuals, nor subordinates of individuals, who made the original decision or action that has given rise to the grievance. This would require that the provider that made the decision or performed the action giving rise to the

grievance would not be able to be the decisionmaker for the grievance. However, this would not preclude State Medicaid agency personnel from reviewing a grievance filed against a provider. Additionally, even for grievances filed about the State's performance, the requirement does not necessarily require review from separate departments or entities. With firewalls as needed, reviewers may be from the same department (or a different department) so long as the necessary expertise and independence standards are met, and the reviewer takes into account the information described in § 441.301(c)(7)(iii)(C)(*3*)(*ii*). We are not making modifications to § 441.301(c)(7)(iii)(C)(*3*) based on these comments.

Comment: One commenter questioned if the intent of the requirement we proposed at § 441.301(c)(7)(iii)(C)(*3*)(*iii*) is to require a ''de novo'' review of the grievances.

Response: De novo review typically refers to a standard of review of a matter on appeal after a trial court or administrative body has reached a determination. If a matter is being reviewed *de novo,* the reviewer is reviewing the whole matter as if it is freshly presented to them, without regard for what the prior decisionmaker determined, or their rationale supporting that determination. We did not specify in the regulation text (either proposed or finalized) whether this process is intended as a *de novo* review of grievances, as reference to *de novo* review would have been inapplicable. The general intent of the grievance system we proposed at § 441.301(c)(7) is not to address specific determinations that are being appealed, as would be the case in the fair hearing process. The grievance system is intended to address a beneficiary's dissatisfaction or complaint related to the State's or provider's performance of person-centered planning or HCBS settings requirements. We expect that the grievance system will typically represent the first opportunity a beneficiary has had to present their concerns directly to the State. Because there likely has not been an initial determination to consider and possibly affirm or reverse, we do not believe *de novo* review is applicable.

For example, consider two scenarios in which a provider fails to send a personal care assistant to two beneficiary's homes. For Beneficiary A, the failure was because the provider forgot to ensure a worker was scheduled to deliver the services. For Beneficiary B, the provider decided, unilaterally, that Beneficiary B had been authorized more personal care services than the provider believed was necessary and thus refused to send a personal care assistant to Beneficiary B's home. In both scenarios, Beneficiary A and Beneficiary B could file grievances about the provider's failure to provide services as outlined in the person-centered care plan or attempt to change the service plan without going through the process required in § 441.301(c)(1) through (3). The proper focus in both cases would be on whether the provider provided services in accordance with the current person-centered care plan. We would not expect in Beneficiary B's situation that the State would treat the provider's actions as a formal determination requiring *de novo* review (such as reviewing whether the provider's objections to the number of service hours in the service plan were valid, or making the beneficiary prove that the service hours were needed). Further, even if there has been an initial decision by a provider or State that the beneficiary disputes, we did not intend the grievance system to operate like a formal legal proceeding (that is, an administrative hearing or trial) and, again therefore, we do not believe the concept of *de novo* review is applicable.

Comment: One commenter suggested that we amend the definition of ''skilled professional medical personnel'' to allow the designation to apply to staff administering the grievance process, which would make the activity eligible for a 75 percent Federal matching rate.

Response: We are not amending the definition of skilled professional medical personnel in this final rule. The term ''skilled professional medical personnel'' is defined at § 432.2 as physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. The term explicitly does not include other, nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers, or administrators of public assistance programs of the Medicaid program. Per § 432.50, the FFP rate for skilled professional medical personnel and directly supporting staff of the Medicaid agency is 75 percent. We do not intend to require that the administrative activities required for grievance process must be administered by personnel with specialized medical education and training. Even for those who meet the criteria to be considered skilled professional medical personnel, only the portion of their activities that require their advanced skills and expertise would be eligible for the enhanced matching rate. If similar functions are performed by non-skilled professional medical personnel, then the activities themselves would not qualify for the higher matching rate.

Comment: One commenter requested clarification as to whether a telephonic communication would satisfy the proposed requirement at § 441.301(c)(7)(iii)(C)(*4*) that the State provide a beneficiary with a reasonable opportunity face-to-face, including through the use of audio or video technology.

Response: We believe that audio-only telephone calls, when requested by the beneficiary and with the inclusion of any necessary accommodations, satisfy this requirement.

Comment: One commenter recommended that we revise proposed § 441.301(c)(7)(iii)(C)(*4*) by removing the word ''limited'' from before ''time available,'' as the commenter believed the inclusion of the word ''limited'' was unnecessary.

Response: We disagree with the commenter's statement that the word ''limited'' is unnecessary. The language in this requirement was intended to mirror similar language in the managed care grievance process requirements at § 438.406(b)(4). Further, we believe it is important that beneficiaries understand the timeframes associated with the grievance resolutions and understand that it is intended, for their benefit, to be a time-limited process.

Comment: One commenter recommended that we mandate a minimum number of days afforded to a beneficiary to review their record and submit additional germane evidence and testimony to the State agency before resolution. The commenter noted that the proposed regulation merely requires that the State agency provide the beneficiary with ''a reasonable opportunity.'' The commenter regarded this as a vague standard and was concerned that States would not grant beneficiaries sufficient time. The commenter noted that beneficiaries with disabilities or complex medical issues may need additional time and supports to prepare evidence and testimony. The commenter suggested that granting beneficiaries a minimum of 21 days to prepare their evidence and testimony after receipt of the agency record would ensure that the State provided the record well in advance of the resolution deadline and would protect beneficiaries from the imposition of unreasonable timeframes to prepare.

Response: We note that § 441.301(c)(7)(iii)(C)(*4*) requires that

the State provide the beneficiary a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance, while § 441.301(c)(7)(iii)(C)(*5*) requires the State to provide the beneficiary with their case file and other records sufficiently in advance of the resolution timeframe for grievances. We are unclear on which provision the commenter is recommending we modify. We decline to modify either provision by prescribing specific deadlines within the overall resolution timeframe, to allow States to develop flexible processes to accommodate beneficiaries. We expect that States will develop appropriate processes to allow beneficiaries to request postponements or rescheduling of any face-to-face hearings that they have requested if they find they need more time to prepare, or other situations arise that would prevent a beneficiary from being able to participate in the hearing.

We also note that we are finalizing a requirement at § 441.301(c)(7)(v)(C) to allow beneficiaries to have the option of requesting 14-day extensions if (for any reason) a beneficiary requires additional time beyond the 90-day resolution timeframe we are finalizing at § 441.301(c)(7)(v)(B).

Comment: Several commenters expressed concern about legal representation during the process. One commenter stated that beneficiaries should get access to State-provided legal assistance. Another commenter requested that, if a beneficiary is unable to afford an attorney, the opposing party not be allowed an attorney.

Response: As discussed in a prior response, beneficiaries have flexibility in determining who will assist them throughout the grievance process—which could, if the beneficiary chose, include assistance from a legal professional. We believe that the grievance system should be easy to navigate and largely non-adversarial, such that beneficiaries would not be required, nor feel pressured, to have legal representation. We also believe that at least some portion of grievances filed will be for minor issues that do not require a formal inquiry. We agree with commenters that it is preferable that hearings neither be, nor have the appearance of being, imbalanced in terms of support for the beneficiary. We encourage States, as they develop their policies, to consider what level of assistance beneficiaries will need during face-to-face meetings and ensure that reasonable assistance is provided.

Comment: One commenter stated that § 441.301(c)(7)(iii)(C)(*5*) should be revised to expand the documents beyond the beneficiary's ''case file.'' The commenter recommended that the regulations require that the State obtain relevant files and other information held by the provider and then provide that information to the beneficiary. The commenter stated that, particularly in cases involving residential providers, provider-maintained information will be relevant and often pivotal.

Response: We disagree and believe adding this language is unnecessary. We believe that the term, case file, could have several meanings, depending on the circumstances, and could include the records related to the beneficiary's services maintained by the provider that would be obtained by the State as part of review of the grievance. We also note that proposed § 441.301(c)(7)(iii)(C)(*5*) already requires beneficiaries to receive other documents and records, as well as new and current evidence considered or relied upon by the State related to the grievance. We believe relevant records from providers could fall into these categories, depending on the record and the circumstances by which the State obtained it. We do not intend our requirement at § 441.301(c)(7)(iii)(C)(*5*), as proposed and being finalized in this rule, to amend any existing obligations for confidentiality of certain records and we expect States to comply with applicable Federal and State laws and regulations governing confidentiality of those records in determining what records to provide to the beneficiary related to their grievance in compliance with § 441.301(c)(7)(iii)(C)(*5*). We decline to make modifications to § 441.301(c)(7)(iii)(C)(*5*) as requested by the commenter.

Comment: One commenter suggested that we require that the grievance system be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Response: We had proposed at § 441.301(c)(7)(iii)(C)(*5*) that medical records being used as part of a grievance be handled in compliance with 45 CFR 164.510(b) (a provision of the HIPAA Privacy Rule), to ensure that protected health information (PHI) used during the grievance review are obtained and used with beneficiaries' authorization. In general, whenever a beneficiary's PHI may be obtained, maintained, or disclosed by a State agency that is a covered entity as defined in 45 CFR 160.103 (such as a State Medicaid agency), States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records. We also note that 45 CFR 164.510(b) is just one provision of the HIPAA Privacy Rule that permits the disclosure of PHI, and other provisions may also permit the disclosure of PHI (such as disclosure of PHI to personal representatives under 45 CFR 164.502(g)); other permissions may also apply in addition to what is cited here and included in the regulatory text of this final rule. Upon further review, we have determined that, given that a number of requirements of the HIPAA Privacy Rule may apply to the obtaining and sharing of beneficiaries' information, we are finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

Finally, we also note that individuals who believe their health information privacy has been violated may file a complaint with the HHS Office for Civil Rights at *https://www.hhs.gov/hipaa/filing-a-complaint/index.html.*

After consideration of public comments, we are finalizing § 441.301(c)(7)(iii)(A) as proposed, with the following modification. We are finalizing § 441.301(c)(7)(iii)(A)(1) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary or provide the beneficiary with assistance or representation throughout the grievance process with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(2) as proposed.

We are finalizing requirements at § 441.301(c)(7)(iii)(B) as proposed, with the following modifications. We are finalizing § 441.301(c)(7)(iii)(B)(*1*) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7). We are finalizing § 441.301(c)(7)(iii)(B)(*2*) with modifications by: (1) adding to States' obligation the requirement that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system; (2) modifying language to refer to individuals with Limited English Proficiency; and (3) clarifying that auxiliary aids and services must be made available where necessary to ensure effective communication. We are finalizing § 441.301(c)(7)(iii)(B)(*3*) with modifications to require that States ensure that punitive or retaliatory actions (rather than just punitive actions) are neither threatened nor taken. We are also adding language to specify that the punitive or retaliatory actions cannot be threatened or taken

against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)

For reasons we discuss in greater detail in the next section (section II.B.2.c. of this rule) we are finalizing § 441.301(c)(7)(iii)(B)(*4*) with a modification to remove the reference to expedited grievances. We are finalizing § 441.301(c)(7)(iii)(B)(*5*) with a modification to change the language to refer to individuals with Limited English Proficiency. We are finalizing § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.

We are finalizing § 441.301(c)(7)(iii)(C)(*1*) through (*5*) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons and adding the word and at the end of § 441.301(c)(7)(iii)(C)(*5*) to accurately reflect that § 441.301(c)(7)(iii)(C)(*1*) through (*6*) are elements of a list, not separate declarative statements. Additionally, for reasons we discuss in greater detail in a later section (section II.B.2.d.) because we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), we are finalizing § 441.301(c)(7)(iii)(C)(*5*) with modifications to remove references to § 441.301(c)(7)(v)(B)(1) and (2) and add a reference to § 441.301(c)(7)(v). We are also finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

c. Filing Timeframe (§ 441.301(c)(7)(iv))

At § 441.301(c)(7)(iv)(A), we proposed to require that the beneficiary be able to file a grievance at any time. At § 441.301(c)(7)(iv)(B), we proposed to require that beneficiaries be permitted to request expedited resolution of a grievance, whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, such as if, for example, a beneficiary cannot access personal care services authorized in the person-centered service plan.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters made suggestions or submitted clarifying questions about our proposal at § 441.301(c)(7)(iv)(A) that beneficiaries be able to file a grievance at any time. One commenter requested clarification on whether our intent was to prohibit limits on the timeframe between the occurrence of the subject of the grievance and the date when the individual files a grievance. Another commenter noted that there should be a 90-day time limit on when beneficiaries can file grievances.

Response: We do not intend for beneficiaries' ability to file grievances to be time-limited. We appreciate commenters' concerns regarding this issue; however, we defer to the rationale we used when declining to add a timeframe cap in the managed care grievance filing process (81 FR 27511). In the managed care grievance process, § 438.402(c)(2)(i) specifies that enrollees may file a grievance with their managed care plan at any time. As we previously noted, grievances do not progress to the level of a State fair hearing, which is a time-sensitive process; therefore, we found it unnecessary to include filing limits because grievances are resolved without having to consider the time limits of other processes (81 FR 27511).

We understand that States may be concerned about revisiting grievance issues that occurred in the past, but we believe this is a normal part of providing services and that beneficiaries should be permitted to file a grievance at any time. We also note, that, as discussed in more detail below, States believe that educating beneficiaries about the grievance process will take time; therefore, we do not want to prevent beneficiaries from filing grievances in cases where the delay in filing was because the beneficiary was not initially aware of their ability to file a grievance.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for expedited resolutions when there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare.

Several commenters, however, believed that the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for an expedited resolution was unclear or overly broad and requested additional clarification as to what would constitute a grievance warranting expedited resolution. Some of these commenters stated that technical assistance would be needed to help States identify the criteria for determining whether a resolution should be expedited, and how to proceed if a beneficiary disagrees with the State's determination that a grievance request should be expedited or resolved in the standard timeframe. One commenter raised the concern that if a beneficiary's request for an expedited resolution was denied, they may follow up with submitting another grievance or file a fair hearing request. Another commenter suggested that expedited resolutions should be defined as being contingent on the timely receipt of information from the beneficiary.

Some commenters noted that the expedited resolution process's focus on health, safety, and welfare could lead to duplication with other systems, including the critical incident system. They expressed the belief that there are separate channels to address health and safety concerns. For this reason, a few commenters suggested that there should only be one standard grievance resolution and notice timeline of 90 calendar days. A few commenters also suggested that we should not have an expedited resolution process in the FFS grievance system because there is not such a process in the managed care grievance system (as described in 42 CFR part 438, subpart F).

One commenter stated that, in their experience, few grievances were about issues affecting beneficiaries' health and safety, and thus it would not be appropriate to create a requirement for an expedited process as it was defined in proposed § 441.301(c)(7)(iv)(B). The commenter offered examples of typical grievances, based on the commenter's experience with operating a State grievance system. The commenter noted that many grievances involve education about the HCBS program (for example, additional services and limitations), information about available providers in their area as an alternative to their current provider, dissatisfaction with their paid caregiver, and frustrations with provider workforce shortages.

Response: We are persuaded by commenters' feedback summarized here, as well as comments summarized later in this section regarding the expedited resolution timeframe. After consideration of public comments, as discussed here in section II.B.2, we are not finalizing § 441.301(c)(7)(iv)(B) and are removing other references to the expedited resolution process where it appears in § 441.301(c)(7) in this final rule.

In particular, we are persuaded by the concern that the expedited resolution process as proposed could create overlap with the critical incident system, which is described in section II.B.3 of this final rule. We believe that the critical incident system is the most appropriate mechanism for investigating situations when a beneficiary has experienced actual harm or substantial risks to their health and safety. We do not want there to be a delay in the investigation of a critical incident

because it was incorrectly filed as a grievance, nor do we want matters that should be investigated as critical incidents resolved only in the grievance process.

In addition, as some commenters correctly noted, the managed care requirements at 42 CFR part 438, subpart F, do not include an expedited grievance resolution process. We have not identified a compelling reason why beneficiaries receiving HCBS through FFS systems should need an expedited resolution process for grievances when no similar process has, as yet, been deemed necessary in the managed care system. After reexamining these requirements in light of comments received, we do not wish to create misalignment between managed care and FFS systems' grievance resolution processes.

In general, we agree with the commenter that it is likely that many grievances filed would not meet the standard we proposed for expedited resolution (and, as noted above, if they did meet the standard, they are likely candidates for the critical incident or fair hearings systems). However, we envision that there remains the potential for some grievances to require immediate attention and intervention, even if they do not rise to the level of a critical incident (as defined in § 441.302(a)(6)(i)(A)) or do not qualify for a fair hearing (as set out in part 431, subpart E). Therefore, we encourage States to include in their grievance system a system for identifying, triaging, and expediting resolution of grievances that require, according to the State's criteria, prioritization and prompt resolution.

After consideration of the comments received about § 441.301(c)(7)(iv), we are finalizing our proposal at § 441.301(c)(7)(iv) with modification by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). Additionally, we are removing references to the expedited resolution process in § 441.301(c)(7)(iii)(B)(*4*). We are also removing requirements related to the expedited resolution process in § 441.301(c)(7)(v). These changes are discussed in their respective sections below.

d. Resolution and Notification (§ 441.301(c)(7)(v))

At § 441.301(c)(7)(v), we proposed resolution and notification requirements for grievances. Specifically, at § 441.301(c)(7)(v)(A), we proposed to require that States resolve and provide notice of resolution related to each grievance as quickly as the beneficiary's health, safety, and welfare requires and within State-established timeframes that do not exceed the standard and expedited timeframes proposed in § 441.301(c)(7)(v)(B). At § 441.301(c)(7)(v)(B)(1), we proposed to require that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. At § 441.301(c)(7)(v)(B)(2), we proposed to require that expedited resolution of a grievance and notice must occur within 14 calendar days of receipt of the grievance.

At § 441.301(c)(7)(v)(C), we proposed that States be permitted to extend the timeframes for the standard resolution and expedited resolution of grievances by up to 14 calendar days if the beneficiary requests the extension, or the State documents that there is need for additional information and how the delay is in the beneficiary's interest. At § 441.301(c)(7)(v)(D), we proposed to require that States make reasonable efforts to give the beneficiary prompt oral notice of the delay, give the beneficiary written notice, within 2 calendar days of determining a need for a delay but no later than the timeframes in paragraph (c)(7)(v)(B), of the reason for the decision to extend the timeframe, and resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires, if the State extends the timeframe for a standard resolution or an expedited resolution.

We also proposed at § 441.301(c)(7)(iv)(B) and (c)(7)(v)(B)(*2*) that beneficiaries be permitted to request, and the State provide for, expedited resolution of a grievance. However, we noted that these proposed requirements differ from the current grievance system requirements for Medicaid managed care plans at part 438, subpart F, which do not include specific requirements for an expedited resolution of a grievance. We solicited comment on whether part 438, subpart F should be amended to include the proposed requirements for expedited resolution of a grievance at § 441.301(c)(7)(iv)(B) and (v)(B)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We note that, as discussed in the previous section, we are not finalizing the expedited resolution process at § 441.301(c)(7)(iv)(B). We will discuss the impact of this change to the requirements in § 441.301(c)(7)(v) in our response to the comments below.

Comment: A few commenters requested that we provide additional information to clarify what is expected for a grievance to be considered resolved.

Response: We believe that the resolutions of grievances can take many forms and may vary on a case-by-case basis, and thus we decline to revise the requirements at § 441.301(c)(7)(v) to provide a more specific definition. We proposed and are finalizing as discussed in this section II.B.2 that a beneficiary may file a grievance even if the beneficiary does not request remedial action. We expect that grievances will vary not only in severity and urgency but will also vary according to the formality of the response. Some grievances, as noted in a response above, may require only a simple acknowledgment of the concern. Others may require immediate action(s), including intervention(s) with or action(s) taken against the provider. Still others may involve the State setting up a long-term corrective action plan or monitoring, consistent with applicable State laws governing such. We believe that a critical part of the grievance process involves collecting input from the beneficiary filing the grievance on the resolution or outcome they hope to achieve through the grievance process. This may include instances in which the beneficiary wishes to bring a concern to the State's attention but is not necessarily pursuing a specific resolution.

Comment: A few commenters raised concerns or questions about how States should ensure compliance with resolutions. One commenter noted the importance of ensuring corrective actions are taken in response to grievances so that policy and systems transformation can take place in a timely manner. One commenter requested that we provide States with more tools to ensure provider compliance, including appropriate monetary and nonmonetary penalties. Another commenter stated that the grievance resolution process should include an order for the creation of a corrective action plan and subsequent monitoring.

Response: We appreciate the commenters' suggestions, but we decline to add specific actions to the requirements at § 441.301(c)(7)(v). As noted above, we believe that there will be variety in both grievances and resolutions. It would be difficult, and perhaps detrimental, to establish a set of Federal penalties that may be over- or under-responsive to the range of matters heard in the grievance process. Thus, we want to retain flexibility in the

regulatory requirements to allow State grievance systems to respond appropriately to each situation. We expect that States will apply a reasonable interpretation to the requirement that the States ''resolve'' the grievance. For instance, if resolution reasonably requires a corrective action plan for a provider (for grievances resolved against providers) or a corrective action plan for the State (for grievances resolved against the State), we expect that a corrective action plan would be executed and monitored as part of the resolution in accordance with applicable State laws. Through State law and regulations, States can create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

Comment: Several commenters suggested that the grievance resolution process should include formal follow-up requirements. To ensure proper follow-up, one commenter recommended that the regulations specify that grievances and their resolutions be reviewed at the subsequent person-centered planning process. One commenter recommended that the State should perform a follow up at 30 and 90 days after the resolution.

Response: We decline to add specific follow-up requirements to § 441.301(c)(7)(v). As discussed in prior responses, we believe that grievances are likely to take many forms. We agree that, in some instances, follow-up or ongoing monitoring may be a critical element of a particular resolution and, thus, should be included. In other cases, the grievance may not require follow-up and, thus, a formal follow-up requirement would impose an unnecessary administrative burden. There may also be instances in which a beneficiary may not wish to be repeatedly contacted after they believe the matter has been resolved. We believe that determining the appropriateness of when, and how, to monitor outcomes of grievances should be part of policies States develop for their grievance system.

Comment: One commenter recommended that we revise the requirement at § 441.301(c)(7)(v)(A) to require that the State solicit more information from beneficiaries on how a delayed resolution could hurt the beneficiary. One commenter suggested that we include the language from this provision in the timeframe requirement for expedited grievances at § 441.301(c)(7)(v)(B)(2) so that the requirement reads, ''as expeditiously as the beneficiary's health condition requires and no longer than 14 calendar days after the State receives the grievance.''

Response: We decline to make the suggested modifications to the requirement at § 441.301(c)(7)(v)(A). We clarify that this requirement at § 441.301(c)(7)(v)(A) sets a general expectation for expeditious resolutions for all grievances. We encourage States to ensure that beneficiaries provide, in their grievances, detailed information about their concerns (including negative impacts they are experiencing or believe they will experience). However, we have specifically not set requirements for the amount or type of information beneficiaries must submit when filing a grievance, as we do not wish to inadvertently mandate a process that is administratively burdensome for beneficiaries. We believe that commenters may have interpreted this requirement as a means of identifying grievances being filed for expedited resolution, which was not the intent. Additionally, as discussed above, we are not finalizing the requirement for an expedited resolution at § 441.301(c)(iv)(B)(*2*).

We also note that, consistent with our discussion above related to concerns about confusion between the purpose of the grievance system and the critical incident system described in § 441.302(a)(6), we are revising the language in this provision. Specifically, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance and provide notice as expeditiously as the beneficiary's health condition requires, instead of our proposal, which would have required that such notice be provided as expeditiously as the beneficiary's health, safety, and welfare requires. We believe this avoids confusion with the critical incident system and aligns the language with a parallel requirement in the managed care grievance requirements at § 438.408(a), as well as our language in §§ 441.301(c)(7)(v)(D)(*3*) (pertaining to expeditious resolution during extensions). We believe that ''health condition'' may be broadly interpreted to refer both to physical and mental health and well-being of the beneficiary.

Comment: A few commenters supported our proposal at § 441.301(c)(7)(v)(B)(*1*) that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. However, some commenters, while not specifically opposing the 90-day timeframe, expressed concerns that the timeframe proposed for resolving grievances may not always allow for a thorough investigation. One commenter noted that, while this timeframe might allow for investigation and resolution of some grievances, other grievances might require more extensive investigation (such as interviews, on-site visits, legal review and consultation, and request for additional documentation) and could take longer. The commenter also worried about the time involved in allowing the beneficiary a reasonable opportunity to present evidence face-to-face and in writing, as well as access to their case file to review in advance.

Conversely, a number of commenters recommended that the standard resolution timeframe be shortened to 45 days. Many of these commenters stated that 90 days is too long for an individual to wait for resolution if they are experiencing a serious violation of their rights or access to services.

Response: We agree with commenters that some grievances may take longer than 90 days to resolve properly and note that these extenuating circumstances can be addressed through the use of the 14-day extension we are finalizing at § 441.301(c)(7)(v)(C) if the conditions set forth in that requirement are met. We also agree with commenters that grievances should be resolved as expeditiously as possible, but we do not agree that cutting the proposed timeframe in half (to 45 days) would be a sufficient timeframe. We based our proposal of 90 calendar days on the current timeframe for resolution in the managed care grievance system at § 438.408(b), and we do not find reason to believe that FFS grievances would require less time to resolve than grievances in the managed care system. We do not wish to set a timeframe that encourages hasty investigations, nor the overuse of the 14-day extensions. We also note that 90 calendar days is the maximum allowed timeframe and that States may choose to set a shorter timeframe, or several timeframes for different types of grievances, so long as none of the timeframes exceed 90 calendar days. We are finalizing the 90-calendar day timeframe for resolutions as proposed.

Comment: One commenter noted that the proposed timeframe of 14 days for expedited resolution was too long and suggested that it be reduced to 7 days. On the other hand, many commenters expressed concerns about staff capacity necessary to respond to expedited grievances within 14 calendar days, as well as the feasibility of completing investigations within the proposed 14-day timeframe. Commenters believed that, given the potential seriousness of grievance inquiries, it may be difficult

for all necessary information to be gathered in 14 days and to grant the beneficiary a reasonable opportunity to present evidence in a face-to-face meeting. Several commenters recommended that, if finalizing an expedited resolution timeframe, we extend the timeframe to 30 calendar days, and one commenter recommended 30 business days.

Response: As discussed above, we are not finalizing the requirement for an expedited resolution process. In addition to the comments summarized above about the process itself, we agree with commenters that if a beneficiary has filed a grievance and wishes to present evidence and participate in a face-to-face meeting with the decisionmaker, 7 calendar days, or even 14 calendar days, may not be sufficient time for all relevant materials to be gathered and reviewed by the beneficiary and decisionmaker, nor to arrange for a resolution meeting. As discussed above, we are encouraging States to create their own processes for expediting resolution of certain grievances. We believe that there will be some grievances filed that may (and should) be resolved almost immediately, including by a referral to the critical incident system or fair hearings process. We note that several commenters suggested that 30 days is a reasonable timeframe for expediting resolutions, and States may want to take that recommendation under consideration when developing their own processes.

Consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing § 441.301(c)(7)(v)(B)(*2*).

Comment: One commenter noted that imposing any timelines for resolving grievances could detract from staff resources needed to investigate critical incidents, particularly if the grievance and critical incident systems use the same staff.

Response: We recognize that States will have to supply staff and resources for both the grievance and critical incident systems that we are finalizing in this rule. We will provide technical assistance to States as needed to help identify ways to manage both systems, including setting priorities and managing the critical incident investigation and grievance resolution timeframes.

Comment: A number of commenters responded to our invitation to comment on whether part 438, subpart F should be amended to include the proposed expedited resolution requirements at § 441.301(c)(7)(iv)(B) and (v)(B)(*2*). Several commenters recommended that expedited procedures be extended to the managed care grievance procedures at part 438 subpart F. However, several commenters opposed adding expedited resolution timeframes to part 438 subpart F. Similar to the opposition presented to including expedited resolutions in the FFS grievance system, these commenters believed that very few expressions of dissatisfaction require expedited resolution and that other mechanisms exist to address health and safety concerns in a timely manner. A few commenters also provided suggestions on possible changes to the managed care grievance requirements, such as adding a prohibition of punitive action against beneficiaries who file grievances.

Response: We will take these comments under consideration. We note that we are not, at this time, finalizing an expedited resolution process in the FFS grievance system and are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) and at § 441.301(c)(7)(v)(B)(*2*) for such a process. We also note that, while outside the scope of this proposal, we will take other recommendations regarding potential changes to the managed care grievance process under consideration as well.

Comment: A few commenters noted support for the proposal at § 441.301(c)(7)(v)(C) that States be permitted to extend the timeframes for the resolution of grievances by up to 14 calendar days.

Response: We thank the commenters for their support.

We did not receive comments on the requirements we proposed at § 441.301(c)(7)(v)(D).

After consideration of public comments, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. Additionally, consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), redesignating § 441.301(c)(7)(v)(B)(1) as § 441.301(c)(7)(v)(B), and retitling § 441.301(c)(7)(v)(B) as ''Resolution timeframes.'' We are also removing the word ''standard'' in § 441.301(c)(7)(v)(B)(1) (which we are finalizing at § 441.301(c)(7)(v)(B)) since the finalized requirements do not distinguish between ''standard resolution'' and other types of resolutions.

We are finalizing § 441.301(c)(7)(v)(C), with a technical correction to redesignate paragraphs (C)(*1)*(i) and (C)(*1*)(ii) as (C)(*1*) and (C)(*2*), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, with minor technical corrections. Specifically, we are changing the periods at the end of § 441.301(c)(7)(v)(D)(*1*) and (*2*) to semi-colons and adding ''and'' at the end of § 441.301(c)(7)(v)(D)(*2*).

e. Notice of Resolution (§ 441.301(c)(7)(vi))

We proposed at § 441.301(c)(7)(vi) requirements related to the notice of resolution for beneficiaries. Specifically, at § 441.301(c)(7)(vi)(A), we proposed to require that States establish a method for written notice to beneficiaries and that the method meet the availability and accessibility requirements at § 435.905(b). At § 441.301(c)(7)(vi)(B), we proposed to require that States make reasonable efforts to provide oral notice of resolution for expedited resolutions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that we expand the requirements proposed at § 441.301(c)(7)(vi) pertaining to the information beneficiaries receive at the resolution of their grievance. The commenters requested we include a requirement that the notice explain what the grievance is, the information considered, the necessary remedial actions (if any) for resolution, and the ability to request further review.

Response: We encourage States to include this information in resolution notices as appropriate, but we decline to make changes to this requirement in our final rule. We note that this requirement, as written, is consistent with the parallel requirement in § 438.408(d), which provides States with flexibility in developing a method by which managed care plans will notify enrollees of resolutions. We intend to provide States with this same flexibility in the FFS system, as we see no compelling reason to impose more rigid requirements on one system than the other.

We also note that, consistent with the discussion above not to finalize the expedited resolution process, we are not finalizing § 441.301(c)(7)(vi)(B), which requires oral notice for expedited resolutions. We expect that States, should they decide to include an expedited resolution process in their grievance system, would develop an

appropriate system for notifying beneficiaries of these resolutions.

After consideration of the comments received, we are finalizing § 441.301(c)(7)(vi)(A) without substantive changes. However, consistent with our decision (discussed above) not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the requirement we proposed relating to the expedited resolution process at § 441.301(c)(7)(vi)(B) and redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).

f. Recordkeeping (§ 441.301(c)(7)(vii))

We proposed at § 441.301(c)(7)(vii) recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we proposed to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B), we proposed to require that the record of each grievance must contain at a minimum the following information: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we proposed to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(vii)(A) to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures, and for the proposal at § 441.301(c)(7)(vii)(C) that grievance records would be available upon CMS's request. A few commenters were also specifically supportive of what they regarded as the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

One commenter observed that there will be important lessons and conclusions that may be drawn from the data that should help the State to take steps to deter future service provider actions that lead to grievances. The commenter also hoped that such data could lead to educational opportunities to refine State and service provider knowledge of HCBS settings and person-centered service plan rules, and data should be collected on the efficacy of such educational interventions. One commenter suggested that we require qualitative, as well as quantitative, reporting.

Response: We decline to make any additional changes to our proposal at § 441.301(c)(7)(vii) in this final rule, but we agree with the commenters that the data and records that States collect as part of the grievance process may be critical in helping States improve their HCBS programs. While we are not finalizing specific requirements for how States must use this data, promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, will likely be included in the technical assistance that will be available to States during the implementation period.

Comment: A few commenters recommended requiring States to make information on grievances publicly available, such as by releasing an annual report on the anonymized grievances received in the previous 12 months, categorized by issue, severity, and resolution or lack of resolution. One commenter suggested that such a report would enhance transparency and could assist with quality improvement by providing States, providers, and consumer advocates with insight into grievance patterns and trends. Another commenter recommended that we require public online disclosure of grievance details and resolutions. The commenter noted this would help individuals make informed choices about providers and would encourage compliance with person-centered planning and settings requirements. One commenter, presuming that the State's recordkeeping system would be made publicly available, suggested that we include the name of the decision maker in the records so that CMS, researchers, and advocacy groups can ensure that decision makers are making unbiased decisions.

Response: We did not propose that States publicly report information about grievance resolutions in this final rule; we note, for instance, that we did not include reporting on the grievance system as part of the reporting requirement being finalized at § 441.311, nor are we requiring that States report information about grievances as part of the website posting requirement being finalized at § 441.313. We decline to make any changes in this final rule to require such public reporting.

We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about grievances. Relatedly, some beneficiaries may not want grievances published about specific providers, as some commenters suggest, as this would further complicate anonymity when some providers only serve a few clients. We are concerned also that public disclosure could have a chilling effect if beneficiaries believed their grievance could be made part of a public report. While we agree that, over time, data about trends in grievances could be useful to both the States and external interested parties in promoting systemic improvements of HCBS, we defer to States to determine when and how to make this information public and for what purpose. We also note that the specific recommendation to add the name of the decision maker to the record is addressed in another response later in this section.

Comment: One commenter recommended that we establish a process for an annual or regular review of the States' summary of issues and the States' resolution of the issues. Another commenter recommended requiring an independent evaluator periodically review States' grievance processes to identify common barriers, trends, participation rates, and effectiveness of resolutions.

Response: When developing the proposed requirements at § 441.301(c)(7), we did not intend to create a formal system in which we would routinely review individual resolutions made by States' grievance systems and are not persuaded otherwise after review of public comments received. As discussed further in this section II.B., we proposed, and are finalizing, the requirement at § 441.301(c)(7)(vii)(C) that States must make records available to us upon request. This provides CMS with authority to review records should we need to review the functioning of a State's grievance system on a case-by-case basis.

We believe that the grievance system's designated decision makers are generally in the best position to determine appropriate resolutions to beneficiaries' concerns and that the need to review individual records should be decided on a case-by-case basis. We do agree regular review of the States' grievance systems is a good

suggestion, and we will take it under consideration for future guidance and rulemaking. Similarly, we are not requiring that States have their grievance system reviewed by an independent evaluator in this final rule—in part because we believe many States will likely do this anyway, as part of their standard audit processes. However, we agree that having the system regularly reviewed by an independent entity is a good practice that States may consider.

Comment: A few commenters suggested specific categories of information to be added to the record of each grievance proposed at § 441.301(c)(7)(vii)(B). One commenter suggested that all information considered should be included as a category in the record of each grievance. A few commenters recommended we add that the name of the decisionmaker be included in the record to ensure that conflict of interest requirements at § 441.301(c)(7)(iii)(C)(*3*) are preserved.

Response: We thank commenters for their suggestions, but we decline to add new record requirements for States at § 441.301(c)(7)(vii)(B). We believe capturing the names of staff and individuals who decided the outcome of each grievance is an operational and internal matter for States. States can record whatever information about a grievance resolution that they deem appropriate in addition to what is required. We believe § 441.301(c)(7)(vii)(B) as finalized reflects an appropriate minimum level of detail. We note that § 441.301(c)(7)(vii)(B) aligns with the managed care grievance system recordkeeping requirement at § 438.416.

After consideration of public comments received, we are finalizing § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(*1*) through (*5*) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons, to accurately reflect that § 441.301(c)(7)(vii)(B)(*1*) through (*6*) are elements of a nonexhaustive list, not separate declarative statements. We are also adding the word ''and'' to the end of § 441.301(c)(7)(vii)(B)(*5*).

g. Applicability Date (§ 441.301(c)(7)(viii))

In the proposed rule (88 FR 27977), we recognized that many States may need time to implement the proposed grievance system requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. However, we noted that the absence of a grievance system in FFS HCBS systems poses a substantial risk of harm to beneficiaries. We proposed at § 441.301(c)(7)(viii) that the requirements at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. A 2-year time period after the effective date of the final rule for States to implement these requirements reflected our attempt to balance two competing challenges: (1) the fact that there is a gap in existing regulations for FFS HCBS grievance processes related to important HCBS beneficiary protection issues involving person-centered planning and HCBS settings requirements; and (2) feedback from States and other interested parties that it could take 1 to 2 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in the proposed rule (88 FR 27971 through 27995) as whole. We solicited comments on overall burden for States to meet the requirements of this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (1 year to 18 months) or longer timeframe (3 to 4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal at § 441.301(c)(7)(viii) that the requirement at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. However, one commenter, stating that these grievance protections will be vital to HCBS beneficiaries, recommended that States be required to come into compliance within 18 months after the effective date of the regulations.

A few commenters expressed concerns about the burden they believe will be associated with developing a grievance system, particularly in States that do not already have grievance processes in place. Commenters believed that it would take significant resources to help beneficiaries understand what rights they can claim under the grievance system. Commenters also described costs or activities such as: funding and statutory change requests to State legislatures; administrative rulemaking; IT and administrative system design and development, which may include vendor procurement; collaboration with other State agencies or agency divisions; partnering with providers for implementation; hiring and training new staff; and approval of implementation advance planning documents by CMS. These commenters suggested alternative effective dates ranging from 3 to 5 years. One commenter also suggested an effective date of 4 years after CMS releases relevant subregulatory guidance.

Response: We appreciate the fact that States will have to expend resources in developing the grievance system, particularly States that do not currently have grievance systems for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Because of the activities that some States will have to perform to develop the grievance system shared by commenters, we agree that requiring an earlier timeframe of 18 months is not realistic. We also appreciate, and agree with, the sense of urgency expressed by commenters. We believe it is important to prioritize giving beneficiaries the opportunity to have their concerns heard. In this final rule, we have provided States with as much flexibility as possible to build on or retain existing grievance systems and have kept specific information systems requirements to a minimum. We have also reduced some potential initial administrative challenges by not finalizing a formal expedited resolution requirement and by allowing States to decide whether, and how, to implement such a policy. After consideration of public comments received as discussed herein, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that **States must comply with** the requirements at § 441.301(c)(7) **beginning** 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font). We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

Comment: A few commenters requested enhanced FMAP to support implementation and operationalization

of the grievance process. Two commenters recommended that, in addition to providing 90 percent FFP for information systems improvements, we should offer 75 percent FFP for all quality-related activities, including operational costs associated with a grievance system. The commenters suggested this would create parity between the States whose service delivery systems are largely FFS and the States with managed care services that can receive 75 percent FFP for External Quality Review (EQR) activities.

Response: We note that enhanced FMAP is available for certain activities related to administering the Medicaid program and designing, developing, implementing, and operating certain IT systems.[60] However, Federal matching rates are established by Congress and CMS does not have the authority to change or increase them, nor do we have the authority to add additional activities not specified in statute into the scope of an existing enhanced FMAP. We also do not agree that providing broader enhanced match for the FFS grievance system would create parity with managed care, as we believe this is an inaccurate characterization of payments related to the managed care grievance systems. While commenters are correct that States can receive 75 percent enhanced match for EQR activities, which are listed at § 438.358, these activities are primarily validation and review of data on performance measures; the operation of a grievance system is not listed as an EQR activity. We also note that the associated administrative costs for MCOs, PIHPs, and PAHPs are variable and negotiated with the State as part of their contracts.

After consideration of public comments received, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that States must comply with the requirements at § 441.301(c)(7) beginning 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font.) We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

h. Application to Other Authorities

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options also must comply with the HCBS Settings Rule and with similar person-centered planning and service plan requirements, we proposed to include these grievance requirements within the applicable regulatory sections. Specifically, we proposed to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively.

Also, consistent with our proposal for section 1915(c) waivers, we proposed to apply the proposed grievance requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries and our authority at section 2402(a)(3)(B)(ii) of the Affordable Care Act to require a complaint system for beneficiaries. We stated that the same arguments for applying these requirements for section 1915(c) waivers are equally applicable to these other HCBS authorities. We requested comment on the application of the grievance system provisions to section 1915(i), (j), and (k) authorities. We also noted that, in the language added to § 441.464(d)(2)(v), the proposed grievance requirements apply when self-directed personal assistance services authorized under section 1915(j) include services under a section 1915(c) waiver program.

As described in the proposed rule (88 FR 27978), we did not propose to apply these requirements to section 1905(a) services. Specifically, we considered whether to also apply the proposed requirements to section 1905(a) ''medical assistance'' in the form of State plan personal care services, home health services, and case management services, but did not propose these requirements apply to any section 1905(a) State plan services because section 1905(a) services are not required to comply with HCBS settings requirements and because the person-centered planning and service plan requirements for most section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We solicited comment, seeing the value in discussing and seeking public input, on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments and our responses.

Comment: A few commenters supported the proposal to apply the grievance system provisions proposed for section 1915(c) at § 441.301(c)(7) to sections 1915(i), (j) and (k) authorities. They agreed with the goal of aligning the different HCBS program authorities and promoted consistency with managed care.

Response: We thank commenters for their support.

Comment: One commenter supported the application of the grievance requirements to self-directed personal assistance services under section 1915(j) of the Act as well. This commenter noted that, during the pandemic, there was no clear way to file a grievance with Medicaid concerning a lack of access to direct care workers, for example.

One commenter, on the other hand, questioned the operationalization of the grievance process for self-directed personal care service models under sections 1915(j) and (k), where the beneficiary acts as the employer for purposes of hiring, training, supervising, and firing, their provider, if necessary. This commenter was concerned that allowing beneficiaries to file grievances against their provider would erode a beneficiary's responsibilities as the employer. Another commenter, while supporting application of the grievance process to section 1915(j) self-directed services, did suggest that implementing this requirement in self-directed models may require additional time and guidance.

Response: We believe it would be inappropriate to exclude beneficiaries enrolled in self-directed services delivery models from the grievance system and decline to do so in this final rule. As noted by other commenters, beneficiaries enrolled in self-directed

[60] For a current list of activities eligible for this enhanced FMAP, refer to: MACPAC, ''Federal Match Rates for Medicaid Administrative Activities,'' last access: October 22, 2023. *https://www.macpac.gov/federal-match-rates-for-medicaid-administrative-activities/.*

services may experience systemic challenges with their services; they may also interact with other providers in addition to their self-directed service provider (such as the entity providing financial management services). We also note that the grievance system is a venue for expressing concerns about violations of the HCBS settings requirements, which may be relevant to some beneficiaries in self-directed programs. We do not believe that additional time needs to be granted specifically for inclusion of beneficiaries using self-directed services.

Comment: Several commenters responded to our request for comment on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services. A few commenters supported the proposal not to extend the requirements to section 1905(a) services on the basis that these services are not subject to the same person-centered planning and HCBS settings rules. Additionally, several commenters also believed the expansion of these requirements to section 1905(a) State plan services would pose additional challenges to State Medicaid and operating agencies. One commenter noted that, in States that deliver section 1905(a) State plan services and section 1915(c) services through different agencies or agency divisions, implementation could prove challenging and costly. A few commenters stated that States should be encouraged (but not required) to implement the proposed provisions to their section 1905(a) State plan services.

However, a few commenters supported extending the grievance system requirements to section 1905(a) services. Among these commenters, a few commenters recommended that CMS apply the grievance system requirements specifically to mental health rehabilitative services delivered under section 1905(a) services. These services, some commenters stated, are delivered to large numbers of Medicaid beneficiaries, particularly those with mental health needs. These commenters elaborated on concerns that, otherwise, there would be disparities between individuals receiving similar services from the same State Medicaid agency under different authorities, and that many Medicaid recipients with mental health disabilities receiving services under the section 1905(a) authority would not have recourse if their rights were violated. One commenter also suggested that mental health rehabilitative services are considered ''home- and community-based services'' under the broader definition enacted by Congress in the American Rescue Plan Act of 2021.

Response: At this time, we are not requiring inclusion of section 1905(a) services in the State grievance system. That said, we are not convinced by the argument that including section 1905(a) services would simply be too much work, as we do believe it is critical that beneficiaries have access to mechanisms to claim their rights and have their concerns heard. Rather, we note that there are statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. We would need to consider how to define the nature of the grievances that would be filed for section 1905(a) services, given that they do not have the same person-centered planning and HCBS settings rule requirements at § 441.301(c)(1) through (6). As we discussed extensively in this section, the bases for a grievance are providers' and States' performance of the requirements at § 441.301(c)(1) through (6). We believe this definition of grievance provides clear parameters for matters that would be the subject of grievances. We note that person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While person-centered service planning might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

Similarly, the HCBS settings requirements a § 441.301(c)(3) through (6) that apply to section 1915(c) services have counterparts for section 1915(k) services at § 441.530 and for 1915(i) services at § 441.710. (For more discussion of the application of the HCBS settings rule's application to section 1915(c), (i), and (k) services, we refer readers to the final rule published in 2014 at 79 FR 2948.) Section 1915(j) services offered through a section 1915(c) waiver (as specified, for instance, at § 441.452(a)) would also be subject to the HCBS settings requirements at § 441.301(c)(3) through (6). There is not a similar application of the HCBS settings rule to section 1905(a) services.

If we are to apply a grievance process to 1905(a) services, it is likely we would weigh proposing a grievance process for all section 1905(a) services versus for only specific section 1905(a) services. These services are diverse, are offered in diverse settings, and lack the clear regulatory framework that we were able to use in constructing the bases for grievances in section 1915 services. We believe this requires additional consideration and discussion with the public beyond what could be finalized in this current rule.

Though we are not finalizing inclusion of section 1905(a) services in the State grievance system in this rule, we acknowledge that many beneficiaries, including those receiving mental health services, are served by section 1905(a) services and encourage States to consider development of grievance processes to address these beneficiaries' concerns. We appreciate the commenters' suggestions. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

After consideration of public comments, we are finalizing the application of the grievance system requirements for section 1915(c) waivers, as finalized in this rule at § 441.301(c)(7), to the other HCBS authorities under sections 1915(j), 1915(k), and 1915(i). However, after further review, we determined it is necessary to make modifications to our regulations for these other HCBS authorities to clarify this intention. Our proposed regulation text for these HCBS authorities did not accurately reflect or effectuate our proposal to require States to implement and maintain a grievance system, in accordance with § 441.301(c)(7), for these HCBS authorities as well. We are finalizing the regulation text we proposed at §§ 441.464 (for section 1915(j)), 441.555 (for section 1915(k)), and 441.745 (for section 1915(i)) with modification to more clearly specify that a State must implement and maintain a grievance system in accordance with the requirements we are finalizing at § 441.301(c)(7) for HCBS programs they administer under these authorities.

For application to section 1915(j) services, we are not finalizing the amendment we proposed at § 441.464(d)(2)(v), but rather finalizing this new requirement for a grievance system at § 441.464(d)(5). We will retain the current language at § 441.464(d)(2)(v), which indicates that States must include grievance processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.464(d)(5), we are finalizing with modification for clarity and precision that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7), rather

than the language we proposed at § 441.464(d)(2)(v) (Grievance process, as defined in § 441.301(c)(7) when self-directed PAS include services under a section 1915(c) waiver program). We are also finalizing § 441.464(d)(5) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

For application to section 1915(k) services, we are not finalizing the amendment we proposed at § 441.555(b)(2)(iv), but rather finalizing this new requirement for a grievance system at § 441.555(e). We will retain the current language at § 441.555(b)(2)(iv), which indicates that States must include grievances processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.555(e), we are finalizing with modification for clarity and precision that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7), rather than the language we proposed at § 441.555(b)(2)(iv) (Grievance process, as defined in § 441.301(c)(7)). We are also finalizing § 441.555(e) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

For application to section 1915(i) services, we are finalizing the amendment we proposed at § 441.745(a)(1)(iii) with modifications. As proposed, § 441.745(a)(1)(iii) had indicated that a State must provide beneficiaries receiving section 1915(i) services with the opportunity to file a grievance. To clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7) for beneficiaries receiving HCBS under section 1915(i), we are finalizing § 441.745(a)(1)(iii) to specify that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7). We note that several requirements being finalized at § 441.301(c)(7) (such as § 441.301(c)(7)(iii)(A), (B)(*2*), and (C)(*1*), discussed in section II.B.2.b. of this final rule) require States to provide the beneficiary with the opportunity to file grievances in the grievance system. We are also finalizing § 441.745(a)(1)(iii) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(i) of the Act. Additionally, as we are finalizing a new § 441.745(a)(1)(iii) in this rule, we are redesignating the current § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

We also note that while we are finalizing these amendments to regulations under section 1915(j), (k) and (i) authorities, we are not suggesting that States that provide HCBS through multiple authorities must operate a separate grievance process for each program. As discussed earlier in II.B.2. of this preamble, while States are allowed to maintain multiple grievance processes (so long as each process complies with § 441.301(c)(7)), we strongly encourage States to maintain a single, integrated grievance system for all HCBS beneficiaries.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at §§ 441.301(c)(7) as follows:

- We are finalizing the requirement describing the grievance system purpose at § 441.301(c)(7)(i) with technical modifications to specify that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's **performance of** (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6) of § 441.301(c)(7). (New language identified in bold.) We are also adding language to § 441.301(c)(7)(i) stating that the State may contract with other entities to perform activities described in § 441.301(c)(7) but retains responsibility for ensuring performance of and compliance with these provisions. The finalized requirement at § 441.301(c)(7)(i) will read: *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.
- We are finalizing the definition of grievance at § 441.301(c)(7)(ii) with a technical modification, conforming with the modification at § 441.301(c)(7)(i), to specify that a grievance will mean an expression of dissatisfaction or complaint related to the State's or a provider's performance of (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6), regardless of whether remedial action is requested. (New language identified in bold.) We are finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.
- We are finalizing the process requirement at § 441.301(c)(7)(iii)(A) as proposed, with the following exceptions. We are finalizing § 441.301(c)(7)(iii)(A)(*1*) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. The finalized requirement at § 441.301(c)(7)(ii)(A)(*1*) will read: Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(*2*) as proposed.
- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B) as proposed.
- We are finalizing § 441.301(c)(7)(iii)(B)(*1*) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7).
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(*2*) with a modification to specify that States must provide beneficiaries with reasonable assistance in ensuring grievances are appropriately filed with the grievance system. We are also finalizing § 441.307(c)(7)(iii)(B)(2) with modifications to change the term ''individuals who are limited English proficient'' to ''individuals with Limited English Proficiency.'' We are also finalizing with modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication. As finalized, § 441.301(c)(7)(iii)(B)(2) specifies that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms, and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and to provide meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services

where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B)(3) with modifications to require that States ensure that punitive or retaliatory action (rather than just punitive actions) is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf. The finalized requirement at § 441.301(c)(7)(iii)(B)(3) will read: Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)
- We are finalizing the process requirement § 441.301(c)(7)(iii)(B)(4) with a modification to remove the reference to expedited grievances. The finalized requirements at § 441.301(c)(7)(iii)(B)(4) will read: Accept grievances and requests for extension of timeframes from the beneficiary.
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(5) with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency.
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.
- We are finalizing the requirements at § 441.301(c)(7)(iii)(C)(*4*) and (*5*) with a modification to replace the reference to § 441.301(c)(7)(v)(B)(1) and (2) and adding a reference to § 441.301(c)(7)(v). We are also finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the reference to 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).
- Aside from the modifications noted previously to § 441.301(c)(7)(iii)(C)(*4*) and (5), we are finalizing § 441.301(c)(7)(iii)(C) as proposed, with minor formatting changes.
- We are finalizing the filing timeframe requirement at § 441.301(c)(7)(iv) with modifications by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). The finalized requirement at 441.301(c)(7)(iv) will read: *Filing timeframes.* A beneficiary may file a grievance at any time.
- We are finalizing the resolution and notification requirement at § 441.301(c)(7)(v)(A) with a modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. The finalized requirement at § 441.301(c)(7)(v)(A) will read: *Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.
- We are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(*2*). Instead, we are redesignating § 441.301(c)(7)(v)(B)(*1*) as § 441.301(c)(7)(v)(B) and retitling § 441.301(c)(7)(v)(B) as ''Resolution timeframes.'' We are also removing the word ''standard'' from § 441.301(c)(7)(v)(B). The finalized requirement at § 441.301(c)(7)(v)(B) will read: *Resolution timeframes.* For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.
- We are finalizing the timeframe extension requirement at § 441.301(c)(7)(v)(C) and (D) without substantive changes. We are finalizing § 441.301(c)(7)(v)(C) with a technical modification to redesignate paragraphs (C)(*1*)(i) and (C)(*1*)(ii) as (C)(*1*) and (C)(*2*), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, but with a technical modification to change the periods at the end of § 441.301(c)(7)(v)(D)(*1*) and (*2*) to semi-colons, and adding ''and'' at the end of § 441.301(c)(7)(v)(D)(*2*).
- We are finalizing the notice format requirement at § 441.301(c)(7)(vi)(A) without substantive modification. However, we are not finalizing the proposal relating to the expedited resolution process at § 441.301(c)(7)(vi)(B). Therefore, we are redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).
- We are finalizing the recordkeeping requirements at § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(*1*) through (*5*) with semi-colons rather than periods at the end of each paragraph, and with the word ''and'' at the end of § 441.301(c)(7)(vii)(B)(*5*).
- We are finalizing the applicability date requirements at § 441.301(c)(7)(viii) to specify that States must comply with the requirement at paragraph (c)(7) beginning 2 years from the effective date of this final rule.

Additionally, we are finalizing the application of the grievance process requirements at § 441.301(c)(7) to section 1915(j), (k) and (i) authorities as follows:

- For application to section 1915(j) services, we are not finalizing a reference at § 441.464(d)(2)(v), as we had proposed, but rather finalizing a new requirement at § 441.464(d)(5) that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.
- For application to section 1915(k) services, we are not finalizing a reference at § 441.555(b)(2)(iv), as we had proposed, but rather finalizing a new requirement at § 441.555(e) that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.
- For application to section 1915(i) services, we are finalizing a new § 441.745(a)(1)(iii) with modification to clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act. We are redesignating the existing § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

3. Incident Management System (§§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v) and 441.745(b)(1)(i))

Section 1902(a)(19) of the Act requires States to provide safeguards as may be necessary to assure that eligibility for care and services will be determined, and that such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients. Section 1915(c)(2)(A) of the Act and current Federal regulations at § 441.302(a) require that States have in place necessary safeguards to protect the health and welfare of individuals receiving section 1915(c) waiver program services. Further, as discussed previously in section II.B.1. of this rule, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more a more consistent

and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[61] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and oversight of a system to qualify and monitor providers.

As noted earlier in section II.B.1. of this rule, we released guidance for section 1915(c) waiver programs included in the 2014 guidance,[62] which noted that States should report on State-developed performance measures to demonstrate that they meet six assurances, including a Health and Welfare assurance for States to demonstrate that they have designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance highlighted, related to the Health and Welfare assurance, the following:

- The State demonstrates on an ongoing basis that it identifies, addresses, and seeks to prevent instances of abuse, neglect, exploitation, and unexplained death;
- The State demonstrates that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible;
- The State's policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed; and
- The State establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Consistent with the expectations for other performance measures, the 2014 guidance noted that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their Health and Welfare performance measures.

Despite States implementing these statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and States' adherence to related subregulatory guidance, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [63] (referred to as the Joint Report, developed by ACL, OCR, and the OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm.

In addition, in 2016 and 2017, OIG released several reports on their review of States' compliance with Federal and State requirements regarding critical incident reporting and monitoring.[64] [65] [66] OIG found that several States did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving individuals receiving HCBS through waivers. In particular, the reports indicated that:

- Critical incidents were not reported correctly;
- Adequate training to identify appropriate action steps for reported critical incidents or reports of abuse or neglect was not provided to State staff;
- Appropriate data sets to trend and track critical incidents were not accessible to State staff; and
- Critical incidents were not clearly defined, making it difficult to identify potential abuse or neglect.

In 2016, we conducted three State audits based at least in part on concerns regarding health and welfare and media coverage on abuse, neglect, or exploitation issues.[67] We found that these three States had not been meeting their section 1915(c) waiver assurances, similar to findings reported by the OIG. In two cases, for the incidents of concern, tracking and trending of critical incidents were not present. Further, in at least two of the States, staffing at appropriate levels was identified as an issue.

In January 2018, the United States Government Accountability Office (GAO) released a report on a study of 48 States that covered assisted living services.[68] The GAO found large inconsistencies between States in their definition of a critical incident and their system's ability to report, track, and collect information on critical incidents that have occurred. States also varied in their oversight methods, as well as the type of information they were reviewing as part of this oversight. The GAO recommended that requiring States to report information on incidents (such as the type and severity of incidents and the number of incidents) would strengthen the effectiveness of State and Federal oversight.

In July 2019, we issued a survey to States that operate section 1915(c) waivers, requesting information on their approach to administering incident management systems. The goal of the survey was to obtain a comprehensive understanding of how States organize their incident management system to best respond to, resolve, monitor, and prevent critical incidents in their waiver programs. The survey found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

[61] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

[62] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf*.

[63] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf*.

[64] HHS OIG. ''Connecticut did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' May 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400002.pdf*.

[65] HHS OIG. ''Massachusetts did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' July 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400008.pdf*.

[66] HHS OIG. ''Maine did not comply with Federal and State requirements for critical incidents involving Medicaid beneficiaries with developmental disabilities.'' August 2017. Accessed at *https://oig.hhs.gov/oas/reports/region1/11600001.pdf*.

[67] Presentation by CMS for Advancing States: Quality in the HCBS Waiver—Health and Welfare. See: *http://www.nasuad.org/sites/nasuad/files/Final%20Quality%20201.pdf*.

[68] Government Accountability Office. ''Medicaid assisted living services—improved Federal oversight of beneficiary health and welfare is needed.'' January 2018. Accessed at *https://www.gao.gov/assets/690/689302.pdf*.

Additionally, during various public engagement activities conducted with interested parties over the past several years, we have heard that ensuring access to HCBS requires that we must first ensure health and safety systems are in place across all States, a theme underscored by the Joint Report.

a. Incident Management System Requirements (§ 441.302(a)(6))

Based on these findings and reports, under the authorities at sections 1902(a)(19) and 1915(c)(2)(A) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed a new requirement at § 441.302(a)(6) to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. This proposal is intended to ensure standardized requirements for States regarding incidents that harm or place a beneficiary at risk of harm and is based on our experience working with States as part of the section 1915(c) waiver program and informed by the incident management survey described previously in this section of the final rule. In the absence of an incident management system, people receiving section 1915(c) waiver program services are at risk of preventable or intentional harm. As such, we believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We proposed similar requirements for section 1915(i), (j) and (k) HCBS programs at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and 441.745(b)(1)(i); these are discussed further in section II.B.3.i of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal at § 441.302(a)(6) to require States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. Additionally, these commenters noted that the proposed requirements for this incident management system can ensure States standardize data and processes for critical incident monitoring, identify trends, and influence timely oversight of responses to incidents to minimize health and safety risks for beneficiaries receiving HCBS.

Several commenters stated that establishing an incident management system, including requirements for data-driven analytics and trend reporting, would help to better inform States and providers by creating new collaborative models to measure improvements to better ensure quality of life for HCBS beneficiaries. In the same vein, one commenter noted that States should use the data and information collected on critical incidents to develop strategies to reduce or eliminate the risk of abuse, neglect, or exploitation; to enable discovery of root cause for occurrence of critical incidents; and to identify actions to influence critical incidents proactively, instead of reactively.

Response: We appreciate the support for our proposal and agree that requiring States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents will ensure that States are better informed and more able to identify root causes for the occurrence of critical incidents, enabling them to act more proactively to influence and prevent the occurrence of such incidents.

Comment: A few commenters requested we clarify how States can fully address critical incidents for dually eligible beneficiaries who are enrolled in managed care plans, when the managed care plan does not have access to Medicare claims data. In the same vein, they were also concerned that States would require extensive resources to utilize the Medicare claims data.

These commenters also requested clarification on the feasibility of reporting across Medicare and Medicaid in dual eligible special needs plan (D–SNP) contracts.

Response: Since 2011, we have provided States access to Medicare data for dually-eligible beneficiaries, including for beneficiaries in different categories of dual eligibility, free-of-charge via the Medicare-Medicaid Data Sharing Program.[69] Information on the Medicare-Medicaid Data Sharing Program, including how to request data and the standard data sharing agreements, is available through the State Data Resource Center.[70]

We proposed that the incident management system requirements, as specified at § 441.302(a)(6) and as finalized in this rule, will apply to section 1915(c)(i), (j), and (k) services delivered through managed care plans. We also note that dually eligible beneficiaries enrolled in managed care plans known as fully integrated dual eligible special needs plans (FIDE SNP) and highly integrated dual eligible special needs plans (HIDE SNP), are subject to the incident management requirements at § 441.302(a)(6) as finalized. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: A few commenters expressed concern that the requirements we proposed for this incident management system generally seemed to be more focused on documentation of critical incidents, rather than impacting quality and outcomes for HCBS participants to ensure optimal health and welfare. One commenter recommended that States should assure that resolution of critical incidents focuses on preventing harm to the HCBS participant(s) involved in the critical incident. This commenter also suggested that States should take actions to not only prevent further harm to HCBS participant(s) involved in a critical incident, but actions based on the critical incident should be taken to prevent further harm to all HCBS participants.

Response: We believe the requirements we proposed at § 441.302(a)(6), and as finalized in this rule, give States the flexibility to decide how to design and implement their incident management system. We encourage States to consider implementing quality improvement processes as part of their incident management systems, as quality improvement processes can help States to promote the health and welfare of beneficiaries by addressing systemic issues in their HCBS programs. We also note that the purpose of tracking and trending critical incidents is to assist States in understanding patterns that require interventions to promote improvement and prevent the recurrence of harm to beneficiaries.

We also refer readers to the requirements currently set forth at § 438.330(b)(5)(ii) that MCOs, PHIPs, and PAHPs participate in efforts by the State to prevent, detect, and remediate critical incidents, consistent with assuring beneficiary health and welfare as required in § 441.302 and § 441.703(a). Further, as noted herein, the six assurances and related

[69] See Medicare-Medicaid Data Sharing Program at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccesstoMedicareData.*

[70] See State Data Resource Center at *https://www.statedataresourcecenter.com/home/contact-us.*

subassurances for section 1915(c) waiver programs, including the Health and Welfare assurance, as set forth in the 2014 guidance, continue to apply. In addition, as discussed in section II.B.8. of this final rule, the HCBS Quality Measure Set reporting requirements include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set requirements being finalized in this rule are distinct and severable from the incident management requirements being finalized at § 441.302(a)(6), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

After consideration of these public comments, we are finalizing our proposal to require at § 441.302(a)(6) that States must provide an assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents as proposed.

b. Critical Incident Definition (§ 441.302(a)(6)(i)(A))

At § 441.302(a)(6)(i)(A) through (G), we proposed new requirements for States' incident management systems. Specifically, at § 441.302(a)(6)(i)(A), we proposed to establish a standard definition of a critical incident to include, at a minimum, verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

We proposed the Federal minimum standard definition of a critical incident at § 441.302(a)(6)(i)(A) to address the lack of a standardized Federal definition for the type of events or instances that States should consider a critical incident that must be reported by a provider to the State and considered for an investigation by the State to assess whether the incident was the result of abuse, neglect, or exploitation, and whether it could have been prevented. The definition we proposed at § 441.302(a)(6)(i)(A) is based on internal analyses of data and information obtained through a CMS survey of States' incident management systems, commonalities across definitions, and common gaps in States' definitions of critical incidents (for instance, that many States do not consider sexual assault to be a critical incident).

We also requested comment on whether there are specific types of events or instances of serious harm to section 1915(c) waiver participants, such as identity theft or fraud, that would not be captured by the proposed definition and that should be included, and whether the inclusion of any specific types of events or instances of harm in the proposed definition would lead to the overidentification of critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed minimum standard definition of a critical incident. Commenters expressed that the proposed requirements at § 441.302(a)(6)(i)(A) establish a minimum Federal definition of a critical incident which would help to standardize practices across States and HCBS programs to better serve and prevent harm or risk of harm for beneficiaries. A few commenters noted the standardized Federal minimum definition of a critical incident will increase consistency across States, section 1915(c) waivers, and HCBS programs. A few commenters suggested CMS further explain the critical incident definition to minimize misinterpretation, stating that explanations of definitions for each type of critical incident could ensure reporting is uniform and consistent across all State programs and services. These commenters stated that without a uniform understanding of each type of critical incident, critical incidents could be over or under reported. Similarly, several other commenters suggested that the definition of critical incident we proposed is overly broad, expressing it could impede the State's coordination with other agencies and interested parties. These commenters indicated that more explanation of the definitions of critical incident at § 441.302(a)(6)(i)(A) could help to address varying interpretations in implementation of the proposed requirements, noting that each State Medicaid agency or interested parties could independently establish meaning.

Response: We disagree with commenters that the proposed definition of critical incident is overly broad. We believe that the proposed requirements at § 441.302(a)(6)(i)(A) provide States with a comprehensive minimum standard definition of a critical incident. We recommend that States view the definition as a minimum Federal standard. States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations and the specific characteristics of their HCBS programs. We plan to provide technical assistance, as needed, to States if they have questions about the types of incidents that should be included in the standardized definition, and how this definition relates to existing critical incident definitions already in use.

Comment: Commenters responded to our request for comment on whether there were specific types of events or instances of serious harm that would not be captured by the proposed critical incident definition and should be included. A few commenters suggested that we broaden the definition of critical incident and suggested that the following types of incidents be included in the proposed definition of critical incident at § 441.302(a)(6)(i)(A): abuse between HCBS waiver housemates; expression of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary; lack of direct care workers; physical or emotional harm suffered by participant; falls with severe or moderate injury/illness; missed or delayed provision of services identified in the person-centered plan; refusal of service; self-neglect; and a range of harmful things beneficiaries may experience.

Alternatively, a few commenters recommended that CMS not expand the minimum definition of critical incident further, indicating the critical incident definition offers flexibility to States to expand their critical incident definition to fit the HCBS program and population served by the State. Commenters expressed that CMS should provide technical assistance, for all States, including for States that already have an incident management system with critical incident definitions and policies and programs in place.

Response: We appreciate commenters sharing these suggestions. We note that many of these types of events would be captured by the minimum standard definition. For instance, we would consider abuse between HCBS waiver housemates to fall under verbal, physical, sexual, psychological, or emotional abuse. Similarly, expressions of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary may be considered a critical incident. If a lack of direct care workers, a refusal of service, or missed or delayed provision of services identified in the person-centered service plan results in

harm or risk of risk from the failure of a provider to deliver needed services, we would expect a State to consider those events as instances of neglect. Physical or emotional harm suffered by a participant as a result of one or more types of events included in our definition of critical incidents or that results in death would also be captured as a critical incident. Falls with severe or moderate injury/illness may be considered critical incidents depending on whether they occur as a result of an event included in our definition of critical incidents. They would also be considered critical incidents if they result in death. Some of these events, such as missed or delayed provision of services identified in the person-centered service plan, could also meet the definition of a grievance and be appropriate for consideration under the grievance system, which we are finalizing as part of a separate provision in § 441.301(c)(7) (discussed in section II.B.2 of this rule.)

We decline to include refusing a service or self-neglect in the minimum standard definition because we intend this definition to focus on incidents that occur during the course of service delivery. However, States may include these events in their own definitions.

We are unsure what the commenter intended by ''range of harmful things beneficiaries may experience'' and are unable to respond directly to that recommendation.

We appreciate these comments and will take this feedback into consideration when developing resources for States on the incident management system's requirements.

Comment: One commenter stated that we should consider whether what constitutes a critical incident might differ between adult and child beneficiaries and recommended that pediatricians could assist States in development and implementation of incident management requirements, including critical incident requirements. This commenter also stated that data and information for children receiving HCBS and housed in pediatric health systems should be linked with the State electronic critical incident system proposed at § 441.302(a)(6)(i)(B).

Response: As previously discussed, our proposal is to establish a minimum Federal definition, and States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations. We also encourage States to include input from interested parties, including experts in children receiving HCBS, when developing and implementing their incident management systems and policies and procedures to meet the proposed requirements. We discuss requirements for data and information sharing and electronic systems in more detail below in this section II.B.3. of the rule.

Comment: Several commenters provided feedback about the inclusion of medication errors resulting in a telephone call to or a consultation with a poison control center in the proposed critical incident definition at § 441.302(a)(6)(i)(A)(*5*). One commenter expressed support for the reporting of a medication error resulting in a telephone call to or a consultation with a poison control center, and agreed they should be reported by the provider to the State. Another commenter expressed that beneficiaries receiving HCBS are encouraged to be independent and have the right to self-determination, and completing investigations on medication errors could be infringing upon HCBS beneficiaries' self-determination. One commenter requested we consider that managed care plans do not typically receive member data from poison control centers unless they are contracted with the managed care plan to provide this notification, making it difficult to track incidents that result in a consultation with the poison control center unless this data is captured elsewhere in member claims data. One commenter expressed concern that including a medication error in the definition of critical incidents could be problematic since not all providers who serve HCBS beneficiaries are clinical staff who can render a professional clinical determination of medication error, which could result in medication errors being over or under reported and skew data reports.

Response: We plan to provide States with technical assistance to help address issues raised by providers in reporting any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services, including medication errors resulting in a telephone call to or a consultation with a poison control center. Because we also are finalizing § 441.302(a)(6)(i)(C) as described in II.B.3.d. of this rule, we confirm that States must require providers to report to them any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. As such, a provider would be expected to report a medication error resulting in a contact with a poison control center if the medication error occurred during the delivery of services or a result of the failure to deliver services. We believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving HCBS.

Comment: One commenter requested that CMS clarify that in addition to audio-only telephone, that the use of audio or video technology be made acceptable to satisfy the requirement proposed at § 441.302(a)(6)(i)(A)(*5*) that the State adopt the minimum standard definition for critical incident for a medication error resulting in contact with a poison control center.

Response: We do not have the authority to define additional communication types or consultation methods for poison control centers. We decline to add ''use of audio or video technology'' to the requirement proposed at § 441.302(a)(6)(i)(A)(*5*). We encourage States to collaborate with their State and local poison control centers to understand the types of consultation that are acceptable and make requests for additional communication types or consultation methods for poison control centers.

Comment: Several commenters responded to our solicitation to comment on whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) should include other specific types of events or instances of serious harm to beneficiaries receiving HCBS, such as identity theft or fraud. Most commenters responding to the request for comment recommended that CMS not expand the critical incident definition to include identity theft or fraud, noting it could create duplication of existing investigative and reporting processes. Alternatively, a few commenters supported the inclusion of identity theft and fraud in the critical incident definition. One commenter recommended that CMS provide additional guidance on identity theft or fraud in the context of exploitation, including financial exploitation if added to the minimum critical incident definition. One commenter expressed concern with including identity theft or fraud in the proposed critical incident definition, except when the individual has been formally and legally judged incompetent to make relevant decisions.

Response: We agree with commenters that expanding the critical incident definition at § 441.302(a)(6)(i)(A) to include identity theft or fraud could

create duplication of existing Federal investigative agencies and reporting processes. Therefore, we have not identified a compelling reason to add other types of incidents, such as identity theft or fraud, to the standardized minimum definition of critical incidents we proposed and are finalizing in this rule.

Comment: One commenter specifically responded to the request for comment soliciting whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) includes any specific types of events or instances of harm that would lead to the overidentification of critical incidents. The commenter supported the proposed definition, noting it would not result in overidentification of critical incidents. This commenter noted that, although the events included in the critical incident definition they use are not the same as those in the proposed critical incident definition at § 441.302(a)(6)(i)(A), they believed that the proposed definition would not cause overidentification of critical incidents because their policies require any incident, not solely those that are defined, to be reported.

Response: We appreciate the support for our proposal.

After consideration of these public comments, we are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.

c. Electronic Critical Incident Systems (§ 441.302(a)(6)(i)(B))

At § 441.302(a)(6)(i)(B), we proposed that States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We also solicited comment on the burden associated with requiring States to have electronic critical incident systems and whether there is specific functionality, such as unique identifiers, that should be required or encouraged for such systems. As part of our proposal, we also encouraged, but did not propose to require, States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the Interoperability Standards Advisory (ISA).[71]

We received public comments on these proposals. Below is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.302(a)(6)(i)(B), that a State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. A few commenters expressed concern about the impact of the proposed requirements on States that already have multiple incident management systems, including electronic systems, for different programs, administered by different operating agencies. Commenters requested that we allow States flexibility to design the electronic critical incident systems, which we proposed to require at § 441.302(a)(6)(i)(B), by taking into account existing State incident management systems and processes which fit their unique program and systems structures. A few commenters were especially concerned about the impact on States that already enable electronic collection of critical incidents and questioned whether a single incident management system is required to be implemented across all waivers and authorities, or whether a separate system can be implemented for each waiver or program. Commenters expressed concern about having to consolidate current incident management systems, designed based on State infrastructure, into a single electronic system.

Response: We acknowledge that some States currently have electronic incident management systems in place for HCBS, and it is not our intent for States to abandon these systems. We encourage States to build upon existing incident management system infrastructure and protocols to meet the electronic critical incident systems requirements we proposed at § 441.302(a)(6)(i)(B) and are finalizing in this rule.

We believe that a single electronic critical incident system may best enable the State to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. For example, in the absence of a single electronic critical incident system, States may have more difficulty developing and implementing a comprehensive plan to address and resolve critical incidents across HCBS programs and authorities. A single electronic incident management system could also better enable the State to track critical incidents for providers that deliver services in multiple HCBS programs or under different HCBS authorities, identify systemic causes of critical incidents, or detect patterns of preventable critical incidents and, in turn, implement strategies to more effectively prevent critical incidents.

We assume that some States may need to make at least some changes to their existing systems to fully comply with the requirements at § 441.302(a)(6)(i)(B). We have attempted to provide the State with as much flexibility as possible in the design of their incident management system. As such, the State may opt to maintain multiple systems that comply with the requirements at § 441.302(a)(6).

We encourage each State to consider developing a single electronic critical incident system for all of their HCBS programs under section 1915(c), (i), (j), and (k) authorities.

However, if a State chooses to implement multiple systems, we strongly encourage the State to share data among those systems to enable the development and implementation of a comprehensive plan to address and resolve critical incidents for HCBS beneficiaries and track and trend incidents for specific providers. We note that the State is responsible for ensuring compliance with the requirements of applicable Federal or State laws and regulations governing confidentiality, privacy, and security of certain information and records.

Comment: Several commenters recommended that CMS consider providing additional funding opportunities to assist States in the development and implementation of electronic critical incident systems we proposed to require at § 441.302(a)(6)(i)(B).

Response: As noted in the proposed rule (88 FR 27979), in Medicaid, enhanced Federal financial participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable

[71] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), *and Functional Assessment Standardized Items* (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

Federal requirements.[72] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[73] However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[74]

Comment: A few commenters supported CMS encouraging States to advance the interoperable exchange of HCBS data by adopting standards in the Interoperability Standards Advisory (ISA), and requested we further promote, support, and incentivize the development of better interoperability infrastructure to facilitate more seamless data sharing between States, providers, and managed care plans.

Response: While we did not propose any specific requirements related to interoperability for the electronic incident management system, States should ensure the advancement of the interoperable exchange of HCBS data, to further improve the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries to support quality improvement activities that can help promote the health and safety of HCBS beneficiaries. We clarify that, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA) [75] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

Comment: A few commenters recommended CMS not require States to include additional specific functionalities, including unique identifiers.

Response: We agree with commenters to not require or encourage a specific functionality, such as unique identifiers.

After consideration of public comments received, we are finalizing our proposal to require at § 441.302(a)(6)(i)(B) that States use an information system, meeting certain requirements, for electronic data collection, tracking, and trending of critical incident data, as proposed, with minor modifications. We are finalizing § 441.302(a)(6)(i)(B) with the addition of the word ''enables'' and striking ''enables'' from § 441.302(a)(6)(i)(B)(*1*) so that it applies to all paragraphs in § 441.302(a)(6)(i)(B). We are finalizing minor formatting changes to conclude paragraphs (a)(6)(i)(B)(*2*) and (3) with semi-colons.

d. Provider Critical Incident Reporting—During Delivery of or Failure To Deliver Services (§ 441.302(a)(6)(i)(C))

At § 441.302(a)(6)(i)(C), we proposed that States must require providers to report to the State any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. We believe that this proposed requirement will help to specify provider expectations for reporting critical incidents and to ensure that harm that occurs because of the failure to deliver services will be appropriately identified as a critical incident.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement we proposed at § 441.302(a)(6)(i)(C) that a State must require providers to report to the State any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. One commenter expressed that requiring providers to report on any critical incidents that occur during service delivery, or as a result of the failure to deliver authorized services, encourages better, more transparent reporting and provides a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery. Another commenter noted missed or delayed services, especially a pattern of missed or delayed service appointments, can lead to poor health outcomes for beneficiaries.

Response: We appreciate the expressions of support for our proposal.

Comment: A few commenters raised concerns with the requirement we proposed at § 441.302(a)(6)(i)(C) that States require providers to report to them any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or as a result of the failure to deliver services authorized under a section 1915(c) waiver program and as specified in the waiver participant's person-centered service plan. One commenter expressed that this requirement would require reviewers of critical incidents to draw conclusions about the service provider's role, without taking into account a beneficiary's right to privacy, decision making, personal preferences, and autonomy, especially for beneficiaries who live in their own home and/or receive care from different providers. Another commenter expressed concern that, even after a thorough investigation, it is often impossible to definitively substantiate certain allegations of abuse or neglect or determine whether a negative outcome, such as a hospitalization, was the direct result of a critical incident that occurred during the delivery of services or as a result of the failure to deliver services as authorized. A commenter expressed concern that the requirement for providers to report to States any critical incidents that are a result of the failure to deliver authorized services is too broad and could cause critical incident reporting to be ineffective and inconsistent.

Response: We proposed requirements for States regarding the reporting of critical incidents by providers that we believe are important for identifying and addressing incidents of abuse, neglect, exploitation, or other harms that occur during the course of service delivery or as a result of the failure to deliver services. We note that the reporting of a critical incident does not necessarily mean that an action should be taken by the State in response to the critical incident. Further, even if no action is warranted or it is not possible to substantiate an allegation of abuse or neglect, it is still important to have the critical incident reported, and investigation conducted if appropriate, in case, for instance, a pattern later

[72] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[73] See section 1903(a)(3)(B) and § 433.15(b)(4).

[74] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[75] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

emerges that indicates systemic causes of critical incidents or that warrants action by the State.

Comment: A few commenters suggested we modify § 441.302(a)(6) to specify that critical incident records be collected in accordance with applicable privacy laws, such as HIPAA and its implementing regulations.

Response: In consideration of public comments received, we have not identified a compelling reason, and therefore decline, to add a reference to specific privacy laws to the requirements at § 441.302(a)(6). We note that States have existing obligations to comply with applicable Federal and State laws and regulations governing confidentiality, privacy, and security of information, records, and data obtained and maintained in a critical incident system. We note that this regulatory requirement does not modify these obligations to comply with applicable laws.

Comment: One commenter suggested we require States to accept critical incident reports, and acknowledge receipt of the report, directly from beneficiaries or other interested parties, establish a process to accept such reports, and allow reports to be made orally or in writing. The commenter recommended that we should require that punitive action is neither threatened nor taken against any individual who makes a report in good faith.

Response: We decline to modify our proposal to broaden the requirements related to critical incidents we proposed at § 441.302(a)(6)(i)(C) in this final rule. Although we proposed to only require providers to report critical incidents at § 441.301(a)(6)(i)(C), the State is not precluded from accepting the reporting of critical incidents from others, who are not providers, including beneficiaries or other interested parties. We believe that our proposal that the State assure a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery, or as a result of the failure to deliver services, is in the best interest of, and necessary for, protecting the health and welfare of beneficiaries receiving HCBS in section 1915(c) waiver programs and under section 1915(i), (j) and (k) State plan services.

We encourage States to include in their policies and procedures that beneficiaries would not be prohibited from reporting critical incidents and, in doing so, would be free from any punitive action when reporting a critical incident to the State. We have provided States with flexibility to establish their own policies and procedures related to addressing punitive actions against beneficiaries involved in the critical incident process.

After consideration of these public comments, we are finalizing our proposal at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(C) with minor formatting changes to conclude § 441.302(a)(6)(i)(C) with a semi-colon.

e. Data Sources To Identify Unreported Critical Incidents (§ 441.302(a)(6)(i)(D))

At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. We believe that such data can play an important role in identifying serious instances of harm to waiver program participants, which may be unreported by a provider, such as a death that occurs as a result of choking of an individual with a developmental disability residing in a group home, or a burn that occurs because a provider failed to appropriately supervise someone with dementia and that results in an emergency department visit.

We solicited comment on whether States should be required to use these data sources to identify unreported critical incidents, and whether there are other specific data sources that States should be required to use to identify unreported critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.302(a)(6)(i)(D). One commenter noted that these data sources could help establish pathways at the beneficiary and systems levels for reporting, tracking, and addressing issues with person-centered planning and provider noncompliance, and they will also advance efforts to ensure States' ongoing compliance with the HCBS Settings Rule. Another commenter approved of the requirement that States use data sources to identify unreported critical incidents, including claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law, expressing that implementation of this requirement could result in a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery, in working with managed care plans and providers.

Response: We appreciate the support for our proposal.

Comment: Two commenters requested that collaboration with police and law enforcement be included in the data sources under § 441.302(a)(6)(i)(D). One commenter noted CMS should require providers to report to law enforcement in a timely manner any reasonable suspicion of a crime committed against a beneficiary receiving HCBS. Another commenter recommended CMS require providers to report suspicion of a crime to law enforcement. A commenter also questioned whether an investigative agency includes law enforcement. Additionally, a few commenters also recommended that collaboration with the designated Protection & Advocacy (P&A) system for the State be included in the data sources under § 441.302(a)(6)(i)(D), citing that P&A systems have the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

Response: While we intend that § 441.302(a)(6)(i)(D) establishes the minimum requirements for States to use certain data sources to detect unreported critical incidents, States retain flexibility to use additional data sources, such as police and law enforcement data and P&A systems, to identify critical incidents that are unreported by providers. However, we decline to include additional data sources in the regulation at this time. We are concerned that it would be difficult for States to use non-Medicaid data sources, such as data from P&A systems and law enforcement records, to effectively identify unreported critical incidents for Medicaid beneficiaries and that such requirements would be administratively and operationally

burdensome for States to implement. At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, identifying Adult Protective Services or Child Protective Services as examples of State agencies. We encourage the State to include additional State agency data sources to detect unreported critical incidents as defined at § 441.302(a)(6)(i)(D) as appropriate.

Comment: A couple commenters stated that CMS should direct States to take definitive enforcement actions to address provider compliance with the incident management requirements. One commenter proposed to penalize HCBS providers that do not timely report critical incidents by imposing monetary penalties or suspension from the Medicaid program. Another commenter recommended that we allow States to implement an escalation of remedies to address provider reporting, up to and including a separate investigation with sanctions, if necessary.

Response: We reiterate that States already have broad authority to create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

After consideration of public comments we received, we are finalizing our proposal at § 441.302(a)(6)(i)(D), with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(D) with minor formatting changes to conclude § 441.302(a)(6)(i)(D) with a semi-colon.

f. Critical Incident Data Sharing (§ 441.302(a)(6)(i)(E))

At § 441.302(a)(6)(i)(E), we proposed States share information, consistent with the regulations in 42 CFR part 431, subpart F on the status and resolution of investigations. We set the expectation that data sharing could be accomplished through the use of information sharing agreements with other entities in the State responsible for investigating critical incidents if the State refers critical incidents to other entities for investigation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended CMS provide technical assistance related to the data sharing requirements. Commenters noted data sharing barriers in and between the State, agencies, and divisions within in the same agency, influencing successful implementation of the proposed requirements at § 441.302(a)(6)(i)(G).

Response: We appreciate these comments identifying the need for technical assistance related to data and information sharing agreements. We will take this feedback into consideration when developing resources for States on the incident management system requirements.

Further, we generally note that the State is responsible for ensuring its critical incident system(s) comply with all applicable Federal and State laws and regulations governing confidentiality, privacy, and security of records obtained, maintained, and disclosed via this incident management system.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(E) as proposed, with a minor technical modification to clarify that mention of critical incident in § 441.302(a)(6)(i)(E) refers to critical incidents as defined in paragraph (a)(6)(i)(A) of this section (meaning § 441.302).

g. Separate Investigation of Critical Incidents (§ 441.302(a)(6)(i)(F))

At § 441.302(a)(6)(i)(F), we proposed to require the State be required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents, particularly where there could be evidence of serious harm or a pattern of harm to a section 1915(c) waiver program participant for which a provider is responsible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed serious concerns about the requirements we proposed at § 441.302(a)(6)(i)(F), that the State is required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. Commenters recognized the importance of cross-agency collaboration but identified that the timeframes for investigations by investigative agencies, such as Adult Protective Services and Child Protective Services, can be prolonged. Further, opening a separate concurrent investigation at the State level, if the investigative agency fails to report the resolution of an investigation within State-specified timelines, could compromise the integrity of both investigations. Some commenters questioned the feasibility of the requirements at § 441.302(a)(6)(i)(F) due to State statutory provisions around investigative agency responsibilities and allowable data sharing.

Response: These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State Medicaid agency's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents to protect the health and welfare of HCBS beneficiaries. We believe that requiring the State to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes will strengthen the ability of the State Medicaid agency to act quickly and/or separately if investigations by Adult Protective Services, Child Protective Services, or other State agencies are taking longer to address and resolve. Further, it will ensure that the State has the information it needs to take action to protect beneficiary health and safety if a provider is responsible (intentionally or unintentionally) for causing harm to beneficiaries or putting beneficiaries at risk of harm. Additionally, we note that the State Medicaid agency may have the authority to take certain actions against the provider (such as suspend their Medicaid enrollment) that other State agencies, such as Adult Protective

Services or Child Protective Services, are unable to take.

We have provided States with flexibility to establish State-specified timelines to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation and encourage States to take into account specific nuances that may impact the timelines.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(F) as proposed.

h. Reporting (§§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at section 1902(a)(6) of the Act, we proposed to modernize the health and welfare reporting by requiring all States to report on the same Federally prescribed quality measures as opposed to the State-developed measures, which naturally vary State by State. Specifically, at § 441.302(a)(6)(i)(G), we proposed to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We discuss these reporting requirements in our discussion of proposed § 441.311(b)(1). Further, under our authority at sections 1915(c)(2)(A) and 1902(a)(19) of the Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6). Specifically, at § 441.302(a)(6)(ii), we proposed to require that States demonstrate that: an investigation was initiated, within State-specified timeframes, for no less than 90 percent of critical incidents; an investigation was completed and the resolution of the investigation was determined, within State-specified timeframes, for no less than 90 percent of critical incidents; and corrective action was completed, within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action. This minimum performance level strengthens health and welfare reporting requirements while taking into account that there may be legitimate reasons for delays in investigating and addressing critical incidents.

In the proposed rule (88 FR 27980), we considered whether to allow good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent. We opted not to propose good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact a State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters expressed concern about implementing the performance levels at the 90 percent threshold at § 441.302(a)(6)(ii). Alternatively, one commenter recommended the performance level should instead be 100 percent to protect the health and welfare of HCBS beneficiaries, since the minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6) should gauge State performance by how efficiently they conduct critical incident investigations.

Response: We believe the performance levels at the 90 percent threshold sets a high, but achievable standard, for complying with the requirements at § 441.302(a)(6)(ii). Our intention in proposing minimum performance requirements at § 441.302(a)(6)(ii) was to provide a standard by which we could oversee, and hold States accountable, for complying with the requirements for an incident management system that we are finalizing at § 441.302(a)(6). Further it, was intended to strengthen the critical incident requirements while also recognizing that there may be legitimate reasons why critical incident processes occasionally are not completed timely in all instances. However, it is our expectation that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

Comment: A few commenters suggested CMS include a good-cause exception to the incident management performance level for certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges or when the investigating agency requests that the State refrain from contact due to an ongoing and active investigation. Alternatively, a few commenters supported the approach in the proposed rule to not allow good-cause exceptions to the incident management performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We reiterate our belief that the 90 percent minimum performance level sets a high, but achievable standard for States' incident management systems. We underscore that the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. The 90 percent minimum performance level is intended to strengthen incident management system requirements. We also recognize that there may be legitimate reasons why incident management processes occasionally are not completed timely in all instances. We reiterate that our expectation is that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

After consideration of public comments, we are finalizing our proposals at §§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii) as proposed.

i. Applicability Date

We proposed at § 441.302(a)(6)(iii) to provide States with 3 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the burden they believe will be associated with the proposed provision to implement the incident management requirements at § 441.302(a)(6) within 3 years following the effective date of the final rule. Commenters stated that implementation of the incident management requirements as proposed at § 441.302(a)(6)(i)(B) could require

potential State statute and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative effective dates for the incident management system ranging from 4 to 7 years, with the most frequent suggestions at 4 to 5 years to address these concerns.

Response: We believe that 3 years for States to comply with the requirements at § 441.302(a)(6) is realistic and achievable for most of the incident management provisions. However, we agree that the proposed 3-year implementation timeframe for States to comply with the electronic incident management requirements at § 441.302(a)(6)(i)(B) could create hardships for States. We agree that States and managed care plans may require a timeframe longer than 3 years to address funding needs, policy changes, IT procurements, and other systems changes, necessary to implement an electronic incident management system as required at § 441.302(a)(6)(i)(B), which may necessitate 5 years.

After consideration of public comments, we are finalizing § 441.302(a)(6)(iii) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(a)(6)(iii) as Applicability date (rather than Effective date). We are also modifying the applicability date to require that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years from the effective date of the final rule. In addition, we are making a technical correction to clarify that the applicability dates in § 441.302(a)(6)(iii) apply only to the requirements in § 441.302(a)(6). Additionally, we are also finalizing with modification the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy at § 441.302(a)(6)(iii).

j. Application to Other Authorities

At § 441.302(a)(6)(iii), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We proposed that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because of the importance of assuring health and welfare for other HCBS State plan options, we proposed to include the incident management requirements at § 441.302(a)(6) within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v), respectively. We note that a conforming reference to § 441.745(b)(1)(i), although not discussed in preamble of the proposed rule, was included in the proposed rule (88 FR 28086); the reference supports the application of incident management requirements to section 1915(i) services. Consistent with our proposal for section 1915(c) waivers, we based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries. We believe the same arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the requirements at § 441.302(a)(6)(iii), expressing that States must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both in FFS and managed care delivery systems, noting there is no meaningful difference between abuse, neglect, or exploitation perpetrated by a provider paid through a managed care plan or by a provider paid through a FFS delivery system. One commenter recommended we assist States in developing instructions for State incident management systems for work with Medicaid managed care plans and contracted providers in implementing the requirements in § 441.302(a)(6).

Response: We appreciate the support for our proposal. We will take this feedback into consideration when developing technical assistance and other resources for States on the incident management system requirements.

After consideration of public comments received, we are finalizing the proposal at § 441.302(a)(6)(iii) for HCBS delivered under both FFS and managed care delivery systems.

Comment: Several commenters supported the proposal to apply the incident management system requirements at § 441.302(a)(6) to sections 1915(i), (j) and (k) authorities. Commenters expressed that equally applicable requirements for States across waiver authorities can ensure better access, equity, quality, and reporting for HCBS beneficiaries.

Response: We appreciate the support for our proposal.

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care, home health, and case management services. Several commenters supported the proposal not to extend the incident management requirements at § 441.302(a)(6) to section 1905(a) services and expressed that applying these requirements to State plan benefits would pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for 1905(a) services. A few commenters recommended that CMS apply the incident management system requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of commenters suggested that mental health rehabilitative services are considered home- and community-based services under the broader definition enacted by Congress in the American Rescue Plan Act of 2021. They also indicated that many Medicaid beneficiaries with mental health disorders and disabilities receiving services under the section 1905(a) authority would benefit from the beneficiary protections afforded through the incident management system requirements at § 441.302(a)(6).

Response: At this time, we are not mandating inclusion of section 1905(a) services in the State requirements for incident management systems, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. That said, we are not persuaded by the argument that including section 1905(a) services would simply be too much work, as we do believe it is critical that Medicaid beneficiaries have protections for freedom from harm. We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to consider development of critical incident processes to address protections for beneficiaries from harm or events that place a beneficiary at risk of harm.

After consideration of public comments, we are finalizing application of the requirements at § 441.302(a)(6) to other HCBS program authorities within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services. We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) as proposed, with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

k. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at §§ 441.302(a)(6), as follows:

- We are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.
- We are finalizing § 441.302(a)(6)(i)(B) as proposed with the following minor modifications: adding the word ''Enables'' to § 441.302(a)(6)(i)(B) and striking it from § 441.302(a)(6)(i)(B)(1); and minor formatting modifications to conclude § 441.302(a)(6)(i)(B)(2) and (3) with a semi-colon.
- We are finalizing the requirements at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(C) with a minor formatting change so that it concludes with a semi-colon.
- We are finalizing the requirements at § 441.302(a)(6)(i)(D, with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(D) with a minor formatting change so that it concludes with a semi-colon.
- We are finalizing the requirement at § 441.302(a)(6)(i)(E) with a minor formatting modification to change a reference to § 441.302(a)(6)(i)(A) to paragraph (a)(6)(i)(A).
- We are finalizing the requirements at § 441.302(a)(6)(i)(F) and (G) and (a)(6)(ii) as proposed.
- We are finalizing the requirement at § 441.302(a)(6)(iii) with modifications to specify that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule; except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years after the date that is the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 5 years from the effective date of this final rule.
- We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

4. Reporting (§ 441.302(h))

As discussed earlier in section II.B.1. of this rule, section 2402(a)(3)(A) of the Affordable Care Act requires HHS to promulgate regulations to ensure that States develop HCBS systems that are designed to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. We also believe that standardizing reporting across HCBS authorities will streamline and simplify reporting for providers, improve States' and CMS's ability to assess HCBS quality and performance, and better enable States to improve the quality of HCBS programs through the availability of comparative data. Further, section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

To avoid duplicative or conflicting reporting requirements at § 441.302(h), we proposed to amend § 441.302(h) by removing the following language: ''annually''; ''The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on -''; and by removing paragraphs (1) and (2) under § 441.302(h). Further, we proposed to add '', including the data and information as required in § 441.311'' at the end of the new amended text, ''Assurance that the agency will provide CMS with information on the waiver's impact.'' By making these changes, we proposed to consolidate reporting expectations in one new section at proposed § 441.311, described in section II.B.7. of the proposed rule, under our authority at section 1902(a)(6) of the Act and section 2402(a)(3)(A) of the Affordable Care Act. As noted earlier in section II.B.1. of the proposed rule, this reporting will supersede existing reporting for section 1915(c) waivers and standardize reporting across section 1915 HCBS authorities.

We did not receive specific comments on this proposal.

We are finalizing our proposed amendment of § 441.302(h) as proposed.

We did receive comments on proposed § 441.311, described in section II.B.7. of this rule, which establishes a new Reporting Requirements section. Comments on this proposal and our

responses are summarized in section II.B.7. of this final rule.

5. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. Direct care workers are referred to by various names, such as direct support professionals, personal care attendants, and home health aides, within and across States. They perform a variety of roles, including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, and eating) and instrumental activities of daily living (such as cooking, grocery shopping, and managing finances), behavioral supports, employment supports, and other services to promote community integration for older adults and people with disabilities. We discuss the definition of direct care workers in more detail below in the context of our proposed definition of direct care workers.

Direct care workers typically earn low wages and receive limited benefits [76] [77] [78] contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS. Workforce shortages can also reduce the cost-effectiveness of services for State Medicaid agencies that take into account the actual cost of delivering services when determining Medicaid payment rates, such as by increasing the reliance on overtime and temporary staff, which have higher hourly costs than non-overtime wages paid to permanent staff. Further, an insufficient supply of HCBS providers can prevent individuals from transitioning from institutions to home and community-based settings and from receiving HCBS that can prevent institutionalization. HCBS is, on average, less costly than institutional services,[79] [80] and most older adults and people with disabilities prefer to live in the community. Accordingly, limits on the availability of HCBS lessen the ability for State Medicaid programs to deliver LTSS in a cost-effective, beneficiary friendly manner.

Shortages of direct care workers and high rates of turnover also reduce the quality of HCBS. For instance, workforce shortages can prevent individuals from receiving needed services and, in turn, lead to poorer outcomes for people who need HCBS. Insufficient staffing can also make it difficult for providers to achieve quality standards.[81] High rates of turnover can reduce quality of care,[82] including through the loss of experienced and qualified workers and by reducing continuity of care for people receiving HCBS,[83] which is associated with the reduced likelihood of improvement in function among people receiving home health aide services.[84]

While workforce shortages have existed for years, the COVID–19 pandemic exacerbated the problem, leading to higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in retail and other jobs that tend to draw from the same pool of workers.[85] [86] [87] Further, demand for direct care workers is expected to continue rising due to the growing needs of the aging population, the changing ability of aging caregivers to provide supports, the increased provision of services in the most integrated community setting rather than institutional services, and a decline in the number of younger workers available to provide services.[88] [89] [90]

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide coordination for and support each person's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[91] In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for

[76] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[77] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[78] We recognize that there are workforce shortages that may impact access to other Medicaid-covered services aside from HCBS. We are focusing in this rule on addressing workforce shortages in HCBS and continue to assess the feasibility and potential impact of other actions to address workforce shortages in other parts of the health care sector.

[79] Reaves, E.L., & Musumeci, M.B. December 15, 2015. *Medicaid and Long-Term Services and Supports: A Primer.* Kaiser Family Foundation. Accessed at *https://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/*.

[80] Kim, M–Y, Weizenegger, E., & Wysocki, A. July 22, 2022. *Medicaid Beneficiaries Who Use Long-Term Services and Supports: 2019.* Chicago, IL: Mathematica. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf*.

[81] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[82] Newcomer R, Kang T, Faucett J . Consumer-directed personal care: comparing aged and non-aged adult recipient health-related outcomes among those with paid family versus non-relative providers. Home Health Care Serv Q. 2011;30(4):178– 97.

[83] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[84] Russell D, Rosati RJ, Peng TR, Barrón Y, Andreopoulos E . Continuity in the provider of home health aide services and the likelihood of patient improvement in activities of daily living. Home Health Care Manage Pract. 2013;25(1):6–12.

[85] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[86] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[87] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[88] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[89] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[90] Centers for Medicare & Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf*.

[91] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS, while section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure a sufficient number of qualified direct care workers to provide self-directed personal assistance services. To comply with sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, and, specifically, a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We proposed requirements across section 1915(c), (i), (j) and (k) HCBS programs to further this outcome.

a. Assurance of Sufficient Rates (§ 441.302(k))

Consistent with section 1902(a)(30)(A) of the Act and sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, we proposed to require at § 441.302(k) that State Medicaid agencies provide assurance that payment rates for certain HCBS authorized under section 1915(c) of the Act are sufficient to ensure a sufficient direct care workforce (defined and explained later in this section of the rule) to meet the needs of beneficiaries and provide access to services in accordance with the amount, duration, and scope specified in the person-centered service plan, as required under § 441.301(c)(2). We believe that this proposed requirement supports the economy, efficiency, and quality of HCBS authorized under section 1915(c) of the Act, by ensuring that a sufficient portion of State FFS and managed care payments for HCBS go directly to compensation of the direct care workforce.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A significant number of commenters raised the issue of State Medicaid rates for homemaker, home health aide, and personal care services. Many commenters suggested that requiring that a sufficient portion, or even requiring a specific percent, of Medicaid payments be spent on compensation for direct care workers will not address rate sufficiency, which they regard as the underlying cause of low wages for direct care workers. Even commenters who were supportive of § 441.302(k) generally or the proposed minimum performance level at § 441.302(k)(3) (discussed further below) acknowledged that the policies may be more successful if they coincided with rate increases to ensure that providers' service operations remain fully supported. Many commenters recommended that as an alternative to (or in addition to) this proposal, we create requirements that States regularly review and update or increase their rates.

Several commenters were concerned that wages for direct care workers will not increase if the underlying Medicaid payment rates for the services remain low and are not increased. However, one commenter suggested that if a State's Medicaid rates are low, this places even greater importance on ensuring that as much of the rate as possible is going to compensation for direct care workers.

A few commenters expressed the belief that the accountability and transparency created by the proposal, in addition to the associated reporting requirement we proposed at § 441.311(e) (discussed further in section II.B.7. of this rule), would encourage providers to pass more of their Medicaid payments along to direct care worker wages. A few commenters offered anecdotal observations that, when their State allocated additional funds to HCBS providers, the commenters believed the increased funding was not passed along to direct care worker wages. One commenter noted that a permanent payment adequacy requirement is preferable to the temporary pass-through policies that have been enacted for one-time rate increases, because a permanent requirement would not be dependent on rate increases.

Response: While section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies, section 1902(a)(30)(A) of the Act does provide us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates for HCBS under the Medicaid program. Instead, we reiterate that under section 1902(a)(30)(A) of the Act payments must be sufficient to recruit and retain enough providers to ensure care and services are available to beneficiaries; we proposed to implement this requirement by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care.

Broadly speaking, we also do not believe that simply increasing rates alone, without setting guardrails for how the payments are allocated, would ensure that direct care workers' wages will increase. Rather, we agree with commenters who believed that, regardless of the underlying Medicaid rate, requiring a certain amount of Medicaid payments be spent on compensation will help ensure that Medicaid payments are distributed in a way that supports direct care workers, including their recruitment and retention, to the greatest extent possible. While we did not propose, and are not finalizing, a requirement that State Medicaid agencies increase their rates, we anticipate that States will examine their rates to assure they are sufficient to support the direct care workforce to comply with the policy we proposed and are finalizing with modifications, as discussed further herein. We also direct commenters to the proposals discussed in section II.C. of this final rule, which includes a number of provisions related to rate transparency that are intended to support FFS rate sufficiency.

Comment: One commenter recommended that we revise § 441.302(k) to specify that rates must be sufficient to ensure a sufficient number of providers, including members of the direct care workforce. The commenter stated that this revision would match the broader term ''provider'' in section 1902(a)(30)(A) of the Act while highlighting the importance of the direct care workforce.

Response: We appreciate the commenter's feedback, but we decline to make the recommended revision. At this time, we want to make the focus of the requirement explicitly on the individuals who are part of the direct care workforce, whether they act as individual providers (such as by working as an independent contractor), are employed by a provider entity, or otherwise. We agree with the commenter that section 1902(a)(30)(A) of the Act requires that Medicaid payments must be sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent that such care and services are available to the general population in the geographic area. We note that section 1902(a)(30)(A) of the Act also requires that States assure that payments are consistent with efficiency, economy, and quality of care. We agree that enrolling sufficient numbers of

providers is critical to Medicaid service delivery, and that providers in turn may not be able to deliver services if they do not have a sufficient number of direct care workers. As noted in a previous response, we proposed to implement these requirements by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will promote, and be consistent with, economy, efficiency, and quality of care, as required by statute at section 1902(a)(3)(A) of the Act.

Comment: One commenter requested clarification on whether the payment adequacy requirement applies only to the voluntary, nonprofit sector or whether it also applies to State-operated services.

Response: Given the varied nature of HCBS programs, we specifically proposed for the payment adequacy requirement to apply broadly to compensation paid to direct care workers by providers receiving payments for furnishing homemaker, home health aide, or personal care services from the State; we did not propose to apply these requirements to only certain types of providers or their ownership arrangements. We specifically proposed at § 441.302(k)(1)(ii)(G) (which we are finalizing at § 441.302(k)(1)(ii) as discussed later in this section) that a direct care worker, to whom this requirement would apply, may be employed by or contracted with a Medicaid provider, State agency, or third party or delivering services under a self-directed service model. The requirements we proposed, and are finalizing in this section II.B.5, under § 441.302(k) require States to assure that payment rates are adequate to ensure a sufficient direct care workforce by, in turn, ensuring that providers spend a certain percentage of their total payments for certain HCBS on compensation for direct care workers furnishing those HCBS.

After consideration of the comments received, we are finalizing the assurance requirement at § 441.302(k) with modifications as discussed in this section II.B.5 of this final rule. We are finalizing the language we proposed in the introductory paragraph at § 441.302(k) with technical modifications so that it is clear that the reference to person-centered service plans is to beneficiaries' person-centered service plans. The finalized language at § 441.302(k) will read: *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

b. Minimum Performance Requirement and Flexibilities (§ 441.302(k)(2), (3), (4), (5), and (6))

Our proposal at § 441.302(k)(2) and (3) was designed to affect the inextricable link between sufficient payments being received by the direct care workforce and access to and, ultimately, the quality of HCBS received by Medicaid beneficiaries. We believe that this proposed requirement would not only benefit direct care workers but also individuals receiving Medicaid HCBS because supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care. The direct care workforce must be able to attract and retain qualified workers in order for beneficiaries to access providers of the services they have been assessed to need and for the direct care workforce to be comprised of workers with the training, expertise, and experience to meet the diverse and often complex HCBS needs of individuals with disabilities and older adults. Without access to a sufficient pool of direct care workers, individuals are forced to forgo having their needs met, or have them addressed by workers without sufficient training, expertise, or experience to meet their unique needs, both of which could lead to worsening health and quality of life outcomes, loss of independence, and institutionalization.[92] [93] [94] [95] Further, we believe that ensuring adherence to a Federal standard of the percentage of Medicaid payments going to direct care workers is a concrete step in recruitment and retention efforts to stabilize this workforce by enhancing salary competitiveness in the labor market. In the absence of such requirements, we may be unable to support and stabilize the direct care workforce because we would not be able to ensure that the payments are used primarily and substantially to pay for care and services provided by direct care workers. Therefore, at § 441.302(k)(3)(i), we proposed to require that at least 80 percent of all Medicaid payments, including but not limited to base payments and supplemental payments, with respect to the following services be spent on compensation to direct care workers: homemaker services, home health aide services, and personal care services.[96]

While many States have already voluntarily established such minimums for payments authorized under section 1915(c) of the Act,[97] we believe a Federal standard would support ongoing access to, and quality and efficiency of, HCBS. Our proposal was based on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP [98] or other State-led initiatives. We refer readers to our proposed rule for more specific discussion of the feedback we received from States regarding their implementation of similar requirements (88 FR 27984).

We focused our proposed requirement on homemaker services, home health aide services, and personal care services because they are services for which we

[92] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[93] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[94] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

[95] Chong, N., I. Akorbirshoev, J. Caldwell, H.S. Kaye, and M. Mitra. 2021. The relationship between unmet need for home and community-based services and health and community living outcomes. Disability Health Journal. Accessed at *https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953.*

[96] We note that section 2402(a) of the Affordable Care Act applies broadly to all HCBS programs and services funded by HHS. Further, section 2402(a) does not include limits on the scope of services, HCBS authorities, or other factors related to its use of the term HCBS. Therefore, we believe that there is no indication that personal care, homemaker, and home health aide services would fall outside the scope of section 2402(a).

[97] For instance, as part of their required activities to enhance, expand, or strengthen HCBS under ARP section 9817, some States have required that a minimum percentage of rate increases and supplemental payments go to the direct care workforce. See *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html* for more information on ARP section 9817.See *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html* for more information on ARP section 9817.

[98] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

expect that the vast majority of payment should be comprised of compensation for direct care workers. These services are comprised of individualized supports for Medicaid beneficiaries delivered by direct care workers and generally have low equipment or supply costs relative to other services. Further, these are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for homemaker services, home health aide services, and personal care services: (1) 75 percent; (2) 85 percent; and (3) 90 percent. If an alternate minimum percentage was recommended, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters (regardless of whether they supported the overall proposal itself) applauded our acknowledgement of, and efforts to address, HCBS workforce shortages, which many commenters characterized as a ''crisis.'' Many commenters appeared to agree that wages to direct care workers are generally low, and that these low wages contribute to overall workforce challenges. Both providers and beneficiaries submitted comments detailing struggles they have had in hiring and retaining qualified direct care workers. Some of these commenters described the frustration of having to constantly recruit and train new direct care workers. Some commenters described having to turn away new clients due to staff shortages, and beneficiaries reported experiencing delays or reductions in their services due to difficulty in finding direct care workers to provide the services. Many direct care workers also submitted personal examples of the hardships caused by financial strain due to inadequate pay, including having to work long hours at multiple jobs to earn extra income, missing time with their own families, struggling to pay bills, risking exposure to (or contracting) COVID–19, and experiencing burnout and psychological stress. A few of these commenters indicated they had left the direct care workforce due to low wages.

Several commenters stated that the proposed minimum performance requirement, if finalized, would likely lead to increases in wages for direct care workers and strengthen the workforce, which in turn could improve the quality of HCBS. In particular, a number of commenters noted the potential for the proposal to have a positive impact on workers who are Black, other people of color, and women, who are disproportionately represented in the direct care workforce—groups that have historically experienced low wages due to discrimination.

Commenters were able to draw anecdotal connections between wages and worker retention. A few providers, for instance, noted that they had made efforts to increase their workers' wages, and observed that the increase in wages had a positive impact on their staff retention and the number of beneficiaries the providers were able to serve.

A few other commenters noted that there are other factors that may contribute to worker shortages, and recommended that we continue to partner with the Administration for Community Living and other Federal agencies to promote a comprehensive, integrated campaign that addresses multiple facets of the workforce shortage, including promotion of and improvement of social valuation of this work, support of workforce pipelines, changes to immigration policy, and creative strategies for atypical workforce development.

Response: We thank commenters for sharing their personal experiences and perspectives on how they have been affected by the direct care workforce shortage and the low wages paid to many direct care workers. We share the belief that this requirement will create a foundation of support for the direct care workforce, which we believe is fundamental to HCBS delivery. We focused in this proposal on compensation for direct care workers because, as we noted above and many commenters confirmed anecdotally, many direct care workers have been paid low wages for a long time.[99] [100] We recognize that other factors also play important roles in worker retention and shortages. While we will continue to partner with other Federal agencies to address these issues, some of the factors affecting the workforce lie outside of our regulatory purview and are outside of the scope of this proposal.

Comment: A significant number of commenters provided feedback on the idea of having a national minimum performance level (separate from providing comment on what the percentage should be). One commenter, representing several State agencies, supported the intent of the proposal and indicated that the proposed requirements could ''improve recruitment, retention and economic security of the HCBS direct care workforce.'' While offering cautions, the commenter indicated that many States generally support a single national minimum performance requirement, but they also recommended that we consider providing States with flexibility related to the requirement based on provider size, rural/urban status, and risk of closure.

Many commenters expressed concerns that a single national minimum performance level could fail to take into account various factors that might affect the percent of Medicaid payments that is spent on compensation for direct care workers including substantial differences among HCBS waiver programs, such as size, services, populations, service area, and staffing needs; State requirements for providers, such as differences in business operations requirements, licensure costs, staff training requirements, or whether States require providers to maintain physical office space; and local economic environments, including cost of living, taxes, and wage laws. Many commenters requested that we not finalize a minimum performance level, so that providers may be allowed flexibility to allocate their Medicaid payments as they determine to be appropriate. One commenter, while acknowledging a workforce crisis, noted that Area Agencies on Aging and provider organizations are taking steps to improve recruitment and retention and that a Federal mandate such as the 80 percent minimum performance level proposed in the rule is unnecessary, may have unintended consequences, and may complicate State and local efforts currently underway.

Response: After consideration of public comments as described in this section II.B.5 of this rule, we are finalizing a national minimum performance level in this final rule. We believe that not doing so would fail to help address the chronic shortages in the HCBS direct care workforce. In this context, the status quo amounts to minimal oversight over how much of the Medicaid payment is going to support the direct care workers who are

[99] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[100] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

performing the core activities of homemaker, home health aide, and personal care services. While some States have already implemented initiatives to ensure that a certain percentage of Medicaid payments or rate increases are going to direct care worker compensation, as noted above, we believe a Federal requirement is necessary and would be more effective to promote consistency and transparency nationwide.

We agree that there may be State or local circumstances that impact the percent of Medicaid payments that is spent on compensation for direct care workers. Where possible, we have built flexibilities into this requirement as discussed further in this section II.B.5 to ensure that it addresses certain differences among HCBS programs and providers. Specifically, as we discuss in detail later in this section, we are modifying the policy we proposed at § 441.302(k) by: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to ensure certain costs are not included in the minimum performance level calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii) to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k). The specific modifications and the rationale for these modifications are discussed in greater detail in this section II.B.5. of the final rule.

Further, we are modifying the policy we proposed at § 441.302(k) to require States to comply with this HCBS payment adequacy policy beginning 6 years after the effective date of this final rule, rather than the 4 years we proposed. (We discuss this modification to § 441.302(k)(4), being redesignated as § 441.302(k)(8), in section II.B.5.h., of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k).

Ultimately, while we agree that providers generally have flexibility to determine how to spend their Medicaid payments, we believe it is important to reiterate the parameters for payment rates required under section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that payment rates must be economic and efficient; they must not be so high as to be uneconomic or inefficient. This provision also requires payment rates to be consistent with quality of care and sufficient to enlist enough providers to ensure a specified level of access to services for beneficiaries; rates must not be so low as to impermissibly limit beneficiaries' access to care or the quality of care they receive. The Supreme Court in *Armstrong* v. *Exceptional Child Center, Inc.,* in considering this provision, recognized that Congress was ''explicitly conferring enforcement of this judgment-laden standard upon the Secretary[,] . . . thereby achieving 'the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decision-making.' '' [101] We believe that implementing this statutory requirement includes some degree of oversight into how providers are allocating the Medicaid payments that they receive for delivering HCBS to beneficiaries. For example, if providers are spending a high proportion of their Medicaid payments on compensation to direct care workers but beneficiaries have difficulty accessing services and quality is compromised due to an insufficient number of direct care workers, then the payment rate may be too low to satisfy section 1902(a)(30)(A). Conversely, if concerns about access to and quality of services were not present and providers were spending a low proportion of their Medicaid payments on compensation to direct care workers, then the Medicaid payment rate may exceed a level that is economic and efficient, contributing to overhead spending and/or operating margin at levels higher than needed to ensure access and quality.

Comment: While several commenters agreed that a national minimum performance level is authorized by section 1902(a)(30) of the Act, a few other commenters disagreed that this policy is authorized by section 1902(a)(30) of the Act. These latter commenters noted that section 1902(a)(30)(A) of the Act requires each State plan for medical assistance to provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. As such, these commenters contended that this statutory provision applies to State plans, not to CMS, and speaks to the adequacy of payments to Medicaid-enrolled healthcare providers, not the providers' workforce. They stated that section 1902(a)(30)(A) of the Act cannot be read to delegate authority to us to prescribe specific wage pass-through requirements that States must impose upon providers.

Response: We believe that the statutes we cited support the components of our proposal. Regarding the applicability of section 1902(a)(30)(A) of the Act, we refer readers to our prior discussion of section 1902(a)(30)(A) of the Act in section II.B.5.a. of this rule. As we noted in that discussion, section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates. Instead, we proposed that States demonstrate that payments are sufficient to ensure care and services are available to beneficiaries by specifying a percentage of Medicaid payments that States must ensure is spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care. We also disagree that section 1902(a)(30)(A) of the Act speaks only to provider enrollment. We believe that setting a performance level at which States support their State plan assurance that payments are consistent with efficiency, economy, and quality of care is an appropriate use of our oversight authority under section 1902(a)(30)(A) of the Act.

Comment: A few commenters agreed that sections 2402(a)(1) and 2402(a)(3) of the Affordable Care Act authorize the creation of a national minimum

[101] *Armstrong* v. *Exceptional Child Center, Inc.,* 575 U.S. 320, 328–29 (2015) (internal citations omitted).

performance requirement to support the direct care workforce. However, a few commenters disagreed with this application of section 2402(a)(1) of the Affordable Care Act. These commenters noted that section 2402(a)(1) of the Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS) to promulgate regulations to ensure that all States develop service systems that are designed to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and supports and that provides strategies for beneficiaries receiving such services to maximize their independence, including through the use of client-employed providers. Commenters stated that, although this provision speaks to HHS's authority to promulgate regulations, those regulations must pertain to ensuring that States develop systems to appropriately allocate resources to the types of services their beneficiaries need. These commenters contended that section 2402 of the Affordable Care Act allows HHS to, for example, require States to assess whether they should provide services such as delivering healthy meals to certain populations or allow beneficiaries to hire a family member to assist them (and fund the wages), but it does not provide HHS the authority to require States to impose upon providers wage pass-through requirements that are set at a specific minimum performance level.

Response: We disagree with commenters' interpretation of section 2402(a)(1) of the Affordable Care Act. Section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. As discussed throughout this section, one of the most fundamental ways that HCBS programs meet the needs of beneficiaries is by having a sufficient direct care workforce to provide the services beneficiaries have been assessed to need. Without an adequate supply of workers, beneficiaries may not be able to access all the services that they need and that fully reflect their choices or preferences. We believe that setting a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act.

Comment: One commenter did not agree that section 2402(a)(3)(B)(iii) of the Affordable Care Act authorized the application of a minimum performance requirement. The commenter noted that section 2402(a)(3)(B)(iii) of the Affordable Care Act requires the Secretary of HHS to promulgate regulations to ensure that all States develop service systems that are designed to improve coordination among, and the regulation of, all providers of such services under Federally and State-funded programs in order to oversee and monitor all service system functions to assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter stated that this statutory provision both bestows authority upon HHS to promulgate regulations and specifically references the need to ensure an adequate number of direct care workers. However, the commenter noted that, like section 2402(a)(1) of the ACA, section 2402(a)(3)(B)(iii) specifies that HHS's role—and its authority to promulgate such regulations—is limited to ensuring that States develop service systems that assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter also stated that this statutory provision applies only to the self-directed service delivery model and does not authorize HHS to promulgate wage pass-through requirements with respect to services delivered by provider agencies. The commenter stated, generally, that the Medicaid program's fundamental premise is to allow each State or Territory the ability to tailor its program to reflect its unique needs, and that this is at odds with a requirement for States to direct providers' behavior.

Response: We generally disagree with the commenter's analysis of section 2402(a)(3)(B)(iii) of the Affordable Care Act that it does not authorize the application of a minimum performance requirement. Section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure there is a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We believe that, to comply with this statutory requirement, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries (regardless of delivery model), and, specifically, States must have a sufficient number of qualified direct care workers to provide self-directed personal assistance services. In other words, an insufficient direct care workforce generally will impact whether a State has a sufficient number of qualified direct care workers to provide self-directed personal assistance services in compliance with this requirement. However, we do agree that section 2402(a)(3)(B)(iii) of the Affordable Care Act speaks specifically to self-directed services. We cited this authority for the purposes of supporting our inclusion of self-directed services in this proposal.

As noted in prior responses, we believe that section 1902(a)(30)(A) of the Act and 2402(a)(1) of the Affordable Care Act authorize us to set parameters or benchmarks for HCBS expenditures (both including and in addition to expenditures for self-directed personal care services). Section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that Medicaid payments for services are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. Section 2402(a)(1) of the Affordable Care Act requires HHS to ensure States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. States retain flexibility in how they construct their HCBS systems. Rather, we believe the minimum performance requirement we proposed, and are finalizing with modifications in this section II.B.5, sets a benchmark to help us determine whether States are ensuring that their HCBS systems are allocating sufficient resources to support the direct care workforce to ensure there are sufficient providers so that care and services are available to beneficiaries and that these services are consistent with efficiency, economy, and quality of care. We believe that setting such a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act and applies to other HCBS in addition to the self-directed personal care services specifically addressed in section 2402(a)(iii)(B).

Comment: A number of commenters stated that we did not provide enough data to support the proposal for an 80 percent minimum performance level. One commenter suggested that by not providing sufficient data to support the

proposal, we have not fulfilled our obligations under the Administrative Procedure Act.

A number of commenters recommended we collect more data before finalizing a certain percent for the national minimum performance level. Some commenters suggested that a State-by-State analysis of rates and the potential impact of a minimum performance level would need to be performed before setting a minimum performance level. A few of these commenters suggested that helpful data could be collected from States' rate studies, HCBS waiver rates, provider cost reports, or the data we proposed in the proposed rule to be reported to us (including our proposals at § 441.311(e) and § 447.203, which we discuss in sections II.B.7. and II.C. of this rule, respectively). One commenter suggested using the electronic visit verification (EVV) system [102] as a tool for gathering relevant data. Several commenters also suggested that any additional data collection performed to support a national minimum performance level be used to assess unintended consequences of such a level.

A few commenters questioned the specific data relied on for the proposal of an 80 percent minimum performance level. They noted concerns including:

- A lack of support for the claim in the proposed rule that some States have set wage pass-through requirements as high as 90 percent;
- Use of data on the American Rescue Plan Act of 2021 section 9817 funds by a few States to increase worker wages, which have only been relatively recently distributed, and thus reflect limited data;
- State wage pass-through requirements as part of their activities to enhance, expand, or strengthen HCBS under section 9817 the American Rescue Plan Act of 2021were generally only applied to temporary rate increases, not entire rates; and
- Minnesota and Illinois, two States that have wage pass-through requirements, have their requirements set at 72 percent and 77 percent, respectively, and both use different definitions of compensation or direct care worker than what was proposed.

Response: As discussed in the proposed rule (88 FR 27982), we based our proposal on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP [103] or other State-led initiatives. For example, as noted by commenters, Minnesota has established a minimum threshold of 72.5 percent,[104] while Illinois has implemented a minimum threshold of 77 percent, for similar requirements for HCBS payments as we proposed.[105] To further clarify the data that we used to inform our proposal, which was referenced in footnote 81 in the proposed rule (88 FR 27983 to 27984), we note the following examples of different types of States' wage pass-through requirements that States added to spending plans for ARP section 9817:

- Indiana announced a Direct Service Workforce Investment Grant in which 95 percent of the grant funds must be spent on direct service professionals.[106]
- Massachusetts required that HCBS providers use 90 percent of a rate increase to support their direct care workers.[107]
- North Carolina required that 80 percent of its rate increases for certain HCBS be spent on direct care worker wages.[108]
- West Virginia set different wage pass-through requirements (ranging from 50 percent to 100 percent) for the amount of the rate increase that would be allocated to direct care workers providing services to beneficiaries in several of the State's waiver programs.[109]

We acknowledge that we are unable to present a State-by-State study of the impact of a specific minimum performance level on all State Medicaid programs and providers. The variability among HCBS programs (including staffing requirements, service definitions, and rate methodologies) poses challenges to performing and presenting a multi-State analysis of the allocation of Medicaid payments to direct care workers using existing available data, such as rate studies or cost reports. We also note that information from EVV system reporting would only pertain to use of personal care services or home health aide services (not homemaker services) and would not speak to rates. We agree that the reporting requirement we proposed, and are finalizing in this rule, at § 441.311(e) may generate standardized data that is more amenable to national comparisons.

We also believe that the reporting requirement at § 441.311(e) may yield important data that will support transparency around the portion of Medicaid payments being shared with direct care workers; such transparency in and of itself may well encourage States and providers to look critically at their rates and how they are allocated. Further, we believe that gathering and sharing data about the amount of Medicaid dollars that are going to the compensation of workers is a critical step in understanding the ways we can enact policies that support the direct care workforce and thereby help advance access to high quality care for Medicaid beneficiaries. However, we believe that a reporting requirement alone will not be as effective at stabilizing the direct care workforce.

We believe that compensation levels are a significant factor in the creation of a stable workforce, and that a stable workforce will result in better qualified employees, lower turnover, and safer and higher quality care. If individuals are attracted to the HCBS workforce and incentivized to remain employed in it with sufficient compensation, the workforce is more likely to be comprised of workers with the training, knowledge, and experience to meet the diverse and often complex needs of individuals with disabilities and older adults receiving HCBS. A stable and qualified workforce will also enable beneficiaries to access providers of the services they have been assessed to need. As noted in an earlier comment

[102] Section 12006 of the 21st Century Cures Act (Pub. L. 114–255) requires States to have EVV systems for Medicaid personal care services and home health care services.

[103] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

[104] See *https://www.revisor.mn.gov/statutes/cite/256B.85/pdf* for more information.

[105] See *https://casetext.com/regulation/illinois-administrative-code/title-89-social-services/part-240-community-care-program/subpart-t-financial-reporting/section-2402040-minimum-direct-service-worker-costs-for-in-home-service* for more information.

[106] Indiana Family and Social Services Administration, ''HCBS Enhanced FMAP Spending Plan: Direct Service Workforce Investment Grant Program,'' *https://www.in.gov/fssa/ompp/hcbs-enhanced-fmap-spending-plan/.*

[107] Massachusetts Executive Office of Health and Human Services, ''Strengthening Home and Community Based Services and Behavioral Health Services Using American Rescue Plan (ARP) Funding,'' *https://www.mass.gov/info-details/strengthening-home-and-community-based-services-and-behavioral-health-services-using-american-rescue-plan-arp-funding.*

[108] North Carolina Department of Health and Human Services, North Carolina ''January 2023 Quarterly Report for the Implementation of the American Rescue Plan Act of 2021, Section 9817—10% FMAP Increase for HCBS'' *https://medicaid.ncdhhs.gov/hcbs-spending-plan-narrative-january-2023/download?attachment.*

[109] West Virginia Department of Health and Human Resources, ''Spending Plan for Implementation of American Rescue Plan Act of 2021, Section 9817.'' *https://dhhr.wv.gov/bms/News/Documents/WV%20State%20ARP%20HCBS%20Spending%20Plan.pdf.*

summary, commenters almost unanimously agreed that the direct care workforce shortage is posing extensive challenges to HCBS access and quality of care. We believe that setting a minimum performance requirement that we have determined to be reasonable based on available information (and is supported by many commenters) is an appropriate exercise of our responsibility to oversee the sufficiency of Medicaid payments under section 1902(a)(30)(A) of the Act and States' allocation of resources under section 2402(a) of the Affordable Care Act.

We agree that the data from States that implemented wage pass-throughs through activities in their ARP section 9817 spending plans is relatively recent. However, we do not believe that data should be disqualified simply because it was generated recently; such data is likelier to provide a more current snapshot of States' Medicaid rates and the needs of their direct care workforce.

We also agree that States applied wage pass-through requirements to rate increases that they were implementing as part of their ARP section 9817 spending plans and that at least some of these wage pass-through requirements were temporary. As such, these percentages might not be as relevant to the selection of a minimum performance level as a permanent wage pass-through requirement applied to the entire Medicaid rate. That said, we do believe that these data are useful for illustrating that the need to support direct care workers' wages is relevant across the country, and that States and interested parties have not only identified increases in wages for direct care workers as a priority, but they have also identified allocating specific portions of Medicaid rates as an appropriate mechanism for addressing low wages. We echo a comment summarized earlier that the advantage of establishing a permanent minimum performance requirement is that it creates a stable support for the direct care workforce, rather than intermittent increases in compensation that are dependent on specific actions taken by State or Federal legislatures.

As observed by some commenters, the percent we proposed, at 80 percent, is slightly higher than the wage pass-through requirements set by Minnesota and Illinois. We believe that the 80 percent minimum performance level we are finalizing is informed by the current range of the wage pass-through requirements set by those States, but is set slightly higher to encourage further steps towards improving compensation for workers. We also note that we are not required to replicate precisely what certain States have done.

We continue to believe 80 percent is the feasible performance level to ensure that payments made for Medicaid HCBS are appropriately allocated to direct care workers' compensation to ensure sufficient providers for beneficiaries to access HCBS as approved in their person-centered plans. However, given that the 80 percent minimum performance is higher than what States have currently set in terms of permanent wage pass-through requirements, we will provide States with additional time to come into compliance with the 80 percent performance level. We are finalizing at § 441.302(k)(8) a modification to the applicability date for § 441.302(k) to indicate that States must comply with this requirement at § 441.302(k) beginning 6 years after the effective date of this rule, rather than 4 years as proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also finalizing additional flexibilities that States, at their option, may utilize to apply a different percentage for small providers and exempt certain providers that experience hardships from the State's calculation for meeting these performance levels. We also describe below an exemption of the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements.

Comment: A significant number of commenters stated that an 80 percent minimum performance level, if finalized, would not leave providers enough money for costs associated with administrative tasks, programmatic activities, supervision, technology, office or facility expenses, training, or travel reimbursement. Many commenters noted the 80 percent minimum performance level would result in unintended consequences—namely that affected HCBS providers would cut back on services, limit or stop serving Medicaid beneficiaries, or close altogether. A few commenters expressed concern that our proposal would result in fewer new providers enrolling as Medicaid HCBS providers. Many commenters worried that such reductions in available services or the provider pool would reduce, rather than increase, beneficiaries' access to high-quality HCBS. A few commenters worried that HCBS provider closures, as a result of the proposed policy, could result in more beneficiaries moving into institutional settings.

Several commenters also expressed the belief that the 80 percent minimum performance level would discourage innovation among providers. One commenter suggested that providers would be penalized if they relied on assistive technology, remote supports, or other technology solutions to support beneficiaries in lieu of human assistance.

Response: We thank commenters for their feedback. As discussed in greater detail later in this section, we are modifying the policy we proposed at § 441.302(k)(3) to establish certain exceptions from the minimum performance level, and to establish a 6-year effective date, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to exclude certain costs from the minimum performance level calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii) to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k).

We believe that these amended requirements will address some commenters' concerns about leaving providers sufficient administrative funds for certain personnel and administrative activities and will meet the needs of providers that are small or experiencing other challenges in meeting the minimum performance level.

We always encourage providers to find innovative ways to deliver services but believe that these services (even if delivered with the assistance of

technology or telehealth) at their core require direct care workers to provide them. It is difficult to imagine how strategies that do not aim to stabilize direct care worker wages would improve the efficacy or quality of these services. We do believe, however, that placing a limit on the amount of the Medicaid payment going to expenses other than direct care worker compensation could encourage innovative efforts to improve and streamline administrative activities.

In response to commenters' concerns that this proposal would have the unintended consequence of causing program cuts or provider closures, we do not believe this outcome would be the result from implementing the proposed minimum performance level. We believe that the current environment—in which providers and beneficiaries routinely struggle to find qualified direct care workers, and direct care workers leave the HCBS workforce for better-paying jobs—poses a significant threat to access and community integration because there are an insufficient number of direct care workers to meet beneficiaries' needs. In addition, the direct care worker shortage threatens beneficiary access to services and community integration as such shortage may lead to provider closures if providers are unable to find enough workers to deliver services. This shortage also threatens service quality through the loss of well-trained and experienced direct care workers, if left unaddressed. Further, we believe that the modifications we are finalizing to this requirement will help to mitigate these concerns.

Comment: Some commenters (including beneficiaries, providers, labor organizations, disability or legal advocacy organizations, and research and policy organizations) agreed that 80 percent was an appropriate or reasonable payment adequacy requirement. A couple of these commenters based their support on personal experience, including a few who indicated that they were providers, and stated that 80 percent was an achievable minimum performance level. A few commenters pointed out that the medical loss ratio (MLR) for managed care is 85 percent. One commenter suggested that the minimum performance level be increased to 85 percent to align with the MLR. One commenter recommended that the 80 percent standard should account for necessary administration of HCBS programs, including training. This commenter stated that, if it does not account for necessary administration, the payment rates that States and managed care programs have established are likely too low. The commenter also recommended that, once the requirement is implemented, we review whether the percentage should be higher than 80 percent.

A number of commenters suggested alternative, lower minimum performance levels. Several commenters (including providers, State Medicaid agencies, a labor organization, and an advocacy organization) suggested minimum performance levels ranging from 70 percent to 75 percent. A few of the commenters who recommended 75 percent self-identified as providers and believed that 75 percent was achievable based on their own experiences and expenditure calculations. One commenter recommended we mandate a 72.35 percent minimum performance level and change the definition of compensation to exclude the 7.65 percent employer share of FICA taxes for direct care workers; the commenter believed this would reduce confusion regarding employers' shares of taxes and align the definition of compensation with that used by some States. A few commenters recommended 70 percent based on experience with rate studies or provider expenditures in their States.

Several commenters, including providers and commenters representing State agencies, recommended setting a minimum performance level at either 60 percent or 65 percent, based on the commenters' personal experience running a provider agency or overseeing provider agencies. One commenter suggested a minimum performance level of 60 percent based on a hypothetical analysis of one State's HCBS rates and projected expenditures.

While not making specific recommendations, several commenters (mostly providers and State Medicaid agencies) submitted comments that included anecdotal data of what providers spend on compensation; these percentages ranged from 55 to 81 percent.

Response: We thank commenters for engaging in this issue, including sharing their own experiences allocating Medicaid payments. While we found the feedback provided by commenters instructive, both the range of recommendations and the anecdotal nature of information supporting most of the recommendations prevented us from relying on the recommendations to finalize additional modifications to the proposed minimum performance at the provider level requirement at § 441.302(k)(3).

We do not agree that we should increase the minimum performance level upward to match the 85 percent MLR required in managed care as the MLR is a calculation and associated reporting requirement for Medicaid managed care contracts in accordance with § 438.8 and is not specific to HCBS.

Additionally, as discussed previously and in more detailed responses below, we are finalizing some modifications related to the exclusion of certain costs, the inclusion of clinical supervisors in the definition of direct care workers, and options for a small provider minimum performance level and hardship exemptions for some providers that will change somewhat the impact of the minimum performance level. Further, we are modifying the policy we proposed at § 441.302(k) to establish certain exceptions from the minimum performance level proposed at § 441.302(k)(3), and requiring States to comply beginning 6 years after the effective date of this final rule, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement go into effect. We believe these modifications are necessary to balance the goal of stabilizing the direct care workforce with the operational realities faced by providers of varying sizes and locations.

Comment: A few commenters suggested that the minimum performance level, if finalized, should be applied at the State level, rather than the provider level. Commenters suggested that applying the minimum performance level at the State level would create some flexibility, as this would require only that all providers in the State meet the minimum performance level in aggregate. However, a few other commenters recommended that we clarify that the minimum performance level applies at the provider level.

Response: We clarify that we intended to propose that the minimum performance level policy would apply at the provider level, meaning that the State must ensure that each provider spends Medicaid payments they receive for certain HCBS on direct care worker compensation in accordance with the minimum performance level requirement. As noted previously, we believe it is important for States to hold providers individually accountable for how they allocate their Medicaid payments and are finalizing other policies, discussed below and elsewhere in this section II.B.5. of the final rule, for States to accommodate providers that need additional flexibility. We note that there was an error in the heading of § 441.302(k)(3), which was proposed

as ''Minimum performance at the State level.'' We apologize for any confusion this may have caused; we believe that most commenters, based on their comments, understood the minimum performance requirement to apply at the provider level. Accordingly, we are finalizing § 441.302(k)(3) with modification by revising the heading for § 441.302(k)(3) to read ''Minimum performance at the provider level,'' as it was originally intended to read.

Additionally, to ensure that it is understood that the minimum performance level that must be met by the State is calculated as the percentage of total payment (not including excluded costs, which are discussed in greater detail in section II.B.5.d. of this final rule) to a **provider** for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by **the provider's** total compensation to direct care workers. (New text in bold font).

Comment: A significant number of commenters worried that a national minimum performance level, regardless of the percentage, would have a disparate impact on providers that are small, new, in rural or underserved areas, or run by/for people from specific underserved communities (such as indigenous people) or individuals for whom English is a second language. Some commenters worried that the proposal favors large providers and would lead to consolidation of providers. A few other commenters worried that this would mean that beneficiaries would have fewer choices of providers and have to work with larger corporate providers. One commenter worried that a national minimum performance level would have a disparate impact on agency providers (which may have more overhead costs), as opposed to providers of self-directed services.

A number of commenters requested that if we finalize a national payment adequacy requirement, we include additional flexibilities to minimize unintended consequences on certain providers, particularly small and rural providers. One commenter suggested that we allow for ''hardship exemptions'' on a case-by-case basis. One commenter suggested that we allow States to exempt providers that pay workers 200 percent of the Federal Poverty Level. Another commenter suggested that we exempt States from the payment adequacy requirement if the State has a minimum hourly base wage of $15 per hour applicable to direct care workers delivering the affected services.

Other commenters recommended adjustments to the national minimum performance level, rather than exemptions. A few commenters suggested that we allow for a variable payment adequacy requirement or for ''scaling'' of the minimum performance level, adjusted for different provider sizes or different types of services. A few other commenters recommended requiring a range to identify rates, which could vary by provider size, number of Medicaid beneficiaries served, rural or urban status, hardship status (risk of closure), or other characteristics. One commenter suggested the rate could vary by delivery system or service type. A number of commenters recommended that we allow States to set their own payment adequacy requirement.

A small number of commenters raised concerns that requiring a minimum performance level would conflict with 25 U.S.C. 1641, governing how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) may use Medicare and Medicaid funds, and other applicable laws providing for Tribal self-governance and self-determination. One commenter recommended that we exempt IHS and Tribal health programs from the requirement.

Response: We believe that at least some of commenters' concerns about provider impact may be alleviated by some of the modifications we are finalizing to our proposed policy in this section II.B.5. of the final rule. In particular, we are excluding travel costs from the calculation of the minimum performance level, as increased travel expenses were cited as a primary concern for rural providers. (We refer readers to the discussion of the definition of compensation and excluded costs in section II.B.5.d. of this rule, below.)

We note that the purpose of this proposal is not to set a particular wage for direct care workers, but to ensure that Medicaid payments are being allocated in ways that promote efficiency, economy, and quality of care. We believe that all States are accountable to this requirement and should hold their providers accountable. However, we also agree that some small providers may experience additional challenges in meeting a payment adequacy requirement, as any fixed costs must be covered by a smaller pool of revenues than for larger providers, and small providers have fewer opportunities for administrative efficiencies than larger providers do. We share commenters' desires that the minimum performance level not have a disparate impact on small providers, new providers that may still be developing their processes, providers that may, for various reasons, have additional administrative tasks (such as an increased need for interpreter or translation services), or providers that face disparately high costs, such as providers that may have to pay for temporary lodging for direct care workers delivering services to clients in extremely rural areas.

While we are finalizing a minimum performance level at § 441.302(k)(3)(i) as previously discussed that States must apply to most of their providers, we also agreed with commenters' suggestions. We are finalizing our policy with modifications at § 441.302(k)(3)(ii) to provide that States may apply a different minimum percentage to small providers that the States develop in accordance with requirements at § 441.302(k)(4). These modifications at § 441.302(k)(3)(ii) and (k)(4) will allow States the option to require a reasonable number of small providers, as defined using reasonable, objective criteria set by the State through a transparent process that must include public notice and opportunities for comment from interested parties, to meet a different minimum performance level. This separate minimum performance level would also be set by the State based on reasonable, objective criteria through a transparent process that must include public notice and opportunities for comment from interested parties. In order to apply a small provider minimum performance level, States must ensure it is supported by data or other reasonable factors in the State. We also note that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) (discussed in section II.B.7. of this rule) for providers subject to the small provider minimum performance level.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(i), to require that States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time.

We also agree with commenters that some providers may experience hardships with meeting a payment adequacy requirement because, for instance, they are new to serving Medicaid beneficiaries and thus have not had time to develop administrative efficiencies. Additionally, we agree that special attention needs to be paid where a provider may be at risk of closure and could cause beneficiaries to lose access to HCBS in a particular area. We also agree that States are best positioned to identify the nature of the hardships and which providers are experiencing these hardships. As a result, we are finalizing a modification at § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded from the State's calculation of the minimum performance level at § 441.302(k)(3). We note that we expect that most providers would be subject to a hardship exemption on a temporary basis, and that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) for providers with hardship exemptions.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(ii) to require that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

We plan to issue guidance on both the small provider performance level and the hardship exemption and encourage States to consult with CMS as they develop their criteria. However, we note that, for States in which a small proportion of providers (less than 10 percent of the total number of providers of services at § 440.180(b)(2) through (4)) qualify for either the small provider performance level or a hardship exemption, CMS may waive the requirements, at § 441.302(k)(6)(i)(D), for States to report on a plan for small providers to meet the minimum performance level at § 441.302(k)(3)(i) within a reasonable period of time, and at § 441.302(k)(6)(ii)(C), for States to report on a plan for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We are finalizing this waiver at § 441.302(k)(6)(iii).

In addition, we are modifying the date for when States must comply with the requirements at § 441.302(k) to be beginning 6 years after the effective date of the final rule, rather than the 4 years we had proposed. (We refer readers to our discussion in II.B.5.h. of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement goes into effect.

Finally, we are persuaded by commenters who raised concerns about interactions between statutory requirements for IHS and certain Tribal health programs health programs subject to 25 U.S.C. 1641 and the proposed requirement at § 441.302(k). Congress has already passed laws, such as 25 U.S.C. 1641, specifying how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) are to use their Medicaid collections. Because Congress has already specified how such funds must be used, we are finalizing an exemption at § 441.302(k)(7) to the HCBS payment adequacy requirements at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641.

After consideration of the comments received, we are finalizing § 441.302(k)(3) with modifications, as well as finalizing new requirements at § 441.302(k)(4), (5), and (6). The requirements we are finalizing with modifications are as follows:

We are finalizing § 441.302(k)(3) with several modifications to retitle the requirement as *Minimum performance at the provider level* and clarify the components of the required calculation and the services that fall within this requirement. We also made modifications at § 441.302(k)(3) to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641). As finalized, § 441.302(k)(3) specifies that, **except as provided in paragraphs (k)(5) and (7)**, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) *to a provider* for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the *provider's* total compensation to direct care workers. (New text in bold font).

We are modifying the language at § 441.302(k)(3)(i) to read that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii). We are finalizing a new requirement at § 441.302(k)(3)(ii) to read that at the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

We are redesignating the applicability date we proposed at § 441.302(k)(4) as § 441.302(k)(8), as discussed further in section II.B.5.f. of this rule. We are finalizing a new § 441.302(k)(4) and adding new paragraphs (i) and (ii) to provide an option for States to develop reasonable, objective criteria through a transparent process to identify small providers to meet the State-defined small provider minimum performance level; require that the transparent process for developing criteria to identify providers that meet the small provider minimum performance level must include public notice and opportunities for comment from interested parties; and require that the small provider minimum performance level be set based on reasonable, objective criteria the State develops through a transparent process that includes public notice and opportunities for comment from interested parties.

We are finalizing a new § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing

extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded by the State from its calculation of the State's compliance with the minimum performance level at § 441.302(k)(3).

We are finalizing a new provision at § 441.302(k)(6) to require States to report on their development and use of the small provider minimum performance level and hardship exemption. Specifically, at § 441.302(k)(6)(i), States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services at § 440.180(b)(2) through (4) that qualify for the small provider performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time. We are also requiring at § 441.302(k)(6)(ii) that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services at § 440.180(b)(2) through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. Additionally, we are finalizing a waiver at § 441.302(k)(6)(iii) that specifies that CMS may waive the reporting requirements in paragraphs (6)(i)(D) or (6)(ii)(C), as applicable, if the State demonstrates it has applied the small provider minimum performance level at § 441.302(k)(4)(ii) or the hardship exemption at § 441.302(k)(5) to a small proportion of the State's providers.

Finally, we are finalizing a new § 441.302(k)(7) specifying that the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at § 441.302(k).

c. Other Services (§ 441.302(k)(3))

We considered whether the requirements we proposed at § 441.302(k)(3)(i) related to the percent of Medicaid payments going to the direct care workforce should apply to other services in addition to homemaker, home health aide, or personal care services (as set forth at § 440.180(b)(2) through (4)), such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. However, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce. We requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities, we requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services.

We also requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for each specific service that this provision should apply if this provision should apply to other services at § 440.180(b): (1) 65 percent; (2) 70 percent; (3) 75 percent; and (4) 80 percent. Specifically, we requested that commenters respond separately on the minimum percentage of payments for services delivered in a non-residential community-based facility, day center, senior center, or other dedicated physical space, which would be expected to have higher other indirect costs and facility costs built into the Medicaid payment rate than other HCBS. If an alternate minimum percentage is recommended, we requested that commenters provide the rationale for that minimum percentage.

We further clarified that we were requesting comment on a different range of options for the other services at § 440.180(b) than for the services at § 440.180(b)(2) through (4) because we expect that some of the other services at § 440.180(b), such as adult day health and day habilitation services, may have higher other indirect costs and facility costs than the services at § 440.180(b)(2) through (4). We also requested that commenters respond separately on the minimum percentage of payments for facility-based residential services and other facility-based round-the-clock services that have other indirect costs and facility costs that would be paid for at least in part by room and board payments that Medicaid does not cover. If a minimum percentage is recommended for any services, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested additional clarification on how the services we proposed to be included in the requirements at § 441.302(k)(3) were selected. One commenter suggested that we only apply the minimum performance requirement to personal care services. The commenter suggested we could align the requirement with the EVV system reporting requirement,[110] which applies to personal care services, including personal care services delivered as part of habilitation services.

Response: The priority of this proposal is to support the direct care workforce, and to this end we have focused on accountability for services that rely on direct care workers to perform the core activities. As noted in the background discussion of this provision and in previous responses, the services subject to the minimum performance requirement were selected because they are unlikely to have facility costs as part of the rate or as a component of the core service. We also note that the data we reviewed when determining an appropriate minimum performance requirement focused on home-based services, not facility-based services. Additionally, as identified in an analysis performed by CMS, the three services we proposed to be subject to this requirement at § 441.302(k) fall within the taxonomy of home-based services, which are both high-volume and high-cost.[111] Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. Given these similarities among homemaker, home health aide, and personal care

[110] Section 12006 of the 21st Century Cures Act (Pub. L. 114–255).

[111] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

services, we cannot find a justification for removing homemaker and home health aide services from this requirement.

Comment: A few commenters requested that we provide a more specific definition of personal care services. Commenters noted that States do not always use HCBS taxonomies consistently, and personal care services can be applied to a different constellation of activities in different waivers. Similarly, one commenter noted that the lack of definitions in the proposed rule for homemaker, home health aide, and personal care services is problematic because States do not use these terms consistently and use a variety of different terms to describe these services.

Response: We understand that States have service definitions for homemaker, home health aide, and personal care services that differ from the definition of homemaker, home health aide, and personal care services in the section 1915(c) waiver Technical Guide [112] and that States do not always use these terms consistently. However, codifying definitions of homemaker, home health aide, and personal care services would have broad implications for State's HCBS programs that would extend beyond the HCBS payment adequacy requirements in this final rule. We will provide additional subregulatory guidance and technical assistance to aid in implementation of the HCBS payment adequacy requirements and may consider addressing in future rulemaking.

Comment: Many commenters responded to our solicitation for comment on whether we should include habilitation services in the services subject to the minimum performance requirement. Most commenters who responded did not believe that habilitation services should be included in the requirement. They echoed our concerns that these services are likelier to include at least some activities in a provider-operated facility or residential setting, which changes the expected costs of providing and allocation of the payment for these services.

Much of the public feedback around habilitation services focused on the facility or residential portion of those services. Commenters noted that rent, utilities, property maintenance, and other costs associated with residential or facility-based services can vary significantly. One commenter suggested that if residential habilitation was included in the minimum performance requirement, the minimum performance level for residential habilitation should be set at 75 percent to account for additional administrative costs. A few other commenters suggested that a different minimum performance level should be set for habilitation services, if included, but did not specify a particular percentage.

Some commenters also suggested that residential services might require more, or different staffing levels, as well as different types of staff than home-based services, which might change the necessary minimum performance level. Commenters disagreed, however, on whether these staffing differences would necessitate a higher or lower minimum performance level than for in-home services, and commenters did not recommend a percentage to specifically address the perceived differences in staffing. One commenter objected to any discussion of residential settings, out of concern that this would appear to promote congregate settings in violation of the home and community-based settings requirements; the commenter stated that all services should be provided in the community.

Several commenters recommended that we not apply the minimum performance level at § 441.302(k)(3)(i) to habilitation services and encouraged us to collect data on the percent of payments for habilitation services.

Response: We believe that the comments we received affirm our decision not to apply the HCBS payment adequacy policy we are finalizing at § 441.302(k) to habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) due to the number of additional or variable expenses associated with facility-based services. While outside the scope of this final rule, we refer readers to and our requirements for, and the criteria of, a home and community-based setting at § 441.301(c)(4) and (5).

We agree with commenters that additional data collection on habilitation services would be useful. Please refer to the discussion of § 441.311(e) in section II.B.7. of this rule, below.

Comment: Although not necessarily supporting the inclusion of habilitation services in the minimum performance requirement, commenters worried about the impact on beneficiaries receiving habilitation services, who are largely individuals with intellectual or developmental disabilities or behavioral health needs. Some commenters stated that direct care workers who had been providing habilitation services might switch to working for providers that offer homemaker, home health aide, or personal care services because they believed that the requirements at § 441.302(k), if finalized, would lead to increased wages paid to these workers or to Medicaid agencies allocating more resources for these services. One commenter speculated that, if a lower minimum performance level was set for residential habilitation, this would encourage more services to be provided in congregate settings because providers would try to take advantage of the lower minimum performance level. Several commenters that provided services to people with intellectual disabilities and people with mental illness suggested we amend § 441.302(k)(3)(i) to specify an exclusion for direct care workers (or direct service professionals) providing services for individuals with intellectual and developmental disabilities or severe mental illness, as they believed that many of these services are delivered as facility-based habilitation services; the commenters were concerned that these providers have additional non-compensation expenses that are not considered by the proposal, and that it was unclear whether facility-based services were already excluded from the proposal.

Response: We agree that, by excluding habilitation services from this requirement, we are excluding services that are used more frequently by certain populations. This was not our intent, and we do not intend to explicitly exclude certain services from this requirement on the basis of the population receiving the service. However, as noted above, because of differences in these services, we do not believe we can set an appropriate minimum performance level for these services at this time. Although we are not requiring that habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) be included in the minimum performance requirement, States are able to set wage pass-through requirements of their own for such services to promote the stability of the workforce; we also believe that States may naturally adjust rates or wages in other services in response to the implementation of the minimum performance requirement for homemaker, home health aide, and personal care services.

[112] See Centers for Medicare & Medicaid Services, ''Application for a § 1915(c) Home and Community Based Waiver: Instructions, Technical Guide and Review Criteria.'' January 2019. Available *at https://wms-mmdl.cms.gov/WMS/help/35/Instructions_TechnicalGuide_V3.6.pdf.*

Comment: One commenter expressed a concern that the minimum performance requirement would apply to skilled nursing facilities. Several commenters requested that we clarify in § 441.302(k)(3)(i) that direct care workers would be excluded from the minimum performance requirement if they are providing services in residential settings. One commenter requested that we clarify that assisted living facilities or assisted living services are not included in the minimum performance requirement, while another commenter raised concern about a lack of clarity about whether the requirement applies to assisted living facilities.

Response: The requirements we are finalizing in this section II.B. of this rule only apply to HCBS, and the minimum performance requirement at § 441.302(k)(3) applies specifically to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4). However, while the minimum performance requirement would not apply to institutional services (because those are not HCBS), we decline to explicitly restrict the application of this requirement on the basis of different community-based settings. As we noted in prior responses, we selected homemaker, home health aide, and personal care services because these are typically services delivered in the home. However, we acknowledge that beneficiaries may live in different residential settings that are considered homes, and that these services may be bundled with other services delivered to beneficiaries in residential settings.

Comment: A number of commenters requested that we add private duty nursing to the services subject to the minimum performance requirement.

Response: We believe that at least some commenters may be referring to private duty nursing as defined at section 1905(a)(8) of the Act and § 440.80 of our regulations. As discussed in greater detail below in section II.B.5.g. of this rule, we are not planning to require that the minimum performance level be applied to services authorized under section 1905(a) at this time. We note that home health aide services, included in § 440.180(b)(3) but authorized as part of a section 1915(c) waiver, are included in the minimum performance requirement. It is possible that some services that commenters are characterizing as ''private duty nursing'' may fall within the category of a section 1915(c) home health aide service, even as we acknowledge that Federal requirements for private duty nursing specify that these are skilled care services provided by a registered nurse or licensed practical nurse.

Comment: A few commenters recommended that we apply the minimum performance requirement to a number of other services that are experiencing staffing shortages, including: job supports; respite provided in the community; community habilitation services; in-home cognitive rehabilitation therapy; and in-home physical, occupational and speech therapy services. A few commenters suggested, without specifying which services, that the minimum performance requirement ought to be expanded to other services, or that it would be easier to administer if applied to a broader array of services than just homemaker, home health aide, and personal care services.

Response: We thank the commenters for their suggestions and will take them under consideration for potential future rulemaking. As we noted earlier in this section of the final rule, we selected homemaker, home health aide, and personal care services because they are services for which we expect that the vast majority of payment to be comprised of compensation for direct care workers. Further, they are high-volume and high-cost services,[113] and as a result, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. We note that States are able to apply wage pass-through requirements to additional services if they choose.

After consideration of the comments received, we are finalizing our proposed language at § 441.302(k)(3) to apply the minimum performance requirement to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

d. Definition of Compensation (§ 441.302(k)(1)(i))

At § 441.302(k)(1)(i), we proposed to define compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we proposed to define compensation to include the employer share of payroll taxes for direct care workers delivering services under section 1915(c) waivers. We considered whether to include training or other costs in our proposed definition of compensation. However, we determined that a definition that more directly assesses the financial benefits to workers would better ensure that a sufficient portion of the payment for services went to direct care workers, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We requested comment on whether the definition of compensation should include other specific financial and non-financial forms of compensation for direct care workers.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters noted support for our definition of compensation and encouraged us to finalize the definition as proposed.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that workers' overtime pay would not be considered part of the definition of compensation.

Response: Our definition of compensation as proposed at § 441.302(k)(1)(i)(A) included salary, wages, ''and other remuneration as defined by the Fair Labor Standards Act'' and its regulations. As the Fair Labor Standards Act includes overtime pay in its definition of wages, overtime pay therefore is included in our definition of compensation as well.

Comment: Many commenters supported the inclusion of health and dental insurance and sick leave in the definition of benefits at § 441.302(k)(1)(i)(B). A few commenters requested that life insurance, disability insurance, and retirement contributions also be added to this definition. Several commenters also requested clarification as to whether paid time off was included in the definition of compensation, and a few suggested that it should be included.

One commenter noted that our definition of compensation was too broad, particularly the use of the term ''such as'' when describing the inclusion of benefits. The commenter expressed concern that employers could over-include items in compensation by calling them ''benefits.'' One commenter worried that if too many benefits were included in compensation, this would reduce workers' take-home pay.

One commenter expressed concerns that it will be difficult for State

[113] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

Medicaid agencies to quantify benefits included in direct care worker compensation.

Response: We believe that all the items identified by these commenters—life insurance, disability insurance, retirement, and paid time off—would be reasonably considered part of compensation. In its glossary, the Bureau of Labor Statistics (BLS) defines compensation as ''employer costs for wages, salaries, and employee benefits,'' and notes that the National Compensation Survey includes the following categories in employee benefits: insurance (life insurance, health benefits, short-term disability, and long-term disability insurance); paid leave (vacations, holidays, and sick leave); and retirement (defined benefit and defined contribution plans).[114] We believe the items suggested by the commenters align with our intent and are reflected by a common understanding of ''benefits'' as exemplified in the BLS glossary.

To help clarify what is meant by ''benefits,'' we are modifying the language we proposed at § 441.302(k)(1)(i)(B) in this final rule. We are retaining ''health and dental benefits'' but also are adding to the list ''life and disability insurance.'' We note that the definition used by BLS simply refers to health benefits, life insurance, and different types of disability insurance collectively as ''insurance,'' but we believe that spelling out examples of types of insurance is useful here. In the context of our definition, ''insurance'' listed by itself might be unclear (since it could be confused with other types of insurance that would not be considered compensation, like employers' liability insurance), and we wish to make it clear that the benefits must benefit the employee directly. We are also modifying ''sick leave'' to the broader term ''paid leave,'' as this should be understood to cover any time for which the employee is paid, whether it be for sick leave, holidays, vacations, and so forth. We also are adding retirement, which we believe is also a useful blanket term for different types of retirement plans or contributions on the employee's behalf. After consideration of public comments, we are finalizing § 441.302(k)(1)(i)(B) with modification to specify that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

When proposing that benefits be included in the definition of compensation, we intentionally included the phrase ''such as'' to indicate that the examples of benefits provided in the definition is not exhaustive. We did not attempt to list all possible benefits in the regulatory definition, as we believe that would run the risk of creating a definition that is too narrow. We plan to provide technical assistance to States on how to help ensure that providers are applying a reasonable definition of ''benefits'' and are only counting expenses thereunder that would reasonably be considered an employee benefit.

Comment: Some commenters supported including employers' share of payroll taxes in the definition of compensation at § 441.302(k)(1)(i)(C). However, several commenters recommended that this expense be removed from the definition, as these are not expenses included in employees' take-home pay and are the responsibility of the employer. Several commenters requested that employers' contributions to worker's compensation and unemployment insurance be included in the definition of compensation.

Response: It is our intent to include employers' payroll tax contributions for unemployment insurance and workman's compensation (as well as payments required by the Federal Insurance Compensation Act) under § 441.302(k)(1)(i)(C) and thus as part of our definition of compensation for the purposes of the requirements at § 441.302(k). While not necessarily paid directly to the workers, these expenses are paid on their behalf. We also note, for instance, that per the BLS, the National Compensation Survey calls these payroll taxes ''legally mandated employee benefits'' and includes them as part of the definition of ''employee benefits'' for the purposes of determining compensation.[115] We plan to provide technical assistance to States on how to help ensure that providers are including payroll tax contributions for unemployment insurance and workman's compensation when reporting on compensation to workers.

Comment: Several commenters noted support for including tuition reimbursement in the definition of compensation. Several commenters suggested that costs associated with continuing education should also be included as compensation.

Response: We appreciate the commenters' support. We believe the term ''tuition reimbursement'' is broad enough to cover a variety of scenarios in which a provider may choose to reimburse a worker for tuition costs incurred either prior to or during their period of employment.

Comment: A number of commenters supported either including training in the definition of compensation or excluding training from the administrative and other expenses that are not considered compensation under this rule. Some of these commenters noted that certain types of services or programs might involve additional training for staff, such as services delivered to beneficiaries with complex needs. One commenter suggested that raising workers' wages will not necessarily increase service quality if it is not accompanied by better training for staff. Another commenter worried that providers could decide to cut back on training in order to meet the minimum performance level, which could endanger workers. Commenters cited examples of trainings, including in-service trainings and cardiopulmonary resuscitation trainings, as being critical for caring for beneficiaries. Several commenters suggested that direct care workers who serve beneficiaries with higher-acuity needs may require additional training than other direct care workers.

Commenters suggested that, if training was included in the definition of ''compensation'' (or was excluded from administrative and other expenses that are not considered compensation under this rule), training should be defined to include time spent in training, training materials, trainers, and training facilities.

Conversely, one commenter stated that if training was included in the definition of compensation, the minimum performance level should be adjusted further upward (above 80 percent). One commenter stated that if training was included as compensation to direct care workers, this cost should be restricted to the time workers spend in training and not include training materials and payments made to the trainer. One commenter stated that the cost of onboarding new staff should not be considered ''training.'' One commenter expressed skepticism that training was truly a major cost for providers.

Response: We clarify that the time direct care workers spend in training would already be accounted for in the definition of compensation. We agree with commenters on several points: that training is critical to the quality of services; that training needs might vary across (or even within) States' Medicaid HCBS programs, depending on the nature of the services or the acuity of

[114] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

[115] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

the beneficiaries served; that training costs may be difficult to standardize; and that worker training is essential to quality, as well as the health and safety of both the direct care worker and the beneficiary. We do not want to encourage providers to reduce training to cut administrative costs.

However, we are also reluctant upon considering comments to treat all training costs as ''compensation'' to the direct care worker. Trainings, as commenters noted, are often required as part of the job and may vary depending on the services or the needs of the beneficiaries they serve. We are concerned that including training costs in the definition of compensation could mean that direct care workers with higher training requirements would see more of their ''compensation'' going to training expenses, which could cause them to receive lower take-home pay than colleagues with fewer training requirements.

Rather than include training costs in the definition of compensation at § 441.302(k)(1)(i)), we are creating a new definition at § 441.302(k)(1)(iii) to define excluded costs for the purposes of the payment adequacy requirement at § 441.302(k)(3). Excluded costs are those that are not included in the State's calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers required at § 441.302(k)(3). In other words, States would ensure providers deduct these costs from their total Medicaid payments before performing the calculation. We are specifying at § 441.302(k)(3)(iii) that excluded costs are limited to: training costs (such as costs for training materials or payment to qualified trainers); travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and costs of personal protective equipment for direct care workers. This would mean that providers could deduct the total eligible training expenses, travel costs, and personal protective equipment for direct care workers from the total payments they receive for homemaker, home health aide, and personal care services before the compensation percentage is determined for the minimum performance level as required under § 441.302(k)(3).

The training costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the training itself (such as qualified trainers and materials) and are distinct from the compensation paid to a direct care worker participating in the training as part of their employment duties under § 441.302(k)(1)(i).

Comment: One commenter requested clarification as to whether travel expenses were part of the definition of ''compensation.'' Many commenters stated that travel or transportation expenses should be included in the definition of compensation, or not treated as an administrative expense. Many commenters also expressed the concern that it would be difficult to cover the cost of travel as part of administrative expenses and other expenses that are not considered compensation under this rule, especially in rural areas where direct care workers may have to travel large distances to visit clients or transport them to appointments. A few commenters worried that if travel were considered an administrative expense, providers would be reluctant to serve beneficiaries outside of a narrow service area to save on travel expenses. A number of direct care workers shared experiences of having to pay for gas out-of-pocket when they transported beneficiaries and having to shoulder the financial burden of wear-and-tear on their cars. One commenter noted that travel costs are frequently included in rate calculations. Several commenters suggested that ''travel,'' if included in the definition of compensation, should include time workers spent travelling, mileage reimbursement, and public transportation reimbursement.

However, a few commenters specifically noted that travel should not be considered part of the definition of compensation. One commenter noted that due to the variability of travel costs, it would be difficult to include travel in a standardized definition of compensation.

Response: We agree with commenters that certain travel-related expenses should not be considered compensation to direct care workers. Travelling to beneficiaries' homes or assisting them in the community is an essential function of the job, and thus, travel reimbursement is not for the direct care worker's personal benefit.[116] We also agree that travel costs will vary significantly by region and even by beneficiary. We too are concerned that including travel in the definition of compensation could mean that direct care workers with higher travel demands would see more of their compensation going to travel, which could cause them to receive lower take-home pay than colleagues with lower travel demands.

At the same time, we are aware of the critical importance of travel to the delivery of these services and do not want to create unintended consequences. We are persuaded by commenters' concerns that counting travel as an administrative expense could induce some providers to stop serving beneficiaries that live outside certain regions. We would also be concerned if direct care workers were expected to shoulder the financial burden of travel out-of-pocket, as appears to be happening in some cases now.

To preserve beneficiary access to services and avoid burden or disparate impact on beneficiaries, direct care workers, and providers in rural or underserved areas, we are excluding travel costs in this final rule from the calculation of the percent of Medicaid payments for certain services going to compensation for direct care workers. This means that providers can deduct the total travel expenses for direct care workers that providers incur from the total Medicaid payments they receive before the compensation percentage is determined.

In order to reflect the exclusion of travel costs from the payment calculation, we are adding a new § 441.302(k)(1)(iii)(B) that specifies that travel costs (such as reimbursement for mileage or public transportation) may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k)(3). The travel costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the travel itself (such as reimbursement for mileage or public transportation) and are distinct from the compensation paid to a direct care worker for any time spent traveling as part of their employment duties under § 441.302(k)(1)(i). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters expressed concerns about covering the cost of vehicle purchases or maintenance as an administrative expense. One commenter suggested that if travel were included in the definition of compensation, it should include the cost of vehicles or vehicle maintenance.

Response: We note that the payment adequacy requirement applies to Medicaid payments for homemaker services, home health aide services, and personal care services. In our

[116] *See* 29 U.S.C. 207(e)(2) (permitting employers to exclude ''reasonable payments for traveling expenses'' when determining an employee's regular rate of pay under the FLSA); *see also* 29 CFR 778.217 (same).

experience, it is rare that providers would be purchasing vehicles for these services or that vehicle purchases would be part of the rate. We do not expect that the cost of vehicles would be part of excludable travel costs, but we plan to provide technical assistance to States on a case-by-case basis.

Comment: Several commenters noted that personal protective equipment (PPE) for staff should be counted as compensation or that these expenses should not count as an administrative expense. Several direct care workers also shared experiences of having to provide their own PPE during the COVID–19 public health emergency (PHE), and the harms caused to them both physically and financially by contracting COVID–19.

Response: We agree, particularly given the recent experience with the COVID–19 PHE, that PPE should not be treated as an administrative expense. Providing direct care workers with adequate PPE is critical for the health and safety of both the direct care workers and the beneficiaries they serve. We also do not believe that direct care workers should have to pay for PPE out-of-pocket or that it is considered part of their compensation.

Similar to our approach with training and travel above, we are excluding the cost of PPE for direct care workers in this final rule from the calculation of the percentage of payments spent on compensation for direct care workers. In order to reflect the exclusion of PPE costs from the payment calculation, we are adding new §§ 441.302(k)(1)(iii) that specifies that PPE costs for direct care workers may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters requested clarification as to what activities and costs would not be counted as compensation under this rule. A significant number of commenters described other activities or costs they believed should count as compensation, should not be counted as part of non-compensation costs, or simply would not be affordable if providers were left with only 20 percent of the Medicaid rate for personal care, homemaker, or home health aide services. These included costs associated with:

- Administration, including wages paid to administrative and human resources staff, who perform activities such as billing, payroll processing, contracts management, or scheduling client appointments;
- Other business expenses, such as organization accreditation, liability insurance, and licensure.
- Human resources activities, including recruitment activities or advertising for new staff.
- Background checks, drug screening, and medical screening for employees (such as testing staff for tuberculosis prior to starting service delivery).
- Office space and utilities (especially for providers that are required by State law to have a physical office).
- Office supplies, medical supplies, food, or other out-of-pocket expenses for clients, IT, mobile devices (including those used for electronic visit verification), and staff uniforms.
- Non-cash awards to direct care workers, such as parties, staff retreats, gifts for staff, Employee Assistance Programs, or other wellness programs.
- Recordkeeping and complying with quality measures and other reporting requirements.

Commenters noted that these costs are essential to operating a service organization. Commenters also noted that at least some of these costs, such as office space, are fixed costs, or costs that are beyond providers' control.

Response: We believe that most of the items listed above would qualify as administrative expenses, but some activities may be considered compensation or excluded costs under the definitions we are finalizing at § 441.302(k)(1), depending on the context. We clarify that, by designating activities as administrative and other expenses that are not considered compensation under this rule, we do not suggest that they are inessential. However, we also believe, as has been discussed in prior responses, that a vast majority of the payment for homemaker, home health aide, and personal care services must be spent supporting core activities that are performed by direct care workers. As noted by commenters in earlier comment summaries, we also do not want States to allow providers to add so many non-cash benefits to a worker's compensation that their take-home pay is excessively reduced. We plan to provide technical assistance to States to help ensure that States understand what are considered administrative and other expenses that are included in the percentage calculation and what are considered excluded costs.

Comment: Several commenters raised concerns that wages spent for staff conducting certain beneficiary support activities would not be considered compensation. These activities include completing person-centered service plans or scheduling client appointments.

Response: We believe that some of the activities described by commenters are activities that would be performed by staff who would classify as direct care workers, as we proposed to define at § 441.302(k)(1)(ii). We refer readers to our discussion of our proposed definition of direct care workers in the next section below. We plan to provide technical assistance to help States appropriately identify direct care workers and, separately, administrative staff, administrative activities, and other costs that are not considered compensation under this rule.

Comment: A few commenters expressed the concern that employers will shift more administrative activities to direct care workers, to avoid having these activities fall under administrative and other costs that are not considered compensation under this rule. The commenter stated that this could increase burnout for direct care workers.

Response: As discussed earlier, the definition of compensation we proposed, and are finalizing with modification, includes all compensation paid to direct care workers for activities related to their roles as direct care workers. States should ensure providers do not count in the percentage calculation at § 441.302(k)(3) compensation for the time that workers spend on administrative or other tasks unrelated to their roles as direct care workers as compensation to direct care workers. We would not view as permissible under this regulation the shifting of administrative tasks to direct care workers as a way to inflate compensation for direct care workers. However, providers can count as compensation to direct care workers the time that direct care workers spend on tasks, including administrative tasks, such as completing timecards, that are directly related to their roles as direct care workers in providing services to beneficiaries. We plan to provide States with technical assistance on how to accurately capture compensation for workers who provide direct care and perform administrative or other roles. However, we decline to make changes in this final rule based on these comments.

Comment: Several commenters requested clarification on what was included in the denominator of the calculation (in other words, what is meant by ''payments'' when calculating the percent of payments being spent on compensation for direct care workers). One commenter suggested that rather

than requiring 80 percent of Medicaid payments be spent on compensation, we require that 80 percent of all revenue be spent on compensation. One commenter requested clarification about whether, for managed care delivery systems, payment is the State's capitation payment to the MCO or the MCO's payment to the home care provider agency. The commenter also recommended that we require States to set a minimum payment rate that MCOs or other entities pay home care agencies and that the minimum rates be set at a level to pay workers the locally required minimum wage and other compensation as defined in the regulation, and for the home care agency to reserve 20 percent overhead.

A few commenters made specific suggestions for parameters of what should be included or excluded in the denominator, such as:

- Only collected revenue (and not billed charges) would be considered as base or supplemental payments;
- Excluding refunded or recouped payments from current or prior years based on program financial audits;
- Excluding chargebacks; and
- Excluding bad debt.

Response: For Medicaid FFS payments in the denominator of the calculation should include base and supplemental payments (as described in SMDL 21–006 [117]). Those base and supplemental payments should only include payments actually collected, or revenue, rather than billed charges. In addition, refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt should be excluded from those base and supplemental payment amounts. We are available to provide States with technical assistance related to calculating payments for the purpose of determining the percent of all payments that is spent on compensation.

For Medicaid managed care, payments refer to payments from the managed care plan to the provider and not the capitation payment from the State to the managed care plan. Further, for Medicaid managed care, payments in the denominator of the calculation should include only those payments actually collected and exclude refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt. We note that section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies.

As discussed throughout this section (II.B.5), we proposed the requirements at § 441.302(k) using our authority under section 1902(a)(30)(A) of the Act, which requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe section 1902(a)(30)(A) of the Act speaks specifically to Medicaid payments, not to all revenue received by providers (which may be from various sources); thus, we decline to modify the requirement to affect non-Medicaid revenues.

Comment: One commenter requested that revenue from value-based care (VBC) arrangements in managed care be exempt from the calculation so as not to disrupt State or managed care efforts moving toward VBC or to disincentivize providers from pursuing innovative strategies to improve health and financial outcomes such as lowering emergency room visits, inpatient utilization, and admissions from HCBS to inpatient settings such as nursing facilities. The commenter also noted that providers must make numerous additional investments above and beyond typical compensation rates for a VBC or pay-for-performance (PFP) arrangement to work. Additionally, the commenter noted, VBC and PFP programs rely on lengthy cycles of data, tracking, analysis, and reconciliation before additional payments are made. The commenter stated that, if these types of payments are included in the denominator of the calculation, this will prove disruptive to these programs.

Response: We appreciate the commenter raising these concerns and agree that VBC, PFP, and other unique payment arrangements that reward and support quality over quantity are important, and it was not our intention to appear to discourage them or minimize their value. However, given the wide-ranging designs of such payments and that most HCBS are often not included in these arrangements, we are not requiring a specific way to address them in this final rule. We also decline to adopt the commenter's suggestion to exempt revenue from VBC arrangements in managed care from the calculation of the percent of Medicaid payments for certain HCBS that is spent on compensation of direct care workers, as such an exemption would undermine the intent of the proposal and the usefulness of the data for assessing the percentage of all Medicaid payments for certain HCBS that is spent on compensation for direct care workers. We plan to provide States with technical assistance as needed on how to include revenues from VBC, PFP, and other unique payment arrangements in the calculation.

After consideration of the comments received, we are finalizing § 441.302(k)(1)(i) with a modification to clarify at § 441.302(k)(1)(i)(B) that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

We are also finalizing a new definition at § 441.302(k)(1)(iii) to define excluded costs, which are costs that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers. In other words, States must ensure providers deduct these costs from their total Medicaid payments before performing the calculation required at § 441.302(k)(3)). Such costs are limited to: (A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); (B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and (C) Costs of personal protective equipment for direct care workers.

e. Definition of Direct Care Worker (§ 441.302(k)(1)(ii))

At § 441.302(k)(1)(ii), we proposed to define direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. Specifically, we proposed to define direct care workers to include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or

[117] CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at *https://www.medicaid.gov/sites/default/files/2021-12/smd21006.pdf.*

other services to promote community integration. We further identified in the preamble of the proposed rule that our definition of direct care worker is intended to exclude nurses in supervisory or administrative roles who are not directly providing nursing services to people receiving HCBS.

Our proposed definition of direct care worker was intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles across States that direct care workers may have. We included workers with professional degrees, such as nurses, in our proposed definition because of the important roles that direct care workers with professional degrees play in the care and services of people receiving HCBS, and because excluding workers with professional degrees may increase the complexity of reporting, and may unfairly punish States, managed care plans, and providers that disproportionately rely on workers with professional degrees in the delivery of HCBS. We also proposed to define direct care workers to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. This proposed definition is in recognition of the varied service delivery models and employment relationships that can exist in HCBS waivers. We requested comment on whether there are other specific types of direct care workers that should be included in the definition, and whether any of the types of workers listed should be excluded from the definition of direct care worker.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported finalizing the definition of direct care worker as proposed. However, one commenter opposed the entire definition. The commenter noted that the definition, which resembles a definition of direct care worker used by the Department of Labor, is distinguishable from the definition used by the Bureau of Labor Statistics. The commenter recommended that no definition should be finalized until there has been an interagency workgroup to review and coordinate the different definitions.

Response: As discussed earlier in this section II.B.5.e. of this rule, our proposed definition of direct care worker was intended to capture the diversity of roles and titles across States that direct care workers may have. It was also intended to include individuals in the varied service delivery models and employment relationships that can exist in HCBS waivers. As discussed later in this section II.B.5.e. of this rule, we are finalizing the definition of direct care worker largely as proposed with a modification to clarify that direct care workers include nurses and other staff providing clinical supervision, as we do not want to discourage clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. We believe that the definition of direct care worker, as finalized, appropriately defines direct care worker for the specific purposes of the requirements in § 441.302(k), and we note that it was subject to interagency review.

Comment: Several commenters supported including clinicians (such as those we proposed at § 441.302(k)(1)(ii)(A)) in the definition of direct care worker. Commenters noted that providers are often required to have clinicians on staff and that such clinicians are critical to ensuring quality of care. A few commenters, however, expressed ambivalence or reservations about including clinicians in the definition of direct care worker. One commenter noted that some States do not include nurses in their State definitions of direct care worker. A few commenters observed that because clinicians (including nurses) generally earn higher wages, providers that employ clinicians will have an easier time reaching the minimum performance level for direct care worker compensation or that the higher wages of clinicians will mask the lower wages of direct care workers who do not have professional degrees and generally earn lower wages.

Response: We continue to believe it is appropriate to include clinicians (such as registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) in the definition of direct care worker and are finalizing the definition in this final rule with these clinicians included. There is a shortage of nurses and other clinicians delivering HCBS, and we believe it is important to support these members of the HCBS workforce (especially as they also work directly with beneficiaries). We echo observations from commenters that some services are required to be delivered or monitored by clinicians. We also would not want to discourage clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. Therefore, we are clarifying that our definition of direct care worker is intended to include nurses and other staff who directly provide services to beneficiaries or who provide clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision. We are finalizing a modification at the end of § 441.302(k)(1)(ii)(F) to specifically include nurses and other staff providing clinical supervision.

Comment: One commenter suggested that if a State requires that a program employ a nurse to perform occasional beneficiary visits, the State should pay the nurses directly, rather than requiring the providers to pay them.

Response: We thank the commenter for this suggestion. While we do not intend to establish specific requirements for how States pay for services provided by nurses, we agree that this could be a solution for States that would prefer for providers to reach the payment adequacy requirement without relying on salaries for clinical staff. We decline to make changes in this final rule based on this comment.

Comment: A number of commenters requested that we include private duty nurses, including registered nurses, licensed practical nurses, and certified nursing assistants, in the definition of direct care worker.

Response: We note that private duty nurses are not necessarily a separate category of worker, but rather registered nurses, licensed practical nurses, or certified nursing assistants who provide services classified and billed as private duty nursing. As a technical matter, we clarify that only registered nurses and licensed practical nurses may provide private duty nursing services authorized under § 440.80. As discussed above, these types of clinicians are included in the definition of direct care worker in § 441.302(k)(1)(i)(A) so long as they are providing one of the three HCBS services specified in the minimum performance requirement (homemaker, home health aide, or personal care services). However, private duty nursing is not one of the services we have proposed, and are finalizing, for application of this the minimum performance requirement.

Comment: Many commenters recommended that nurse supervisors be included in the definition of direct care workers. Several of these commenters noted that these are required positions for their programs. Some commenters observed that nurse supervisors perform important activities like supervising and training other direct care workers,

coordinating beneficiaries' care, or completing documentation and other paperwork specific to beneficiaries' care (as opposed to paperwork related to business administration). Several commenters stated that clinical supervision is critical to the quality of HCBS. A few commenters noted that nurse supervisors sometimes visit beneficiaries or provide direct services when filling in for absent direct care workers.

One commenter noted support for excluding general administrative or supervisory staff from the definition of direct care workers. A few commenters expressed concerns about the exclusion of administrative or supervisory staff who may sometimes also provide services to beneficiaries. Some of these commenters noted that especially during workforce shortages, administrative staff or supervisors may fill in for direct care workers. A couple of commenters requested clarification on how wages for staff who perform both direct care work and administrative or supervisory work should be counted for the purposes of complying with the minimum performance level. One commenter requested clarification on whether first line supervisors of direct support professionals are included in the definition of direct care workers.

Several commenters stated that they opposed the exclusion of supervisory or managerial staff because these are required positions for their programs. Several commenters noted that staff who provide supervision or perform administrative tasks, such as understanding and reviewing compliance and other regulatory requirements, are critical to quality. One commenter expressed the concern that excluding supervisory or managerial staff from the 80 percent minimum performance level would mean that providers would have to lower the salaries of these positions, and then in turn may have trouble filling these positions. One commenter raised concerns about ''wage compression,'' with providers reducing wages for higher-skilled jobs or paying these jobs more like entry-level jobs.

Response: We are persuaded that nurses or other staff who provide clinical oversight and training for direct care workers participate in activities directly related to beneficiary care (such as completing or reviewing documentation of care), are qualified to provide services directly to beneficiaries, and periodically interact with beneficiaries should be included in the definition of direct care workers at § 441.302(k)(1)(ii). As noted earlier, we are modifying our definition of direct care worker at § 441.302(k)(1)(ii)(F) to clarify that it includes nurses and other staff providing clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision (such as overseeing business operations).

While we acknowledge that administrative staff and administrative supervisors are often required staff and perform essential functions (including quality and compliance reporting and recordkeeping), we believe it is critical for the economic and efficient use of Medicaid funds that the vast majority of Medicaid payment for homemaker, home health aide, and personal care services must go to supporting the core activities of that service; the core activities of homemaker, home health aide, and personal care services are performed by direct care workers. As discussed above, evidence specifically shows that direct care workers are paid low wages and, thus, our priority is ensuring a greater share of Medicaid payments go to direct care workers' compensation. If there is an insufficient number of direct care workers employed by a provider, then those HCBS cannot be delivered, and beneficiaries may not be able to access the HCBS they need. We will continue to partner with States to help providers find efficient ways to support their administrative and reporting requirements.

Comment: Many commenters expressed concern that direct support professionals were excluded from the definition of direct care worker, as direct care workers are often associated with provision of services to older adults and people with physical disabilities, while direct service professionals typically provide services to people with intellectual and developmental disabilities.

Response: We note that direct support professionals are explicitly included in the definition of direct care worker at § 441.302(k)(1)(ii)(C), so there is no need to further modify the definition of direct care worker in response to these comments. If someone designated by their State as a direct support professional provides a service that is subject to the minimum performance requirement, their compensation will be included in the calculation for the minimum performance level.

Comment: One commenter suggested that payments to contract employees should not count toward the minimum performance level.

Response: Given the varied nature of HCBS programs, we specifically proposed for the definition of direct care worker at § 441.302(k)(1)(ii)(G) to encompass a broad array of employment relationships. We cannot find sufficient justification for excluding certain types of employment relationships from this requirement and are finalizing our definition of direct care worker to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model, as proposed. However, we are making a technical modification for clarity to not finalize § 441.302(k)(1)(ii)(G) and to add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii).

Comment: One commenter opposed including workers who deliver services via a self-directed services delivery model in the definition of direct care workers. They noted that including these workers would ''chip away at the uniqueness at the heart of the self-direction paradigm,'' unintentionally burden self-directed employers and employees, reduce autonomy by introducing a single title for a wide variety of caregiving types, and would not recognize the flexible and interdependent nature of self-direction or the fact that Medicaid beneficiaries who self-direct their services do not retain the funds that remain in budgets at the end of the year.

Response: We thank the commenter for raising their concerns. We decline to make modifications to the definition of direct care worker to exclude direct care workers providing services in self-directed services delivery models generally. We believe it is important for States to have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, as required by section 2402(a)(1) of the Affordable Care Act, regardless of whether they are receiving services through a self-directed services delivery model or a model that is not self-directed. Further, we believe it is important for States to have a sufficient number of qualified direct care workers to provide self-directed personal assistance services, as required by section 2402(a)(3)(B)(iii) of the Affordable Care Act.

However, we do agree that there are certain self-directed services delivery models for which the minimum performance level at (k)(3) would not be appropriate. We intend to apply the requirements at § 441.302(k)(3) to models in which the beneficiary directing the services is not setting the payment rate for the worker (such as

agency-provider models). We do not intend to apply the requirements to self-directed services delivered through models in which the beneficiary sets the payment rate for the worker (such as in individual budget authority models). In the latter scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation. We are finalizing a new requirement at § 441.302(k)(2)(ii) that clarifies this policy; this requirement is discussed in greater detail in section II.B.5.g. of this final rule.

After consideration of the comments received, we are finalizing the definition of direct care worker at § 441.302(k)(1)(ii) with technical modifications for clarity to change the term, Medicaid-eligible individuals, to the term, Medicaid beneficiaries, in both § 441.302(k)(1)(ii)(A) and (F). We are finalizing § 441.302(k)(1)(ii) with a modification at the end of § 441.302(k)(1)(ii)(F) to provide that direct care workers include nurses and other staff providing clinical supervision. The finalized revised text at § 441.302(k)(1)(ii)(F) will read: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving HCBS available under this subpart, including nurses and other staff providing clinical supervision. We are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

f. Reporting (§ 441.302(k)(2))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At § 441.302(k)(2), under our authority at section 1902(a)(6) of the Act, we proposed to require that States demonstrate that they meet the minimum performance level at § 441.302(k)(3)(i) through new Federal reporting requirements at § 441.311(e). We discuss these reporting requirements in our discussion of proposed § 441.311(e) in section II.B.7 of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also direct the reader to the discussion of § 441.311(e) in section II.B.7. of this final rule for additional comments and responses.

Comment: A number of commenters, while not supporting the minimum performance requirement, did express support for the requirement that States must collect and report data on the percent of Medicaid payments for certain HCBS going to compensation of direct care workers. Commenters noted this reporting could yield important data about the compensation to workers and allow for national comparisons.

Response: We agree with commenters that the reporting requirement proposed at § 441.311(e) will yield important data about compensation to workers that will help support the HCBS direct care workforce and promote better oversight of how Medicaid payments for certain services are used.

We note that, while several commenters encouraged us to finalize the reporting requirement at § 441.311(e) without finalizing the minimum performance requirement at § 441.302(k)(3), no commenter suggested that we finalize the minimum performance requirement without a reporting requirement. We believe that the reference included in § 441.302(k)(2) to the reporting requirement at § 441.311(e) is necessary for CMS to oversee States' compliance with the minimum performance requirement at § 441.302(k)(3); however, the reporting requirement at § 441.311(e) is distinct and severable from the minimum performance requirement at § 441.302(k). As discussed in more detail in section II.B.7, the reporting requirement at § 441.311(e), which we are finalizing with modifications, addresses a broader universe of services than is included in the minimum performance level at § 441.302(k)(3) and has an earlier applicability date than the date we are finalizing at § 441.302(k)(8) (discussed later in this section). While we are finalizing both the minimum performance requirement at § 441.302(k)(3) and the payment adequacy reporting requirement, as amended, at § 441.311(e), these represent distinct policies, and we believe that the reporting requirement can (and will) function independently from the minimum performance requirement.

Comment: Several commenters suggested that we add a requirement to § 441.302(k)(2) that would require States, as part of their assurances of compliance with the minimum percentage requirement, to acknowledge and explain any differences between the actual payment rates for home care services and the rate most recently recommended by the interested parties' advisory group under § 447.203(b)(6) of this final rule and discussed in section II.C. of this rule. The commenters suggested that if the actual rate is lower than the recommended rate, the State would also need to explain why it is sufficient to ensure access to services.

Response: Although the interested parties' advisory group will provide an invaluable perspective on the adequacy of rates, as discussed in greater detail later in this preamble, the role of the group finalized at § 447.203(b)(6) is advisory. States will not be required to follow the recommendations of the group. We believe the policies as we are finalizing strike the right balance of accountability and flexibility for wholly new rate processes. We further note the recommendations of the interested parties' advisory group will be posted publicly for review. Finally, we note that we are also finalizing steps a State must take to demonstrate adequate access to services when proposing a rate reduction or restructuring in circumstances that could result in diminished access to care.

After consideration of the comments received, we are finalizing § 441.302(k)(2) with modifications. For reasons discussed in section II.B.5.g. of this final rule, at § 441.302, we are redesignating paragraph (k)(2) as paragraph (k)(2)(i) to allow for the addition of a new requirement at paragraph (k)(2)(ii) regarding treatment of certain payment data under self-directed services delivery models.

As discussed in section II.B.5.b. of this rule, we are finalizing reporting requirements at § 441.302(k)(6) to ensure accountability in the States' use of the small provider minimum performance level and hardship exemptions. To clarify that States must comply with this requirement, as well as the reporting requirement at § 441.311(e), we are finalizing references to § 441.302(k)(6) in § 441.302(k)(2)(i). We also are finalizing a technical modification for clarity that the State must demonstrate **annually**, consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). (New text in bold font).

g. Application to Other Authorities (Proposed at § 441.302(k)(4), Finalized at § 441.302(k)(8); and §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi))

At § 441.302(k)(4), we proposed to apply the HCBS requirements described in the proposed rule to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(k) with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because workforce shortages exist under other HCBS authorities, which include many of the same types of services to address activities of daily living or instrumental activities of daily living as under section 1915(c) waiver authority, we proposed to include these requirements within the applicable regulatory sections. Specifically, we proposed to apply the proposed requirements at § 441.302(k) to section 1915 (j), (k), and (i) State plan at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(30)(A) of the Act to ensure payments to HCBS providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of payment adequacy provisions across section 1915(i), (j), and (k) authorities. As noted earlier in section II.B.4. of the proposed rule, to accommodate the addition of new language at § 441.464(e) and (f), we proposed to renumber existing § 441.464(e) as paragraph (g) and existing § 441.464(f) as paragraph (h). We requested comment on whether we should exempt, from these requirements, services delivered using any self-directed service delivery model under any Medicaid authority.

We considered whether to also apply these proposed payment adequacy requirements to section 1905(a) ''medical assistance'' State plan personal care and home health services. However, we did not propose that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We requested comment on whether we should apply these requirements to section 1905(a) State plan personal care and home health services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported holding providers delivering care in managed care delivery systems accountable for paying a sufficient amount to direct care workers. A few commenters requested that we clarify how this requirement would apply to MCOs, PIHPs, and PAHPs. One commenter noted that managed care plans do not control the payment rates that contracted providers pay their direct care workers.

A few commenters requested that we clarify managed care plans' responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We acknowledge commenters' broad concerns about how these requirements will apply to managed care plans and will provide technical assistance regarding specific questions as they are raised during implementation. However, we are finalizing our proposal to apply the requirements at § 441.302(k) to both managed care and FFS delivery systems. We clarify here that the requirements in § 441.302(k) are the ultimate responsibility of States, regardless of whether their HCBS are delivered through an FFS delivery system, managed care delivery system, or both. The minimum performance requirement applies at the provider level, not the managed care plan level. We expect that States will develop an appropriate process with their managed care plans should the State determine that managed care plans have some role in activities such as the data collection or reporting required in § 441.302(k)(2) (being finalized as § 441.302(k)(2)(i)). We agree that managed care plans do not control payment rates that contracted providers pay their direct care workers and reiterate that the focus of § 441.302(k) is on the percentage of the payment to providers that is passed along as compensation to direct care workers.

We plan to provide technical assistance to States with managed care delivery systems to minimize provider reporting and accounting burden and to address questions related to bundled payments that include the affected services (homemaker, home health aide, and personal care services).

Comment: A few commenters specifically noted support for applying the payment adequacy requirement to programs authorized under all section 1915 authorities. One commenter did not support applying this requirement to ''all 1915 waiver authorities'' but did not provide a specific rationale for their recommendation.

Response: We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) (applying § 441.302(k) to section 1915(j), (k) and (i) services, respectively) with minor technical modifications as noted later in this section II.B.5.g. of this final rule.

Comment: A number of commenters expressed concerns about the application of the minimum performance level to self-directed services authorized under sections 1915(j) and 1915(k) of the Act. A few commenters, while not necessarily suggesting that self-directed services should be excluded from the payment adequacy requirement, believed that it would take more time and additional guidance to implement the requirement for self-directed services.

Some commenters raised concerns about the application of the requirement to specific models of self-direction, particularly the self-directed model with service budget (as defined in § 441.545(b)) (often referred to as the individual budget authority model), in which the beneficiary sets the direct care worker's wages. Some commenters worried that the application of the minimum performance level to such

models would put the individual beneficiary in the position of acting as a provider for this purpose. Other commenters were concerned that if the minimum performance level was applied to these self-directed services delivery models, beneficiaries would have to apply a set percent of their budget to compensation of workers and thus would lose the flexibility of determining how their budget was spent or what to pay their direct care workers. One commenter pointed out that beneficiaries in self-directed services delivery models do not personally keep unspent funds and, thus, do not stand to profit by lowering direct care workers' wages. A few commenters also requested clarification of how the payment adequacy requirement would impact the co-employment relationship in self-directed services. One commenter noted that the vast majority of HCBS furnished under self-directed services delivery models are paid so that the entire payment rate goes toward direct care worker's wages and other associated costs such as employer taxes, workers' compensation, and other employer requirements such as State-mandated paid sick leave, while payment for financial management services is paid separately. In these models, nearly 100 percent of the payment rate goes toward the direct care worker's wages and associated costs, which would create an unfair comparison to agency-directed services.

A few commenters noted that it would be undesirable to apply the minimum performance level to HCBS furnished via self-directed services delivery models because these services involve additional activities and costs not associated with other types of services. These commenters noted that services furnished via self-directed services delivery models involve more training and human resources support for the beneficiaries to help them hire and direct their workers. One commenter stated that the proposed minimum performance level of 80 percent would be too high to accommodate other non-compensation activities included in self-directed services delivery models, such as employment or day activities, case management, and back up supports.

On the other hand, some commenters noted that self-directed services delivery models should be included in the payment adequacy requirements and that it is important to support compensation for direct care workers who provide HCBS via self-directed services delivery models. One commenter noted that most personal care services in the commenter's State are furnished via self-directed services delivery models.

Response: We agree with commenters that the minimum performance requirement may be difficult to apply (and, in fact, may simply be inapplicable) to self-directed services delivery models with service budget authority in which the beneficiary directing the services sets the worker's wages as the payment rate for the service (such as models meeting the definition of § 441.545(b) for section 1915(k) services, or self-directed services typically authorized under the section 1915(j) authority).

We also agree with one commenter who noted that, because of the separate payment of financial management services, nearly all of the payments for personal care, homemaker, and home health aide services furnished via self-directed services delivery models with service budget authority are spent on compensation for direct care workers. We believe that applying the minimum performance requirement to such models would be ineffectual and an unnecessary burden on States.

We believe the minimum performance requirement is appropriate when applied to a Medicaid rate for self-directed services that includes both compensation to direct care workers and administrative activities and in which the beneficiary did not set the payment rate for the worker.

We note that at least some of the ''non-compensation activities'' identified by one commenter, such as employment or day activities and case management, do not appear to fall under the specific services to which we proposed, and are finalizing, for the minimum performance requirement to apply, and therefore, they would not likely be subject to the minimum performance requirement as finalized.

To clarify the application of § 441.302(k) to HCBS furnished via self-directed services delivery models, we are finalizing a new requirement at § 441.302(k)(2)(ii), specifying that, if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the general application of § 441.302(k) to HCBS authorized under section 1915(j), (k), and (i) authorities, with the understanding that some services delivered under these authorities will fall under the exception for self-directed services delivery models being finalized at § 441.302(k)(2)(ii).

We note that the exception at § 441.302(k)(2)(ii) directs States to exclude certain data from the specified excluded self-directed services models when establishing compliance with the minimum performance level or small provider performance level at § 441.302(k)(3). We believe, however, that the regulation text at § 441.302(k) requiring States to assure that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans applies to all self-directed services models offered under all section 1915 authorities.

Comment: Commenters were mixed in their support for excluding section 1905(a) services from the payment adequacy requirement. A few commenters expressed strong support for extending the payment adequacy requirement to services authorized under section 1905(a), particularly commenters writing from States in which larger numbers of beneficiaries receive section 1905(a) State plan services. One commenter expressed concern that not including section 1905(a) services would disproportionately exclude direct care workers providing services to children or adults with intellectual and developmental disabilities. One commenter noted that section 1902(a)(6) of the Act gives CMS the authority to apply the requirement section 1905(a) services.

However, several commenters did not support applying the requirement to section 1905(a) State plan services. Many of these commenters simply did not support applying the minimum performance requirement to services under any authority. A few commenters agreed with our concerns that applying the payment adequacy requirement to section 1905(a) State plan services would pose a particular burden on States due to differences in how these services are delivered and monitored.

Several commenters expressed concerns about potential unintended consequences of not applying the minimum performance requirement to section 1905(a) State plan services. In particular, some commenters raised concerns that direct care workers would stop working for providers that deliver section 1905(a) services, in favor of working for providers that were subject to the minimum performance requirement. On the other hand, a few

commenters worried that providers would stop providing services under section 1915 authorities and switch to providing section 1905(a) services to avoid having to comply with the payment adequacy requirement.

Response: At this time, we are not requiring the application of the HCBS payment adequacy requirements at § 441.302(k) to section 1905(a) services. Given our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will take these comments under consideration for any potential future rulemaking regarding section 1905(a) services.

Comment: One commenter requested clarification as to whether the payment adequacy requirements would apply to services delivered under section 1115 authority.

Response: At § 441.302(k)(4) (which we are finalizing at § 441.302(k)(8)), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems, including those authorized under section 1115(a) of the Act. We are finalizing this requirement in this final rule, with modifications as noted herein, including retaining the application to managed care delivery systems authorized section 1115(a).

After consideration of public comments, and for reasons discussed in sections II.B.5.b. and II.B.5.h. of this rule, we are finalizing § 441.302(k)(4) with modifications to redesignate § 441.302(k)(4) as § 441.302(k)(8) and change the date for States to comply with the requirements at § 441.302(k) from 4 years to 6 years. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy.

As finalized, the redesignated § 441.302(k)(8) reads: *Applicability date.* **States must comply with the** requirements **set forth in paragraph (k) of this section** beginning *6* years after the effective date of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes **homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4)** in the MCO's, PIHP's, or PAHP's contract, ***the first rating period for contracts with the MCO, PIHP, or PAHP beginning*** on or after **the date that is** *6* years after the **effective** date of this paragraph. (New language identified in bold.)

After consideration of the comments, as noted above in this section, we are finalizing a requirement at § 441.302(k)(2)(ii) specifying that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the application of § 441.302(k) to section 1915(j), (k), and (i) services with minor modifications. We are finalizing a technical modification to clarify that the reference to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) is to beneficiaries' person-centered service plans. We are also clarifying in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) that while § 441.302(k) applies to services delivered under these authorities, references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i), as appropriate.

Additionally, to ensure application of all relevant requirements of § 441.302(k) to section 1915(i) and (k) authorities, we are also finalizing a modification to §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively. (We note that discussion of the finalization of §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) is in II.B.7. of this final rule.) We note that while we are applying the requirement at § 441.302(k)(6) to section 1915(j), (k), and (k) authorities, States would only be required to comply with this reporting requirement if the State provided services under these authorities described in § 441.302(k)(2)(i) and if the State meets the other criteria set forth in § 441.302(k)(6).

h. Applicability Date (Proposed at § 441.302(k)(4), Being Finalized at § 441.302(k)(8))

As noted throughout the HCBS provisions in this preamble, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these proposed payment adequacy requirements. We expect that these activities will take longer than similar activities for other HCBS provisions in the rule. Further, we expect that it will take a substantial amount of time for managed care plans and providers to establish the necessary systems, data collection tools, and processes necessary to collect the required information to report to States. As a result, we proposed at § 441.302(k)(4), to provide States with 4 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 4 years after the effective date of the final rule to implement these requirements. Similar to our rationale in other sections, this proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered the overall burden of the proposed rule as a whole in proposing the effective date for the payment adequacy provision. We invited comments on the overall burden associated with implementing this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (such as 3 years) or longer timeframe (such as 5 years) to implement the payment adequacy provisions and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: A few commenters supported our proposal that the minimum performance requirement go into effect four years after the publication of this final rule. One commenter noted that 4 years should be sufficient time for States and providers to make necessary adjustments. A few commenters noted that 4 years was too long, given the urgency of the workforce shortage. One commenter suggested that we require the minimum performance requirement go into effect January 1, 2025, while another commenter suggested a 2-year effective date. One commenter suggested the requirement should go into effect in 3 years, to align with some of the other proposed effective dates in this rule.

Other commenters recommended that we allow for a longer effective date, such as 6 years. Commenters noted that large-scale changes, such as what would be required to comply with the minimum performance requirement, would take time.

Several commenters suggested that compliance with the minimum performance requirement be phased in over time to give providers and States an opportunity to adjust their systems and policies.

Response: While we are sympathetic to commenters' sense of urgency regarding the workforce shortage, we do not believe it is realistic for States to comply with the requirements earlier than the proposed four years. We agree with commenters that, for some States, ensuring that a minimum percent of Medicaid payments go to direct care worker compensation (and tracking compliance with this requirement) will require a period of adjustment. We do expect that providers should already be aware of their Medicaid revenues and what they pay their workers; however, we acknowledge that they may not already be reporting this information to the States and that the States will need to work with their providers to develop an appropriate reporting mechanism. We also understand that some providers will have to adjust how they operate their business in order to meet the required minimum performance level. We also acknowledge that we will need to provide additional subregulatory guidance and technical assistance to aid in implementation.

We agree with commenters that a slightly longer date for States to comply with the requirements is necessary. We believe that the complementary reporting requirement at § 441.311I (discussed in section II.B.7. of this rule) can be leveraged to create a transition period to aid States in their compliance with § 441.302(k)(3). As such, we are finalizing § 441.302(k)(8) with a modification to change the date for States to comply with the requirements from 4 years to 6 years. The data collected as part of § 441.311(e) will give States feedback on how close they are to reaching the minimum performance level and will help CMS develop targeted technical assistance for States that are farther away from attaining compliance. For States electing to create a State-defined minimum performance level for small providers, this period between reporting and performance will also allow States to make any necessary adjustments to their State-defined minimum performance levels. It will also allow States to make any necessary adjustments to their criteria for hardship exemptions and to identify providers who need hardship exemptions. We will continue to use our standard enforcement tools and discretion, as appropriate, when the requirements at §§ 441.302(k) go into effect.

As noted in section II.B.5.b. and II.B.5.h. of this section, we are creating new requirements at § 441.302(k)(4) through (7) and thus are redesignating proposed § 441.302(k)(4) as § 441.302(k)(8) and finalizing § 441.302(k)(8) with the modifications as noted in section II.B.5.b. of this final rule. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.302(k) as follows:

- We are finalizing the assurance requirement at § 441.302(k) with technical modifications.
- We are finalizing § 441.302(k)(1) with a technical modification.
- The definition of compensation at § 441.302(k)(1)(i) (now also at § 441.311(e)(1)(i)) and finalized as proposed, with the exception of § 441.302(k)(1)(i)(B) (now also at § 441.311(e)(1)(i)(B)), which is revised to read: Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement).
- The definition of direct care worker at § 441.302(k)(1)(ii) (now also at § 441.311(e)(ii)) is finalized with technical modifications to § 441.302(k)(1)(ii)(A) and (F) (now also at § 441.311(e)(1)(ii)(A) and (F)). We are also finalizing the following addition at the end of § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)), including nurses and other staff providing clinical supervision. The revised text at § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)) will read as follows: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision. In addition, we are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model.
- A definition of excluded costs is finalized at § 441.302(k)(1)(iii) (now also at § 441.311(e)(1)(iii)) as follows:

Excluded costs means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

- Section 441.302(k)(2) is finalized with modifications. We are redesignating the language at § 441.302(k)(2) as § 441.302(k)(2)(i). We are finalizing § 441.302(k)(2)(i) to include references to the reporting requirements that are finalized at

§§ 441.302(k)(6) and 441.311(e) and the exception finalized at § 441.302(k)(2)(ii). We also made a technical modification for clarity that the State must demonstrate **annually,** consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). In addition, we made technical modifications for clarity and precision to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies and to specify that these requirements apply to services authorized under section 1915(c) of the Act, unless excepted under § 441.302(k)(2)(ii).

- We are finalizing at new requirement at § 441.302(k)(2)(ii) that clarifies that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State would not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).
- Section 441.302(k)(3) is finalized with several modifications to retitle the requirement as ''*Minimum performance at the provider level*'' and clarify the components of the required calculation and the services that fall within this requirement. Section 441.302(k)(3) is also finalized with modifications to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641).
- Section 441.302(k)(3)(i) is finalized with a clarification that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii).
- Section 441.302(k)(3)(ii) is amended to add an option for States to set a State-defined small provider minimum performance level. As finalized, § 441.302(k)(3)(ii) reads: (ii) At the State's option, providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) on total compensation for direct care workers who furnish those services.
- An option for States to develop criteria to identify small providers to meet the State-defined small provider minimum performance level is added at new § 441.302(k)(4).
- An option for States to provide some providers with a hardship exemption is added at new § 441.302(k)(5).
- Reporting requirements are finalized at § 441.302(k)(6), establishing reporting requirements for States that utilize the small provider minimum performance level and hardship exemption options finalized at § 441.302(k)(4)(ii) and (k)(5), as well as a waiver of these requirements that may be granted under certain circumstances.
- An exemption from the requirements at § 441.302(k) is finalized for IHS and Tribal health programs subject to 25 U.S.C. 1641 at § 441.302(k)(7).
- Section 441.302(k)(4) is renumbered as § 441.302(k)(8) and is finalized, with other technical modifications, to specify that States must comply with the requirements set forth at § 441.302(k)(8) beginning 6 years from the effective date of this final Rule.
- We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) with technical modification to clarify that the references to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) are to beneficiaries' person-centered service plans. We are also finalizing modifications to clarify that § 441.302(k) applies to services delivered under these authorities, except that references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i) of the Act, as appropriate.
- We are finalizing a modification to §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively.

6. Supporting Documentation Required (§ 441.303(f)(6))

As discussed in the proposed rule (88 FR 27986), States vary in whether they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services. This can overestimate the number of people who need Medicaid-covered HCBS because the waiting lists may include individuals who are not eligible for services. According to the Kaiser Family Foundation, over half of people on HCBS waiting lists live in States that do not screen people on waiting lists for eligibility.[118]

We have not previously required States to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[119] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists. In addition, we have found, over the past several years in particular, that some States are operating waiting lists for their section 1915(c) waiver programs despite serving fewer people than their CMS-approved enrollment limit or cap, even though States are expected to enroll individuals up to their CMS-approved enrollment limit or cap before imposing a waiting list. However, because we do not routinely collect information on States' use of waiting lists and the number of people on waiting lists, we are unable to determine the extent to which States are operating such unauthorized waiting lists or to work with States to address these unauthorized waiting lists.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information as the Secretary may from time to time require, and to comply with such provisions as the

[118] Burns, A., M. O'Malley Watts, M. Ammula. A Look at Waiting lists for Home and Community-Based Services from 2016 to 2021. Kaiser Family Foundation. *https://www.kff.org/47f8e6f/.*

[119] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

Secretary may from time to time find necessary to assure the correctness and verification of such reports. Based on the authority found at section 1902(a)(6) of the Act, we proposed to require information from States on waiting lists to improve public transparency and processes related to States' HCBS waiting lists and ensure that we are able to adequately oversee and monitor States' use of waiting lists in their section 1915(c) waiver programs. To address new proposed requirements at § 441.311(d)(1), described in section II.B.7. of this rule, on State reporting on waiting lists, we proposed to amend § 441.303(f)(6) by adding a sentence to the end of the existing regulatory text to require that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also received a number of comments on the related reporting requirement at § 441.311(d). Those comments are addressed in section II.B.7.

Comment: A few commenters shared local data and anecdotal experiences about States' waiting lists, which some described as containing thousands of people and requiring beneficiaries to wait for long periods of time, even years, before accessing services. One commenter observed that as demand for HCBS grows, the waiting lists will also grow. A few commenters expressed concerns that the long waiting times may result in beneficiaries having to enter institutional care. Commenters also noted that beneficiaries and their families experience confusion regarding waiting lists, including how long they will have to remain on the waiting list before receiving services; commenters noted that this confusion or lack of transparency can make it difficult for beneficiaries to make informed decisions or plan for future care needs.

A few commenters specifically supported our proposed amendment to § 441.303(f) that would require States to report information on waiting lists for section 1915(c) waiver programs, which commenters believed would contribute to transparency and provide additional data to help make future changes within HCBS programs. Commenters believed that a requirement to report this information would improve CMS's ability to provide oversight and to hold States accountable for waiting list practices. A few commenters believed that creating reporting requirements for waiting lists is a necessary step toward the larger goal of reducing HCBS waiting lists through expansion of HCBS programs. A few commenters noted this information is critical when requesting additional appropriations from State legislatures to expand HCBS programs.

Response: We thank the commenters for their support and for sharing their experiences and perspectives. We agree that collecting and reporting data on waiting lists is a critical step in identifying unmet needs among beneficiaries and can support the efficient administration and expansion of HCBS programs.

Comment: A few commenters expressed opposition to adding a reporting requirement for section 1915(c) waiver programs. Commenters noted concerns that this requirement would necessitate changes in States' data collection processes and IT systems.

Response: We address commenters' concerns in more detail in the discussion of § 441.311(d) in section II.B.7. of this rule. As we note in that section, we have designed the reporting requirement to minimize administrative burden on States while still generating valuable data about waiting lists needed to support transparency and accountability. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement.

After consideration of the public comments, we are finalizing the requirements at § 441.303(f) as proposed. We note that specific recommendations regarding the reporting requirement are addressed in section II.B.7. as part of the discussion of § 441.311(d).

7. Reporting Requirements (§§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. As discussed in section II.B.1. of the proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we requested States to report on State-developed performance measures across several domains, as part of an overarching HCBS waiver quality strategy. The 2014 guidance established an expectation that States conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures. Under our authority at section 1902(a)(6) of the Act, we proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, to supersede and fully replace the reporting metrics and the minimum 86 percent performance level expectations for States' performance measures described in the 2014 guidance.

The reporting requirements we proposed in the proposed rule represented consolidated feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties on improving and enhancing section 1915(c) waiver performance to integrate nationally standardized quality measures into the reporting requirements, address gaps in existing reporting requirements related to access and the direct service workforce, strengthen health and welfare and person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. The intent of the proposed reporting requirements was to allow us to better assess State compliance with the statutory and regulatory requirements for section 1915(c) waiver programs. As indicated at the end of this preamble section, we proposed that the reporting requirements at § 441.311 also apply to State plan options authorized under section 1915(i), (j) and (k) of the Act, as well as to both FFS and managed care delivery systems, unless otherwise indicated.

We proposed, at § 441.311(a), a regulation setting forth the statutory basis and scope of the reporting requirements in § 441.311.

We did not receive comments on § 441.311(a). Based on further consideration, we are finalizing § 441.311(a) with a modification for clarity to remove ''simplification'' and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act.

We also note that, consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, we intend that each provision in § 441.311 of this final rule is, as finalized, distinct and severable to the extent it does not rely on another final policy or regulation that we proposed. While we intend that each of the provisions being finalized

within § 441.311, and policies and regulations being finalized elsewhere in this rule, present a comprehensive approach for our oversight of States' Medicaid programs and improving HCBS, we also intend that each reporting requirement within § 441.311 is distinct and severable from one another and from other policies and regulations, being finalized in this rule as well as those rules and regulations currently in effect, to the extent applicable.

Specifically, we proposed, and are finalizing, various reporting requirements in § 441.311 to provide mechanisms for us to oversee States' compliance with other policies being finalized in this rule, such as reporting requirements at § 441.311(b)(1) through (2) for incident management system and critical incident requirements under § 441.302(a)(6), as well as to collect data to support future policy considerations to address the direct care worker shortage at § 441.311(e). While we intend them to be distinct and severable, we are finalizing these reporting requirements in § 441.311 to consolidate them in one place in regulation so they are easier to find. They are not interdependent to the extent each does not rely on another final policy or regulation that we proposed and are finalizing in this rule. We believe that the reporting requirements being finalized herein at § 441.311(b)(1) through (4), (c), (d)(1) and (2), and (e) are each valuable on their own and would provide critical data and oversight even in a circumstance where individual provisions within § 441.311 were not finalized or implemented; however, we note that in this final rule, we are finalizing all reporting requirements in § 441.311, albeit some with modifications, as discussed in this section.

a. Compliance Reporting

(1) Incident Management System Assessment (§ 441.311(b)(1) and (2))

As noted earlier in section II.B.3. of this rule, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. This is despite State efforts to implement statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and State adoption of related subregulatory guidance. In addition, a July 2019 survey of States that operate section 1915(c) waivers found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Based on these findings and reports, as well as feedback obtained during various public engagement activities conducted with interested parties over the past several years to standardize and strengthen health and welfare reporting requirements, we proposed new requirements for States' incident management systems at § 441.302(a)(6), as discussed in section II.B.3. of this preamble. We also proposed new reporting requirements that will allow us to better assess State compliance with the requirements at § 441.302(a)(6).

Relying on our authority at section 1902(a)(6) of the Act, at § 441.311(b), we proposed to establish new compliance reporting requirements. Specifically, at § 441.311(b)(1)(i), we proposed to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the requirements at § 441.302(a)(6) that the State operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents, including that:

- The State define critical incidents to meet the proposed minimum standard definition at § 441.302(a)(6)(i)(A);
- The State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents as proposed at § 441.302(a)(6)(i)(B);
- The State require that providers report any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(C);
- The State use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(D);
- The State ensure records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b), and records with protected health information are obtained and used with beneficiary consent at § 441.302(a)(6)(i)(E);
- The State share information on reported incidents, the status and resolution of investigations, such as through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation, as proposed at § 441.302(a)(6)(i)(E); and
- The State separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes as proposed at § 441.302(a)(6)(i)(F).

Given the risk of preventable and intentional harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement for States to report every other year on the results of an incident management system assessment is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. In the absence of such a reporting requirement, we believed that we are unable to determine whether States have effective systems in place to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery; ensure that States are protecting the health and welfare of individuals receiving section 1915(c) waiver program services; and safeguard people receiving section 1915(c) waiver program services from preventable or intentional harm.

In proposing an every 24-month timeframe for reporting, we were attempting to take into account the

likely frequency of State changes to policies, procedures, and information systems, while also balancing State reporting burden and the potential risk to beneficiaries if States have incident management systems that are not compliant with the proposed requirements at § 441.302(a)(6). We believed an every 24-month timeframe for reporting is sufficient to detect substantial changes to policies, procedures, and information systems and ensure that we have accurate information on States' incident management systems. We also proposed, at § 441.311(b)(1)(ii), to allow States to reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined to meet the requirements at proposed § 441.302(a)(6). We invited comments on whether the timeframe for States to report on the results of the incident management system assessment is sufficient or if we should require reporting more frequently (every year) or less frequently (every 3 years). We also invited comment on whether we should require reporting more frequently (every 3 years or every 4 years) for States that are determined to have an incident management system that meets the requirements at § 441.302(a)(6). If an alternate timeframe is recommended, we requested that commenters provide the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the incident management system requirements. Those comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported the proposed incident management requirements being finalized at § 441.302(a)(6), which are the subject of the reporting requirement at § 441.311(b)(1). One commenter questioned how these reporting requirements would interact with current State reporting requirements related to critical incidents or other waiver reporting requirements.

Response: We thank commenters for their support. We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule, including the critical incident reporting requirements. We also expect to modify existing reporting forms, particularly to remove the reporting requirements in the 2014 guidance [120] that are being superseded and fully replaced by the requirements in this final rule. We note that some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process. Further, we expect that States will be able to build on existing systems to comply with the requirements being finalized in this rule at §§ 441.302(a)(6) and 441.311(b)(1) (discussed in sections II.B.3. and II.B.7. of this rule, respectively.) We plan to provide technical assistance to specific State questions, as needed, about how these requirements can align and interact with current practices.

Comment: A few commenters requested clarification on the assessment that is mentioned in § 441.311(b)(1)(i). Commenters requested more information on the contents of the assessment States must perform of their incident management systems and how States should report the results of the assessment. A few commenters requested more detail on the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines. One commenter inquired if States were expected to pay for the assessment. One commenter requested clarification on the deadline for when this assessment must be completed. A few commenters noted that the assessment was required to be performed annually.

Response: The assessment that States perform of their systems will include review of the elements being finalized at § 441.302(a)(6). The requirements we are finalizing in § 441.302(a)(6) is discussed in detail in section II.B.3. of this final rule. The assessment results will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein (and discussed below in this section II.B.7.), States will be required to comply with the reporting requirement for § 441.311(b)(1) beginning 3 years after the effective date of this final rule. This means that States will be required to submit the assessment results to CMS in three years; thus, assessments should be performed in time for States to meet this timeframe. We will be making the required assessment and reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

We anticipate that the costs that States incur to conduct and report on the results of the assessment will be eligible for Federal match as an administrative activity. Current Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including enhancements), and for operation, of mechanized claims processing and information retrieval systems. Under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include the costs that States incur to conduct and report on the results of the incident management assessment.

We also clarify that there is not a requirement that the incident management assessment be performed annually. As discussed in greater detail below, §§ 441.311(b)(1)(i) and (ii) require that States must submit an incident management assessment every 24 months unless CMS determines the system meets the requirements at § 441.302(a)(6), at which point the assessment must be made every 60 months. Assessments of the incident management system need to be performed as part of this assurance schedule. However, States are welcome to perform assessments more frequently than this schedule requires.

Comment: A few commenters requested that we require States to assess whether the State system tracks the reporting of critical incidents to the designated State Protection and Advocacy system at the same time the incident was reported to the State.

Response: We are declining to make modifications to requirements for States system assessments. We note that commenters made a similar request to add this requirement to the system requirements proposed at § 441.302(a)(6). We also declined to add the requirement to § 441.302(a)(6). We refer readers to section II.B.3. of this rule for the related discussion. However, States are welcome to add other factors to their system assessment beyond the requirements we are finalizing in this rule.

[120] We note that, although States will no longer be expected to meet the reporting requirements and 86 percent minimum performance level in the 2014 guidance, the six assurances and related subassurances in the 2014 guidance continue to apply.

Comment: One commenter requested clarification on the consequences of a State's incident management system being found to be non-compliant with § 441.302(a)(6).

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States with incident management systems that are determined by the assessment to not be compliant with the requirements at § 441.302(a)(6). Additionally, States that do not have compliant systems will be required to perform assessments every 24 months, as required by § 441.311(b)(1)(i) until CMS determines that the system meets the requirements of § 441.302(a)(6) and the State can reduce reporting frequency to every 60 months, as provided by § 441.311(b)(1)(ii). We are not making any changes in this final rule based on this comment.

Comment: A few commenters supported the proposals at § 441.311(b)(1)(i) and (ii) that States must provide the required assessment every 24 months and, if the system is determined to be compliant, every 60 months. One commenter encouraged us to reduce the frequency in § 441.311(b)(1)(i) to one year. One commenter suggested that States should provide assessments on their systems every 1 to 2 years, and if the State's system has been deemed to be in compliance, the assessment should be provided every 3 to 4 years.

A few commenters, however, believed that the reporting frequency should be increased. One commenter recommended this reporting should occur every three years. A few commenters worried that 24 months would not be sufficient time for States to submit the assessment to CMS, and implement any system changes, which might require IT systems updates and acquiring additional funding from State legislatures. One commenter suggested that the assessment should be submitted every 5 years to align with the waiver renewal cycle.

One commenter noted that requiring an assessment every 24 months will create an unnecessary duplication of work. The commenter agreed with the need for an initial assessment but contended that the ongoing assessments were unnecessary, as States could independently monitor ongoing operations and make quality improvements and system updates as needed.

Response: We continue to believe that 24 months (and, for compliant systems, 60 months) is an appropriate frequency that ensures accountability without being overly burdensome. We refer readers to our prior response regarding situations in which we determine, based on the State's assessment, that its system does not meet the requirements finalized at § 441.302(a)(6).

We do not agree that requiring a regular schedule of system review is duplicative. If a State is already conducting regular system reviews as part of a quality improvement process, that review can form the basis for the every 24-month or, as appropriate, every 60-month assessment. We believe that for States that may not already have such processes in place, some regular schedule of review is necessary to ensure that over time, systems do not fall out of compliance. We also would encourage States to use these assessments as opportunities to conduct more comprehensive audits or reviews to identify opportunities for system improvements.

After consideration of the comments received, we are finalizing the reporting frequency in § 441.311(b)(1)(i) with a technical modification for clarity that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are finalizing § 441.311(b)(1)(ii) as proposed.

(2) Critical Incidents (§ 441.311(b)(2))

As discussed earlier in section II.B.4. of the proposed rule, at § 441.302(a)(6)(i)(A), we proposed to require States to define critical incidents at a minimum as verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

Based on the same rationale as discussed previously in section II.B.7.a.(1) of this preamble related to the proposed incident management system assessment reporting requirement, at § 441.311(b)(2), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report annually on the number and percent of critical incidents for which an investigation was initiated within State-specified timeframes; number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes; and number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes. We intended to use the information generated from the proposed reporting requirements at § 441.311(b)(2)(i) through (iii) to determine if States meet the requirements at § 441.302(a)(6)(ii).[121] Given the risk of harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement at § 441.311(b)(2) for States to report annually on critical incidents is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We invited comments on the timeframe for States to report on the critical incidents, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the minimum performance requirements for critical incident investigations proposed in § 441.302(a)(6), which form the basis of the reporting requirement at § 441.311(b)(2). These comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported our proposal at § 441.311(b)(2). One commenter observed that the current lack of standardized incident management systems across all States puts beneficiaries at risk and believed that the critical incident reporting requirements will help to prevent adverse experiences, increase accountability for States, and provide beneficiaries with an avenue of redress when they experience harm.

Response: We thank commenters for their support.

Comment: A few commenters opposed the reporting requirement at § 441.311(b)(2). One commenter

[121] We note that there was a typographical error in the NPRM at 88 FR 27987, incorrectly identifying the proposed reporting requirements at § 441.311(b)(2)(ii) through (iv), rather § 441.311(b)(2)(i) through (iii).

believed that building the necessary IT systems to complete the reporting will impose an extraordinary cost to States and take years to develop, test, and implement. Another commenter expressed concerns that the reporting requirements would necessitate a restructuring of some States' critical incident management, including revising policies, procedures, trainings, and processes.

Response: As discussed in the proposed rule (88 FR 27978), since 2014, States operating section 1915(c) waiver programs have been expected to demonstrate on an ongoing basis that they identify, address, and seek to prevent instances of abuse, neglect, exploitation, and unexplained death, and demonstrate that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible. While we acknowledge that some States may have to make some adjustments to their systems, we expect that most will be able to build on existing systems to achieve this reporting. We plan to offer States technical assistance as needed to support questions they may have about adjustments they need to make to existing policies, tracking, and reporting systems. We decline to make any changes in this final rule based on these comments.

Comment: A few commenters requested that we share more details about the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines.

Response: The reporting requirement at § 441.311(b)(2) will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein and discussed in this section II.B.7. of the rule, States must comply with the reporting requirement at § 441.311(b)(2) beginning 3 years from the effective date of this final rule]. Prior to that applicability date, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

Comment: One commenter requested clarification on whether the reporting was statewide or could be submitted for each program. The commenter noted that for States operating multiple critical incident systems, or tracking critical incidents at the program level, reporting of data at an aggregate statewide level will not only prove operationally challenging, but it could also limit the ability to identify and address program-specific issues.

Response: States are expected to report aggregated statewide data for this requirement. We believe that a State could track critical incidents by program at the State level and then aggregate this data for the purposes of the reporting requirement at § 441.311(b)(2). We plan to offer technical assistance to States, as needed, that have decentralized critical incident systems to facilitate the aggregated statewide reporting. We also note that States will be able to provide input into the reporting instrument when it is shared for public comment during the Paperwork Reduction Act notice and public comment process.

Comment: One commenter was critical of the proposed reporting metrics at § 441.311(b)(2), believing that the focus of the metrics was too much on timeliness: timely initiation of investigations, timely resolutions, and timely corrective action. The commenter did not believe that there was sufficient focus on the substance of the incidents. A few commenters recommended that we add the following metrics to § 441.311(b)(2): the number of critical incidents in each year, categorized by type of incident and extent of injury or by severity; whether corrective action was needed; whether corrective action was performed; whether any corrective action addressed the needs of current participants or future participants (or both); and whether corrective action adequately addressed participants' needs.

One commenter stated that the information should be reported to the public, although in a format that protects the anonymity of the beneficiary and filer. The commenter also suggested that a separate section of the public report should provide information on substantiated critical incidents by provider, including the service provider's owner and the name under which they are doing business.

Response: We disagree that the metrics in § 441.311(b)(2) focus only on timeliness. Inherent in these metrics is the expectation that States will promptly investigate and resolve critical incidents, which we believe is the essential purpose of the critical incident system. We developed the reporting requirement at § 441.311(b)(2) to strike a balance between collecting enough information to enable Federal oversight of the States' system designed to investigate and resolve critical incidents and imposing as minimal an administrative burden on States and providers as possible. We believe it is important for States to have flexibility in how they design their system to identify, report, triage, investigate, resolve, track, and trend critical incidents as set forth in the proposed requirements at § 441.302(a)(6), which we are finalizing as discussed in section II.B.3. We also believe that requiring a broad, national reporting requirement for States to report critical incident timeliness data will provide a mechanism to assess whether States are complying with their own timeframes for investigating, resolving, and implementing corrective actions, and to ensure States are complying with their own established processes for reviewing and addressing critical incidents.

We did not propose, and are not finalizing, specific requirements for how States must use this data. We will likely include promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, in technical assistance for States to aid in implementation.

We note that the data required in § 441.311(b)(2) is included in the public posting requirement we are finalizing at § 441.313 (discussed in greater detail in II.B.9. of this final rule). We are not requiring that States publicly report specific information about critical incidents, including the names of providers involved in critical incidents. We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about critical incidents. While we agree that, over time, qualitative data about trends in critical incidents could be useful to both States and other interested parties in promoting systemic improvements in their HCBS programs, we defer to States to determine when and how to make this information public, in accordance with applicable laws governing confidentiality of such information, and for what purpose.

Comment: A few commenters supported the proposal that this data should be reported on an annual basis. A few commenters recommended less frequent reporting, such as every two years, to reduce burden.

One commenter, while not necessarily recommending a different reporting frequency, noted that reporting requirements must take into account the unique factors that impact the length of time it could take to complete an

investigation or conduct corrective action. The commenter noted that depending on the nature of the corrective action and when the corrective action process begins in a reporting year, annual reporting may result in misleading data about the number of resolved critical incidents or completed corrective actions.

Response: Given the importance and time-sensitive nature of critical incident investigations, resolutions, and corrective actions, we believe it is necessary to collect this data on an annual basis so we may monitor these systems. We also clarify that the reporting is not intended to track how many critical incidents were investigated, resolved, or resulted in completed corrective actions in a reporting year; the requirement is to report how many critical incidents were investigated, resolved, or resulted in completed corrective actions within State-specified timeframes during the reporting period. Thus, even if the reporting period falls in the middle of a critical incident resolution or corrective action, these incidents would not be reported as ''non-compliant'' if they were still within the State-specified timeframes for completion.

After consideration of these comments, we are finalizing the introductory text at § 441.311(b)(2), with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also simplifying the title and moving the reference to § 441.302(a)(6)(i)(A) from the title of § 441.311(b)(2) to the introductory text. As finalized, the introductory text at § 441.311(b)(2) will specify that the State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(b)(2)(i) through (iii) as proposed.

(3) Person-Centered Planning (§ 441.311(b)(3))

Under the authority of section 1902(a)(6) of the Act, we proposed at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). Specifically, at § 441.311(b)(3)(i), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. At § 441.311(b)(3)(ii), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a reassessment of functional need within the past 12 months. These proposed requirements were based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance. As discussed in section II.B.7. of the preamble for the proposed rule, this feedback indicated that we should strengthen person-centered planning reporting requirements and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. These proposed requirements were also based on feedback received through the RFI [122] discussed earlier about the need to standardize reporting and set minimum standards for HCBS.

As discussed in section II.B.1. of the preamble for the proposed rule, we proposed a revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the re-assessment does not indicate a need for changes. As such, for the purpose of the reporting requirement at § 441.311(b)(3)(ii), beneficiaries would be considered to have had a person-centered service plan updated as a result of the re-assessment if it is documented that the required re-assessment did not indicate a need for changes.

For both of the metrics at § 441.301(c)(3)(ii), we proposed to allow States to report a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the waiver program for at least 365 days.

We invited comments on whether there are other specific compliance metrics related to person-centered planning that we should require States to report, either in place of or in addition to the metrics we proposed. We also invited comments on the timeframe for States to report on person-centered planning, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the person-centered service plans minimum performance requirements proposed in § 441.301(c)(3)(ii), which form the basis of the reporting requirement at § 441.311(b)(3). These comments and our responses are in section II.B.1. of this final rule.

Comment: A few commenters expressed support for the requirement that States report annually on the specified performance metrics for person-centered planning. Commenters echoed sentiments that are reflected in section II.B.1. of this final rule, that many States are already regularly performing the assessment and reassessment activities in compliance with the minimum performance standards being finalized in § 441.301(c)(3)(ii) and, thus, reporting on these activities is reasonable.

We did not receive feedback in response to our request for comment on additional or alternative metrics that should be included in the reporting requirement at § 441.311(b)(3).

Response: We thank commenters for their support. We note that the metrics in § 441.311(b)(3) are based on the minimum performance requirements being finalized at § 441.301(c)(3)(ii); comments on these minimum performance standards are discussed in section II.B.1. of this final rule.

Comment: A few commenters expressed reservations about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data.

Response: We intended that the proposed requirement allow States to report data and information for the person-centered service planning reporting metrics at § 441.311(b)(3) using a statistically valid random sampling of beneficiaries would reduce State burden, while still providing valuable data for strengthening States' person-centered service planning processes. We will consider expanding the reporting to capture the full population of beneficiaries receiving HCBS in future rulemaking if it is determined that such an approach gives a more complete picture of person-centered service planning. We note that States may choose to report on the total population for this measure as opposed to a sample, for instance, if doing so better aligns with their data collection process or needs.

We note that, as proposed, we stated in § 441.311(b)(3)(i) and (ii) that the State may report these metrics for a statistically valid random sample of

[122] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

beneficiaries. We are finalizing the requirements at § 441.311(b)(3)(i) and (ii) with a technical modification to specify that the State may report this metric **using statistically valid random sampling** of beneficiaries. (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: One commenter specifically noted that the frequency of annual reporting was feasible. One commenter noted that while the reporting frequency is reasonable, it is important to align with other reporting requirements already placed on States and managed care plans to minimize State and managed care plan reporting burdens.

A few commenters requested clarification on when the report required in § 441.311(b)(3) would be due to CMS and whether we would provide a template for the reporting. One commenter requested clarification on how this aggregated data should be reported, noting that current mechanisms for reporting similar data are waiver specific.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Per § 441.311(f) below, States must comply with the reporting requirement for § 441.311(b)(3) beginning 3 years from the effective date of this final rule]. Specific reporting due dates will be determined through subregulatory guidance; we will work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of the public comments received, we are finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted above to specify that the State may report this metric using statistically valid random sampling of beneficiaries. We are also finalizing a technical correction to the regulation text at § 441.311(b)(3). In the proposed rule (88 FR 27988), we indicated that we were proposing at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). In the publication of the proposed rule, this language was omitted from the regulatory text in error. We are finalizing § 441.311(b)(3) with technical modifications to specify that, to demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually. We are also making a technical modification to indicate that the reporting must be in the form and manner, and at a time, specified by CMS. We believe, based on the language included in the proposed rule (88 FR 27988) and the comments received, that commenters understood the intent of this regulation even with language omitted.

(4) Type, Amount, and Cost of Services (§ 441.311(b)(4))

As discussed previously in section II.B.4. of this preamble, we proposed to amend § 441.302(h) to avoid duplicative or conflicting reporting requirements with the new Reporting Requirements section at proposed § 441.311. In particular, at § 441.302(h), we proposed to remove paragraphs (1) and (2). At § 441.311(b)(4), we proposed to add the language previously at § 441.302(h)(1). In doing so, we proposed to retain the current requirement that States report on the type, amount, and cost of services and to include the reporting requirement in the new consolidated reporting section at § 441.311.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported this proposal.

Response: We thank the commenter for their support.

Comment: One commenter requested clarification on whether the reporting requirement at § 441.311(b)(4) will apply to managed care plans.

Response: The requirement at § 441.311(b)(4) replicates the current requirement at § 441.302(h), which applies to section 1915(c) programs, regardless of whether they are part of a FFS or managed care delivery system.

As stated in the proposed rule (88 FR 27988), it was our intent to consolidate the current reporting requirement at § 441.302(h)(1) with the new requirements being finalized at § 441.311. We note that as this requirement was presented in the proposed rule, we inadvertently struck part of the language from § 441.302(h) that we intended to retain in § 441.311(b)(4) that clarified the reporting frequency (annually) and the object (the 1915(c) waiver's impact on the State plan) of the requirement currently at § 441.302(h)(1). We are concerned that without this omitted language, § 441.311(b)(4) does not include information needed to implement this requirement. We believe that, as we expressed our intent in the proposed rule (88 FR 27988) to retain the reporting requirement at § 441.302(h)(1), readers would have understood that we intended to preserve the essential elements of the reporting.

To ensure that this requirement can be implemented as intended, we are finalizing § 441.311(b)(4) with language from § 441.302(h) to specify that, **annually,** the **State will provide CMS with information on the waiver's impact on** the type, amount, and cost of services provided under the State plan. (Restored language is noted in bold.)

We also specify here that, as the requirement at § 441.302(h) specifies certain reporting for programs authorized under section 1915(c), this new requirement at § 441.311(b)(4) will similarly apply only to section 1915(c) waiver programs. We discuss the impact of this clarification on references to section 1915(j), (k), and (i) services (at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) later in this section.

After consideration of the comments received, and in light of the clarification outlined above, we are finalizing the provision at § 441.311(b)(4) to specify that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan. Further, we are finalizing § 441.311(b)(4) with a technical modification to specify that the information is to be reported in the form and manner, and at a time, specified by CMS.

b. Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c))

At § 441.311(c), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report every other year on the HCBS Quality Measure Set, which is described later in section II.B.8. of the preamble. Specifically, we proposed, at § 441.311(c)(1)(i), to require that States report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the HCBS Quality Measure Set described in section II.B.8. of the final rule, on measures identified in the HCBS Quality Measure Set as mandatory measures for States to report or are identified as measures for which the Secretary will report on behalf of States, and, at § 441.311(c)(1)(ii), to allow States to report on measures in the HCBS Quality Measure Set that are not

identified as mandatory, as described later in this section of the rule.

We proposed every other year for State reporting in recognition of the fact that the current, voluntary HCBS Quality Measure Set is heavily comprised of survey-based measures, which are more burdensome, including for beneficiaries who would be the respondents for the surveys, and costlier to implement than other types of quality measures. Further, we believed that requiring reporting every other year, rather than annually, would better allow States to use the data that they report for quality improvement purposes, as it would provide States with sufficient time to implement interventions that would result in meaningful improvement in performance scores from one reporting period to another. We also proposed this frequency in recognition of the overall burden of the proposed requirement.

Because the delivery of high quality services is in the best interest of Medicaid beneficiaries, we proposed at § 441.311(c)(1)(iii), under our authority at section 1902(a)(19) of the Act, to require States to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.[123]

At § 441.311(c)(1)(iv), we proposed to allow States to establish State performance targets for other measures in the HCBS Quality Measure Set that are not identified as mandatory for States to report or as measures for which the Secretary will report on behalf of States as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those targets.

At § 441.311(c)(2), we proposed to report on behalf of the States, on a subset of measures in the HCBS Quality Measure Set that are identified as measures for which we will report on behalf of States. Further, at § 441.311(c)(3), we proposed to allow, but not require, States to report on measures that are not yet required but will be, and on populations for whom reporting is not yet required but will be phased-in in the future.

We solicited comments on whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, and if so, what that threshold should be. We also invited comments on whether the timeframe for States to report on the measures in HCBS Quality Measure Set is sufficient, whether we should require reporting more frequently (every year) or less frequently (every 3 years), and, if an alternate timeframe is recommended, the rationale for that alternate timeframe. We welcomed comments on any additional changes we should consider in this section.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the HCBS Quality Measure Set requirements proposed at § 441.312. These comments and our responses are in section II.B.8. of this final rule.

Comment: Regarding whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, one commenter recommended exemptions for States to develop improvement strategies if they are performing within the top 5th to 10th percentile of performance targets for the quality measures in the HCBS Quality Measure Set, to alleviate administrative burden. Another commenter discouraged CMS from permitting a compliance threshold exemption for States from developing improvement strategies, emphasizing that all States should be held accountable for providing high-quality care and services to beneficiaries receiving HCBS regardless of performance.

Response: We continue to believe that, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report, or are identified as measures for which we will report on behalf of States, States should establish and describe the quality improvement strategies to achieve the performance targets for those measures.[124] We reiterate our belief that the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, and will allow CMS and States to have comparative quality data on HCBS programs. As such, exempting States from developing improvement strategies for quality measures in the HCBS Quality Measure Set does not align with this intent.

Comment: Several commenters recommended either faster or slower implementation for reporting of the measures in the HCBS Quality Measure Set. A few commenters recommended we change the timeframe requirement for States to report on the quality measures in the HCBS Quality Measure Set to every year. In this same vein, one commenter suggested we align the reporting timelines required for reporting measures in the HCBS Quality Measure Set to other Medicaid, CHIP, Medicare, and Marketplace measure sets, expressing that reporting biennially (every other year) could lock in data lags that could hinder State progress in improving HCBS for beneficiaries. A few commenters recommended alternatives to the HCBS Quality Measure Set biennial reporting time frame. These alternatives included the following: initiating reporting based on State choice; reporting on odd- or even-numbered years; and beginning State reporting upon renewal of their section 1915(c) waiver or based on the State reporting years for their waiver program.

A few commenters expressed concern that the timeframe for reporting measures in the HCBS Quality Measure Set should be longer than every other year, emphasizing the significant amount of systems work, contracting, and survey data needed to capture the necessary data and implement reporting on HCBS measures. Commenters recommended we consider that the implementation of the HCBS Quality Measure Set reporting requirements as proposed at § 441.311(c)(1)(iii) could require State statutory and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative dates for States beginning reporting on the measures in the HCBS Quality Measure Set, ranging from an additional 3 to 5 years to address these concerns.

Response: We continue to believe that a biennial timeframe requirement for States to report on the measures in HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome and are finalizing the frequency of reporting as proposed. We determined that a shorter annual reporting timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make. For

[123] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

[124] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

However, to provide States sufficient time to comply with the requirements finalized at § 441.311(c), we are finalizing at § 441.311(f)(2) an applicability date beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set reporting at § 441.311(c). Our primary purpose in extending the effective date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

In general, we anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or acquire any additional support needed to report on the quality measures in the HCBS Quality Measure Set.

We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A few commenters requested confirmation of whether States with section 1115 demonstrations are expected to comply with the HCBS Quality Measures Set requirements in this final rule.

Response: Yes, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the reporting requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this rule, including the requirements at § 441.311 (and the related quality measure requirements at § 441.312), would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or exclude one or more of the requirements as part of the approval of the demonstration project.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy the ability to report the quality measures in the HCBS Quality Measure Set.

Response: We note that Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including of enhancements), and for operation, of mechanized claims processing and information retrieval systems. We also note that under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include developing and deploying the ability to report the quality measures in the HCBS Quality Measure Set.

Comment: A few commenters expressed that instructions related to the reporting requirements for the quality measures in the HCBS Quality Measures Set, and how they are related to the section 1915(c) waiver reporting requirements, would be helpful for implementing the reporting of the measure set.

Response: We thank commenters for the feedback. We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting and help facilitate compliance with this requirement.

After consideration of public comments received, we are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(f)(2), we are finalizing that States must comply with the reporting requirements at § 441.311(c) beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set. Our primary purpose in extending the applicability date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

c. Access Reporting (§ 441.311(d))

As noted earlier in section II.B.6. of this preamble, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI [125] discussed earlier, indicated that there is a need to improve public transparency and processes related to States' HCBS waiting lists and for standardized reporting on HCBS access, including timeliness of HCBS and the comparability to services received to eligibility for services. At § 441.311(d) we proposed that the State must report to CMS annually on the following, according to the format and specifications provided by CMS. We are finalizing in this rule § 441.311(d) with a technical modification for clarity that requires that the State must report to CMS annually on the following, **in the form and manner, and at a time,** specified by CMS. (New language identified in bold.)

(i) Waiver Waiting Lists (§ 441.311(d)(1)(i))

At § 441.311(d)(1)(i), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States provide a description annually, according to the format and specifications provided by CMS, on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program, if they have a limit on the size of the waiver program and maintain a list of individuals who are waiting to enroll in the waiver program, as described in § 441.303(f)(6). We further proposed to require that this description must include, but be not limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. We also proposed to require States to report, at § 441.311(d)(1)(ii), the number of people on the waiting list, if applicable, and, at § 441.311(d)(1)(iii), the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable. We invited comments on whether there are other specific metrics or reporting requirements related to waiting lists that we should require States to report, either in place of or in addition to the requirements we proposed. We also invited comments on the timeframe for States to report on their waiting lists, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the related requirement at § 441.303(f). Those comments are addressed in section II.B.6. of this rule.

Comment: Many commenters supported the proposal at § 441.311(d)(1) to require States to report on waiting lists, including whether the State screens individuals on the list for eligibility, frequency of re-screening, number of individuals waiting to enroll, and average amount of time newly enrolled individuals were on the waiting list. Commenters

[125] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

believed that this reporting would promote consistency, transparency, oversight, and accountability of waiting list practices and help States identify unmet needs among their Medicaid beneficiaries. Commenters noted that this additional information will better allow interested parties to advocate for policy changes to address underlying causes of waiting lists and expand HCBS programs; one commenter described this requirement as a good ''first step'' to understanding access issues for HCBS waivers.

A few commenters stated this requirement, with its potential to support policies that reduce waiting lists, would help beneficiaries avoid having to turn to institutional care for their LTSS needs. Commenters also noted transparent, understandable data about waiting lists may help individuals and families to make more informed decisions about accessing coverage as they plan for their future.

A few commenters noted that nationally comparable data and information-sharing among States will encourage standardization of waiting list processes and help States identify best practices for reducing waiting lists. Commenters noted that inconsistencies in the way States report data about their waiting lists and the current lack of standardized reporting requirements makes it difficult to form a clear picture of how many people are waiting to receive services, as well as how many of these individuals on the waiting list are actually eligible for services. One commenter suggested that making the waiting list public may lead to needed administrative updates to waiting lists, such as removing duplicate applications or applications from beneficiaries who have moved out of State or passed away.

Response: We agree that this critical data is not currently available in a way that allows for monitoring or comparison on a national level. We believe that this reporting requirement is an important first step in making data publicly available that can be used to identify unmet needs among Medicaid beneficiaries, support policymaking, and improve administrative efficiency.

Comment: A few commenters expressed opposition to, or concerns about, the waiting list reporting requirement at § 441.311(d)(1). A few commenters expressed concerns that the reporting requirement did not align with current State waiting list practices and would require significant change in data collection and IT systems. One commenter was concerned that due to differences in States' HCBS programs, infrastructure, and waiting list practices, attempting to collect and compare data on a national level could be misleading. A few commenters requested clarification on how CMS would use this data to drive meaningful policy changes and improvement in HCBS access. A few commenters stated that the proposed requirements would not address the underlying causes of waiting lists, which they attributed to limited funding for HCBS waiver slots, low Medicaid reimbursement rates, delays or barriers within States' Medicaid eligibility determination processes, or shortages of HCBS direct care workers. A few commenters, while not necessarily opposing the requirement at § 441.311(d)(1), suggested that we focus on gathering information about why States have caps on the number of beneficiaries who may be served by HCBS waivers and why States have waiting lists when they have not met their waiver caps.

One commenter raised a concern that the reporting requirement would cause States to redirect or prioritize resources for waivers with waiting lists at the expense of waivers that currently do not have waiting lists.

Response: We are not currently collecting States' data on their waiting lists and understand that States may have to update data collection systems to comply with this new requirement. We proposed the reporting requirement at § 441.311(d) to strike a balance between collecting enough information to enable Federal oversight of States' waiting list practices and imposing as minimal an administrative burden on States and providers as possible. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement. The reporting requirement at § 441.311(d)(1) is a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices. We acknowledge that differences in States' HCBS programs may initially make comparing States' data challenging, but we believe that collecting this data will help highlight such differences and draw connections between different States' policies and the impact on their beneficiaries' access to HCBS. As noted by other commenters, States may be able to use this data to learn from the experiences of other States.

We acknowledge that there are many underlying causes for States to have long waiting lists, but we believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these waiting lists through data collection. This data will not only help identify situations in which a State appears to be maintaining a waiting list when not all of the waiver's slots are taken but can also facilitate conversations with States about reasons for limitations on waiver enrollment.

We clarify that the purpose of this requirement is to document unmet needs for individuals who are seeking enrollment in HCBS waivers and to identify resources or practices that could be used to improve waiting list processes. As such, our goal is not to require that States shift needed resources away from other areas of their Medicaid programs.

Comment: One commenter requested that we provide reporting tools to help States track the required data. One commenter requested that the data needed for this reporting requirement be derived from the State's own eligibility and service authorization processes, not from providers and beneficiaries, particularly for self-directed services.

Response: We plan to release subregulatory guidance and other tools to assist States with implementation of this reporting requirement. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

While States have flexibility as to how they will gather the data needed to complete this reporting, we encourage States to find ways to rely on administrative data rather than gathering data directly from beneficiaries to meet the reporting requirements.

Comment: A few commenters requested that the information about waiting lists be made available to the public in a consumer-friendly and accessible format in order to facilitate program accountability and potentially improve beneficiary understanding of waiting list information. One commenter suggested that publishing data about the waiting list may help publicize the need for more direct care workers.

Response: As discussed in more detail later in section II.B.9 of this rule, we are finalizing a requirement at § 441.313(a) to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and that provides the results of the reporting requirements at § 441.311 (including this access reporting requirement at § 441.311(d), as well as the incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; and

payment adequacy data, discussed in this section) and the reporting requirements at § 441.302(k)(6). Please refer to the discussion of the website posting requirements in section II.B.9. of this rule.

Comment: One commenter suggested that we consider offering incentives for States to reduce or end waiting lists through a higher FMAP rate for a limited time period. One commenter requested that States be given a grace period and allowed to update their section 1915(c) waivers prior to any punitive action.

Response: We note that the requirement at § 441.311(d)(1) is a reporting requirement intended to encourage transparency and does not include any specific performance measures with which States must comply. To the extent that States are in compliance with existing requirements for section 1915(c) waiver programs, it is also not intended to require that States make changes to their waiver programs or processes. We intend to use our standard enforcement discretion to require State compliance with the reporting requirement, which (as discussed under § 441.311(f) below) will go into effect three years after the effective date of this final rule. In addition, we note that CMS does not have authority to provide States with a higher FMAP rate for any expenditures than has been authorized by statute.

Comment: A number of commenters noted that waiting list terminology, definitions, and processes vary widely among States and even among individual State programs. Commenters observed that some States operate what they refer to as interest lists, preauthorization lists, or similarly named lists, rather than waiting lists. In some cases, individuals can sign up to express interest in a waiver program but may not have yet been assessed for eligibility at the time they joined the interest list. Commenters questioned whether these individuals would be considered ''waiting to enroll'' as described in the proposed rule, as they are waiting to be determined eligible to enroll. Commenters requested clarification as to what data would be collected from States that maintain interest lists or similarly named lists of individuals who have not yet been determined to be eligible for the waiver.

A few commenters expressed concerns that if interest lists are not included in this requirement, States may be encouraged to stop maintaining waiting lists. One commenter noted that if the requirement does apply to interest lists, States that use an interest list approach would have to make significant changes to their processes to meet the waiting list reporting requirement. One commenter observed that in their State, the State maintains a single waiting list for all waivers, which could complicate reporting.

Several commenters requested that we create a definition of a waiting list. One commenter supported what they believed to be our proposed standardized definition of a waiting list (but did not specify what they thought that definition to be). A few commenters requested that we require States to have waiting lists for their waiver programs and that States screen individuals for eligibility prior to placing the individuals on the waiting list.

Response: We intended for the reporting requirement to apply to all States that maintain a list of individuals interested in enrolling in a section 1915(c) waiver program, whether or not the individual has been assessed for eligibility. As we stated in the proposed rule (88 FR 27986), many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services.

We note that the requirement at § 441.311(d)(1) requires States to submit a description of their waiting list that includes information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. This requirement indicates that § 441.311(d)(1) applies to States even if they do not screen the individuals on their list for eligibility. We believe that for the purposes of this requirement individuals who are waiting to be screened for eligibility for the waiver are considered ''waiting to enroll.''

We believe that States that maintain an interest list (or a similarly named list of individuals who have expressed interest in the waiver and are waiting to be assessed for eligibility) can report the same information required in § 441.311(d)(1) as States that maintain lists of individuals who have been screened for eligibility. We expect, for instance, that States typically would have information about the number of individuals who are on an interest list and how long those individuals have been on those lists. If a State maintains two separate lists for a waiver—a list of individuals who have been screened for eligibility for the waiver and a list of individuals who have expressed interest in enrolling in the waiver but have not yet been screened—the State should report on both to meet the reporting requirements at § 441.311(d)(1).

As we did not propose a formal definition of waiting list, nor a requirement for States to maintain a waiting list of individuals who have been screened for eligibility, we will not add these components to the finalized § 441.311(d). States retain flexibility in determining whether or not to maintain a list of individuals who are interested in enrolling in the waiver (whether or not the individual has been screened for eligibility). We will take commenters' recommendations into consideration for future policymaking if, after monitoring reporting generated by § 441.311(d), we identify the need for further standardization of these processes.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding the waiting list. One commenter recommended that we not add more metrics to § 441.311(d)(1). Several commenters did suggest additional metrics. Many of these commenters believed that more detailed data would allow for a better assessment of overall unmet needs and disparities within the waiting lists. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, Tribal status, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Disaggregated data on beneficiaries' dual eligible status, disability, diagnosis, functional status, level of care, and risk of institutionalization;
- Whether States maintain separate waiting lists or registries for beneficiaries who are eligible for HCBS but have been determined by the State to not have a need prioritized by the State for enrollment in the waiver;
- The criteria used to determine beneficiaries' placement and movement within a waiting list;
- How much time individuals spend waiting for an eligibility assessment and how much time elapses between an assessment and service authorization;
- The number of eligibility screens performed on each beneficiary on the waiting list in the past year, and why a rescreen was performed;
- The number of beneficiaries removed from the waiting list due to death, admission to an institutional

setting, or having been rescreened and deemed ineligible;

- The number of beneficiaries on the waiting list who are receiving care through another State Medicaid program, reasons why beneficiaries prefer to remain on the waiting list rather than enroll in other services, and what beneficiary needs remain unmet by other Medicaid programs while a beneficiary is on a waiting list; and
- Whether a participant who has been approved for HCBS waiver services is able to find a provider, how long it took for them to find that provider, and what services they wanted, but could not access because no provider was available.

Response: We thank commenters for their feedback. We will take these recommendations under consideration for future policymaking, but at this time decline to make modifications to the requirements based on these comments.

We believe it is important to strike a balance between collecting enough information to promote transparency around waiting lists and imposing as minimal an administrative burden on States and providers as possible. We also believe that information on whether States screen individuals on their waiting lists, the number of beneficiaries on the waiting list, and the average amount of time beneficiaries enrolled in HCBS waivers spent on the waiting list provides important preliminary data on the States' waiting list practices. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to section 1915(c) HCBS waiver programs in their State.

Comment: One commenter recommended requiring that States report duplicated and unduplicated counts of individuals across waiver program waiting lists.

Response: We have not identified a compelling reason to require that States report unduplicated counts of beneficiaries for all waiver programs. We clarify that the reporting required for § 441.331(d)(1) is for each waiting list; if an individual is on multiple waiting lists, we believe that person should be counted among individuals on each of those waiting lists.

Comment: A few commenters recommended additional metrics that fall outside the scope of reporting on waiting list practices or waiver enrollment, including:

- Whether individuals on waiting lists are also being screened for eligibility for other programs that they may be able to benefit from (for example, Supplemental Nutrition Assistance Program);
- How long it takes a State to approve enrollment in any program that provides Medicaid LTSS, from the date that it receives an application until the date of the approval letter; and
- Additional measures to assess the needs of populations that face barriers to navigating the HCBS programs, applying, and getting on a waiting list.

Response: While these metrics lie outside the scope of the proposed reporting requirements, we will add these to other comments regarding broader HCBS access and equity issues that we will consider for future policymaking.

Comment: A few commenters suggested that we collect data on reasons for long waiting times, such as challenges with workforce availability or provider capacity. Some commenters, particularly those representing States or providers, were concerned that without this information, States and providers would be held responsible for long waiting lists or long waiting times for services that are due to reasons beyond States' or providers' control. One commenter recommended adding a requirement that States describe any conditions, such as State funding priorities, that serve to limit access to the HCBS described in the waiver application. A few commenters recommended adding a requirement to the interested parties' advisory group being finalized at § 447.203 that would require States, through their interested parties' advisory groups, to examine reasons for gaps in services that are revealed by the reporting on waiting lists.

Response: We do not believe it would be feasible at this stage to standardize the collection of qualitative data regarding the causes of waiting lists; this data would also be difficult to validate. As noted in prior responses, the purpose of the requirement at § 441.311(d)(1) is to encourage transparency; the requirement does not include any specific performance measures with which States or providers must comply. We believe that collecting the number of individuals on the waiting list and the length of time individuals spend on waiting list will present quantifiable and comparable baseline data that can facilitate more nuanced conversations with States about potential unmet beneficiary needs and the underlying causes of these unmet needs.

We note that, regarding the interested parties' advisory group being finalized at § 447.203, the requirements at § 447.203 already include an expectation that access reporting that is required by 441.311(d) would be appropriate data for the Interested Parties Advisory Group (IPAG) to consider when making recommendations regarding the sufficiency of rates. We decline to add a specific requirement as suggested by the commenter, as we wish to allow both States and the IPAGs some discretion in determining their approach to examining the impact on payments rates in their State.

Comment: A few commenters supported annual reporting for § 441.311(d)(1). One commenter observed that one of their State agencies had already identified annual reporting on the waiting list as a best practice and was publishing an annual report. One commenter recommended quarterly reporting to encourage States to take more aggressive steps to reduce the size of their waiting lists. A few commenters believed that biennial (every other year) reporting would reduce burden on States and better account for fluctuations in waiting list size that are beyond the State Medicaid agency's control.

One commenter highlighted that waiting list volumes may vary at certain times of year or from year to year, depending on how States structure the release of new waiver slots and the timing of the State legislative sessions where new funding for waiver slots may be approved. The commenter stated that it is important to take these factors into account when considering reporting frequency and when evaluating reported data from year to year.

Response: We are finalizing the annual reporting frequency as proposed at § 441.311(d)(1). We continue to believe that annual reporting on waiting lists strikes the right balance between collecting current data on waiting lists and minimizing burden on States to the greatest extent possible. We believe reporting more frequently than annually may represent an undue burden on States, although States are encouraged to share information with interested parties within their State on a more frequent basis if they are able to do so. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior

to the next public report. We also note that States will likely have to develop or maintain the same data tracking systems regardless of whether the reporting itself is done annually or biennially; we believe the potential reduction in administrative burden by biennial reporting is outweighed by the need for more timely information on waiting lists.

Comment: One commenter requested clarification that the reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project. As discussed later in this section, section II.B.7. of this final rule, we are finalizing the application of the reporting requirements at § 441.311 to section 1915(j), (k), and (i) authorities with modifications to specify that States must only comply with the reporting requirements applicable to the services under these authorities.

After consideration of the commenters received, we are finalizing § 441.311(d)(1) as proposed.

(ii) Reporting on Wait Times for Services and Authorized Service Hours Provided (§ 441.311(d)(2))

At § 441.311(d)(2)(i), based on our authority under section 1902(a)(6) of the Act, we proposed to require States report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. We proposed to focus on these specific services for this reporting requirement because of feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties that timely access to these services is especially challenging and because the failure of States to ensure timely access to these services poses substantial risk to the health, safety, and quality of care of individuals residing independently and in other community-based residences. We believed that having States report this information will assist us in our oversight of State HCBS programs by helping us target our technical assistance and monitoring efforts. We requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

For this metric, we proposed to allow States to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months, rather than for all individuals newly approved to begin receiving these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to the amount of time that it takes for eligible individuals to begin receiving homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed.

At § 441.311(d)(2)(ii), also based on our authority under section 1902(a)(6) of the Act, we proposed to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. For this metric, we further proposed to allow States to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to individuals' use of authorized homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed. We further requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals at § 441.311(d)(2) that States report on the time it takes between service authorization and service delivery and the number of authorized hours compared to the number of hours provided. A few commenters, while characterizing these as imperfect measures, nevertheless noted that the data measurements can help assess systematic issues with provider enrollment and access to care. One commenter observed that similar data is not currently available from their State, and believed this type of data would be useful.

Commenters noted that in their experience, beneficiaries might wait months after being authorized to receive services for the services to actually begin, or do not receive all of the services indicated in their person-centered care plan; these delays and underutilization of services cause a wide array of issues for the beneficiary and their families.

Commenters also noted these proposals complemented the waiver waiting list requirement at § 441.311(d)(1), noting that even when individuals are enrolled in a waiver, this does not always mean that their services start immediately. A few commenters also stated that in their experience, even in States that do not have waiting lists for their waiver programs, beneficiaries may wait long periods of time for the waiver services to begin.

Response: As we discuss further in responses below, we recognize that the reasons for service delays and underutilization are nuanced. The reporting requirements at § 441.311(d)(2) are a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices.

Comment: A few commenters cited factors that may contribute to delays or underutilization of services, some of which are beyond the control of State Medicaid agencies, managed care plans, or providers. Commenters cited challenges including administrative inefficiency, shortages of direct care workers or available providers, and geographic constraints. Other

commenters cited specific obstacles, such as: difficulty in obtaining complete medical information from the beneficiary, delays in the care planning process, additional training requirements for self-directed service workers, lags in providers submitting claims or other delays in claims processing, or unavailability of the beneficiary due to travel, hospitalization, changes in provider, withdrawal from the program, or loss of Medicaid eligibility. A few commenters suggested that in some cases, beneficiaries decline services or are already receiving a different service that meets their needs prior to the new services being authorized.

One commenter noted that there are service delivery delays in care provided under private payers and wondered how these delays compare to those in Medicaid HCBS and whether they may be attributable to the adequacy of the provider network or to reimbursement rates.

A few commenters believed that the requirements at § 441.311(d)(2) would not address these underlying causes of service delays or underutilization and, thus, would not improve access to services. One commenter requested clarification on how this data would be used to promote meaningful change.

On the other hand, some commenters believed that the requirements at § 441.311(d)(2) can help identify unmet needs and uncover some of the causes of these challenges, which in turn can focus efforts on efficient solutions.

Response: We acknowledge that there are many underlying causes for service delays or service underutilization. We believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these delays or underutilization through data collection. Additionally, some of the challenges commenters cited are within the purview of States, managed care plans, or providers to address. If the data demonstrates what appears to be significant delays or underutilization, we believe this information can help facilitate conversations with States, managed care plans, and providers about the reasons for these reporting results.

We also note that the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that were provided. Thus, some of the factors that commenters cited, particularly those involving the behavior of specific beneficiaries, such as failure to provide timely medical data, declining services, or traveling, we believe should not significantly impact the reported numbers unless these obstacles are particularly prevalent (in which case, this may also be an area to identify for policy or program improvement).

Comment: A few commenters opposed the requirements at § 441.311(d)(2). A few commenters suggested that some States or managed care plans are not currently tracking the time between service authorization and the start of services and that it would take significant resources to develop, test, and deploy changes to the State's documentation management system. One commenter noted that it may be difficult to track this data because services are authorized, and claims are paid using different systems or are overseen by different parts of State government. One commenter noted that, while their State does track service utilization data, it would take additional staff resources to comply with the reporting requirements.

Response: We are not currently collecting States' data on the times between service authorization and when services begin, or the number of authorized hours that are being utilized and understand that States may not be tracking all of this data; the absence of this data is what has prompted us to propose the requirement at § 441.311(d)(2). We recognize that, because this data has not previously been tracked by all States, some States may have to update their data collection systems to comply with this new requirement. As discussed elsewhere in this rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. We also note that, under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan.

We developed the reporting requirement at § 441.311(d)(2) to strike a balance between collecting enough information to enable Federal oversight of service delivery and utilization and imposing as minimal an administrative burden on States and providers as possible. We believe the long-term benefits of collecting this data outweigh the initial burden of implementation. Accordingly, we decline to make any changes in this final rule based on these comments.

We are finalizing § 441.311(d)(2)(i) with a modification that we believe will further reduce administrative burden on States. As noted in an earlier comment summary, some commenters noted that in some instances beneficiaries may wait long periods of time to receive services. Upon further consideration, we have determined that the requirement at § 441.311(d)(2) as written may present some data collection challenges in situations in which the beneficiary's date of approval of service and the date when services actually begin are separated by enough time that they fall in two different reporting periods. For instance, if the reporting period aligned with the calendar year, if an individual was approved for services on November 1, 2028, but did not start receiving services until February 1, 2029, it is not clear how that beneficiary's wait time for services would be captured in the reporting period for January 1, 2028, through December 31, 2028. (We note that we are using the calendar year as the reporting period only for the purposes of this example. As discussed later in this section, we will work with States and other interested parties through the Paperwork Reduction Act process to determine the actual reporting period.) It appears that in this circumstance, the State would have to first indicate that the beneficiary had waited 2 months (November 1, 2028, through the end of the reporting period on December 31, 2028); then the State would need to submit updated information for this beneficiary to report the beneficiary's total wait time. This process would need to be repeated on a rolling basis for other beneficiaries whose approval date and service start date fell in different reporting periods. Repeated updates to States' data would be burdensome, make it difficult for States to share meaningful data with CMS and the public, and lead to delays in State reporting of complete data for each reporting period.

To avoid this type of confusion in reporting, we are amending the requirement at § 441.311(d)(2)(i) to specify that the reporting is for individuals **newly** receiving **services,** rather than for individuals newly approved to begin receiving services. (Revised language is noted in bold.) As applied to the example above, this

modification to § 441.311(d)(2)(i) means that the beneficiary whose services began on February 1, 2029 would be included in the January 1, 2029, through December 31, 2029, reporting period; the State would be able to ''look back'' to identify when the services were approved (in the example, services were approved November 1, 2028) and the State would report the beneficiary's total wait time between November 1, 2028 and February 1, 2029. We believe this modification preserves the intention of what we proposed in § 441.311(d)(2)(i)—to measure the time between when a beneficiary was approved to receive services and when the services actually begin—but clarifies and streamlines the reporting process.

Comment: A few commenters expressed concerns that States would use information about unfilled service hours to infer whether or not authorized services are necessary for the beneficiary. These commenters noted that many reasons exist as to why an individual would be unable to receive authorized care on a particular day but still need the care, such as the service provider was unavailable or there was confusion around when and what services were to be delivered on that day. One commenter requested reassurance that the reporting requirement at § 441.311(d)(2)(ii) to report on the average number of hours authorized that are provided would not be used to reduce or limit beneficiaries' access to services. One commenter suggested that we monitor services to ensure that States are not reducing services in response to this data.

Response: The purpose of this reporting requirement at § 441.311(d)(2)(ii) is not to audit individual beneficiaries' service utilization or to use the information as a reason to reduce their authorized service hours. The purpose and intent of the requirement is to identify barriers to beneficiaries' access to services. Accordingly, we decline to make any changes in this final rule based on these comments. However, we note that the State is required at § 441.301(c)(2) to ensure that the person-centered service plan reflects the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports, and this requirement remains unchanged. States and managed care plans should not use the data collected to meet the reporting requirement at § 441.311(d)(2)(ii) to reduce authorized hours.

Comment: One commenter requested clarification on when the approval of services occurs, such as at the time of enrollment or when a physician signs the plan of treatment. The commenter also observed that it will be critical to standardize the data elements that must be captured in this reporting.

Response: Given the variable nature of States' processes, we defer to States to determine when services are considered to have been approved and how this approval date can be tracked consistently for the reported services. We intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which will aid in consistent data reporting. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

Comment: A couple of commenters recommended requiring States to set a target for timeliness (such as 7 days) and measure the percentage of all cases in which the wait time exceeded that target.

Response: At this time, we are focusing on creating baseline data-reporting standards. We will take these recommendations for setting or requiring benchmarks under consideration should we pursue future rulemaking in this area.

Comment: We received responses to our comment solicitation on whether § 441.311(d)(2) should apply to other section 1915(c) services aside from homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

One commenter recommended narrowing the scope of this requirement to personal care services only and removing homemaker and home health aide services from the requirement. The commenter contended that homemaker services do not cover activities of daily living which are typically associated with direct care to HCBS beneficiaries. The commenter also noted that home health aide services are typically offered under the Medicaid State plan rather than a section 1915(c) waiver. The commenter concluded that limiting the requirement to personal care services would allow CMS and States to concentrate on highly utilized personal care services and would make the requirement more operationally feasible for States.

On the other hand, a few commenters advocated for extending the reporting requirements to all HCBS. One of these commenters suggested that applying the requirement to only a few services would create an unintended consequence of focusing more attention on certain services and the populations receiving those services, at the expense of other beneficiaries. A few of these commenters also pointed out that other services are experiencing direct care worker shortages that could be contributing to service delays or underutilization that need to be identified.

One commenter suggested that we add services offered by specialty providers, such as occupational therapists, physical therapists, or speech-language pathologists, to the requirement.

A couple of commenters recommended extending the requirement to include services typically delivered to people with intellectual or developmental disabilities, such as habilitation services. Similar to the reasons cited by commenters for extending the requirement to all HCBS, commenters in favor of extending the requirements to include habilitation noted that these services are critical and beneficiaries who receive them are experiencing delays in services or other access issues. However, one commenter requested that we not extend these requirements to habilitation services, citing concerns that some States' information systems are not equipped to track this information for habilitation services. The commenter also noted that differences between habilitation services and other types of HCBS require additional study and consideration prior to applying these reporting requirements for habilitation services.

Response: We believe that the services proposed for inclusion in this requirement include activities of daily living that are critical to beneficiaries' health, safety, and ability to live successfully in the community. Additionally, as identified in an analysis performed by CMS, the three services fall within the taxonomy of home-based services, which are both high-volume and high cost.[126] Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of frequently used services. Given the similarities among homemaker, home health aide, and personal care services, we cannot find a justification for removing homemaker

[126] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

and home health aide services from this requirement.

Because we want to start by focusing on a selection of high-volume, high-cost services, we do not at this time intend to expand the reporting requirement to all HCBS. We do agree with commenters that services in addition to homemaker, home health aide, and personal care services may be particularly vulnerable to delays due to shortages in the direct care workforce. For that reason, we are extending the requirement to habilitation services in this final rule which, like homemaker, home health aide, and personal care services, tend to be hands-on services that are delivered by direct care workers who often earn lower wages. We believe that expanding the reporting to include habilitation services will ensure that beneficiary populations, namely individuals with intellectual or developmental disabilities who commonly receive personal care services as part of their habilitation services, are not excluded from our efforts to support the direct care workforce.

We acknowledge the comment that habilitation services are unique from other services, but also cannot identify reasons why these differences should exclude them from this reporting requirement.

After consideration of these comments and the benefits of aligning reporting requirements across services, we are finalizing the reporting requirements at § 441.311(d)(2)(i) and (ii) with a modification to include homemaker, home health aide, personal care, and habilitation services, as set forth at § 440.180(b)(2) through (4) and (6).

Comment: One commenter requested clarification on whether § 441.311(d)(2) would apply to services in both managed care and FFS delivery systems. One commenter requested that we require reporting on managed care plans' prior authorization practices, including differing lengths of authorizations and untimely authorizations that were not in place or renewed prior to the date of expected services. The commenter noted that missing authorizations may cause disruptions in payments to providers and threaten the continuity of beneficiaries' access to the services.

Response: The reporting requirements apply to services delivered under both FFS and managed care delivery systems. For additional information, we refer readers to the discussion of §§ 441.311(f) and 438.72(b) below. We note that a State may consider requiring reporting on specific managed care processes through its contracts with managed care plans.

Comment: A few commenters requested clarification as to whether the requirements at § 441.311(d)(2) would apply to self-directed services. A few commenters raised specific questions or concerns about the application of the reporting requirements at § 441.311(d)(2) to self-directed services, particularly self-directed service models with individual budget authority. Commenters noted that the inherent flexibility of these services might make reporting on the utilization of service hours particularly misleading. One commenter noted that, when an individual selects an independent worker to provide services, that worker might have to go through background checks and training that would make it appear that the service delivery is delayed. One commenter worried that States would become concerned with the appearance of delays in the delivery of self-directed services and discourage beneficiaries from seeking self-directed services. Another commenter pointed out that since beneficiaries might use their budget authority to purchase equipment or devices that replace some hands-on services, or may choose to adjust their service schedules, service utilization data on these services might inaccurately suggest that the beneficiary is being underserved. On the other hand, one commenter recommended that self-directed services be included in this reporting. Another commenter stated that from their personal experience as a provider, beneficiaries receiving self-directed services tend to have higher service utilization rates than beneficiaries in agency-directed services. One commenter suggested that data on all models of self-directed services be tailored to the unique needs of the model, such as by requiring reporting on the percent of the budget used rather than the number of service hours. Another commenter suggested that additional guidance would be needed to apply the reporting requirements to self-directed models.

Response: As discussed in section II.B.7.e. of this final rule, these reporting requirements will apply to self-directed services. We thank commenters for raising these concerns. As noted earlier, we intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which should aid in reporting on self-directed services. As noted in a prior response, the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that are provided. Thus, some of the factors that commenters cited, such as additional training for self-directed service workers or individual beneficiaries' changes in schedules, should not significantly impact the reported numbers. However, we will work with States to monitor this issue.

Comment: A few commenters raised concerns about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data. Commenters were concerned that using a sample could mask disparities or fail to identify individuals with particularly acute unmet needs. One commenter suggested that if we permit reporting on a random sample, we add a requirement that the data must include information on race, ethnicity, and population (such as older adults, people with intellectual and developmental disabilities, and people with physical disabilities) in order to identify disparities in service delivery.

Response: To minimize State reporting burden, we are finalizing the requirement to allow States to report data for § 441.311(d)(2) using statistically valid random sampling. We believe that due to variety in States' current tracking systems, some States might find reporting using statistically valid random sampling to be more manageable and auditable than attempting to report on all beneficiaries. We will consider expanding reporting to the full population in future rulemaking if it is determined that such an approach gives a more complete picture of service delivery. We note that States may choose to report on the full population, as opposed to sampling their beneficiaries, if for instance, doing so better aligns with their data collection process or needs.

We are finalizing the requirements at § 441.311(d)(2)(i) and (ii) with a technical modification to specify that the State may report this metric using **statistically valid random sampling of beneficiaries.** (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding service delivery and utilization. One commenter

recommended that we not add more metrics to § 441.311(d)(2). Several commenters did suggest additional metrics. Many of these commenters noted that more detailed data would allow for a better assessment of overall unmet needs and disparities within service delivery. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Tracking the total number of beneficiaries who received service authorizations versus the number of beneficiaries who received services;
- Tracking why services are not provided or why a beneficiary declines a service;
- Disaggregated data by HCBS authority and population (including dual eligibility), delivery system, provider type, and managed care plan; and
- Tracking beneficiaries' long-term access to services or other metrics to measure continuity of care and how the care contributes to beneficiaries' goals and outcomes.

One commenter, while not recommending that we require the measure for all States, shared a State's experience of including a measure to assess missed visits in its managed LTSS program. The commenter observed that this required a significant amount of time to identify legitimate reasons for services to not have been provided and to build the system mechanisms to capture that data, which was primarily identified through case management record review.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time, we decline to modify the metrics required at § 441.311(d)(2) based on these comments.

As noted in previous responses, we do not believe it would be feasible at this stage to standardize the collection of certain types of qualitative data, such as reasons for delayed or undelivered services, or how the services contribute to beneficiaries' outcomes; this data would also be difficult to validate and, as noted by one commenter, time-consuming to implement.

We believe it is important to strike a balance between collecting information to promote transparency around service times and utilization and imposing as minimal an administrative burden on States and providers as possible. We also believe that the reporting requirements at § 441.311(d)(2) are straightforward metrics on which to begin reporting. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services and may consider additional reporting requirements in the future.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to HCBS waivers in their State.

Comment: A few commenters recommended additional metrics that fall outside the scope of the reporting in § 441.311(d)(2). One commenter recommended collecting data on case manager or service coordinator caseloads. A few commenters recommended measuring time between an individual's date of application and their eligibility determination, and the time between an individual's eligibility determination and the plan of care development or authorization for services.

Another commenter noted that a cause of delay in receiving HCBS may be due to delays in the development of care plans that are required for HCBS delivery to begin. The commenter noted that a potential solution to this specific barrier is the use of provisional plans of care, which are discussed in Olmstead Letter #3.[127] The commenter recommend that we affirm that HCBS provisional plans of care are an available option and require States to report on usage of such plans.

Response: We thank commenters and note these comments are not directly related to the proposed requirements in § 441.311(d), and thus we decline to make modifications to § 441.311(d) based on these suggestions. We plan to consider the comments as we regard broader HCBS access and equity issues for future policymaking. We also note that while requiring use of provisional care plans would be outside the of scope of this requirement, we agree with the commenter that the use of provisional care plans as described in Olmstead Letter #3 may help avoid the delay of services pending the development of the care plan.[128] In this letter, we explain that we will accept, as meeting requirements, a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented. During this time, the relevant agencies work with the beneficiary to develop and finalize a ''comprehensive plan of care,'' which goes into effect as soon as practically possible, and at least within 60 days.

Comment: One commenter recommended that we allow States the option to choose one of the proposed criteria in § 441.311(d)(2) on which to report or to propose a different metric on which to report. The commenter believed this would permit flexibility in reporting on and context for data related to timeliness of initiation of service planning and service delivery. The commenter believed that this could serve as the first stage in a phased approach for access reporting.

Response: We thank the commenter for their suggestion. However, we believe it is important to take steps to establish nationally comparable data, which would require States to report on the same metrics. As discussed in previous responses, we are not finalizing any additional metrics for § 441.311(d)(2) and believe that the two metrics included in this requirement are a reasonable first step in data collection.

Comment: A few commenters supported annual reporting for § 441.311(d)(2). One commenter noted that annual reporting will better monitor service interruptions due to shortages of direct care workers. One commenter noted that a beneficiary's service utilization can fluctuate significantly even from month to month. One commenter believed that biennial (every other year) reporting would reduce burden on States.

Response: We are finalizing the annual reporting frequency as proposed

[127] Refer to Centers for Medicare and Medicaid Services, ''Olmstead Letter #3, Attachment 3–a.'' July 25, 2000. Available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf;*. The commenter notes that in Olmstead Letter #3, Attachment 3–a (*https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd072500b.pdf*), CMS explains that it ''will accept as meeting the requirements of the law a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented.'' During this time, the relevant agencies work with the beneficiary to develop and finalize a ''comprehensive plan of care,'' which goes into effect as soon as practically possible, and at least within 60 days.

[128] Centers for Medicare and Medicaid Services, ''Olmstead Letter #3, Attachment 3–a.'' July 25, 2000, which is available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf.*

in § 441.311(d)(2). We continue to believe that annual reporting strikes the right balance between collecting current data and minimizing burden on States to the greatest extent possible. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior to the next public report.

After consideration of the comments received, we are finalizing the requirements at § 441.311(d)(2), with modifications. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months, rather than for individuals newly approved to begin receiving services. We are also finalizing a modification so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries.

We note that we are finalizing § 441.311(d)(2) with technical corrections. As a result of modifying § 441.311(d)(2) to include habilitation services, we are modifying the title of this provision to specify *Access to homemaker, home health aide, personal care, and habilitation services.* We are also finalizing a technical modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are as ''set forth'' in § 440.180(b)(2) through (4) and (6), rather than as ''listed'' in.

d. Payment Adequacy (§ 441.311(e))

At § 441.311(e), we proposed new reporting requirements for section 1915(c) waivers, under our authority at section 1902(a)(6) of the Act, requiring that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. For the same reasoning discussed in section II.B.5. of this preamble, we have focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. These are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We also believed that this reporting requirement could serve as the mechanism by which States demonstrated that they meet the proposed HCBS Payment Adequacy requirements at § 441.302(k).

We considered whether the proposed reporting requirements at § 441.311(e) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services for individuals with chronic mental illness. We had selected homemaker, home health aide, and personal care services (as defined at § 440.180(b)(2) through (4)) for this reporting requirement to align with the payment adequacy minimum performance requirement at § 441.302(k)(3), which is discussed in section II.B.5. of this preamble. However, we requested comment on whether States should be required to report annually on the percent of payments for other services listed at § 440.180(b) spent on compensation for direct care workers and, in particular, on the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services spent on compensation for direct care workers.

We further proposed that States separately report for each service subject to the reporting requirement and, within each service, separately report on payments for services that are self-directed. We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance with the requirement at § 441.302(k) and decided that the proposed requirement would be most effective to demonstrate State compliance. We requested comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments, and whether we should reduce the frequency of reporting to every other year.

To minimize burden on States and providers, we proposed that States report in the aggregate for each service across all of their services across all programs as opposed to separately report for each waiver or HCBS program. However, we requested comment on whether we should require States to report on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. We also requested comment on whether we should require States to report on median hourly wage and on compensation by category.

In consideration of additional burden reduction for certain providers, we requested comment on whether we should allow States the option to exclude, from their reporting to us, payments to providers of agency directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service. We also requested comment on whether we should establish a specific limit on this exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms of Medicaid revenues for the service, number of Medicaid beneficiaries served, or number of direct care workers serving Medicaid beneficiaries.

We proposed that payments for self-directed services by States should be included in these reporting requirements, although we noted feedback from interested parties indicating that compensation for direct care workers in self-directed models tends to be higher and may comprise a higher percentage of the payments for services than other HCBS. This decision not to exclude them was based on the importance of ensuring a sufficient direct care workforce for self-directed services. We requested comment on whether we should allow States to exclude payments for self-directed services from these reporting requirements.

We note that, for clarity, we are aligning the definitions of compensation, direct care worker, and excluded costs at § 441.311(e)(1) with those we are finalizing in § 441.302(k)(1). As a result, the reporting requirement we proposed at § 441.311(e) is finalized at § 441.311(e)(2)(i), as discussed below. While we consider the reporting requirement at § 441.311(e) to be distinct and severable from the payment adequacy requirements in § 441.302(k), we believe that the reverse is not the case—that § 441.302(k) does rely on the reporting mechanism at § 441.311(e) to establish compliance with the minimum performance requirement at § 441.302(k)(3). As such, we believe it is advantageous to have aligned definitions.

We received public comments on this proposal. The following is a summary of

the comments we received and our responses.

Comment: Several commenters expressed general support for our proposed requirement at § 441.311(e) that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. Commenters believed that this requirement would provide data about how Medicaid payments are being spent, which would improve oversight and enable meaningful comparisons across programs. One commenter requested clarification on the intent of the reporting requirement.

Commenters also believed that this requirement would ensure compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Several commenters, however, expressed support for finalizing this reporting requirement, but not for finalizing the minimum performance requirement at § 441.302(k)(3). These commenters noted that the reporting requirement by itself would yield useful data that would support payment transparency in HCBS programs.

Response: This requirement is intended to help track the percent of Medicaid payments for certain HCBS that is spent on compensation for direct care workers. As we discussed extensively in section II.B.5. of this rule, we believe that ensuring that a significant portion of payments for these hands-on services is spent on compensation for direct care workers aligns with our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care. We do note that this reporting requirement also is a mechanism by which States demonstrate compliance with the payment adequacy requirements at § 441.302(k), which is discussed in detail in section II.B.5. of this rule.

While we are finalizing the payment adequacy requirements at § 441.302(k), we agree that the value provided by this reporting requirement is distinct and severable from the minimum performance requirement and serves as a standalone requirement. To clarify the distinction between this reporting requirement and the payment adequacy requirement at § 411.302(k), we are revising the language at § 411.311(e)(2) to remove the reference to the minimum performance requirement at § 411.302(k)(3). We believe this will better demonstrate that the reporting requirement has a function aside from demonstrating compliance with § 411.302(k). We also believe this to be necessary because, as discussed further below, we are finalizing the reporting requirement at § 411.311(e)(2) to include reporting of data related to habilitation services, which are not subject to the minimum performance requirement at § 411.302(k)(3). Thus, we believe retaining the reference to § 411.302(k)(3) would cause some confusion.

Comment: A few commenters opposed the reporting requirement proposed at § 441.311(e) (which we are finalizing at § 411.311(e)(2)). These commenters noted that the reporting requirement would increase administrative burden and administrative costs for providers; a few commenters believed the increase in administrative tasks would undermine the goal of the minimum performance requirement at § 441.302(k)(3) to reduce providers' spending on administrative activities.

Other commenters expressed concern that this requirement would create a burden for States. One commenter, although recognizing the need for more data about compensation to direct care workers, believed that most States do not currently collect this type of data and would require significant time, administrative effort, and expense to collect, compile, report, and analyze the data in a meaningful way. A few commenters stated that States would need to make significant changes to current billing and reporting practices and IT in order to isolate the use of reimbursements for the three specified services from the larger menu of services a provider typically offers. A couple of commenters expressed concerns about the time and resources it would take to educate providers about the requirements and their reporting responsibilities.

Additionally, a few commenters expressed concerns about whether States have the capacity to validate the accuracy of providers' reports and conduct audits, especially in States with a large number of providers. One commenter expressed concern about the cost associated with hiring and training independent auditors to audit providers' reported compensation of direct care workers. One commenter shared first-hand experience with implementing a wage pass-through requirement as part of the State's spending plan under ARP section 9817; the commenter regarded the process of monitoring and validating the percentage of payments going to direct care workers as administratively burdensome.

Response: We acknowledge that complying with this reporting requirement will necessitate certain expenditures of resources and time on the part of providers and States. As noted by commenters, we believe that the value of the data collected through their efforts makes these expenditures of resources worthwhile. As discussed further below, we are finalizing the redesignated § 441.311(e)(2)(i) to require only aggregated data by service, as proposed, which we believe will reduce burden on both providers and States.

We believe that, generally speaking, States and providers should already have information about the amount of Medicaid payments providers receive for specific services, and that providers likely already track expenditures on wages and benefits for their workers. We also believe that the simpler, aggregated reporting will be easier for States to validate and include in their existing auditing processes.

However, to ensure that States are prepared to comply with this reporting, we are adding a requirement at § 441.311(e)(3) to require that States must report, one year prior to the applicability date for (e)(2)(i) of this section, on their readiness to comply with the reporting requirement in (e)(2)(i) of this section. This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2)(i) and provide targeted technical assistance to States as needed.

Comment: A couple of commenters requested that CMS issue subregulatory guidance or share best practices to assist with strategies for collecting data and ensuring compliance with the requirement. One commenter recommended that we work with States to determine the most efficient way to gather comparable, useful data to inform future rate policies, including exploring whether existing State tools could meet the requirement or could do so with modification.

A few commenters raised particular concerns about cost reports, which they believed would be necessary for implementing the reporting requirement. Commenters stated that without standardized cost reports, it will be difficult to ensure consistent and comparable data reporting across programs. Some of these commenters noted that, in States that do not currently require cost reports, this will present a new burden for both providers and States. A couple of commenters worried that providers may lack both the familiarity and the resources to complete cost reports. A few commenters requested that CMS

develop a standard cost reporting template to ensure accurate data collection and assessment of compliance across all States.

A couple of commenters, noting the language proposed in § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that the reporting will be at the time and in the form and matter specified by CMS, requested additional information regarding the method of submission and the methodology that will be required for the calculations used in the report.

Response: We intend to release subregulatory guidance to assist States with implementation of this requirement, and we plan to also provide technical assistance and best practices to help States identify ways to use existing infrastructure or tools to gather and report. Further, as noted earlier, we intend to provide States with technical specifications for the new reporting requirements in this final rule, which will aid in consistent data reporting. In addition, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Through that process, the public will have the opportunity to review and provide feedback on the elements of the required State reports, including the methodology of the calculations, as well as the timing and format of the report to us.

As discussed further below, we are finalizing the requirement at § 441.311(e)(2)(i) (originally proposed at § 441.311(e)) that States need only report aggregated data by service. We believe this will reduce the overall burden on States and providers and reduce the need for complex cost reporting.

Comment: One commenter requested enhanced FMAP for costs associated with the reporting requirement.

Response: Enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[129] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[130] We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[131] We decline to make any changes in this final rule based on this comment.

Comment: One commenter suggested that, instead of requiring reporting on the percentage of Medicaid payments going to compensation for direct care workers, we should require States to report annually on how their rates are determined and if the State's rate review included factors such as current wage rates, inflation, required costs of business, and increasing health insurance rates. Another commenter recommended that CMS consider implementing a regular review and assessment to determine if State Medicaid rates provide competitive wages for the direct care workforce and review how these wages are funded in the various payment models.

Response: We focused this particular proposal on the allocation of Medicaid payments, not on rate setting or rate methodology. Such considerations are outside the scope of this proposal. However, we direct readers to the discussion in Documentation of Access to Care and Service Payment Rates (section II.C. of this final rule) which may speak to readers' interests in rate transparency and analysis. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested clarification of the enforcement mechanisms for the reporting requirement.

Response: In terms of enforcing compliance of the States' obligation to submit reports as required at § 441.311(e), we intend to use our standard enforcement discretion. In terms of providers' cooperation with States in submitting the data States need to make their reports, we note that States already have broad authority to take enforcement action and create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested that we clarify managed care plans' responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We plan to provide technical assistance to States to address the role of managed care plans in adhering to this reporting requirement, as well as to assist with strategies for addressing bundled payments that include the services affected by this requirement. Also, as discussed in greater detail below, we are not proposing granular reporting (such as requiring data be disaggregated by managed care plan or by HCBS waiver program). Additionally, we would like to emphasize that our intention is that the State requires providers share information about the percent of all of their Medicaid FFS payments and the payment they receive from managed care plans that is being spent on compensation for the direct care workforce; we do not intend that the State should expect providers to provide a separate percent of Medicaid payments from each managed care plan in which they are enrolled, or provide separate calculations based on payment from services provided to non-Medicaid beneficiaries that is separate and distinct from their participation in the Medicaid managed care program. We therefore decline to make any changes in this final rule based on this comment.

Comment: A couple of commenters suggested that we expand reporting to include more HCBS than the three services specified, or even to apply this requirement to all HCBS. One of the commenters noted that, while more work, it would be administratively simpler to report on a broader array of services, rather than trying to isolate data for a few HCBS. One of the commenters recommended that we could phase in these expanded reporting requirements, beginning with homemaker, home health aide, and personal care services.

Response: As discussed below, we are expanding this reporting requirement in this final rule to include habilitation services. We tailored this requirement to address the services that are most likely to be delivered by direct care workers who predominantly earn lower wages. At this time, we do not intend to expand the requirement beyond homemaker, home health aide, personal care, and habilitation services. However, we note that States are free to collect additional information for State use if the States believe this would simplify administration or they would like to track allocations of Medicaid payments to direct care workers providing other types of HCBS.

[129] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[130] See section 1903(a)(3)(B) and § 433.15(b)(4).

[131] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

Comment: In response to our request for comments, a few commenters recommended expanding the reporting requirement to include the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services that is spent on compensation for direct care workers. One commenter believed that it was important to include habilitation because, in the absence of such data, individuals with developmental disabilities will be disadvantaged since habilitation is a primary vehicle for the delivery of support services to people with intellectual and developmental disabilities in most States. Another commenter believed this information would be critical for determining any future minimum performance level for compensation to direct care workers that was applied to habilitation services.

A few commenters, on the other hand, did not support including habilitation services, but did not specify reasons why these services should be excluded.

Response: We agree with commenters that collecting information about habilitation services would yield useful data about the allocation of Medicaid payments in support of the direct care workforce. Like homemaker, home health aide, and personal care services, habilitation services also tend to be hands-on services that are delivered by direct care workers who often earn lower wages. However, a key difference between habilitation services and the services that were initially selected for this reporting requirement is that they may include facility costs if the service includes residential habilitation or day habilitation. Reporting on habilitation could be useful in better understanding these costs as well, as it will allow for a comparison between the facility-based habilitation services and in-home services. We also agree with commenters that, as habilitation services are more often delivered to people with intellectual and developmental disabilities, excluding habilitation services will disproportionately impact beneficiaries with intellectual and developmental disabilities.

While we agree with commenters that it is important to collect data on habilitation services, we also acknowledge that, as noted above, some services include facility costs that may impact the percent of Medicaid payments being spent on compensation for direct care workers. Similar to our proposed requirement at § 441.311(e), that self-directed services be reported separately, we also are requiring that services that include facility costs in the Medicaid rate be reported separately; this way, we can observe the differences between the allocation of payments in facility-based services versus services that are provided solely in the beneficiary's home or in community settings that are not facilities.

After consideration of the comments, we are adding habilitation services to this reporting requirement being finalized at § 441.311(e)(2)(i). We are modifying the requirement at § 441.311(e)(2)(i) to specify that the services included in this requirement are those set forth at § 440.180(b)(2) through (4) and (6). We note that § 440.180(b)(6) refers to habilitation services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. Thus, we are also specifying that services with facility costs included in the Medicaid rate must be reported separately. These categories will be further described in subregulatory guidance. We approximate this distinction in this reporting requirement through the separate depiction of services with facility costs.

Comment: One commenter recommended that we exclude nurses and direct care workers who provide nursing assistance from this reporting requirement. Another commenter suggested that we should require data to be stratified by workforce. This commenter worried that without this disaggregation, workers who typically earn lower wages (such as personal care assistants) will be ''overshadowed'' in the data by workers who typically earn higher wages (such as nurses). The commenter believed this lack of transparency within the data would limit targeted interventions and advocacy for the lowest-paid positions within HCBS.

Response: Nurses and staff who provide nursing assistance are included in the definition of direct care worker we are finalizing at § 441.311(e)(1)(ii), as discussed previously. While some of the underlying rationale of this reporting requirement is related to concerns about low wages earned by some direct care workers, our broader concern is the health of the HCBS workforce as a whole. The HCBS workforce is experiencing a shortage of workers in all categories, including clinicians and nursing assistants. These workers provide direct, hands-on services to beneficiaries and may in some cases be required to provide or supervise the services. We do not believe excluding them from the reporting serves our larger interests in supporting the direct care workforce overall. For that reason, we also do not believe that it is necessary to include a Federal reporting requirement that compensation to nurses should be reported separately, as our primary interest is in tracking the allocation of Medicaid payments to the direct care workers who are delivering the services. As noted above, States may choose to disaggregate data (for State use) for different categories of direct care workers in order to examine workforce issues at the State level.

Comment: Several commenters responded to our request for comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments. A few commenters opposed an attestation rather than a reporting requirement. These commenters agreed that the reporting requirement is the most effective means of verifying States' compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Commenters also noted that the reporting requirement, rather than an attestation only, will yield granular data that will allow for comparison across States and, within States, across providers and service categories; such data, commenters believe, will enable States to better understand the impact of payment levels on access and adjust their rates accordingly, as well as prove useful for CMS's Federal oversight of beneficiaries' access.

A few commenters, on the other hand, supported requiring an attestation in lieu of a reporting requirement. Commenters, who mostly represented State agencies, preferred the option as being less burdensome and allowing for more flexibility. One commenter suggested that such an attestation could still be a means of limited data collection and proposed that, as part of an attestation, we provide States with a standardized reporting tool to assess whether their rates are sufficient to ensure a livable wage for direct care workers.

A couple of commenters noted that, while an attestation would be helpful to Medicaid programs, some Medicaid agencies noted that they would still need to collect at least some provider-level data to ensure compliance.

Response: We agree with commenters that a reporting requirement will be more effective and useful at monitoring and understanding the allocation of Medicaid payments to compensation for direct care workers, especially as this reporting requirement is intended to do more than simply demonstrate compliance with the payment adequacy requirements at § 441.302(k). We also

are persuaded by commenters' observations that, even with an attestation, States would still need to collect data from providers to ascertain the accuracy of their attestation. In light of the fact that an attestation would only slightly reduce burden and would not result in data collection that would allow for national comparisons, we are moving forward with the reporting requirement rather than replacing it with an attestation.

Comment: Several commenters responded to our proposal at § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that reporting would be required annually as well as our request for comment on whether we should reduce the frequency of reporting to every other year. A few commenters supported our proposal that this reporting would be collected annually. One commenter believed that reporting less frequently than every year would result in the reporting of out-of-date data and would delay identification of problems in the HCBS system that could cause access issues for beneficiaries. Another commenter noted that the value of the data for rate-setting and the work of the interested party advisory group (discussed in section II.C.2. of this final rule, specifically in the discussion of § 447.203(b)(6)) outweighs any potential burden of annual reporting.

A few commenters supported reporting every two years, rather than an annual reporting period. One commenter made the specific suggestion that the reporting should be every two years with a 12-month lag to better ensure accurate reporting. Commenters who supported reporting every 2 years stated that this would allow States sufficient time to collect data, conduct necessary follow-up activities, and publish data while also helping them better balance this requirement with other compliance and reporting activities. One commenter opposed an annual reporting period because it misaligned with their State's cycle of rate methodology review, which occurs every three to five years.

One commenter proposed an alternative reporting frequency of 3 years, but with the expectation that States would be collecting the data quarterly and analyzing the data annually. The commenter noted this frequency would also give the MAC and BAG (discussed in section II.A. of this rule) time to react to the data prior to its being reported to CMS.

Response: We agree that if too much time lapses between each reporting period, the reports, when released, will become quickly out of date. We also appreciate commenters' observations that interested parties, including advisory groups, might rely on this data when making recommendations for Medicaid rates or examining HCBS workforce issues; this places even greater importance on timely data. We also note that, as discussed further below, we are finalizing the requirement that only aggregated data must be reported, which should reduce burden on States and providers and make annual reporting manageable. We note that while annual reporting may be more frequent than States' rate review process, collecting this data annually will allow States to track trends in workforce compensation that they could include in their rate reviews.

We decline to add a requirement specifying how frequently States should review the data they collect. The purpose of this requirement is, in part, to establish the frequency with which States must submit a report to CMS, which we proposed as being on an annual basis. We do not intend to require that States collect and internally review their data quarterly; however, States may choose to do so if feasible and useful. We expect that, at minimum, States will review and analyze the data they receive on an annual basis as part of their submission of the report required by § 441.311(e)(2)(i).

Comment: One commenter specifically noted support for the requirement at § 441.311(e) that States report separately for each service subject to the reporting requirement. A few commenters requested that we finalize the requirement to allow States to report aggregated data to minimize burden. A few commenters suggested that aggregate reporting would be preferable to a more granular approach (such as reporting on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level; reporting on median hourly wage and on compensation by category).

Response: As noted in our background discussion of this provision, we believe that reporting on aggregated data by service strikes the best balance between monitoring the proportion of Medicaid payments that are being spent on compensation for direct care workers and avoiding unnecessary data collection and burden on States and providers.

Comment: We received responses to our request for comment on whether we should require States to report on the percent of payments for certain HCBS that is spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. A number of commenters supported more granular reporting, which they believed would yield more valuable data and support transparency. Several commenters supported reporting at the delivery system level, which commenters believed would help capture differences between managed care and FFS. A few of these commenters also suggested that for managed care delivery systems, reporting should also be disaggregated by plan. One commenter also suggested that within managed care reporting, States should report separately for services delivered to dually eligible beneficiaries.

A few commenters supported breaking down the reporting by HCBS program.

One commenter noted that both provider payments and direct care worker compensation can have considerable variations across all of a State's programs and having this information would be useful for State policymakers as they develop payment rates. This commenter believed that States and providers must already be tracking which services are provided under each program.

A few commenters supported reporting at the population level. Suggestions for what would be included in the population level reporting included race, ethnicity, and geographic location. One commenter believed that demographic information about beneficiaries and their geographic regions would help address barriers to access that are unique to certain populations and areas (such as access issues in rural regions). One commenter, however, believed that collecting data at the population level was not feasible.

Commenters made suggestions for additional details to add to the reporting requirement, including reporting on:

- Direct care worker turnover;
- Compensation to workers by setting (services delivered at home, residential, or facility-based day settings); and
- The number of direct care workers who are considered W–2 employees versus independent contractors.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time are moving forward with finalizing the language in the requirement at § 441.311(e)(2)(i) specifying that States must report the percent of total Medicaid payments spent on compensation to direct care workers by service. We note that a few of the suggestions are outside of the

scope of this proposal, which is intended for States to report data about the percent of payments for certain HCBS that is spent on compensation for direct care workers, not for providers to report on the demographics or employment status of each of their workers, nor on granular beneficiary-level data. We direct readers who are interested to data collection about beneficiaries, including demographic data, to the discussion of the HCBS Quality Measure Set in section II.B.8. of this rule.

As noted in previous responses, we believe it is important to strike a balance between collecting enough information to enable Federal oversight of how Medicaid payments are being allocated and imposing as minimum an administrative burden on States and providers as possible. We believe that the data on the percent of Medicaid payments going to compensation for direct care workers is sufficient to help us ensure that a significant portion of Medicaid payments for these hands-on services goes to the direct care workforce, which in turn supports our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and workforce needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support direct care workers in their State.

Comment: One commenter also recommended collecting data specifically designed to measure the impact of the payment adequacy minimum performance requirement (which we are finalizing at § 441.302(k)) on the HCBS provider network. The commenter suggested we collect data on:

- The number of providers employing direct care workers that opened or closed before and after the effective date of the minimum performance requirement;
- The number of beneficiaries (particularly those with higher needs) for whom providers started or discontinued service provision before and after the effective date of the minimum performance requirement;
- The number of health and safety waiver requests that were received before and after the effective date of the minimum performance requirement; and
- The causal factors service providers cite when closing their business before and after the rule becomes effective.

Response: As the reporting requirement proposed at § 441.311(e) was intended only to measure the percent of Medicaid rates going to direct care worker compensation, recommendations for data collection regarding provider behavior are outside of the scope of our proposal.

However, we note that there are already data collection requirements for some HCBS regarding the number of beneficiaries served through a section 1915(k) program (as required at § 441.580) or annual reporting on the projected number of beneficiaries who will be served under section 1915(i) (as required at § 441.745(a)(1)).

Additionally, we are finalizing other reporting requirements in this final rule that may speak to some of the commenter's concerns. Specifically, we note that we are finalizing a rate disclosure process (discussed in section II.C., particularly under § 447.203(c)), which will include identification of the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for certain services, including homemaker, home health aide, personal care, and habilitation services defined at § 440.180(b)(2) through (4) and (6). We also note that the reporting requirement finalized in the previous section of this rule (under § 441.311(d)) will require reporting on the following metrics related to beneficiary access to homemaker, home health aide, personal care, and habilitation services: the average amount of time from when services are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months; and the percent of authorized hours for the services that are provided within the past 12 months. We note that these other reporting requirements, as finalized, will go into effect prior to the finalized effective date for the payment adequacy minimum performance requirement. This means that there will be data collected for these metrics both before and after the implementation of the payment adequacy requirement at § 441.302(k). Finally, we note that we do not know what the commenter is referring to by using the term, health and safety waiver requests.

Comment: Commenters responded to our request for comment on whether we should require States to report on median hourly wage and on compensation by category. A number of commenters supported adding this level of detail to the reporting requirement. Commenters noted that this level of reporting would help monitor workforce compensation generally, including identifying whether there were compensation disparities across service types. A few commenters also suggested this data would help track the impact of the payment adequacy minimum performance requirement (required at § 441.302(k)(3)) on workforce compensation. One commenter also suggested that this data could be helpful to the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)). A few commenters also recommended that we require collection of specific details on other provider expenditures, such as for travel, training, administrative expenses, or other non-compensation program expenses.

One commenter, however, noted that median hourly wage and compensation by category reporting could be duplicative of other measures and required reporting.

Response: We thank commenters for their thoughtful feedback. In the proposed rule, in addition to requesting comment on whether we should require reporting on median hourly wages, in a separate proposal (under § 447.203(b)(3)) we had proposed a payment rate disclosure process for HCBS that included providing information about the hourly Medicaid rates paid for homemaker, home health aide, and personal care services. The proposals under § 447.203(b)(3) were standalone reporting requirements unrelated to the reporting requirement at § 441.311(e). As discussed in section II.C. of this final rule, the payment rate disclosure process at § 447.203(b)(3) is being finalized with modifications to include habilitation services in the reporting requirement. We do not see a need to finalize an additional reporting process that may be duplicative of both data and burden.

Additionally, upon consideration of the comments, we have identified no compelling reason to require a Federal requirement for disaggregating the data by compensation category. We believe that employee benefits, in addition to wages, are also integral to direct care workers. (We refer readers to the discussion in section II.B.5. of this rule, which includes concerns raised by public commenters about the lack of benefits for direct care workers.) Additionally, the third component of compensation—employers' share of payroll taxes—is a fixed cost. While States may want to collect this disaggregated data from providers to observe local compensation trends or to

share with the interested parties advisory group, we are not adding a requirement for this disaggregation as part of the required State reporting at § 441.311(e).

Comment: In response to our request for comment, a few commenters recommended that we allow States to exclude from their reporting to CMS payments to providers of agency-directed services that have low Medicaid revenues or serve a small number of beneficiaries. We did not receive feedback on metrics for determining which providers would be eligible for such an exclusion, nor on possible caps or limits for an exclusion.

One commenter noted that excluding certain providers due to size, revenue, or geography would create further inequities in the HCBS field and be administratively infeasible to implement. A couple of commenters worried that excluding small providers would create perverse incentives for providers to remain small by failing to hire additional workers or declining to serve additional beneficiaries.

Response: We are concerned that excluding certain providers from the reporting requirement at § 441.311(e) would not support the goals of this requirement to promote transparency about how Medicaid payments are being allocated.

For clarity, we also note that the reporting requirement we proposed at § 441.311(e), and are finalizing at § 441.311(e)(2)(i), requires each State to report to CMS annually on the percentage of Medicaid payments for certain services that is spent on compensation for direct care workers. We intend that each State collect and report this data regardless of whether the State establishes, and their providers meet, the hardship exemption we are finalizing at § 441.302(k)(5) or the small provider requirements at § 441.302(k)(3)(ii) and (4). We do note that, under the requirements we are finalizing at § 441.302(k)(6), the State must report additional information regarding any small provider requirements or hardship exemptions the State develops and implements.

However, we are finalizing the reporting requirement at § 441.311(e) with modification, adding § 441.311(e)(4) to exclude data from Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the required reporting. As discussed in section II.B.5.b. of this final rule, the requirements being finalized at § 441.302(k) conflict with statutory requirements at 25 U.S.C. 1641, and we are finalizing, at § 441.302(k)(7), an exemption to the payment adequacy requirement at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641. Given the conflict between § 441.302(k) and the statutory requirements at 25 U.S.C. 1641, we would likely be unable to use HCBS payment adequacy data from IHS and the Tribal health programs subject to 25 U.S.C. 1641 to inform future policymaking related to how IHS or Tribal health programs spend Medicaid payments they receive, including on direct care worker compensation. Further, we do not want data from the exempted IHS and Tribal health programs to skew the other data States would collect and report to CMS under § 441.311(e), which CMS intends to use to evaluate direct care worker compensation nationally and inform policymaking to address the workforce shortage.

Comment: A few commenters suggested other metrics that could be used as the basis for an exception to the reporting requirement. One commenter suggested that an exception could be made for providers in areas (defined as a city, county, or grouping of zip codes) with a documented deficit of service providers accepting new clients. One commenter recommended that any provider who pays a full-time direct care worker at an hourly rate that exceeds 200 percent of the Federal poverty level be exempted from reporting. Another commenter suggested that if a provider can demonstrate they spend more than 85 percent of Medicaid payments on compensation should be exempted from any detailed cost reporting.

Response: As noted above, we are finalizing the reporting requirement without exceptions for providers. However, we appreciate the recommendations for possible exceptions criteria and will take these into consideration for future policymaking.

Comment: One commenter requested that we exclude self-directed services from reporting. However, we received a number of comments encouraging us to include self-directed services in the reporting as proposed and agreeing that these services should be reported separately. A few of these commenters stated that self-directed services should be reported separately from agency-provided services, due to the differences in these service models.

A few commenters, however, believed that the reporting for self-directed services should be further broken down by whether the service is provided by an independent worker or by a worker who is employed by an agency. One commenter noted that our rationale for separating out self-directed services was that compensation for workers in self-directed models tends to be higher and to comprise a greater percentage of Medicaid payment for services, which the commenter believed to be true of services delivered by independent providers, but not necessarily of self-directed services delivered through agency models.

One commenter noted that some States might have challenges in distinguishing payments for self-directed services delivered via agency models, as these payments may appear in claims processing as traditional HCBS agency payments, rather than as self-directed services.

Response: We agree with commenters that, in terms of the percent of the payment going to compensation for direct care workers, there will be significant differences between the percent for services delivered by independent workers hired by the beneficiary for whom the beneficiary sets the payment rate under a self-directed services delivery model versus those delivered by a worker employed by a provider. In particular, we are concerned that this reporting requirement might not yield meaningful data if applied to the self-directed services delivery models in which the individual beneficiary determines the wage paid directly to the direct care worker out of the beneficiary's service budget (such as models meeting the definition at § 441.545(b) for section 1915(k) services, self-directed services typically authorized under section 1915(j)). We believe the reporting requirement on the percentage of payments going to compensation for direct care workers is only appropriate when applied to a Medicaid rate that includes both compensation to direct care workers and administrative activities. In the former scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation; in the latter scenario, we expect the payment rate to a provider includes both the direct care worker's compensation and administrative costs for the provider.

Based on the comments received, and to ensure we are collecting only meaningful data that demonstrates the percent of Medicaid payments that are going to direct care worker compensation, we are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies, if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4)

and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section. We note that self-directed homemaker, home health aide, personal care, or habilitation services delivered through self-directed services models not described in § 441.311(e)(2)(ii) would still be part of the reporting requirements finalized at § 441.311(e)(2)(i).

After consideration of the comments received, we are finalizing § 441.311(e) with modifications. As discussed in section II.B.5. of this final rule, we are replicating at § 441.311(e)(1)(i), (1)(ii), and (1)(iii) the finalized definitions at § 441.302(k)(1)(i), (k)(1)(ii), and (k)(1)(iii), respectively.

At § 441.311, we are redesignating paragraph (e) as paragraph (e)(2)(i). At finalized § 441.311(e)(2)(i), we are making a technical modification to remove the reference to the definition of direct care workers at § 441.302(k)(1). As we are also adding the definition of direct care workers at § 441.311(e)(1)(ii), the reference to § 441.302(k)(1) is unnecessary. We are finalizing § 441.311(e)(2)(i) with substantive modifications to specify that the State must report to CMS annually on the percentage of total payments **(not including excluded costs)**, to include habilitation services (as set forth in § 440.180(b)(6)) in the reporting, and to specify that States must report separately **for** services **delivered in a provider-operated physical location for which** facility-**related costs are included in the payment rate**. (Revised text in bold font). We are also finalizing § 441.311(e)(2)(i) with technical modifications to: include references to § 441.311(e)(2)(ii) and (4); clarify that the provision applies to services as **set forth** in § 440.180(b)(2) through (4) and (6) (as opposed to services at § 440.180(b)(2) through (4) that are authorized under section 1915(c) of the Act); and clarify that reporting is at the time and in the form and manner specified by CMS.

We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

We are finalizing a new § 441.311(e)(3), requiring that the State must report, one year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

We are finalizing a new § 441.311(e)(4) to require States to exclude data from the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the required reporting at § 441.311(e), as well as to require that States not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under § 441.311(e)(2).

e. Applicability Date (§ 441.311(f))

We proposed at § 441.311(f)(1) to provide States with 3 years to implement the compliance reporting requirements at § 441.311(b), the HCBS Quality Measure Set reporting requirements at § 441.311(c), and the access reporting requirements at § 441.311(d) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. This time period was based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these proposed reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as whole. We invited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

In addition, we proposed at § 441.311(f)(2) to provide States with 4 years to implement the payment adequacy reporting requirements at § 441.311(e) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 4 years after the effective date of the final rule to implement these requirements. This time period was intended to align with the effective date for the HCBS payment adequacy requirements at § 441.302(k), which are discussed in section II.B.5. of this preamble. It was also based on feedback from States and other interested parties that it could take 3 to 4 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as a whole. We solicited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (3 years) or longer timeframe (5 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the effective dates in § 441.311(f). One commenter noted that the effective dates appear to be appropriate and necessary to ensure that data is reported accurately and uniformly. One commenter suggested that States should begin to report on person-centered planning within 2 years. One commenter noted particular support for the longer four-year timeframe for the payment adequacy reporting requirements at § 441.311(e), which the commenter noted recognized the additional complexity of this provision. A few commenters stated that they support the 4-year effective date for § 441.311(e) but would advocate for a 6-year effective date if the payment adequacy minimum performance level in § 441.302(k) is also being finalized.

A number of commenters noted that while they are supportive of each of these proposals individually, they were nevertheless concerned that the number of new requirements will be difficult to implement cost-effectively and accurately in the proposed timeframes. Several commenters noted that proposed data elements required in § 441.311 are beyond what the States

currently collect and—even if the States are able to expand on existing systems—will require policy and process changes and system updates and will place strain on existing staff resources; some commenters stated these changes may require seeking appropriations from State legislatures for additional staff or system upgrades, as well as acquiring vendor support, which could take additional time. A few commenters noted their States would face challenges in coordinating data collection across multiple systems, which may be administered by different agencies or contracted entities. A few commenters noted the feasibility of compliance with § 441.311 will depend on how quickly CMS can provide subregulatory guidance on the reporting requirements; these commenters requested that we set an effective date of 3 or 4 years after the release of subregulatory guidance.

While commenters requested that we extend the timeframes in § 441.311(f), we received few suggestions for how much additional time would be needed. A few commenters suggested alternative timeframes of 4 to 6 years for the provisions in § 441.311. One commenter suggested that timeframes should be specifically waived for self-directed services and that States should be required to submit transition plans for implementing the requirements for self-directed services.

Response: We are finalizing the substance of § 441.311(f) as proposed, but with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.311(f) as Applicability dates (rather than Effective dates). We are also modifying the language at § 441.311(f) to specify the dates when States must comply with the requirements in § 441.311(f), rather than stating the dates when the requirements in § 441.311(f) are effective, beginning a specified number of years after the effective date of the final rule.

As noted above in section II.B.7.b. of the rule, we have determined it is necessary to provide States with an additional year for compliance with the quality measure set reporting requirement at § 441.311(c). Our primary purpose in extending the date for States to comply is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

Regarding the dates for States to comply with the other requirements in § 441.311, as discussed throughout this section, we continue to believe that many of these requirements build on activities that States have already been doing as part of the administration of their HCBS programs and will work with States to identify ways to leverage existing data collection tools and update their current systems as efficiently as possible.

We also acknowledge that complying with these reporting requirements will necessitate expenditures of resources and time on the part of States, managed care plans, and (in some cases) providers. We believe that the value of the data collected through their efforts makes this expenditure of resources worthwhile. This data captures information related to beneficiaries' health and safety (addressed by the incident management system and critical incident reporting in § 441.311(b)(1) and (2)) and beneficiaries' long-standing concerns about access to HCBS waivers and services (addressed by the person-centered planning and access reporting requirements in § 441.311(b)(3) and (d)). These data are urgently needed, and we do not want to postpone implementation of this reporting further than proposed.

Additionally, the data collected as part of the payment adequacy reporting requirement in § 441.311(e) not only addresses the current workforce shortages that are impacting service delivery, but the data are also going to be relied on by the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)) to develop recommendations to the State on Medicaid rates for certain HCBS. We do not believe the interests of beneficiaries, providers, workers, or States are served by delaying the collection and publication of this information. As a result, we are declining to make changes in this final rule based on these comments. We plan to provide technical assistance to States experiencing challenges implementing specific reporting requirements.

Comment: A few commenters, while not opposing the proposed dates that the reporting requirements become effective, noted that it is important to align these reporting requirements with other reporting requirements in States and for managed care plans to minimize State and managed care plan reporting burdens. Commenters also believed that streamlining reporting requirements across programs could help to ensure that States and CMS do not analyze similar data that report on the same populations and same or similar programs across different timeframes, which would complicate findings.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance; we plan to work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of public comments, we are finalizing § 441.311(f) with minor modifications to correct erroneous uses of the word ''effective.'' We are removing from § 441.311(f)(1) the date for States to comply with the quality measure set reporting requirements date and adding it to § 441.311(f)(2) so that States will have 4 years from the effective date of this final rule to comply with those requirements.

We are also finalizing in § 441.311(f)(1) and (2) a modification to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are specifying at § 441.311(f)(1) that States must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.

We are specifying at § 441.311(f)(2) that States must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after the effective date of this final rule.

f. Application to Other Authorities (§§ 441.311(f), 441.474(c), 441.580(i), and 441.745(a)(1)(iii))

At § 441.311(f), we proposed to apply all of the reporting requirements described in § 441.311 to services delivered under FFS and managed care

delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs, and as noted in the Medicaid context this would include consistent administration between FFS and managed care programs. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As discussed earlier in section II.B.1. of this preamble, the proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance, also discussed earlier in section II.B.1. of this preamble. We expect that States may implement some of the requirements proposed in the proposed rule in advance of any effective date. We will work with States to phase out the 2014 guidance as they implement the requirements in this final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs, and because these reporting requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the requirements at § 441.311 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.580(i), we proposed to renumber existing § 441.580(i) as § 441.580(j).

We considered whether to also apply these reporting requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we proposed that these requirements not apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for sections 1915(c), (i), (j), and (k) services and because the person-centered planning, service plan, and waiting list requirements that comprise a significant portion of these reporting requirements have little to no relevance for section 1905(a) services, in comparison to section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authority. We requested comment on whether we should establish similar reporting requirements for section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services.

We noted that we expected that we would establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements including related to sampling requirements (where States are permitted to report on a sample of beneficiaries rather than on all individuals who meet the inclusion criteria for the reporting requirement), and amend existing templates and establish new templates under the Paperwork Reduction Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported applying the proposed reporting requirements at § 441.311 to services delivered under managed care, noting that it is important to gather data on services across delivery systems. A few commenters requested clarification on whether, or how, the reporting requirements applied to services delivered under managed care.

Response: The reporting requirements in this section apply to services in both FFS and managed care delivery systems. We note that comments about the application of specific provisions to managed care are addressed in the sections above. As needed, we plan to provide technical assistance to States that have additional questions.

Comment: A few commenters expressed support for applying reporting requirements at § 441.311 to services delivered through other section 1915 authorities. A few commenters, while not necessarily recommending that we exclude self-directed services authorized under section 1915(j), noted that because of differences in self-directed services, we should consider extending timeframes for implementation in self-directed services or release additional guidance specific to self-directed services.

Response: We are finalizing our proposal to extend the reporting requirements in this section to services offered under sections 1915(i), (j), and (k). We note that comments about the application of specific provisions to self-directed care are addressed in the sections above. While we do not believe it is necessary to extend timeframes for the implementation of the reporting requirements in section 1915(j) self-directed services, we plan to provide technical assistance to States that have additional questions.

Comment: One commenter requested clarification that the waiver reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project.

We also note that, similar to the concern raised by commenters about the applicability of § 441.311(d)(1), as discussed in section II.B.7.a.4. of this

rule, § 441.311(b)(4) also applies only to section 1915(c) programs.

Comment: A few commenters requested that we extend the reporting requirements at § 441.311 to section 1905(a) services. Commenters noted that, in some States, many people receive services through section 1905(a). A few commenters also raised concerns that there would be a disparate impact on certain populations or less oversight of certain services if reporting requirements were not extended to services under section 1905(a), such as personal care, home health, or rehabilitative services. A few commenters recommended not extending the reporting requirements to section 1905(a) services at this time, citing concerns about additional burden.

Response: At this time, we are not mandating inclusion of section 1905(a) services in the reporting requirements at § 441.311. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider these comments provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are not persuaded by the argument that including section 1905(a) services would simply be too much work, as we do agree that transparency, accountability, and oversight are critical for all HCBS. However, we are continuing to review statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act that could impact how these requirements would apply to section 1905(a) services. We also note that we have not extended the minimum performance requirements for incident management, person-centered planning, or payment adequacy to section 1905(a) services (refer to discussions in sections II.B.1., II.B.3, and II.B.5. of this final rule, respectively, for more detail on those discussions). Furthermore, as section 1905(a) service do not have waiting lists, the requirement at § 441.311(d)(1) would not be applicable to these services.

After consideration of the comments received, we are finalizing application of § 441.311 to section 1915(j), (k), and (i) authorities. We are making modifications at §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k) and (i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.311 as follows:

- We are finalizing § 441.311(a) with a modification for clarity to remove ''simplification'' and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act .
- We are finalizing the incident management system compliance requirement at § 441.311(b) with a technical modification for clarity in § 441.311(b)(1)(i) that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS.
- We are finalizing the critical incident compliance requirement at § 441.311(b)(2) with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. For consistency, we are also simplifying the title and removing the reference to § 441.302(a)(6)(i)(A) from the title of § 441.311(b)(2).
- We are finalizing the person-centered planning reporting requirement at § 441.311(b)(3) with a technical modification to specify at § 441.311(b)(3), to demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted previously, to specify that the State may report this metric using statistically valid random sampling of beneficiaries.
- We are finalizing the reporting requirement at § 441.311(b)(4) with a modification to restore language that was erroneously omitted, and with additional technical modifications so that § 441.311(b)(4) specifies that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.
- We are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(c), we are finalizing a date of 4 years, rather than 3 years, for States to comply with the HCBS Quality Measure Set reporting requirements at § 441.311(c).
- We are finalizing the access reporting requirement at § 441.311(d) with a technical modification to specify that reporting will be in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(d)(1) as proposed. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months, rather than for individuals newly approved to begin receiving services. We are finalizing the requirements at § 441.311(d)(2), with modifications so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries. We are modifying the title of this provision at § 441.311(d)(2) to specify *Access to homemaker, home health aide, personal care, and habilitation services.* We are also finalizing a technical modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are, as set forth in § 440.180(b)(2) through (4) and (6), rather than, as listed in, as noted in the proposed rule.
- We are replicating at § 441.311(e)(1)(i) through (iii) the finalized definitions at § 441.302(k)(1)(i), through (iii), respectively.
- We are redesignating § 441.311(e) as § 441.311(e)(2)(i) and finalizing § 441.311(e)(2)(i) with modifications to specify that, except as provided at (e)(2)(ii) and (4), the State must report to CMS annually on the total percentage of payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

• We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

• We are finalizing a new § 441.311(e)(3), requiring that the State must report, 1 year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

• We are finalizing a new § 441.311(e)(4) to require States to exclude the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2).

• We are finalizing § 441.311(f) with modification to move the date that States are required to comply with the quality measure reporting at § 441.311(c) from § 441.311(f)(1) to § 441.311(f)(2), and to clarify the language regarding applicability dates in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract.

• We are finalizing §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k), and (i) of the Act, respectively.

8. Home and Community-Based Services (HCBS) Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)).

On July 21, 2022, we issued State Medicaid Director Letter #22–003 [132] to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. It is intended to promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. It is also intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. By providing States and other interested parties with a set of nationally standardized measures to assess HCBS quality and outcomes and by facilitating access to information on those measures, we believe that we can reduce the time and resources that States and other interested parties expend on identifying, assessing, and implementing measures for use in HCBS programs.

a. Basis and Scope (§ 441.312(a))

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at sections 1102(a) and 1902(a)(6) of the Act, we proposed a new section, at § 441.312, Home and Community-Based Services Quality Measure Set, to require use of the HCBS Quality Measure Set in section 1915(c) waiver programs and promote public transparency related to the administration of Medicaid-covered HCBS. We proposed to describe the basis and scope for this requirement at § 441.312(a).

In proposing this requirement, we believed that quality is a critical component of efficiency, and as such, having a standardized set of measures used to assess the quality of Medicaid HCBS programs supports the efficient operation of the Medicaid program. Further, we believed that it is necessary for the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act, consistent with section 1902(a)(4) of the Act, as it would establish a process through which we regularly update and maintain the required set of measures at § 441.311(c) in consultation with States and other interested parties (as described later in this section of the rule). The process, as proposed, would ensure that the priorities of interested parties are reflected in the selection of the measures included in the HCBS Quality Measure Set. The process, as proposed, also would ensure that the required set of HCBS quality measures is updated to address gaps in the HCBS Quality Measure Set as new measures are developed and to remove measures that are less relevant or add less value than other available measures, and the HCBS quality measures meets scientific and other standards for quality measures. Due to the constantly evolving field of HCBS quality measurement, we proposed these requirements based on our belief that the failure to establish such a process would result in ongoing reporting by States of measures that do not reflect the priorities of interested parties, measures that offer limited value compared to other measures, and measures that do not meet strong scientific and other standards. It would also result in a lack of reporting on key measurement priority areas, which could be addressed by updating the HCBS Quality Measure Set as new measures are developed. The failure to establish such a process would lead to inefficiency in States' HCBS quality measurement activities through the continued reporting on an outdated set of measures. In other words, we believed that such a process is necessary for the efficient administration of Medicaid-covered HCBS by ensuring that quality measure reporting requirements are focused on the most valuable, useful, and scientifically supported areas of quality measurement, and that quality measures with limited value are removed timely from quality measure reporting requirements.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed basis and scope at § 441.312(a). Several commenters supported the requirements at § 441.312 (a) in its entirety.

Response: We thank the commenters for their support for our proposal.

Comment: A few commenters raised concerns that the HCBS Quality Measure Set is overly prescriptive from a Federal perspective and sets a one-size-fits-all approach, expressing that the responsibility for safeguarding quality in HCBS belong to each State.

Response: We disagree with commenters that the proposed requirement for States to use the HCBS Quality Measure Set is overly

[132] CMS State Medicaid Director Letter. SMD# 22–003 Home and Community-Based Services Quality Measure Set. July 2022. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

prescriptive. CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across services, and instead vary depending on the authorities under which States are delivering services. While we support State flexibility, the lack of standardized measures has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different Medicaid beneficiary populations. We underscore our belief that use of the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. As discussed further in this section II.B.8. of this rule, we are finalizing the requirements at § 441.312(a) as proposed and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: Several commenters requested that CMS align the HCBS quality measures universally across Medicaid programs, recommending streamlining measures across the HCBS Quality Measure Set, the Medicaid and CHIP (MAC) Quality Rating System (QRS), and the Adult Core Set. Further, commenters recommended we consider a minimum set of mandatory quality measures and limit them to a small set, similar to the MAC QRS, and allow States the flexibility to utilize voluntary measures in addition to the minimum mandatory measures, as appropriate. Commenters further noted that States already have implemented measures that may not be included in the quality measures identified in the HCBS Quality Measure Set, and this approach for a small set of mandatory measures could minimize disruption to the quality-related work that is currently being undertaken by States in their Medicaid programs.

One commenter observed that creating a unified reporting structure on mandatory measures would bring a level of discipline and consistency that would foster more reliable data across the Medicaid program, noting that it is imperative to create alignment for data collection across States.

Response: We thank the commenters for this feedback. We will take these comments into consideration when developing and updating the HCBS Quality Measure Set and developing subregulatory guidance on the required use of the HCBS Quality Measure Set. We agree with the commenters on the importance of parsimony, alignment, and harmonization in quality measurement across the Medicaid program, to the extent possible. While we aim to align measures across programs as much as possible, the HCBS Quality Measure Set is designed to promote more common and consistent use of nationally standardized quality measures in HCBS programs and to support States with improving quality and outcomes specifically for beneficiaries receiving HCBS. As a result, we expect the HCBS Quality Measure Set to be in alignment with the MAC QRS and the Child and Adult Core Sets.

We also acknowledge that States are already using quality measures to assess quality in their HCBS programs, and it is not our intent for States to abandon this quality-related work. The measure set is intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. However, States may continue to utilize existing measures not found in the HCBS Quality Measure Set if the States believe they generate valuable information, as long as the measures in the HCBS Quality Measures Set are implemented in accordance with § 441.312, which we are finalizing as discussed further in this section II.B.8. of this rule.

After consideration of the comments received, we are finalizing § 441.312(a) with a minor formatting change to correct punctuation.

b. Definitions (§ 441.312(b))

We proposed a definition at § 441.312(b)(1) for ''Attribution rules,'' to mean the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures in the HCBS Quality Measure Set as described at § 441.312(d)(6). We also proposed a definition at § 441.312(b)(2) for ''Home and Community-Based Services Quality Measure Set'' to mean the Home and Community-Based Services Quality Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comments, including through the **Federal Register**.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed definitions at § 441.312(b).

Response: We thank these commenters for their support.

After consideration of the comments received, we are finalizing at § 441.312(b)(1) the definition of attribution rules as proposed. As discussed in more detail in our discussion of § 441.312(c) in the next section below (section B.8.c. of this rule), we are making several changes related to the frequency of updates to the HCBS Quality Measure Set. To accommodate those changes, we are striking the words, at least every other year, from the definition of the Home and Community-Based Services Quality Measure Set we proposed at § 441.312(b)(2).

As finalized at § 441.312(b)(2) the definition of Home and Community-Based Services Quality Measure Set means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section. We note that the measure updates are specified in § 441.312(c) as finalized, and thus the frequency of updates do not need to be set forth in the definition of the HCBS Quality Measure Set. *Additionally, we are finalizing* § 441.312(b) with a minor technical modification to correct an inadvertent omission in the regulatory text in the proposed rule and are finalizing the addition of the numbers (1) and (2) in front of each definition.

c. Responsibilities of the Secretary (§ 441.312(c))

At § 441.312(c), we described the proposed general process for the HCBS Quality Measure Set that the Secretary will follow to update and maintain the HCBS Quality Measure Set. Specifically, at § 441.312(c)(1), we proposed that the Secretary will identify, and update at

least every other year, through a process that allows for public input and comment, the quality measures to be included in the HCBS Quality Measure Set. At § 441.312(c)(2), we proposed that the Secretary will solicit comment at least every other year with States and other interested parties, which we identified later in this section of the preamble of the proposed rule, to:

- Establish priorities for the development and advancement of the HCBS Quality Measure Set.
- Identify newly developed or other measures that should be added, including to address gaps in the measures included in the HCBS Quality Measure Set.
- Identify measures that should be removed as they no longer strengthen the HCBS Quality Measure Set.
- Ensure that all measures included in the HCBS Quality Measure Set are evidence-based, are meaningful for States, and are feasible for State-level and program-level reporting as appropriate.

The proposed frequency for updating the quality measures included in the HCBS Quality Measure Set was aligned with the proposed frequency at § 441.311(c)(1) for States' reporting of the measures in the HCBS Quality Measure Set. We based other aspects of the proposed process that the Secretary will follow to update and maintain the HCBS Quality Measure Set in part on the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting final rule (88 FR 60278); (hereinafter the ''Mandatory Medicaid and CHIP Core Set Reporting final rule''). We believed that such alignment in processes will ensure consistency and promote efficiency for both CMS and States across Medicaid quality measurement and reporting activities.

At § 441.312(c)(3), we proposed that the Secretary will, in consultation with States and other interested parties, develop and update the measures in the HCBS Quality Measure Set, at least every other year, through a process that allows for public input and comment. We solicited comments on whether the timeframes for updating the measures in the HCBS Quality Measure Set and conducting the process for developing and updating the HCBS Quality Measure Set is sufficient, whether we should conduct these activities more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.312(c)(1) to identify and update the quality measures included in the HCBS Quality Measure Set at least every other year, through a process that allows for public input and comment. One commenter noted that identifying and updating the measures annually, instead of every other year, could maximize the effectiveness of the HCBS Quality Measure Set, especially with a new and rapidly evolving field of HCBS measures, suggesting that an every other year frequency might impact the use of innovative approaches to inform quality improvement in HCBS. Alternatively, several commenters expressed concern and recommended less frequent updates to the HCBS Quality Measure Set, questioning the usefulness of the measures that change every other year and suggesting that taking a longer time between updates to the HCBS Quality Measure Set will minimize financial burden and allow States to more accurately measure improvement over time. In the same vein, one commenter expressed that every other year updates to the measure set might have an effect and impact the usefulness of longitudinal data. These commenters suggested alternative timeframes ranging from 3 to 5 years, with 3 years being the most frequently suggested frequency for updates to the HCBS Quality Measure Set.

Response: We thank commenters for their feedback. In consideration of comments received, we agree that clarification of the frequency in updates to the HCBS Quality Measure Set is required. We note that the proposed process for updating the quality measures included in the Quality Measure Set differs in frequency from, though is based in part on, the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the final rule, ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' (88 FR 60278) (hereinafter the ''Mandatory Medicaid and CHIP Core Set Reporting final rule''). We proposed a frequency for updating the quality measures included in the HCBS Quality Measure Set, which is different from the mandatory annual State reporting of the Core Set measures in the Mandatory Medicaid and CHIP Core Set Reporting final rule, because the HCBS Quality Measure Set was only first released for voluntary use by States in July 2022, while Child, Adult, and Health Home Core Sets voluntary reporting has been in place for a number of years. Further, a substantial portion of the measures included in the HCBS Quality Measure Set, particularly compared to the Child, Adult, and Health Home Core Sets, is derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. We recognize that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. Upon further consideration, we assure States that CMS will not update the measure set to add new measures or retire existing measures more frequently than every other year, and are modifying the beginning date as no later than December 31, 2026, instead of 2025. We note that, while the finalized requirement will allow CMS to add new measures or retire existing measures every other year, CMS intends to retain each of the measures in the measure set for at least 5 years to ensure the availability of longitudinal data, unless there are serious issues associated with the measures (such as related to measure reliability or validity) or States' use of the measures (such as excessive cost of State data collection and reporting or insurmountable technical issues with State reporting on the measures).

After consideration of the comments received about the frequency of updating the quality measures in § 441.312(c)(1), we are finalizing § 441.312(c)(1) with modifications to require that the Secretary shall identify and update **quality measures no more frequently than** every other year, beginning no later than December 31, 202**6,** the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section). (New language identified in bold.)

We are also finalizing a new requirement at § 441.312(c)(2) to require the Secretary to **make** technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. This addition is intended to ensure that the measures included in the measure set are accurate and up to date, and that we may correct errors, clarify information related to the measures, and align with updated technical specifications of measure stewards, particularly given the revision to § 441.312(c)(2) to indicate that CMS will not update the HCBS Quality Measure Set more frequently than every other

year. To accommodate the new requirement at § 441.312(c)(2), we have renumbered the provisions proposed at §§ 441.312(c)(2) and (3) to §§ 441.312(c)(3) and (4), respectively.

We are finalizing redesignated § 441.312(c)(3)(iv) with a minor technical modification for clarity to specify that the Secretary shall ensure that all measures included in the Home and Community-Based Services Quality Measure Set reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate. We are also finalizing the redesignated requirement at § 441.312(c)(4) with a modification to replace the words, at least, with the words, no more frequently than, to require that the Secretary, in consultation with States, develop and update, no more frequently than every other year, the Home and Community-Based Services Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[133] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[134] However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[135] We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA) [136] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

We plan to provide States with technical assistance and subregulatory guidance to support implementation of the HCBS Quality Measure Set.

After consideration of the comments received, we are finalizing § 441.312(c) with modifications. We are finalizing § 441.312(c)(1) with modifications to require that the Secretary shall identify, and update no more frequently than every other year, beginning no later than **December 31, 2026**, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section. (New language identified in bold.)

We are finalizing § 441.312(c)(2) without substantive changes, but we are redesignating the requirement as § 441.312(c)(3). We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. We are also redesignating what had been proposed as § 441.312(c)(3) as (c)(4) and finalizing the redesignated § 441.312(c)(4) with a modification to replace the word at least with no more frequently than.

d. Process for Developing and Updating the HCBS Quality Measure Set (§ 441.311(d))

At proposed § 441.312(d), we described the proposed process for developing and updating the HCBS Quality Measure Set. Specifically, we proposed that the Secretary will address the following through a process to:

- Identify all measures in the HCBS Quality Measure Set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on States' behalf, measures that States can elect to have the Secretary report on their behalf, as well as the measures that the Secretary will provide States with additional time to report and the amount of additional time.
- Inform States how to collect and calculate data on the measures.
- Provide a standardized format and reporting schedule for reporting the measures.
- Provide procedures that States must follow in reporting the measure data.
- Identify specific populations for which States must report the measures, including people enrolled in a specific delivery system type such as those enrolled in a managed care plan or receiving services on a fee-for-service basis, people who are dually eligible for Medicare and Medicaid, older adults, people with physical disabilities, people with intellectual or developmental disabilities, people who have serious mental illness, and people who have other health conditions; and provide attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population.
- Identify the measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary.
- Describe how to establish State performance targets for each of the measures.

As discussed in section II.B.8. of the proposed rule (88 FR 27992 through 27993), we anticipated that, for State reporting on the measures in the HCBS Quality Measure Set, as outlined in the reporting requirements we proposed at § 441.311, the technical information on attribution rules described at proposed § 441.312(d)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in the Medicaid waiver. This ensures the State has enough time to furnish services during the measurement period. In the technical information, we anticipated we would set attribution rules to address transitions in Medicaid eligibility, enrollment in Medicare, or transitions between different delivery systems or managed care plans, within a reporting year, for example, based on the length of time beneficiaries was enrolled in each. We invited comment on other considerations we should address in the attribution rules or other topics we should address in the technical information.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided input on the proposed process

[133] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[134] See section 1903(a)(3)(B) and § 433.15(b)(4).

[135] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[136] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

that the Secretary will follow to update and maintain the HCBS Quality Measure Set. A few commenters recommended that, to advance meaningful quality improvement and measurement, we should prioritize the importance of a measure and a measure's usability and use for measure selection and suggested an additional evaluative category of advancing equity. A couple of commenters suggested that we should consider implementing a process to determine if quality measures are based on person-centered planning principles, emphasizing that many of the measures in the HCBS Quality Measure Set are more system and process-oriented, rather than focused on assessing and improving person-centered experiences and preferences. One commenter recommended we conduct a broad-based public review of possible quality measures and domains for individuals with intellectual and developmental disabilities to inform the quality measures process. Another commenter suggested that we include an oral health measure for beneficiaries receiving HCBS in the selection of measures for the HCBS Quality Measure Set. A few commenters recommended we prioritize the development and inclusion of culturally and linguistically appropriate measures within the HCBS Quality Measure Set, prioritizing reporting of the most feasible measures, aligning the CMS Core Sets, to capture the experiences and outcomes of diverse populations and ensure that HCBS programs address the unique needs and preferences of beneficiaries from different cultural backgrounds.

Response: At § 441.312(d), we described the general process that the Secretary will follow to update and maintain the HCBS Quality Measure Set.

We underscore the importance of alignment in quality measurement across the Medicaid program, to the extent possible. We proposed at § 441.312(d)(7), that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

After further consideration, we have identified that including Tribal status as a measure stratification factor is misaligned, as it is not included as a measure stratification factor for the Adult Core Set as defined in the Mandatory Medicaid and CHIP Core Set Reporting final rule. We are also concerned that this additional measure stratification factor will create additional burden for States. After further consideration, to ensure alignment in Medicaid quality measurement and alignment of the HCBS Quality Measure Set with the Adult Core Set, we are removing Tribal status as a measure stratification factor at § 441.312(d)(7). We note that Tribal status could be included as a measure stratification factor under such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with § 441.312(b)(2) and (g).

At § 441.312(d), we proposed and are finalizing the process for developing and updating the HCBS Quality Measure Set. At § 441.312(d)(5) the process for developing and updating the HCBS Quality Measure Set includes the identification of the beneficiary populations for which States are required to report the HCBS quality measures identified by the Secretary. We are finalizing § 441.312(d)(5)(i) with a technical modification, including the identification of the beneficiaries receiving services through specified delivery systems for which States are required to report the HCBS quality measures identified by the Secretary, replacing managed care plan with **MCO, PIHP, or PAHP as defined in § 438.2.** (New language identified in bold.)

Comment: A few commenters requested we clarify how the HCBS Quality Measure Set would relate to measurement for beneficiaries who are dually eligible for Medicare and Medicaid. One commenter further expressed strong support for disaggregation of data for dually eligible beneficiaries, but also questioned whether partial benefit dually eligible beneficiaries were required to be included in the population for quality measurement, as most do not receive HCBS or any other Medicaid benefits.

Response: We plan to provide States with guidance and technical assistance to help address issues specific to dually eligible beneficiaries. Further, inclusion and exclusion criteria for each measure will be addressed through the technical specifications for the measure. We note that, to the extent that dual-eligible beneficiaries are receiving services authorized under section 1915(c), (i), (j), or (k) Medicaid programs and delivered through managed care plans, and meet the inclusion criteria for the measure, they are required to be included in the reporting on that measure. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: One commenter requested that CMS clarify the requirement at § 441.312(d)(7) referencing the subset of measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics, noting that the proposed § 441.312(f) would require States to stratify 100 percent of measures by 7 years after the effective date of the final rule. They emphasized a disconnect between the two provisions, as a subset of measures is not the same as 100 percent of measures and suggest removing the word subset to avoid confusion in implementation.

Response: Reporting of stratified data is a cornerstone of our approach to advancing health equity. We note reporting stratified data helps identify and eliminate health disparities across HCBS populations. As we noted in the proposed rule (88 FR 27993), measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity through data reporting and stratification aligns with E.O. 13985.[137]

At § 441.312(f), in specifying which measures, and by which factors, States must report stratified measures consistent with § 441.312(d)(7), the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate. We reiterate that we considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as discussed in the Mandatory Medicaid and CHIP Core Set Reporting rule (87 FR 51313), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[138] This consistency could not be achieved if each State made its own decisions about which data it

[137] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[138] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

would stratify and by what factors.[139] [140] We also recognize that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify will be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. preserved and model accuracy is improved. In consideration of these factors we are finalizing at § 441.312(d)(7) that the subset of measures among the measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics as proposed.

In response to the commenter's observation regarding when 100 percent of the measures must be stratified, we note that, for reasons discussed in greater detail in section II.B.7. and II.B.8.e. of this final rule, we are modifying the requirement at § 441.311(f) to change the timing by which measures must be stratified. As finalized, § 441.311(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

After consideration of the comments received, we are finalizing § 441.312(d)(1) through (6) and (8) as proposed. We are finalizing § 441.312(d)(7) with modification to remove Tribal status as a stratification factor. As finalized, § 441.312(d)(7) provides that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures among the measures in the HCBS Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

e. Phasing In of Certain Reporting (§ 441.311(e) and (f))

At § 441.312(e), we proposed, in the process for developing and updating the HCBS Quality Measure Set described at proposed § 441.312(d), that the Secretary consider the complexity of State reporting and allow for the phase-in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and developmental disabilities. At § 441.312(f), we proposed that, in specifying the measures and the factors by which States must report stratified measures, the Secretary will consider whether such stratified sampling can be accomplished based on valid statistical methods, without risking a violation of beneficiary privacy, and, for measures obtained from surveys, whether the original survey instrument collects the variables or factors necessary to stratify the measures.

We considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as we noted was discussed in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[141] This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.[142] [143]

In the proposed rule, we recognized that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also noted that there are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to us and to States due to several factors, including the fact that Medicaid applicants and beneficiaries are not required to provide race and ethnicity data. Second, when States with smaller populations and less diversity stratify data, it may be possible to identify individual data, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards and therefore not publicly reported to avoid a potential violation of privacy.[144]

We also acknowledged that we may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify would be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. The Transformed Medicaid Statistical Information System (T–MSIS), for example, currently has the capability to stratify some HCBS Quality Measure Set measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T–MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, we have developed the capacity to impute race and ethnicity using a version of the Bayesian Improved Surname Geocoding (BISG) method [145] that includes Medicaid-specific enhancements to optimize accuracy, and are able to stratify by race and ethnicity, urban/rural status, and sex.

With these challenges in mind, we proposed that stratification by States in reporting of HCBS Quality Measure Set data would be implemented through a phased-in approach in which the Secretary would specify which measures and by which factors States must stratify reported measures. At § 441.312(f), we proposed that States would be required to provide stratified data for 25 percent of the measures in the HCBS Quality Measure Set for

[139] Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[140] National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[141] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

[142] Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[143] National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[144] CMS Cell Size Suppression Policy, Issued 2020: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy* or the cell suppression standards of the associated measure stewards.

[145] Elliott, Marc N., et al. ''Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities.'' *Health Services and Outcomes Research Methodology* 9.2 (2009): 69–83.

which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. We noted that the percentages listed here aligned with the proposed phase-in of equity reporting in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278). However, the timeframe associated with each percentage of measures to phase-in equity reporting that we proposed in this rule is different with a slower phase-in, in large part because when compared to the Child, Adult, and Health Home Core Sets, the HCBS Measure Set in its current form includes a substantial number of measures that are derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. In addition, the slower phase-in was also intended to take into consideration the overall burden of the reporting requirements and that States have less experience with the HCBS Quality Measure Set. Specifically, the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278) requires States to provide stratified data for 25 percent of measures within 2 years after the effective date of the final rule, 50 percent of measures within 3 years after the effective date of the final rule, and 100 percent of measures within 5 years after the effective date of the final rule.

In our proposed rule, we determined that our proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with E.O. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),[146] because we were balancing the importance of being able to identify differences in outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We recognized that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. We reminded States that enhanced FFP is available at a 90 percent match rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[147] Enhanced FFP at a 75 percent match rate is also available for operations of such systems, in accordance with applicable Federal requirements.[148] We also encouraged States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the ISA.[149]

We invited comments on the proposed schedule for phasing in reporting of HCBS Quality Measure Set data. We also solicited comment on whether we should phase-in reporting on all of the measures in the HCBS Quality Measure Set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal at § 441.312(f) in its entirety.

Response: We thank the commenters for their support of our proposed requirements.

Comment: Several commenters submitted recommendations and requests related to the details of stratified reporting, such as definitions of specific categories of populations, data suppression policies, how to handle missing data, and different measures of delivery systems.

Response: We believe that stratified data would enable us and States to identify the health and quality of life outcomes of underserved populations and potential differences in outcomes based on race, ethnicity, sex, age, rural/urban status, disability, language, and other such factors on measures contained in the HCBS Quality Measure Set. We refer readers to section II.B.8. of the proposed rule (88 FR 27993) for a detailed discussion of stratified data and sampling.

We expect to align with Department of Health and Human Services (HHS) data standards for stratification, based on the disaggregation of the 1997 Office of Management and Budget (OMB) Statistical Policy Directive No 15.[150] We expect to update HCBS Quality Measure Set reporting stratification categories if there are any changes to OMB or HHS Data Standards. We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: Several commenters supported all the proposed requirements for stratification but recommended either faster or slower implementation. A couple of commenters suggested that States be required to report stratified data by 3 years after the effective date of this final rule rather than phase in this requirement. Multiple commenters provided alternate phase-in schedules for stratification of the HCBS Quality Measure Set, with the most frequent suggestions to add two to five years to the phase-in timeline for data stratification requirements for the measures in the HCBS Quality Measure Set. Some commenters expressed that they supported a staggered implementation timeline of the data stratification requirements and noted that additional time and flexibility for States could make compliance more attainable because of State legislative, budgeting, procurement, and contracting requirements. Another commenter, who represents State agencies, emphasized that many States have long-standing challenges with collecting complete demographic data on Medicaid beneficiaries, and they expressed concerns with small samples, staffing capacity, survey fatigue, and problems identifying baseline demographics. One commenter recommended that the initial implementation of stratification occur with a rolling start date by State, based on waiver renewal date.

Response: We continue to believe that the time frame for States to implement stratification of data on quality measures in the HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome. We determined that a shorter phase timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that

[146] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[147] See section 1903(a)(3)(A)(i) of the Act and § 433.15(b)(3), 80 FR 75817 through 75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[148] See section 1903(a)(3)(B) and § 433.15(b)(4).

[149] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services), and Functional Assessment Standardized Items (https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

[150] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53*.

States may be required to make, in order to collect these data for reporting. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

As discussed in section II.B.7. of this final rule, we are finalizing at § 441.311(f)(2) that States must comply with the HCBS Quality Measure Set reporting requirement at § 441.311(c) beginning 4 years after the effective date of this final rule, rather than 3 years. We are making this modification in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing as described in this section II.B.8. of this rule. To align with this modification, we are finalizing the phase-in requirement at § 441.312(f). As finalized, § 441.312(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

We anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or any additional support needed to report on the quality measures in HCBS Quality Measure Set. However, as described at finalized § 441.312(e), we will consider the complexity of State reporting and allow for the phase in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and disabilities. Further, we plan to work collaboratively with States to provide technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data.

Response: As discussed above, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[151] This may include improving data reporting, which could promote greater health equity.

We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the ISA [152] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities. We further clarify that States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records.

After consideration of the comments we received, we are finalizing § 441.312(e) as proposed.

We are finalizing § 441.312(f) with a modification to require that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

[151] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[152] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

e. Consultation With Interested Parties (§ 441.312(g))

At § 441.312(g), we proposed the list of interested parties with whom the Secretary must consult to specify and update the quality measures established in the HCBS Quality Measure Set. The proposed list of interested parties included: State Medicaid Agencies and agencies that administer Medicaid-covered HCBS; health care and HCBS professionals who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs; health care and HCBS professionals, providers, and direct care workers who provide services to older adults, children and adults with disabilities and complex medical and behavioral health care needs who live in urban and rural areas or who are members of groups at increased risk for poor outcomes; HCBS providers; direct care workers and organizations representing direct care workers; consumers and national organizations representing consumers; organizations and individuals with expertise in HCBS quality measurement; voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care; measure development experts; and other interested parties the Secretary may determine appropriate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters commended our proposal at § 441.312(g) to consult and receive input from interested parties. These commenters expressed they are encouraged by the continued collaboration with CMS in identifying and updating the HCBS Quality Measure Set. A few commenters shared suggestions for others to include as interested parties, mentioning managed care plans, community representatives from underserved communities, family members, and caregivers.

Response: We appreciate the submission of these comments and will take them into consideration as the Secretary carries out the responsibilities at § 441.312(g).

Comment: One commenter recommended we establish an ongoing process of consultation with States and interested parties to make updates to the quality measures in the HCBS Quality Measure Set in a longer cycle between updates based on consensus, such as 5 years. This commenter emphasized this

approach can assure interested parties that the measure set will continue to be developed over time based on new information and priorities and help avoid making changes too rapidly to be sustained by States.

Response: We appreciate the submission of these comments. As noted previously, we are finalizing § 441.312(c)(1) and (2) with modifications to indicate that we will identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the HCBS Quality Measure Set as defined in paragraph (b) of this section.

We will make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate. Additionally, as discussed in greater detail in section II.B.7. of this final rule, we are giving States more time to engage with interested parties by finalizing an applicability date of 4 years, rather than 3 years, for the requirement that States must comply with the HCBS Quality Measure Set reporting at § 441.311(c). We are making this revision in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g).

After consideration of the comments received, we are finalizing § 441.312(g) as proposed.

f. Application to Other Authorities (§§ 441.474(c), 441.585(d), and 441.745(b)(1)(v))

Because these quality measurement requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the proposed requirements at § 441.312 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.585(d), and 441.745(b)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across sections 1915(i), (j), and (k) authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to apply the HCBS Quality Measure Set requirements at § 441.312 to sections 1915(i), (j) and (k) authorities, stating there should be equally applicable requirements for States across authorities to ensure consistency, coordination, and alignment across quality improvement activities for these HCBS beneficiaries.

Alternatively, a few commenters expressed that applying the HCBS Quality Measure Set requirements across sections 1915(i), (j) and (k) authorities could pose challenges for States since the application of quality measure data collection and reporting for these HCBS authorities is mixed among States. One commenter requested an exemption for the section 1915(i) authority, noting that implementing the HCBS Quality Measure Set requirements for this authority is onerous, since the service array for section 1915(i) programs is more limited than in section 1915(c) programs.

Response: We thank commenters for their support. We note that States can cover the same services under section 1915(i) as they can cover under section 1915(c) of the Act. As such, exempting States from implementing the HCBS Quality Measure Set requirements under section 1915(i) does not align with our intent, which is to ensure consistency and alignment in reporting requirements across HCBS authorities. We are finalizing our proposal to apply the HCBS Quality Measure Set requirements to sections 1915(c), (i), (j) and (k) authorities and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

After consideration of the comments received, we are finalizing the application of § 441.312 to section 1915(j) services by finalizing a reference to § 441.312 at § 441.474(c). (Note that we also discuss finalization of §§ 441.474(c) in section II.B.7. of this final rule.) We are finalizing the application of § 441.312 to sections 1915(k) and 1915(i) services at §§ 441.585(d) and 441.745(b)(1)(v) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.312 as follows:

- We are finalizing § 441.312(a) with a minor technical change.
- We are finalizing the definition of attribution rules and Home and Community-Based Services Quality Measure Set at § 441.312(b)(1) with a minor formatting change.
- We are finalizing the responsibilities of the Secretary at § 441.312(c)(1) with technical modifications to revise the frequency for updating the measure set to no more frequently than every other year and replace December 31, 2025 with December 31, 2026.
- We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.
- We are redesignating § 441.312(c)(2) as paragraphs (c)(3) and finalizing with minor technical modification.
- We are redesignating § 441.312(c)(3) as § 441.312(c)(4) and finalizing § 441.312(c)(4) with a minor technical modification to replace ''at least'' with ''no more frequently than.''
- We are finalizing § 441.312(d)(i) as proposed with a modification for clarity to replace managed care plan with MCO, PIHP or PAHP as defined in § 438.2.
- We are finalizing § 441.312(e) as proposed.
- We are finalizing the requirement at § 441.312(f) with a technical modification in the dates by when a certain percent of measures are to be stratified, delaying each deadline by one year.
- We are finalizing § 441.312(g) as proposed.
- We are finalizing the reference to § 441.312 in § 441.474(c) as proposed.
- We are finalizing the requirements at §§ 441.585(d) and 441.745(b)(1)(v) with modification to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

9. Website Transparency (§§ 441.313, 441.486, 441.595, and 441.750)

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Under our authority at section 1102(a) of the Act, we proposed a new section, at § 441.313, titled Website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS. As noted in the proposed rule, we believe quality is a critical component of efficiency, as payments

for services that are low quality do not produce their desired effects and, as such, are more wasteful than payments for services that are high quality. The proposed approach was based on feedback we obtained during various public engagement activities conducted with States and other interested parties over the past several years that it is difficult to find information on HCBS access, quality, and outcomes in many States. As a result, it is not possible for beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid HCBS. We believe that the website transparency requirements support the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act by promoting public transparency and the accountability of the quality and performance of Medicaid HCBS systems, as the availability of such information improves the ability of interested parties to hold States accountable for the quality and performance of their HCBS systems.

a. Website Availability and Accessibility (§ 441.313(a))

At § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and provides the results of the reporting requirements under § 441.311 (specifically, incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; access data; and payment adequacy data). We solicited comment on whether the requirements at § 435.905(b) are sufficient to ensure the availability and accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the availability and accessibility of the information.

We received public comment on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the website transparency provisions at § 441.313(a), emphasizing that advancing the collection of information and data by States is important to enable the ability of the public, including beneficiaries, to be able to access and compare performance results across States for the reporting requirements proposed at § 441.311.

Response: We appreciate the support for our proposal and thank commenters for their feedback. We note that consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, while the intent of § 441.313 is for States to post all information collected under §§ 441.302(k)(6) and 441.311 as required, we believe that the website posting requirements being finalized herein at § 441.313 would provide critical data to the public even in a circumstance where individual provisions at §§ 441.302(k)(6) and 441.311 were not finalized or implemented. We do acknowledge that § 441.313 is interrelated with §§ 441.302(k)(6) and 441.311 to the extent that if one of the reporting requirements was not finalized or implemented, posting of the data collected under that particular requirement would not be available to post on the website as required at § 441.313. However, if one or more of the reporting requirements at §§ 441.302(k)(6) and 441.311 is finalized and implemented, then States must post this data on the website as required in § 441.313, as finalized. We note that in this final rule, we are finalizing the reporting requirement at § 441.302(k)(6) (as discussed in section II.B.5. of this final rule) and the reporting requirements proposed in § 441.311 (with modifications, as discussed in section II.B.7. of this final rule.)

Comment: One commenter requested we consider providing additional FMAP for the website creation and support needed to conduct the public posting of information and data required under § 441.311 on the State web page, including to address increased staff time and effort to answer questions regarding the public information required to be reported.

Response: We note we do not have authority to permit States to claim Medicaid expenditures at enhanced FMAP rates that are not specified in statute. As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[153] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[154] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[155] We plan to provide States with technical assistance related to the availability of enhanced FMAP to support the implementation of the requirements in this final rule.

After consideration of the comments received, we are finalizing the introductory paragraph at § 441.313(a) as proposed with one modification to include the additional reporting requirements to specify that the State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311.

b. Website Data and Information (§ 441.313(a)(1))

We proposed at § 441.313(a)(1) to require that the data and information States are required to report under § 441.311 be provided on one web page, either directly or by linking to the web pages of the MCO, PAHP, PIHP, or primary care case management entity that is authorized to provide services. We solicited comment on whether States should be permitted to link to web pages of these managed care plans and whether we should limit the number of separate web pages that a State could link to, in place of directly reporting the information on its own web page.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported and noted that the States should have one central web page operated and housed solely by the State to ensure data and information is reported consistently across their HCBS programs. One of the commenters suggested a State could, in their centralized State web page, give users the opportunity to filter by provider, managed care plan, or locality and include contact information for managed care plans. A few commenters generally supported permitting States to link to web pages of managed care plans to meet the proposed requirement.

Another commenter identified that beneficiaries may rely on their managed care plan's website for information instead of the State website and

[153] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[154] See section 1903(a)(3)(B) and § 433.15(b)(4).

[155] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

recommended limiting web page links to managed care plans' websites, raising concern that requiring States to post the data and information from the managed care plans could be duplicative and lead to user confusion if website updates between the State and managed care plans were not synched. A few commenters emphasized that having multiple managed care plan web page links to access the data and information that States are required to report under § 441.311 could place a burden on beneficiaries, consumers, and the public, to find and navigate the unique displays of managed care plan websites.

Response: We thank commenters for their suggestions. We have attempted to provide States with as much flexibility as possible in reporting of data and information required at § 441.311. State and managed care plan reporting of required data and information must be available and accessible for HCBS beneficiaries and other interested parties, without placing undue burden on them. Upon further consideration, we agree that it adds a undue level of complexity and the potential for duplicate sources of the data and information by requiring the State to link to individual web pages of managed care plans.

After consideration of these public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and made minor formatting changes. We plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: One commenter agreed that the State should link to managed care plan web pages to report on the results of the reporting requirements at § 441.311, rather than have the managed care plans forward these results to the State to report on their State website. This commenter also recommended requiring the same language and format requirements in § 438.10(d) apply to § 441.33 and noted that many States serve Medicaid HCBS participants who receive services under managed LTSS and FFS, and that misalignment could occur between the regulations for managed care and FFS.

Response: Managed care plan websites required at § 438.10(c)(3) are already subject to the requirements at § 438.10(d), and we have not identified a compelling reason to make a similar reference in § 441.311. We decline to add mention of § 438.10(d) and are finalizing the requirements at § 441.311 as proposed.

After consideration of public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to require the State to include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2. We also are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and make minor formatting changes.

c. Accessibility of Information (§ 441.313(a)(2))

At § 441.313(a)(2), we proposed to require that the website include clear and easy to understand labels on documents and links. We requested comments on whether these requirements are sufficient to ensure the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the accessibility of the information.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters recommended we recognize the communication needs of deaf, hard of hearing, deaf-blind, and blind individuals, including those who have low vision, emphasizing that these beneficiaries should have access to culturally and linguistically competent services, as well as services and auxiliary aids pursuant to Title II of the Americans with Disabilities Act (ADA) of 1990 and section 504 of the Rehabilitation Act of 1973 (section 504). They also recommended that we reference the Twenty-First Century Communications and Video Accessibility Act of 2010 (Pub. L. 111–260), which includes the use of clear language, icons, captioned videos, American Sign Language, and suitable color contrast. The commenters emphasized that any website materials and reports should be written with accommodations, including large print and braille, to ensure beneficiaries have equal, effective, and meaningful website communication. One commenter recommend that we also consider that due to the ''digital divide'' many HCBS beneficiaries do not have easy access to the internet and recommended we require States and managed care plans to share the information posted on their websites in an alternative format at the beneficiary's request.

Response: We confirm that our proposal requires States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter, which requires the provision of auxiliary aids and services at no cost to individuals with disabilities in accordance with the ADA and section 504. We have attempted to provide the State with as much flexibility as possible in the design of their website. We agree that State and managed care plan websites must be available and accessible for people receiving HCBS and other HCBS interested parties. Further, we note that States' websites are subject to State or local laws regarding accessibility, and States must comply with other applicable laws independent of the requirements at § 441.313(a).

We encourage States to identify inequities for HCBS beneficiaries who have insufficient internet access and develop mechanisms to communicate website information that is available and accessible.

After consideration of comments received, we are finalizing § 441.313(a)(2) as proposed.

d. Website Operation Verification (§ 441.313(a)(3))

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. We requested comment on whether this timeframe is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters responded to our comment solicitation, expressing alternative timeframes related to the requirements at § 441.313(a)(3). Two commenters suggested websites should be updated on a more frequent monthly basis to ensure accuracy and functionality. A few other commenters suggested that websites should be updated semi-annually. Alternatively, another commenter requested that the verification of web content be completed annually to minimize administrative burden on States with significant web content to review and verify.

Response: We agree that accurate function of the website and the timeliness of the information is important. We note in section II.B.9. of the proposed rule (88 FR 27995 through 27996), and reiterate here, that we believe promoting public transparency and accountability of the quality and performance of Medicaid HCBS systems, and the availability of such information will improve the ability of

beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid. We believe that verification quarterly, is reasonable taking into account the level of complexity required for such State reporting. We decline to make any changes to § 441.313(a)(3) in this final rule.

After consideration of the comments received, we are finalizing § 441.313(a)(3) as proposed.

e. Oral and Written Translation Requirements (§ 441.313(a)(4))

At § 441.313(a)(4), we proposed to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll free and TTY/TDY telephone number.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.313(a)(4), One commenter further stated that, to ensure best quality, instructions to States on expectations for conducting translation in non-English languages to support the availability of oral interpretation in all languages and to assure uniformity across State policies to implement this component of the provision would be helpful. A few commenters opposed the proposed requirements at § 441.313(a)(4), expressing concern about the State financial and administrative burden that could occur due to the necessity to hire vendors to meet the expectations to conduct translation in non-English languages as required.

Response: We believe that the proposed requirements at § 441.313(a)(4) are important for ensuring that the required information on the website is accessible to people receiving HCBS and other interested parties. We reiterate, as noted in the proposed rule (88 FR 27979 and 27995), in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[156] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[157] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[158]

After consideration of comments received, we are finalizing the requirements at § 441.313(a)(4) as proposed.

f. CMS Website Reporting (§ 441.313(b))

We proposed at § 441.313(b) that CMS report on its website the information reported by States to us under § 441.311. For example, we envisioned that we will update CMS's website to provide HCBS comparative information reported by States that can be compared to HCBS information shared by other States. We also envisioned using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard.[159]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that CMS would report on its own website the results of the data and information required to be reported under § 441.311, noting this enables easier comparison of results across States and serve as a single information source for users. One commenter suggested we consider a source, such as an HCBS hub, as defined by the commenter, on the CMS website, where users can quickly be directed to State HCBS programs and contracted managed care plan website pages.

One commenter suggested we initiate a best practice using the CMS website as an example for States to follow and share input with States on developing their websites to meet the requirements at § 441.313(a). Another commenter recommended we convene a technical expert panel of relevant interested parties to create a set of guidelines and best practices that States could leverage to meet the proposed website transparency requirements at § 441.313(a) to offset States' time and resource investments in building the website, and to assist with minimizing the State's risk of updating websites that do not meet requirements.

Response: We appreciate the submission of these comments and will take this feedback into consideration as CMS updates its website to report on the results of the data and information required to be reported under § 441.311.

After consideration of the comments received, we decline to make any changes to § 441.313(b) in this final rule and are finalizing as proposed.

g. Applicability Dates (§ 441.313(c))

We proposed at § 441.313(c) to provide States with 3 years to implement these requirements in FFS delivery systems. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or section 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. We based this proposed time period primarily on the effective date for State reporting at § 441.311.

We solicited comments on whether this timeframe is sufficient, whether we should require a longer timeframe (4 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

We received comments on this proposal. Below is a summary of the comments and our responses.

Comment: Most commenters supported the timeframe of 3 years following the effective date of the final rule to implement the website transparency requirements at § 441.313, emphasizing that these requirements facilitate the process of comparing results across States and create a single source where beneficiaries, providers, advocates, and policymakers can find a ''wealth of information about HCBS access.'' One commenter expressed support for the proposed section regarding transparency related to the administration of Medicaid-covered HCBS but did not believe it should take 3 years to implement. A few commenters also expressed concerns about the challenges they believe will be associated with the website transparency requirements at § 441.313, due to administrative burden States may face with significant web content to

[156] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[157] See section 1903(a)(3)(B) and § 433.15(b)(4).

[158] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[159] CMS's Medicaid and CHIP Scorecard. Accessed at *https://www.medicaid.gov/state-overviews/scorecard/index.html.*

review and verify to implement the provision.

Response: We believe that 3 years is a realistic and achievable timeframe for States to comply with the website transparency requirements, and we have not identified a compelling reason make changes to this date. We are finalizing the requirement at § 441.3131(c) as proposed with modifications as described later in this section. We reiterate, as noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[160] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[161] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[162]

After consideration of public comments, we are finalizing the substance of § 441.313(c) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and to make technical modifications at § 441.313(c) to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.313(c) as Applicability date (rather than Effective date). We are also modifying the language at § 441.313(c) to specify that States must comply *with the* requirements in § 441.313(c) *beginning* 3 years from the effective date of this final rule.

h. Application to Managed Care and Fee-for Service (§§ 441.486, 441.595, and 441.750)

As discussed in section II.B.1. of the proposed rule, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.313, with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because we proposed to apply the reporting requirements at § 441.311 to other HCBS State plan options, we also proposed to include these website transparency requirements within the applicable regulatory sections. Specifically, we proposed to apply the requirements of § 441.313 to section 1915(j), (k), and (i) State plan services at §§ 441.486, 441.595, and 441.750, respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1102(a) of the Act to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. We believe the same reasons for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We solicited comment on the application of these provisions across section 1915(i), (j), and (k) authorities.

We did not receive public comments on this provision.

After consideration of public comments received on this rule, we are finalizing the application of the website transparency requirements at § 441.313 to section 1915(j), (k), and (i) State plan services. We are finalizing our proposed requirements at §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.313 as follows:

- We are finalizing the requirement at § 441.313(c), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.313(c) to specify that States must comply with the requirements as described in § 441.313(c) of this section beginning 3 years after the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.
- We are finalizing at §§ 441.313(a) and (b) with minor technical modifications to include the additional requirements at § 441.302(k)(6).
- We are finalizing the requirements at § 441.313(c) with minor formatting changes.
- We are finalizing §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

10. Applicability of Proposed Requirements to Managed Care Delivery Systems

As discussed earlier in sections II.B.1., II.B.4., II.B.5., II.B.7., and II.J. of this rule, we proposed to apply the requirements we proposed at §§ 441.301(c)(3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 to both FFS and managed care delivery systems. Although the proposed provisions at §§ 441.301(c)(3), 441.302(a)(6) and (k), 441.311, and 441.313 would apply to LTSS programs that use a managed care delivery system to deliver services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities, we believe incorporating a reference in 42 CFR part 438 would be helpful to States and managed care plans. Therefore, we proposed to add a cross reference to the requirements in proposed § 438.72 to be explicit that States that include HCBS in their MCO's, PIHP's, or PAHP's contracts would have to comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6) and (k), 441.311, and 441.313. We believed this would make the obligations of States that implement LTSS programs through a managed care delivery system clear, consistent, and easy to locate. While we believed the list proposed in § 438.72 would help States easily identify the provisions related to LTSS, we identified that a provision specified in any other section of 42 CFR part 438 or any other Federal regulation but omitted from § 438.72, is still in full force and effect. We also noted that § 438.208(c)(3)(ii) currently references § 441.301(c)(1) and (2). We did not propose any changes to the regulatory

[160] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[161] See section 1903(a)(3)(B) and § 433.15(b)(4).

[162] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

language at § 441.301(c)(1) or (2) or to § 438.208(c)(3)(ii) in the proposed rule. We included § 441.301(c)(1) and (2) in the proposed regulatory language at § 438.72 so that it would be clear that the requirements at § 441.301(c)(1) and (2) continue to apply.

We received various comments and questions about how specific provisions would be implemented in managed care contexts; these comments and our responses are addressed in the sections pertaining to those provisions. We did not receive other comments specifically on this proposal at § 438.72.

Upon further review, we have determined it necessary to make a clarifying correction to § 438.72, which we are finalizing with modifications. We proposed that § 438.72(b) would read that the State must comply with the review of the person-centered service plan requirements at § 441.301(c)(1) through (3), the incident management system requirements at § 441.302(a)(6), the payment adequacy requirements at § 441.302(k), the reporting requirements at § 441.311, and the website transparency requirements at § 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities. We noted that in some cases, our description of the references in the regulations did not align with the titles of those regulations (such as at § 441.302(a)(6), in which only § 441.302(a)(6)(i) is specifically titled requirements, although our intent was for States to comply with § 441.302(a)(6)(i) through (iii). To avoid confusion due to any misaligned language, we are removing the narrative descriptions of the requirements and retaining just the references to the regulatory text.

After consideration of public comments, we are finalizing § 438.72(b) with this modification, which will read that the State must comply with requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

C. Documentation of Access to Care and Service Payment Rates (§ 447.203)

Section 1902(a)(30)(A) of the Act requires that State plans ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Through the provisions we are finalizing in § 447.203, we are establishing an updated process through which States will be required to document, and we will ensure, compliance with the requirements of section 1902(a)(30)(A) of the Act.

In the 2015 final rule with comment period, we codified a process that requires States to complete and make public AMRPs that analyze and inform determinations of the sufficiency of access to care (which may vary by geographic location in the State) and are used to inform State policies affecting access to Medicaid services, including provider payment rates. The AMRP must specify data elements that support the State's analysis of whether beneficiaries have sufficient access to care, based on data, trends, and factors that measure beneficiary needs, availability of care through enrolled providers, and utilization of services. States are required to update their AMRPs at regular intervals and whenever the State proposes to reduce FFS provider payment rates or restructure them in circumstances when the changes could result in diminished access. Specifically, the AMRP process at § 447.203 before this final rule (which we refer to in this final rule preamble as the previous AMRP process) required States to consider the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The analysis further required consideration of beneficiary and provider input, and an analysis of the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates within geographic areas of the State, for each of the services reviewed, by the provider types and sites of service. While the previous regulations included broad requirements for what an acceptable methodology used to conduct this analysis must include, States retained discretion in establishing their processes, including but not limited to the specification of data sources and analytical methodologies to be used. For example, States were broadly required to include actual or estimated levels of provider payments available from other payers; however, States retained discretion on which payers they reported on, including where the payment data was sourced from. The result has been a large analytical burden on States without a standardization that allows us and other interested parties to compare data between States to understand whether the Federal access standards are successfully achieving access consistent with section 1902(a)(30)(A) of the Act for beneficiaries nationwide.

Through the previous AMRP process, we aimed to create a transparent and data-driven process through which to ensure State compliance with section 1902(a)(30)(A) of the Act. Following publication of the 2011 proposed rule and as discussed in both the 2015 final rule with comment period and the 2016 final rule, as we worked with States to implement the previous AMRP requirements, many States expressed concerns about the rule.[163] [164] [165] States were concerned about the administrative burden of completing the previous AMRPs and questioned whether the previous AMRP process is the most effective way to establish that access to care in a State's Medicaid program meets statutory requirements. States with high managed care enrollment were also concerned about the previous AMRP process because the few remaining FFS populations in their State often reside in long-term care facilities or require only specialized care that is ''carved out'' of managed care (that is, not covered under the State's contract with managed care plans), but long-term care and specialized care services were not required to be analyzed under the previous AMRP process. We have also heard concerns from other interested parties, including medical associations and non-profit organizations, that the 2015 final rule with comment period afforded States too much discretion in developing access measures which could lead to ineffective monitoring and enforcement, as well as challenges comparing access across States. One commenter on the 2015 final rule was concerned that States had too much discretion in ''. . . setting standards and access measure . . .'' and ''. . . whether they have met their chosen standards'' as this process relies on self-regulation rather than ''an independent, objective third party as the primary arbiter of a State's compliance

[163] 76 FR 26341.

[164] 80 FR 67576 at 67583 and 67584.

[165] 81 FR 21479 at 21479.

. . .'' [166] Another commenter stated that ''CMS should designate a limited and standardized set of data measures that would be collected rather than leaving the decision of which data measures to use to State discretion'' as this would ''enable the development of key, valid, and uniform measures; more effective monitoring and enforcement; and will ensure comparability of objective measures across the States.'' [167] At the time of publication of the 2011 proposed rule and 2015 final rule with comment period, we noted our belief that a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act, including setting standardized access to care data measures, could prove difficult given then-current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles.[168] [169]

Separately, the Supreme Court, in *Armstrong* v. *Exceptional Child Center, Inc.,* 575 U.S. 320 (2015), ruled that Medicaid providers and beneficiaries do not have a direct private right of action against States to challenge Medicaid payment rates in Federal courts. This decision means provider and beneficiary legal challenges against States are unavailable in Federal court to supplement our oversight as a means of ensuring compliance with section 1902(a)(30)(A) of the Act. The Armstrong decision also underscored HHS' and CMS' unique responsibility for resolving issues concerning the interpretation and implementation of section 1902(a)(30)(A) of the Act. The Supreme Court's Armstrong decision placed added importance on CMS' administrative review of SPAs proposing to reduce or restructure FFS payment rates. Accordingly, the 2015 final rule with comment period was an effort to establish a more robust oversight and enforcement strategy with respect to section 1902(a)(30)(A) of the Act.

In consideration of State agencies' and other interested parties' feedback on the previous AMRP process, as well as CMS' obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are updating the requirements in § 447.203. We are rescinding and replacing the AMRP requirements previously in § 447.203(b)(1) through (8) with a streamlined and standardized process, described in § 447.203(b) and (c). This change is informed by a center-wide review of our policy and processes regarding access to care for all facets of the Medicaid program. The 2015 final rule with comment period acknowledged our need to better understand FFS rate actions and their potential impact on State programs, and the requirements we finalized require a considerable amount of data from States. To ensure States were meeting the statutory requirement under section 1902(a)(30)(A) of the Act, the previous AMRP process was originally intended to establish a transparent data-driven process for States to measure the current status of access to services within the State and utilize this process for monitoring access when proposing rate reductions and restructurings.[170] As the rule took effect and as we reviewed States' previous AMRPs, we found that some rate reductions and restructurings had much smaller impacts than others. The 2017 SMDL reflected the experience that certain payment rate changes would not likely result in diminished access to care and do not require the substantial review of access data that generally is required under the 2015 final rule with comment period. Since publication of the 2019 CMCS Informational Bulletin stating the agency's intention to establish a new access strategy, we have developed the new process we are finalizing in this final rule that considers the lessons learned under the previous AMRP process, and emphasizes transparency and data analysis, with specific requirements varying depending on the State's current payment levels relative to Medicare, the magnitude of the proposed rate reduction or restructuring, and any access to care concerns raised to State Medicaid agency by interested parties. With these provisions, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

We received public comments on our overall approach to a new access strategy as well as broad comments about multiple provisions in the rule. We received some comments that were outside of the scope of the proposed rule entirely (for example, related to access in managed care and coverage of services), and therefore, are not addressed in this final rule. We also note that some commenters expressed general support for all of the provisions in section II.C. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.C related to FFS access), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.C. of this final rule are intended to present a comprehensive approach to ensuring that FFS payment rates are adequate to ensure statutorily sufficient access for beneficiaries, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.A. (MAC and BAC) and II.B. (HCBS) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.C is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.B of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the payment rate transparency publication requirement (section II.C.2.a. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to the comparative payment rate analysis requirement and the payment rate disclosure publication requirement (sections II.C.2.b. of this final rule, which we further intend are severable from each other). These provisions are in turn also severable from the interested parties advisory group provision in section II.C.2.c. of this final rule, the State analysis procedures for rate reduction and restructuring SPAs in section II.C.3. of this final rule, and from the Medicaid provider participation and

[166] American Medical Association, Comment Letter on 2015 Final Rule with Comment Period (January 4, 2016), *https://www.regulations.gov/comment/CMS-2011-0062-0328.*

[167] American Association of Retired Persons, Comment Letter on 2011 Propose Rule (July 5, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0121.*

[168] 76 FR 26341 at 26349.

[169] 80 FR 67576 at 67577, 67579, 67590.

[170] 80 FR 67576 at 67577.

public process to inform access to care policies in section II.C.4. of this final rule, and each of these in turn is intended to be severable from each other.

The following is a summary of the general comments we received on our proposal to rescind the previous AMRP requirements in § 447.203(b)(1) through (8) and replace them with a streamlined and standardized process in § 447.203(b) and (c), and our responses.

Comment: We received general support from most commenters for our proposal to rescind the AMRP process finalized in the 2015 final rule with comment period in its entirety and replace it with new requirements for payment rate transparency and State analysis procedures for rate reductions and restructuring as described in the proposed rule to ensure compliance with section 1902(a)(30)(A) of the Act. We also received commenter feedback encouraging CMS to ensure the process replacing the AMRPs is robust and public, and that it ensures access to critical services is measured adequately.

Response: We thank the commenters for their support and are finalizing the rescission of the previous AMRP process in its entirety and its replacement with the new requirements as proposed, apart from some minor revisions to the proposed regulatory language, which we address in detail later in this final rule. As of the effective date of this final rule, States are no longer required to submit AMRPs to CMS as previously required in § 447.203(b)(1) through (8). We believe our new policies are robust and that they ensure public transparency and that access to critical services is measured adequately.

Comment: While most commenters generally supported the proposal to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, a couple of commenters recommended that CMS maintain some or all of the AMRP process for certain providers (that is, FQHCs, clinics, dental care providers, and community mental health providers), in addition to the newly proposed payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. Additionally, these commenters raised concerns that the newly proposed requirements focused exclusively on fee schedule payment rate transparency and comparison to Medicare payment rates; therefore, FQHCs, clinics, dental care providers, and community mental health providers would be excluded from the proposed payment rate transparency and comparative payment rate analysis provisions because these providers generally are not paid fee schedule payment rates (within the meaning of this final rule) and/or lack corresponding Medicare payment rates. One commenter recommended keeping the AMRP requirements in place as a separate process for analyzing access to primary care services provided by FQHCs, clinics, or dental providers if these providers are excluded from the payment rate transparency and comparative payment rate disclosure as a way to assess access to care to these services and providers as they were previously included in the AMRP requirements. Another commenter stated that, in comparison to the AMRPs, the provisions in the proposed rule are an oversimplified approach to evaluating Medicaid FFS payment rates and do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services.

Response: We acknowledge these commenters' support for the previous AMRP process and suggestion to continue to subject payment rates for FQHCs, clinics (as defined in § 440.90), dental care providers, and community mental health providers to the previous AMRP process. However, we are not incorporating this suggestion, to ensure a consistent approach to evaluating access to care within FFS and across delivery systems that more appropriately balances administrative burden on States and us with the usefulness of the process for ensuring that payment rates comply with section 1902(a)(30)(A) of the Act.

To address commenters' concerns about services being excluded from the payment rate transparency provision in § 447.203(b)(1), we will briefly address which payment rates are and are not subject to the payment rate transparency provisions, but this issue is discussed in greater detail in a later comment response. For purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. To the extent a State pays fee schedule payment rates for clinic services (as defined in § 440.90), dental services, and community mental health services that meet the previously stated description, those payment rates are subject to the payment rate transparency provisions in § 447.203(b)(1). As for the comparative payment rate analysis requirements in § 447.203(b)(2)–(3), as discussed in greater detail later in this final rule, only codes included on the CMS-published list of evaluation and management (E/M) Current Procedural Terminology or Healthcare Common Procedure Coding System (HCPCS) CPT/HCPCS codes are subject to the analysis.

Additionally, as further discussed in a later comment response, States use provider-specific cost and visit data for a particular benefit category to set the prospective payment system (PPS) rates that are paid to FQHCs or rural health clinics (RHCs) in a process governed by section 1902(bb) of the Act. Because States utilize these data rather than fee schedule payment rates within the meaning of this final rule, those rates paid to FQHCs and RHCs are not subject to the new payment rate transparency provisions in § 447.203(b)(1) or the comparative payment rate analysis requirements in § 447.203(b)(2) through (3). Lastly, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC, RHC, clinic (as defined in § 440.90), dental, and community mental health services are subject to access analyses in § 447.203(c) for proposed rate reductions and restructuring.

While we recognize that there may be multiple approaches to evaluating access to care for Medicaid beneficiaries, we respectfully disagree with the commenter that the payment rate transparency and State analysis procedures for rate reductions and restructuring are an oversimplified approach for evaluating Medicaid FFS payment rates. As part of a comprehensive review of our policy and processes regarding access to care for all facets of the Medicaid program, we proposed a more streamlined approach, as compared to previous AMRP process, that we intended better to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act.

Additionally, we disagree with the commenter that, in comparison to the previous AMRP process, the provisions in the proposed rule do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services. The provisions of this final rule serve as one part of our comprehensive efforts to ensure that payment levels across the continuum of behavioral health services are economic and efficient, as well as consistent with quality and access consistent with the statute. As we discussed in the proposed rule, we limited the scope of behavioral health services subject to

comparative payment rate analysis to include only outpatient services.[171] For this final rule, we have revised the outpatient behavioral health services category of service in § 447.203(b)(2)(iii), which we are finalizing as ''Outpatient mental health and substance use disorder services.'' This revision will ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this **Federal Register**) and reflects a more granular level of service description. As this category of service remains outpatient, this allows us to focus on ambulatory care provided by practitioners in an office-based setting without duplicating existing Federal requirements for demonstrating compliance with applicable upper payment limits (UPLs) and the supplemental payment reporting requirements under section 1903(bb) of the Act. Therefore, between the comparative payment rate analysis requirements that we are finalizing in this rule (including outpatient mental health and substance use disorder services) and existing UPL and supplemental payment reporting requirements (including requirements specific to inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals), we believe that States and CMS will have available sufficient information about inpatient and outpatient mental health and substance use disorder services payment rates to appropriately monitor payment levels across the continuum of mental health and substance use disorder services.

Comment: Several commenters raised concerns about administrative burden on States to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements. Commenters were generally concerned about the compounding effect on already overburdened State resources that would be required to meet these provisions, the other HCBS and MAC and BAG provisions of the proposed rule, and the provisions of the Managed Care proposed rule. Specifically for the payment rate transparency provisions under § 447.203(b), commenters were generally concerned about the significant amount of State resources (including number of staff, staff time, and financial expense) that would be required to collect, prepare, analyze, and publish the data and information required.

[171] 88 FR 27960 at 28006.

Additionally, a few commenters expressed concerns about the burden associated with the proposed rule and stated that they did not believe the requirement to publish Medicaid payment rates through the payment rate transparency publication would benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is sufficient. One commenter stated that they expect their State Medicaid program to limit future program enhancements and improvements because they would need to redirect resources to complying with the provisions of the proposed rule, if finalized.

Response: We appreciate the commenters' concerns, and we would like to note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. We are also providing States with a full 2-year compliance period between the effective date of this final rule and the initial applicability date of July 1, 2026, rather than 6 or 9 months as finalized with the previous AMRP process.[172] Given that the previously referenced requirements of this final rule should be less burdensome for States than the rescinded, previous AMRP requirements, and the length of time States have to prepare to implement these new requirements, we expect that States will be able to meet the payment rate transparency, interested parties' advisory group, and State analysis procedures for payment rate reductions or payment restructuring requirements, if a rate reduction or restructuring is proposed through a SPA, without needing to limit future program enhancements or increase the level of State resources dedicated to ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We would also like to reassure States that the provisions of § 447.203(b)(1) in this final rule include flexibilities that could further ease the burden on States. For example, the payment rate transparency publication requirements described in paragraph (b)(1) and paragraph (b)(1)(ii) have limited formatting requirements, and therefore we expect many States that already publish at least some of their Medicaid FFS fee schedule payment rates directly on fee schedules posted on the State agency's website would only need to make minor revisions or updates (if any) to comply with the new requirements with respect to these already-published payment rates. States are not required to create new fee schedules if their published payment rate information is already organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for each covered service, consistent with § 447.203(b)(1). Additionally, because commenters informed us that some States use a contractor to maintain their fee schedules on the contractor's website, we have revised the language in § 447.203(b)(1) to permit the State to ''publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public'' by removing the proposed requirement that the payment rates be published on a website that is ''developed and maintained by the single State agency.'' This flexibility is being provided for States to continue utilizing a contractor to develop fee schedules as well as utilizing a contractor's (or other third party's) website to publish the payment rate transparency publication so long as the State publishes a readily accessible link on its State-maintained website to the required content and ensures on an ongoing basis that the linked content meets all applicable requirements of this final rule. We continue to require that ''[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website'' in § 447.203(b)(1)(ii). We acknowledge that States utilization of contractors to meet certain programmatic responsibilities is a common occurrence, and with this modification, we are ensuring flexibility for States to rely on these relationships to meet the payment rate transparency publication requirement.

With respect to the comparative payment rate analysis in § 447.203(b)(2) and (3), as discussed in the proposed

[172] In the 2015 final rule with comment period (80 FR 67576), the previous AMRPs were originally due on July 1 providing States with approximately 6 months between the final rule effective date of January 4, 2016, and due date of July 1, 2016. Based on comments received on the 2015 final rule with comment period, the 2016 final rule (81 FR 21479) extended the due date to October 1, 2016, providing States with an additional 3 months to submit their first AMRPs for a total of approximately 9 months from the effective date of the 2015 final rule when States were first notified they would be required to submit AMRPs.

rule, States have the flexibility to map their geographical areas to those used for Medicare payment for purposes of meeting the requirement that States break down their payment rates by geographical location, as applicable.[173] We will provide States with a list of the CPT/HCPCS codes to be used for comparison in subregulatory guidance, including an example list, that will be issued prior to the effective date of this final rule.[174] While the first published list will be an example list of codes that would have been subject to the comparative payment rate analysis if it were in effect for CY 2023, we will publish the initial list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis no later than June 30, 2025, to provide States 1 full calendar year between the issuance of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis, as described in the proposed rule.[175]

For the payment rate disclosure in § 447.203(b)(2) and (3), which requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, as discussed in detail in a later response to comments in this section, there is no Medicare comparison component. Because the disclosure will reflect only the State's payment rate data, we chose not to specify codes; this will provide States more flexibility in meeting the requirements in line with each State's unique circumstances. For example, the payment rate disclosure requirements can accommodate the flexibility States have in setting their payment rates and methodologies for personal care, home health aide, homemaker, and habilitation services, as well as the provider types licensed to deliver these services to beneficiaries.

We disagree with commenters that the requirement to publish Medicaid payment rates through the payment rate transparency publication would not benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is sufficient. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. By publishing their Medicaid payment rates publicly, States will be providing the necessary information to evaluate if State payment rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area and interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.[176] Also as discussed in section V.D. of the proposed rule, we considered, but did not propose, to require Medicaid payment information be directly submitted to CMS, rather than publicly published, because this requirement to publicly display payment rate information is methodologically similar to the previous regulation at § 447.203, which required previous AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance, and are carrying it forward into the provisions finalized in this rule.[177] Additionally, the Supreme Court's *Armstrong* decision underscored the importance of CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates.

Comment: A couple of commenters requested clarification regarding CMS exempting States that deliver all of their Medicaid services through managed care from all of the payment rate transparency provisions under § 447.203(b).

Response: All States are required to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure provisions finalized in this rule under § 447.203(b), regardless of the quantity of services covered or delivered or beneficiaries enrolled in managed care. Due to coverage transition periods, such as where an individual is Medicaid eligible but not yet enrolled in a managed care plan or benefits are covered retroactively,[178] even States that generally enroll all beneficiaries into managed care plans pay for some services on a FFS basis that are carved out of the managed care plan contracts, and therefore, are expected to have Medicaid FFS fee schedule payment rates in effect. Such Medicaid FFS fee schedule payment rates are subject to the provisions finalized in this rule under § 447.203(b).

Comment: Several commenters requested CMS clearly define the services considered to be categories of services subject to all provisions under § 447.203(b). One commenter requested CMS publish information regarding the timing of when States can expect the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis.

Response: For the payment rate transparency requirements in § 447.203(b)(1), as further discussed in a later response to comments in this section, services for which providers are paid Medicaid FFS fee schedule payment rates within the meaning of this final rule, which generally are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary, are subject to the requirements of § 447.203(b)(1)(i) through (vi).

For the comparative payment rate analysis described in § 447.203(b)(3)(i), the list of the E/M CPT/HCPCS codes that specifies the services subject to the analysis will be published in subregulatory guidance. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the services that would be subject to the comparative payment rate analysis through the identification of specific E/M CPT/HCPCS codes that are in effect for CY 2023. In other words, the example list of E/M CPT/HCPCS codes includes codes that meet the following criteria: the code is effective for CY 2023; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the hypothetical comparative payment rate analysis (CY 2023) and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called

[173] 88 FR 27960 at 28013.

[174] 88 FR 27960 at 28008.

[175] 88 FR 27960 at 28008 through 28009.

[176] 88 FR 27960 at 27967.

[177] 88 FR 27960 at 28075.

[178] Once an individual is enrolled in Medicaid, coverage is effective either on the date of application or the first day of the month of application. Benefits also may be covered retroactively for up to three months prior to the month of application if the individual would have been eligible during that period had he or she applied. Coverage generally stops at the end of the month in which a person no longer meets the requirements for eligibility. *https://www.medicaid.gov/medicaid/eligibility/index.html.*

outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare Physician Fee Schedule (PFS) with a Medicare established relative value unit (RVU) and payment amount for CY 2023. As discussed in the proposed rule, we expect to provide States with approximately 1 full calendar year of access to the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS rule for a calendar year to provide States with sufficient time to develop and publish their comparative payment rate analyses as described in § 447.203(b)(4).[179] Therefore, we expect that the first CMS-published list of the E/M CPT/HCPCS codes that actually will be subject to the comparative payment rate analysis requirements will be published by July 1, 2025 for CY 2025, to facilitate States' publication of their comparative payment rate analyses by the applicability date of July 1, 2026.

The categories of services subject to the payment rate disclosure requirements described in § 447.203(b)(3)(ii), as discussed later in this preamble, are personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority. We are not identifying codes for these categories of services because States may use a wide variety of codes to bill and pay for these services, and because the payment rate disclosure does not have a comparison element that would necessitate uniformity with another payer. While we encourage States to organize their payment rate disclosure on a code basis, when possible, for clarity and formatting consistency with the comparative payment rate analysis, States have flexibility in meeting the payment rate disclosure requirements to ensure each State's unique circumstances can be accounted for in the disclosure.

Comment: Several commenters urged CMS to delay the proposed applicability date of the § 447.203(b) provisions, including the compliance actions described in § 447.203(b)(5), to allow States sufficient time for compliance. Commenters stated that the amount of recently proposed Federal changes, including this rulemaking and the Managed Care proposed rule, raised concerns about State resources necessary to comply with all new Federal regulations. Some commenters expressed concern that withholding administrative FFP would further hinder States' ability to meet the requirements and CMS should only act after exhausting all other efforts to ensure States are compliant (including adopting a tiered approach to enforcement and directly engaging with non-compliant States to create a corrective action plan).

Commenters suggested the following alternative applicability dates: approximately 3 years from the effective date of a final rule (that is, January 1, 2027), 4 years (that is, January 1, 2028), or 5 years (that is, January 1, 2029). Alternatively, a few commenters urged CMS to accelerate the proposed applicability date of the § 447.203(b) provisions by one year from January 1, 2026, to January 1, 2025, to ensure payment rate information is published timely to help address questions about access, particularly for HCBS. In addition to the proposed compliance procedures described in § 447.203(b)(5), a couple of commenters suggested CMS publish an annual calendar for States to follow and CMS should also report on the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.

Response: We are finalizing the payment rate transparency requirements in § 447.203(b) with an applicability date of July 1, 2026, which is 6 months later than we proposed. This date is an alternative applicability date that was described in the proposed rule to allow for States to have a period of at least 2 years between the effective date of the final rule and the applicability date for the § 447.203(b) provisions. The July 1, 2026, applicability date applies to the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. For payment rate transparency, the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026. For the comparative payment rate analysis and payment rate disclosure, the initial comparative payment rate analysis and payment rate disclosure must include Medicaid payment rates in effect as of July 1, 2025, and be published no later than July 1, 2026. As finalized in this rule, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year included in the comparative payment rate analysis must be effective for the same time period for the same set of E/M CPT/HCPCS codes used for the base Medicaid FFS fee schedule payment rate. The Medicare PFS is published through annual notice and comment rulemaking, and takes effect January 1 of the upcoming calendar year. As discussed in the proposed rule, we acknowledged that Medicare may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes and we would like to reemphasize that we expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the requirements in paragraphs (b)(2) through (4).[180] States are required to use the Medicare non-facility payment rates as established in the Medicare PFS final rule for calendar year 2025 for purposes of the initial comparative payment rate analysis to be published by July 1, 2026. In accordance with paragraph (b)(4), the comparative payment rate analysis is required to be updated no less than every 2 years and by no later than July 1 of the second year following the most recent update, therefore, the second comparative payment rate analysis would be for calendar year 2027, the third analysis would be for calendar year 2029, so on and so forth. Each comparative payment rate analysis would use the respective year's CMS published list of E/M CPT/HCPCS codes which will be updated by CMS approximately one full calendar year before the due date of the next comparative payment rate analysis and the list will include changes made to the AMA CPT Editorial Panel and the Medicare PFS based on the most recent Medicare PFS final rule, as described in the proposed rule.[181]

We are not finalizing the alternative applicability dates, including dates sooner and later than the July 1, 2026, due date finalized in this rule, as suggested by commenters. We are not accelerating the date as we are mindful of the numerous new regulatory requirements established in this final rule, the Managed Care final rule (as published elsewhere in this **Federal Register**), and the Streamlining Eligibility & Enrollment final rule. We want to ensure States have adequate time to implement all newly finalized provisions, with at least 2 years between the effective date and applicability date as described in the proposed rule.[182] We

[179] 88 FR 27960 at 28008–28009.

[180] 88 FR 27960 at 28009.

[181] 88 FR 27960 at 28008.

[182] 88 FR 27960 at 28008.

are also not delaying the applicability date as we believe the applicability date for the provisions finalized in section II.C. of this final rule are reasonable given that States should have their Medicaid FFS fee schedule payment rates data readily available, Medicare payment rate data are publicly available, and we are making available supportive guidance and templates with this final rule. In the beginning of section II. of this final rule, we include a table with the provisions and relevant timing information and applicability dates of all provisions in the rule. We believe this table delivers the information the commenter was seeking. We expect the information published in this final rule is sufficient for States to comply in a timely manner and we currently do not intend to publish a calendar in any other format. We are finalizing the compliance provisions at § 447.203(b)(5) as proposed. While we currently do not intend to publish a report of the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, as suggested by a couple of commenters, given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A number of commenters suggested CMS conduct the proposed payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure on behalf of States to ensure a consistent, national approach to analyzing and publishing payment rate information. These commenters stated CMS could do this by requiring States to submit their fee schedules to CMS or CMS could collect fee schedule rate information during the SPA approval process. Specifically for the payment rate disclosure, two commenters suggested using existing data collection tools, specifically the State of the Workforce Survey, to source the information required for the disclosure to ease burden on States.[183] Additionally, a couple of commenters suggested CMS create a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use, including data analysis, if the proposed requirements are applied to States.

Response: As described in section V.D.3 of this final rule, prior to the issuance of the 2023 proposed rule, we specifically considered ways for CMS to produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates.[184] We decided not to propose this approach because it would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it and then validate the data with States to ensure the publication is accurate, in addition to introducing uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Given the increased lag time associated with T–MSIS data and uncertainty in results that would diminish the utility of the comparative payment rate analysis, we decided producing and publishing the analysis would likely result in inaccuracies, resulting in burden on States to correspond with CMS to provide missing information and correct other information. After considering, and ultimately not proposing, CMS complete a comparative payment rate analysis on behalf of States, we did not further consider conducting the payment rate transparency publication or payment rate disclosure on behalf of States due to the previously stated reasons (that is, lagging data from T–MSIS and the need that would remain to validate data with States).

We are not creating a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use as suggested by commenters because we are striving to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. Requiring States to submit the information they already published on their State or contractor's website would be duplicative and create additional burden on States. We acknowledge that we could also pull data from State or contractor websites to create a central Federal repository; however, we intend our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements; providing States with support during the compliance period; and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Additionally, we believe that the States, as stewards of Medicaid payment rate information in each of their Medicaid programs, are the party in the best position to publish and analyze their own payment rate information. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

While we appreciate the suggestion to utilize existing data collection tools, specifically the State of the Workforce Survey, we will not be relying on the State of the Workforce Survey because the data do not include all States, the District of Columbia, and the Territories (2021 Survey only sourced data from 28 States and the District of Columbia);), account for payment rate variation by population (pediatric and adult), provider type, and geographical location (2021 Survey only includes mean starting wage, the median starting wage, as well as the minimum and maximum starting hourly wages); or include individual providers (2021 Survey only sourced data from provider agencies). Accordingly, it would not be a sufficient data source to meet the requirements for the payment rate disclosure as finalized in this final rule.

Comment: We received some comments about CMS requiring States to change their payment rates. A couple of commenters requested CMS require States to change their payment rates when deficiencies are identified through the payment rate transparency publication, comparative payment rate analysis, or payment rate disclosure; when provider shortages are documented; and when reimbursement or payment rates fall below a certain threshold, such as 50 percent of the corresponding Medicare payment rate; however, most commenters who suggested CMS set a threshold did not

[183] The State of the Workforce Survey collects comprehensive data on provider agencies and the Direct Support Professional (DSP) workforce providing direct supports to adults (age 18 and over) with intellectual and developmental disabilities (IDD). The goal of the survey and the resulting data is to help States examine workforce challenges, identify areas for further investigation, benchmark their workforce data, measure improvements made through policy or programmatic changes, and compare their State data to those of other States and the NCI–IDD average. *https://idd.nationalcoreindicators.org/staff-providers/.*

[184] 88 FR 27960 at 28075.

suggest a specific number for the threshold. One commenter specifically asked if CMS would require States to increase institutional service payment rates. The commenter was concerned that an increase in a direct care worker's Medicaid hourly rate, without a corresponding increase in a Medicaid payment rate for institutional services, would result in fewer hours of care able to be delivered. We received one comment requesting CMS to expressly permit States to pay more than Medicare for services furnished through the FFS system. Additionally, one commenter expressed caution that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid.

Response: To clarify, the provisions in this final rule do not require States to change their payment rates. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Specifically, we did not propose, nor are we finalizing, a requirement that States must increase their institutional or non-institutional service payment rates through this final rule. Based on the information provided by the commenter (and without additional information about providers, such as, number of providers in a State or number of provider accepting new patients or accepting Medicaid), we understand the concerns raised to generally be an issue with a State's limitations on service coverage (that is, a coverage limit of $1,000/month limit on institutional services is insufficient for the amount of care required). While we do not have the authority to require States to change their Medicaid payment rates, we remind States that the Medicaid program is a Federal-State partnership and States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, quality of care, and access as required by section 1902(a)(30)(A) of the Act and a coverage limit could be inconsistent with this standard. We encourage the commenter to utilize the public process procedures described in § 447.204 to raise these concerns with their State. We also did not propose and are not finalizing a regulatory change that explicitly permits States to pay more than Medicare for services furnished through the FFS system. We acknowledge that existing UPL requirements limit Medicaid payments to a reasonable estimate of what Medicare would have paid.[185] However, outside of the services subject to UPL requirements limiting aggregate State Medicaid payment amounts, as the Medicaid program is a Federal-State partnership, States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, and quality of care as required by section 1902(a)(30)(A) of the Act. Currently, States can set FFS payment rates that are more than Medicare for numerous services, provided any applicable aggregate UPL is satisfied, and creating an explicit permission in regulation would not change the existing flexibilities States have in setting their payment rates.

We understand the commenter's concerns that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid. We acknowledged in the proposed rule that there may be other causes of access to care issues outside of provider payment rates, such as beneficiaries experiencing difficulty scheduling behavioral health care appointments due to a provider shortage where the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population.[186] However, we believe it is important to address one of the potential causes of access to care issues: payment rates that are not sufficient to enlist an adequate supply of providers as required by section 1902(a)(30)(A) of the Act. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider additional areas of access to care outside of payment rates to help inform any future rulemaking to promote improved access to care, as appropriate.

Comment: A number of commenters requested CMS provide States with guidance, templates, tools, examples, or descriptions of acceptable forms for publishing the payment rates, comparative payment rate analysis, and payment rate disclosure to ensure States understand how to comply with these provisions. A few commenters requested guidance on specific aspects of provisions of the proposed rule: accessible web pages and accounting for additional ways payment rates can vary (such as site of service and patient acuity). Those commenters also noted that some States use value-based payment (VBP) methodologies and requested guidance on how the various provisions of the proposed rule has accounted for these payment methodologies. Additionally, a couple of commenters suggested CMS provide guidance to the public to ensure the newly published data are understandable.

Response: Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023; illustrative examples of compliant payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications (including to meet accessibility standards); and a template to support completion of the additional State rate analysis under § 447.203(c)(2). We encourage States to review the subregulatory guidance to be issued prior to the effective date of this final rule and reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis and any other requirement of this final rule.

We are only requiring the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure include payment rate breakdowns by population (pediatric and adult), provider type, and geographical location, as applicable. Payment rate variations by site of service are not required, but States have flexibility to include this optional payment rate break down in the payment rate transparency publication. While not required in this final rule, should a State opt to breakdown their payment rates by site of service, the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service at any site of service. At State option, the State could also include additional payment rate breakdowns a provider might receive at other sites of service in the State (for example: office, inpatient hospital, school, mobile unit, urgent

[185] § 447.272 for inpatient hospitals, § 447.321 for outpatient hospitals and clinic services, § 447.325 for other inpatient and outpatient facilities (nursing facilities, intermediate care facilities for the developmentally disabled (ICF/DD), psychiatric residential treatment facilities (PRTF), and institutions for mental disease (IMDs).

[186] 88 FR 27960 at 28016.

care facility, nursing facility). We did not propose or finalize in this rule a requirement for States to include a payment rate breakdown for site of services because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Additionally, payment rate variations based on patient acuity are also not explicitly required in the payment rate transparency publication. Payment adjustments for patient acuity generally are limited to institutional settings (for example, inpatient hospitals and nursing facilities). Should a State opt to breakdown their payment rates by patient acuity, to the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service to any patient. At State option, the State could also include additional payment rate breakdowns the provider might receive for other levels of patient acuity. We also acknowledge that prospective payment system rates, such as Medicare's Patient Driven Payment Model (PDPM) for nursing facilities and inpatient prospective payment system (IPPS) for inpatient hospitals, typically account for patient acuity. As further discussed in a later response to comments in this section, PPS rates for inpatient hospital, outpatient hospital, and nursing facility services that are paid to most hospitals and nursing facilities and are payments based on a predetermined, fixed amount are subject to the payment rate transparency provision in this final rule. This is because these PPS rates are typically known in advance of a provider delivering a service to a beneficiary and fall into the scope of a Medicaid FFS fee schedule payment rate within the meaning of this final rule, as discussed in a later response to comments in this section.

We understand the commenters' concerns about ensuring the various payment rate transparency publications of this final rule are understandable to the public. We expect State publications of Medicaid payment rate transparency information, comparative payment rate analysis, and payment rate disclosures that comply with the requirements of this final rule to be transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. Therefore, we do not anticipate a need for guidance for the public at this time, but we will continue to assess once the requirements are in effect.

Comment: A couple of commenters suggested CMS conduct provider shortage assessments and engage providers, beneficiary advocacy organizations, direct service workers, caregivers, and other relevant interested parties in the data collection and analysis processes in the proposed rule and create a Federal-level public comment process within the CMS review of SPAs and HCBS waiver applications or renewals.

Response: We appreciate the commenters' suggestions; however, we did not propose to conduct provider shortage assessments, or to engage with interested parties in the data collection and analysis processes outside of the work of the interested parties' advisory group in § 447.203(b)(6). After obtaining implementation experience of these new policies, we will keep these suggestions in mind as we consider whether additional requirements may be appropriate to propose through future rulemaking.

Comment: One commenter suggested CMS consider future rulemaking to require States survey HCBS participants and their support systems to identify additional access issues and perceived causes, with a particular focus on assessing access related to unpaid and paid support. The commenter provided an example of a parent of an adult child providing a significant number of hours, both paid and unpaid, which the commenter suggested could be an indicator that the family cannot find a qualified provider for the services.

Response: We appreciate the commenter's suggestion. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter questioned the relationship between higher payment rates in FFS and higher rates of accepting new Medicaid patients, as well as the potential for affecting rates across payers and delivery systems, noting that even if the State raise the rates for the Medicaid FFS that does not mean that Medicaid or Medicare managed care plans, including managed care plans for individuals dually eligible for both Medicare and Medicaid, also will raise their provider payment rates. The commenter noted that raising the rates for Medicaid FFS does not mean that the State will ensure that the managed care plans operating in the State also pay higher rates, noting that practitioners are less likely to accept Medicaid if the managed care plans do not raise payment rates to align when FFS rates have been increased.

Response: We appreciate the views of the commenter. The provisions of § 447.203(c) only apply to Medicaid FFS, and do not apply to Medicaid managed care plans. Requirements for Medicaid managed care are discussed in the Medicaid Managed Care final rule (as published elsewhere in this **Federal Register**). Payment rates that managed care plans pay to providers are not required to be set at the Medicaid FFS rate levels as managed care is a risk-based arrangement whereby States pay managed care plans prospective capitation rates, and plans contract with network providers and negotiate provider payment rates. Managed care plans have their own access to care requirements, including the network adequacy requirements in 42 CFR 438.68. Managed care plan capitation rates are subject to actuarial soundness requirements at § 438.4.

1. Fully Fee-For-Service States

We solicited comments on whether additional access standards for States with a fully FFS delivery system may be appropriate. Because the timeliness standards of the proposed Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality proposed rule (Managed Care proposed rule) at § 438.68 would not apply to any care delivery in such States, we stated that we were considering whether a narrow application of timeliness standards to fully FFS States that closely mirrored the proposed appointment wait time standards, secret shopper survey requirements, and publication requirements (as applied to outpatient mental health and substance use disorder, adult and pediatric; primary care, adult and pediatric; obstetrics and gynecology; and an additional type of

service determined by the State) in that rule might be appropriate. Given that timeliness standards would apply directly to States, we also solicited comments on a potentially appropriate method for CMS to collect data demonstrating that States meet the established standards at least 90 percent of the time.

In developing the proposed rule, with respect to FFS, our intent and focus was on replacing the previous AMRP process. While we saw value in discussing and seeking public input on timeliness standards for fully FFS States that would mirror those proposed in the Managed Care proposed rule, creating additional alignment between the delivery systems, we were mindful of the volume of proposed changes that would require State resources for implementation. Therefore, we chose to maintain our goal with the FFS provisions of this access rule to replace the previous AMRP process, and we believed that timeliness standards were better suited to a larger, ongoing access strategy, to be considered and proposed in future rulemaking. Nevertheless, we saw value in gauging the appetite for CMS to adopt timeliness standards in fully FFS States, and as such included a short section about the possibility of those standards in the fully FFS context in the proposed rule. Although we are not finalizing any FFS timeliness standards in this final rule, we intend to propose them in future rulemaking, informed by the comments received on this discussion in the proposed rule. Additionally, by keeping this current rulemaking focused on replacing the previous AMRP process and not implementing FFS timeliness standards at this time, we afford ourselves an opportunity to observe and learn from those standards being established in managed care (and in the marketplace). Those experiences will provide greater insights into how to best propose these standards in FFS and provide time to engage with interested parties on how we might best include newly proposed FFS timeliness standards in existing requirements, including those we are finalizing in this rule, mitigating unnecessary burden on States.

We received public comments in response to this request for comment. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted general support for timeliness standards for fully FFS States. Generally, these commenters agreed that there is value in aligning access monitoring strategies across delivery systems so that all Medicaid beneficiaries would benefit from a new policy, and that these standards could improve access by confirming whether beneficiaries are actually able to access care in a timely manner. Some commenters had suggestions if CMS were to adopt timeliness standards in FFS, such as phasing in the requirements over time or by service, collecting information on geographic variations in wait times, and either applying the standards to all FFS programs or allowing exception for States with minimal covered services delivered through FFS. Others cited concerns that they would want a future proposal to address, such as establishing protections for providers who do not have direct control over their scheduling. Commenters varied on whether they believed providers should have to perform any additional work to meet new standards, with one requesting that providers, not just States, be held accountable for outcomes based on these standards, while another commenter wanted to ensure these requirements would not add any burden on providers. One commenter suggested including provider surveys in addition to participant surveys.

Response: We appreciate the support expressed by a number of commenters for the concept of applying timeliness standards in fully FFS delivery systems as a further means to ensure beneficiary access to covered services. We are also grateful for the suggestions that will allow us to formulate future proposed rulemaking that considers various needs and concerns. We note that the request for comment was with respect to fully FFS States (that deliver no services through managed care), but we will consider for future rulemaking whether to expand on that limit, for example, applying standards to States that cover only a small number of services through managed care delivery, to apply them to FFS generally, or to maintain the focus on fully FFS States. We intend to use the experience of the managed care plans and the States implementing timeliness requirements to assess things like a phased-in approach, or whether such standards should be proposed for FFS delivery systems in non-fully FFS States.

Comment: We received a number of comments expressing general opposition to establishing timeliness standards for services delivered on a FFS basis, particularly in the context of implementing them simultaneously with the other access provisions in the proposed rule. These commenters expressed concern about the burden, both in time and cost, of establishing the necessary administrative infrastructure to meet timeliness requirements as well as the requirements proposed in the proposed rule. One commenter suggested CMS explore how these areas could be better monitored using existing data collections and processes. Another pointed out the differences in available resources between managed care and FFS, such as increased matching rates associated with managed care External Quality Review that does not exist with respect to FFS Medicaid, making FFS timeliness standards more cost prohibitive to implement. Another commenter pointed out that in FFS delivery systems, States would not know whether wait time issues identified through monitoring were specific to Medicaid or whether similar wait time issues were encountered by other patients with other payers.

Response: We understand the concerns about burden on States, and for that reason we limited the proposed rule and are only finalizing provisions that, generally, serve to replace the previous AMRP process. We see value in the oversight and positive program outcomes that could be achieved through proposing and implementing FFS timeliness standards in the future, and also understand there will be differences between managed care and FFS that create unique issues to address in any future proposal. For example, there are differences in how providers interact with plans in a managed care system versus how they interact with the State Medicaid agency in a FFS system. There are also differences in the idea of a ''network'' between these delivery models that may impact how we would assess network adequacy. We will explore how we can best support States with the administrative burden, and how we can establish standards that identify problems unique to providing services to Medicaid beneficiaries.

Comment: Many commenters expressed support for specific aspects of our request, such as for establishing wait time standards in a FFS delivery system or utilizing secret shopper surveys for oversight. These commenters generally pointed to the access improvements such standards can provide, as they would highlight where there are deficiencies in finding available providers. One commenter shared personal experience of longer wait times as a Medicaid beneficiary than those experienced by non-Medicaid enrollees. One commenter shared suggestions regarding which benefit categories needed more focus, both for oversight and in length of wait times, and this commenter along with a couple others encouraged CMS to align with the Health Insurance

Marketplace®.[187] Another commenter cautioned that provider shortages must be addressed as part of the overall access strategy.

Response: We appreciate hearing from commenters on the specifics of the timeliness standards request for comments, as we hope to use this feedback to inform and enhance a future set of proposals. We also fully intend to include lessons from the experience of the marketplace and Medicaid managed care in proposing these future standards for the FFS delivery system and will continue to engage with interested parties between now and when we undertake future rulemaking on this topic. We agree that provider shortages present a challenge to access and the efficacy of wait time standards, and we will examine how best to acknowledge that reality while holding States and providers to appropriate standards.

Comment: Several commenters opposed the specific standards listed in our request for comment. One encouraged CMS to achieve its access goals through a focus on payment adequacy rather than wait times. Similarly, another requested CMS allow States to provide verification and assurances of sufficient access through other, existing data collection mechanisms. Another stated wait time standards that do not account for differences in provider availability, as in whether there are sufficient providers in a geographic area to meet the standards based on the beneficiary population in that area, would not achieve the desired effect of increasing access. One commenter expressed that a secret survey process would be duplicative of existing directory review processes already undertaken by States and would also force States to switch vendors from an existing outside entity performing the role, and stated CMS should instead allow States to continue with current practices that achieve a similar purpose. Another questioned the data integrity of a secret survey approach to oversight, stating there are inherent challenges in collecting consistent information.

Response: We intend to make every effort to utilize existing processes and to mitigate duplication wherever possible when we propose FFS timeliness standards in the future. However, we are exploring proposing these standards because, in our view, appointment wait time maximums and secret shopper surveys may provide for unique and valuable oversight of access that we may wish to propose in the future. As stated previously, in this rule we prioritized a replacement for an existing rate-based process, but our evaluation and enhancement of means to ensure beneficiary access will be ongoing. We will utilize lessons learned from the implementation of timeliness standards under managed care to inform our future FFS proposals.

Comment: Some commenters were unclear as to whether CMS was proposing to implement the timeliness standards for fully FFS States as proposed in the Managed Care proposed rule. One commenter was concerned how and when CMS would communicate to States that these requirements had taken effect. Another pointed out specifically that CMS had included preamble language without including proposed regulatory text or burden estimates, which they noted would be significant. The commenter was concerned that the public had not been afforded a meaningful opportunity for notice and comment.

Response: We apologize for the confusion experienced by some as to whether this section of the rule was intended as a proposed policy. This discussion in the proposed rule was a request for comment, not a proposed policy. We intend to propose these timeliness standards under FFS in future rulemaking, affording States and other interested parties the ability to examine a complete proposal and provide comments that we would consider in a subsequent finalization decision. We are not finalizing any timeliness standards for FFS delivery systems in this final rule.

2. Documentation of Access to Care and Service Payment Rates (§ 447.203(b))

We proposed to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, including a new process to promote payment rate transparency. This new proposed process would require States to publish their FFS Medicaid payment rates in a clearly accessible, public location on the State's website, as described later in this section. Then, for certain services, States would be required to conduct a comparative payment rate analysis between the States' Medicaid payment rates and Medicare rates or provide a payment rate disclosure for certain HCBS that would permit CMS to develop and publish HCBS payment benchmark data.

a. Payment Rate Transparency § 447.203(b)(1)

In paragraph (b)(1), we proposed to require the State agency to publish all Medicaid FFS payment rates on a website developed and maintained by the single State agency that is accessible to the general public. We proposed that published Medicaid FFS payment rates would include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. We also proposed to require that the website be easily reached from a hyperlink on the State Medicaid agency's website.

Within this payment rate publication, we proposed that FFS Medicaid payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. We also proposed that, if the rates vary, the State must separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

We noted that longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. Under Title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and implementing regulations, qualified individuals with disabilities may not be excluded from participation in, or denied the benefits of any programs or activities of the covered entity, or otherwise be subjected to discrimination by any covered entity, on the basis of disability, and programs must be accessible to people with disabilities.[188] Individuals with disabilities are entitled to communication that is as effective as communication for people without disabilities, including through the provision of auxiliary aids and services.[189] Section 1557 of the Affordable Care Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide

[187] Health Insurance Marketplace® is a registered service mark of the US Department of Health & Human Services.

[188] 29 U.S.C. 794; 42 U.S.C. 18116(a); 42 U.S.C. 12132; 28 CFR 35.130(a); 45 CFR 84.4 (a); 45 CFR 92.2(b).

[189] 28 CFR 35.160; 45 CFR 92.102; *see also* 45 CFR 84.52(d).

meaningful access to their health programs or activities for individuals with limited English proficiency, which may include the provision of interpreting services and translations when reasonable.[190]

We proposed that for States that pay varying Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, those States would need to separately identify their Medicaid FFS payment rates in the payment rate transparency publication by each grouping or multiple groupings, when applicable to a State's program. In the event rates vary according to these factors, as later discussed in this final rule, our intent is that a member of the public be readily able to determine the payment amount that will be made, accounting for all relevant circumstances. For example, a State that varies their Medicaid FFS payment rates by population may pay for a service identified by code 99202 when provided to a child at a rate of $110.00 and when provided to an adult at a rate of $80.00. Because the Medicaid FFS payment rates vary based on population, both of these Medicaid FFS payment rates would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication. As another example, a State that varies their Medicaid FFS payment rates by provider type may pay for 99202 when delivered by a physician at a rate of $50.00, and when delivered by a nurse practitioner or physician assistant at a rate of $45.00.

In the proposed rule, we acknowledged that we are aware that some State plans include language that non-physician practitioners (NPPs), such as a nurse practitioner or physician assistant, are paid a percentage of the State's fee schedule rate. Because the Medicaid FFS payment rates vary by provider type, both of the Medicaid FFS payment rates in both situations (fee schedule rates of $50.00 and $45.00) would need to be separately identified as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication, regardless of whether the State has individually specified each amount certain in its approved payment schedule or has State plan language specifying the nurse practitioner or physician assistant rate as a percentage of the physician rate. Additionally, for example, a State that varies their Medicaid FFS payment rates by geographical location may pay for 99202 delivered in a rural area at a rate of $70, in an urban or non-rural area as a rate of $60, and in a major metropolitan area as a rate of $50. We are also aware that States may vary their Medicaid FFS payment rates by geographical location by zip code, by metropolitan or micropolitan areas, or other geographical location breakdowns determined by the State. Because the Medicaid FFS payment rates vary based on geographical location, all Medicaid FFS payment rates based on geographical location would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication.

For a State that varies its Medicaid FFS payment rates by any combination of these groupings, then the payment rate transparency publication would be required to reflect these multiple groupings. For example, the State would be required to separately identify the rate for a physician billing 99202 provided to a child in a rural area, the rate for a nurse practitioner billing 99202 provided to a child in a rural area, the rate for a physician billing 99202 provided to an adult in a rural area, the rate for a nurse practitioner billing 99202 provided to an adult in a rural area, the rate for a physician billing 99202 provided to a child in an urban area, the rate for a nurse practitioner billing 99202 provided to a child in an urban area, and so on. We proposed that this information would be required to be presented clearly so that a member of the public can readily determine the payment rate for a service that would be paid for each grouping or combination of groupings (population (pediatric and adult), provider type, and geographical location), as applicable. We acknowledged that States may also pay a single Statewide rate regardless of population (pediatric and adult), provider type, and geographical location, and as such would only need to list the single Statewide rate in their payment rate transparency publication.

We acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' Medicaid FFS payment rates vary based on these groupings. Despite the additional burden, we noted our belief that the additional level of granularity in the payment rate transparency publication is important for ensuring compliance with section 1902(a)(30)(A) of the Act, given State Medicaid programs rely on multiple provider types to deliver similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each area of each State.

We further proposed that Medicaid FFS payment rates published under the proposed payment rate transparency requirement would only include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. To ensure maximum transparency in the case of a bundled fee schedule payment rate or rate determined by a similar payment methodology where a single payment rate is used to pay for multiple services, we proposed that the State must identify each constituent service included in the bundled fee schedule payment rate or rate determined by a similar payment methodology. We also proposed that the State must identify how much of the bundled fee schedule payment rate or rate determined by a similar payment methodology is allocated to each constituent service under the State's payment methodology. For example, if a State's fee schedule lists a bundled fee schedule rate that pays for day treatment under the rehabilitation benefit and the following services are included in the day treatment bundle: community based psychiatric rehabilitation and support services, individual therapy, and group therapy, then the State would need to identify community based psychiatric rehabilitation and support services, individual therapy, and group therapy separately and each portion of the bundled fee schedule payment rate for day treatment that is allocated to community based psychiatric rehabilitation and support services, individual therapy, and group therapy. We proposed to require States identify the portion of the bundled fee that is allocable to each constituent service included in the bundled fee schedule payment rate, which would add an additional level of granularity to the payment rate transparency publication to enable a member of the public to readily be able to determine the payment amount that would be made for a service, accounting for all relevant circumstances, including the payment rates for each constituent service within a bundle and as a standalone service. We also proposed to require that the website be easily reached from a hyperlink to ensure transparency of payment rate information is available to beneficiaries, providers, CMS, and other interested parties.

In the proposed rule, we proposed the initial publication of Medicaid FFS

[190] 45 CFR 92.101; *see also https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.*

payment rates would occur no later than January 1, 2026, and include approved Medicaid FFS payment rates in effect as of that date, January 1, 2026. We proposed this timeframe to provide States with at least 2 years from the possible effective date of the final rule, if this proposal were finalized, to comply with the payment rate transparency requirement. We explained that the proposed timeframe would initially set a consistent baseline for all States to first publish their payment rate transparency information and then set a clear schedule for States to update their payment rates based on the cadence of the individual States' payment rate changes.

We noted that the same initial publication due date for all States to publish their payment rates would promote comparability between States' payment rate transparency publications. In proposing an initial due date applicable to all States, we reasoned that, once States would begin making updates to their payment rate transparency publications, there would be a clear distinction between States that have recently updated their payment rates and States that have long maintained the same payment rates. For example, say two States initially publish their payment rates for E/M CPT code 99202 (office or outpatient visit for a new patient) at $50. One State annually increases its payment rate by 5 percent over the next 2 years, and would update its payment rate transparency publication accordingly in 2027 with a payment rate of $52.50, then in 2028 with a payment rate of $55.13, while the other State's payment rate for the same service remains at $50 in 2027 and 2028. The transparency of a State's recent payment rates including the date the payment rates were last updated on the State Medicaid agency's website, as discussed later, as well as the ability to compare payment rates between States on accessible and easily reachable websites, highlights how the proposed payment rate transparency would help to ensure that Medicaid payment rate information is available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues to better ensure compliance with section 1902(a)(30)(A) of the Act.

We also proposed that the initial publication include approved Medicaid FFS payment rates in effect as of January 1, 2026. We proposed this language to narrow the scope of the publication to CMS-approved payment rates and methodologies, thereby excluding any rate changes for which a SPA or similar amendment request is pending CMS review or approval. SPAs are submitted throughout the year, can include retroactive effective dates, and are subject to a CMS review period that varies in duration.[191] [192]

As discussed later in this final rule regarding paragraph (b)(2) and (b)(3), we encouraged States to use the proposed payment rate transparency publication as a source of Medicaid payment rate data for compliance with the paragraph (b)(3)(i)(B) proposed comparative payment rate analysis and paragraph (b)(3)(ii)(B) proposed payment rate disclosure requirements. However, we noted that the comparative payment rate analysis and payment rate disclosure requirements would look to rates in effect one year before the publication of the required analysis or disclosure. We include a more in-depth discussion of the timeframes for publication of the comparative payment rate analysis and payment rate disclosure in paragraph (b)(4) later in this final rule, where we note that the 1-year shift in timeframe is necessitated by the timing of when Medicare publishes their payment rates in November and the rates taking effect on January 1, leaving insufficient time for CMS to publish the code list for States to use for the comparative payment rate analysis and for States develop and publish their comparative payment rate analysis by January 1. We noted that the ongoing payment transparency publication requirements would allow the public to view readily available, current Medicaid payment rates at all times, even if slightly older Medicaid payment rate information must be used for comparative payment rate analyses due to the cadence of Medicare payment rate changes as well as the payment rate disclosure. We are cognizant that the payment rate disclosure does not depend on the availability of Medicare payment rates; however, we proposed to provide States with the same amount of time to comply with both the proposed comparative payment rate analysis and payment rate disclosure requirements.

We stated that, if this proposal were finalized at a time that would not allow for States to have a period of at least 2 years between the effective date of the final rule and the proposed January 1, 2026, due date for the initial publication of Medicaid FFS payment rates, then we proposed an alternative date of July 1, 2026, for the initial publication of Medicaid FFS payment rates and for the initial publication to include approved Medicaid FFS payment rates as of that date, July 1, 2026. This shift would allow more than 2 years from the effective date of this final rule for States to comply with the payment rate transparency requirements.

We proposed to require the that the single State agency include the date the payment rates were last updated on the State Medicaid agency's website. We also proposed to require that the single State agency ensure that Medicaid FFS payment rates are kept current where any necessary updates to the State fee schedules made no later than 1 month following the date of CMS approval of the SPA, section 1915(c) HCBS waiver, or similar amendment revising the provider payment rate or methodology. Finally, in paragraph (b)(1), we proposed that, in the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State would be required to update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate. This provision is intended to capture Medicaid FFS payment rate changes that occur because of previously approved SPAs containing payment rate methodologies. For example, if a State sets its Medicaid payment rates for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) at a percentage of the most recent Medicare fee schedule rate, then the State's payment rate would change when Medicare adopts a new fee schedule rate through the quarterly publications of the Medicare DMEPOS fee schedule, unless otherwise specified in the approved State plan methodology that the State implements a specific quarterly publication, for example, the most recent April Medicare DMEPOS fee schedule. Therefore, the State's Medicaid FFS payment rate automatically updates when Medicare publishes a new fee schedule, without the submission of a SPA because the State's methodology pays a percentage of the most recent State plan-specified Medicare fee schedule rate. In this example, the State would need to

[191] In accordance with 42 CFR 430.20, an approved SPA can be effective no earlier than the first day of the calendar quarter in which an approvable amendment is submitted. For example, a SPA submitted on September 30th can be retroactively effective to July 1st.

[192] In accordance with 42 CFR 430.16, a SPA will be considered approved unless CMS, within 90 days after submission, requests additional information or disapproves the SPA. When additional information is requested by CMS and the State has respond to the request, CMS will then have another 90 days to either approve, disapprove, and request the State withdraw the SPA or the State's response to the request for additional information. This review period includes two 90-day review periods plus additional time when CMS has requested additional information which can result is a wide variety of approval timeframes.

update its Medicaid FFS payment rates in the payment rate transparency publication no later than 1 month after the effective date of the most recent update to the Medicare fee schedule payment rate made applicable under the approved State plan payment methodology.

While there is no current Federal requirement for States to consistently publish their rates in a publicly accessible manner, we noted our awareness that most States already publish at least some of their payment rates through FFS rate schedules on State agency websites. Currently, rate information may not be easily obtained from each State's website in its current publication form, making it difficult to understand the amounts that States pay providers for items and services furnished to Medicaid beneficiaries and to compare Medicaid payment rates to other health care payer rates or across States. However, through this proposal, we sought to ensure all States do so in a format that is publicly accessible and where all Medicaid FFS payment rates can be easily located and understood. The new transparency requirements under this final rule help to ensure that interested parties have access to updated payment rate schedules and can conduct analyses that would provide insights into how State Medicaid payment rates compare to, for example, Medicare payment rates and other States' Medicaid payment rates. The policy intends to help ensure that payments are transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. We solicited comments on the proposed requirement for States to publish their Medicaid FFS payment rates for all services paid on a fee schedule, the proposed structure for Medicaid FFS payment rate transparency publication on the State's website, and the timing of the publication of and updates to the State's Medicaid FFS payment rates for the proposed payment rate transparency requirements in § 447.203(b)(1).

We received public comments on these provisions. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported the proposed payment rate transparency provision at § 447.203(b)(1) in its entirety. A couple of commenters specifically expressed support for ensuring the State's website where the payment rate transparency is published is fully accessible and provides meaningful access for individuals with limited English proficiency. Additionally, a couple of commenters stated that their State already publishes their fee schedules as proposed by the payment rate transparency requirements.

However, a couple of commenters expressed opposition to the proposed payment rate transparency provision in its entirety. Commenters in opposition stated the proposed payment rate transparency requirements would be administratively burdensome for States and that the payment rate transparency publication would not result in a meaningful access analysis. One commenter questioned CMS' authority to require States to publish their payment rates because section 1902(a)(30) of the Act does not explicitly grant CMS this authority.

Response: We thank the commenters for their support of the proposed payment rate transparency provision at § 447.203(b)(1). We are finalizing the payment rate transparency provisions by adding and deleting regulatory language for clarification, making minor revisions to the organizational structure, updating the required timeframe for compliance and for updating payment rates after SPA or other payment authority approval, and incorporating a technical change to account for States submitting SPAs with prospective effective dates. We list and describe the specific revisions we made to the regulatory language for the payment rate transparency provision at § 447.203(b)(1) at the end of this section of responses to comments. The policies in this final rule allow flexibility that we believe will allow some States to use existing fee schedule publications for compliance, and we expect additional States will only need minor revisions. We encourage States that already publish their fee schedules to review the final regulatory language and reach out to CMS with any questions regarding compliance.

We disagree with the commenters regarding administrative burden of the payment rate transparency publication. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule. Specifically for the payment rate transparency publication, and as discussed in a later response to comments, States have flexibility to (1) organize and format their publication, so that they can use existing fee schedule publications for compliance (assuming all requirements in § 447.203(b)(1) are met); (2) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (3) for the initial publication, if necessary historical information about bundled payment rates is unavailable to the State, then the State does not need to include the bundled payment rate breakdown as required in § 447.203(b)(1)(iv) of this final rule (however, we remind States that upon approval of a SPA that revised the bundled payment rate, the State will be required to update the publication to comply with § 447.203(b)(1)(iv)). Additionally, we are providing examples of payment rates that are not subject to the payment rate transparency publication and an illustrative example of a compliant payment rate transparency (including to meet accessibility standards) through subregulatory guidance issued prior to the effective date of this final rule. We expect these flexibilities and clarifications to minimize the State administrative burden commenters expressed concern about, which potentially stemmed from an imprecise understanding of the Medicaid FFS fee schedule payment rates that are required to be published in the payment rate transparency publication. Finally, we would expect that States already have the data for the payment rate transparency publication readily available through existing fee schedules, SPAs, or other internal documentation, so the work to compile that data into a format that complies with this final rule should require minimal effort.

To clarify, the payment rate transparency publication is not an analysis requirement, but a transparency requirement for States to publish their Medicaid FFS fee schedule payment rates, as discussed in detail in a later response to comments in this section. However, an analysis component is being finalized in § 447.203(b)(2) and (3) called the comparative payment rate

analysis, which we believe will result in a meaningful access analysis because it requires States to compare certain of their Medicaid FFS payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. This access analysis will help States and CMS to assess compliance with section 1902(a)(30)(A) of the Act where Medicare payment rates serve as a benchmark for comparing Medicaid payment rates to another of the nation's large public health coverage programs. As described in the proposed rule and in greater detail later in this final rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.[193]

We disagree that we do not have the authority to require States to publish their payment rates. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act, which requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.[194] Transparency, particularly the requirement that States must publicly publish their payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. As noted in the proposed rule, most States already published at least some of their payments through FFS rate schedule on State agency websites.[195] Our efforts finalized in this rule will help ensure all States publish their payment rates consistently and accessibly so interested parties have fundamental information about payment rates and can utilize existing public processes to raise concerns about access. Additionally, the Supreme Court's *Armstrong* decision placed added importance on CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates. The payment rate transparency requirements included in this final rule reflect that statutory responsibility to ensure compliance with section 1902(a)(30)(A) of the Act. We also note that the previous AMRP process that was in effect prior to this final rule established a transparent data-driven process to measure access to care in States, including oversight of provider payment rates, actual or estimated levels of provider payment available from other payers, and the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates. This final rule merely streamlines the approach under the same statutory authority and shared responsibility that applied for the previous AMRP process. We remind States of longstanding, general requirement for the State to maintain statistical, fiscal, and other records necessary for reporting and accountability under § 431.17(b)(2).

Comment: Some commenters expressed concerns about the burden associated with the payment rate transparency publication. They specifically cited concern about meeting strict State-level website accessibility requirements, extensive changes that could be needed to existing claims payment systems (that is, for a State that does not currently include beneficiary copayment information on their existing fee schedules, the State may need to make change requests of their contractor to modify their claims payment system to produce the Medicaid payment information required in the payment rate transparency publication to include the total payment amount a provider would receive inclusive of beneficiary cost sharing), conducting research on when payment rates were last updated, and monthly monitoring of Medicare rates to ensure State fee schedule rates set at a percentage of Medicare are updated timely.

Response: As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the websites containing Medicaid FFS payment rate information. These requirements apply to all State agency, contractor, or other third-party websites and any burden associated with meeting those Federal obligations is not created by policies finalized in this rule. With respect to any State-level accessibility requirements that might exceed Federal requirements, we refer the commenter to the State Medicaid agency or other agency responsible for compliance with State accessibility requirements for guidance or technical assistance concerning State-imposed accessibility requirements.

Regarding commenters' concerns that States would need to change existing claims payment systems (that is, the State may need to make change requests of their contractor to modify their claims payment system to produce the Medicaid payment information required for the payment rate transparency publication that includes beneficiary cost sharing in fee schedule amounts), we want to clarify State claiming and payment systems, and the output of these systems, generally are not subject to the payment rate transparency publication requirements as the provision only applies to Medicaid FFS fee schedule payment rates. We do not anticipate it would be unduly burdensome for a State to maintain its Medicaid FFS fee schedules in an appropriate format outside of its claiming and payment systems. States are not required to publish claims data or data about actual payments made to providers under the payment rate transparency publication provision.

Commenters were concerned about whether beneficiary cost sharing information should be included in the payment rate transparency publication. To clarify, the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. By requiring States to publish the payment amount the Medicaid agency would pay and any beneficiary cost sharing as a single payment amount, we focus on the total Medicaid payment amount a provider would expect to receive for furnishing a given service to a Medicaid beneficiary and which is therefore most relevant to a provider's decision to accept the Medicaid payment rate, thereby furthering our section 1902(a)(30)(A) access goals to ensure payment rates are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Furthermore, this representation of payment rates is consistent with the

[193] 88 FR 27960 at 28011.

[194] 88 FR 27960 at 27967.

[195] 88 FR 27960 at 28000.

comparative payment rate analysis,[196] which minimizes burden on States by requiring the Medicaid FFS fee schedule payment rate be displayed in the same way for both publications. Additionally, we recognize that beneficiary cost sharing amounts can vary depending on the State Medicaid program and the status of the Medicaid enrollee. Therefore, we expect States with cost-sharing requirements could experience additional burden in complying with the payment rate transparency publication, if States were required to remove variable cost sharing amount from the Medicaid FFS fee schedule payment rate for each service subject to the publication.

Regarding commenters' concerns about conducting research on when payment rates were last updated, we want to clarify that the requirement to include the date the rates were last updated refers to a date for the website publication. In other words, the date should provide assurance that the rates on the website are current as of the specified date. We do not expect, nor did we propose, States to examine historical records to find the dates every rate was last updated. However, if a State wishes to include that information for all or a subset of published rates, it can.

Regarding commenters' concerns about monthly monitoring of Medicare rates to ensure the payment rate transparency publication is up to date, firstly, to clarify, only States that set their Medicaid payment rates at a percentage of a Medicare payment rate would be affected by this consideration. For those States that set their Medicaid payments rates as a percentage of a Medicare payment rate, we expect the State to already be monitoring changes in Medicare rates in accordance with their approved payment methodology and §§ 430.10 and 430.20 and part 447, subpart B, which require States to pay the approved State plan payment rates in their State plan effective on or after the approved effective date of the State plan provision. Therefore, if a State's approved State plan pays a rate based on the most current Medicare payment rate for a particular service, then payment of any rate outside of the approved State plan methodology would result in a State plan compliance issue. We expect that States with such payment methodologies routinely are monitoring Medicare payment rates to ensure that their Medicaid payment rates are updated according to the approved methodology. Medicare fee schedule updates are well documented and accessible to States on cms.gov, even in the event of a change to a Medicare payment rate outside the usual cadence of Medicare updates for that rate (an off-cycle update) and keeping up with Medicare fee schedule updates is critical for ensuring a State's payment rate transparency publication is accurate and updated timely.[197]

Comment: A few commenters requested clarification on the format of the payment rate transparency publication, particularly if Medicaid FFS payment rates should be organized by CPT code.

Response: In this final rule, in regard to the payment rate transparency provision, we are not requiring States to publish their payment rates by CPT/HCPCS code, which is required in the comparative payment rate analysis discussed later in this section. However, we encourage States to consider organizing their publication by CPT/HCPCS code, due to the common use of CPT/HCPCS for billing for medical services across the country, including in State Medicaid programs. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all these rates can be easily located and understood. States can determine what organizational and formatting structure is most suitable for organizing rates in a manner that will be easily understood by providers and beneficiaries.

Comment: A couple of commenters requested clarification on the requirement that States separately identify Medicaid FFS fee schedule payment rates by population, specifically inquiring if ''population'' referred to beneficiary demographics or waiver/program population.

Response: As indicated in the regulation text, population refers to beneficiary demographics, specifically adult and pediatric populations. Under this final rule, States will be required to publish their Medicaid FFS fee schedule payment rates separately identified by rates paid for the adult population and the pediatric population, if the rates differ in the State. As stated in the proposed rule, we acknowledge that a State may pay a single Statewide rate regardless of population, provider type, or geographical location, and such a State would only need to list the single Statewide rate in its payment rate transparency publication. We also acknowledge that States define pediatric differently (such as, 18 years old or younger, 19 years old or younger, and 21 years old or younger) and we encourage States to disclose the age range the State's Medicaid program uses in the payment rate transparency publication for transparency purposes.

Comment: Some commenters requested clarification regarding which payments are subject to the payment rate transparency requirements outlined in paragraph (b)(1). Multiple commenters questioned if the following payment methodologies would be subject to the payment rate transparency requirements under paragraph (b)(1): manually priced items (for example, physician administered drugs), provider-specific rates (for example, PPS rates typically paid to FQHCs or all-inclusive per-visit rates typically paid to clinics (we assume commenters meant clinics as defined in § 440.90)), per diem rates, cost and cost-based payment methodologies (including interim payments) typically paid to facility-based providers, and negotiated rates. Additionally, many commenters questioned if disproportionate share hospital (DSH) payments, FFS supplemental payments, or managed care State directed payments (SDPs) would be included in the payment rate transparency publication. A couple of commenters stated that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service because excluding DSH payments and supplemental payments is an inaccurate, incomplete, and misleading representation of a Medicaid provider's actual, overall payments from the Medicaid program.

Response: In § 447.203(b)(1) of the proposed rule, we proposed that ''[t]h State agency is required to publish all Medicaid fee-for-service payment rates . . . . Published Medicaid [FFS] payment rates include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a [FFS] delivery system.'' We acknowledge that this language was not clear that we intended to require the publication requirement to include only Medicaid FFS fee schedule payment rates. Accordingly, in this final rule, we have made some revisions to the proposed regulatory language in § 447.203(b)(1) to change the organizational structure of (b)(1) by adding romanettes and clarify that only Medicaid FFS fee schedule payment rates are required to be published in the payment rate transparency publication. Throughout (b)(1), references to ''fee schedule payment'' were replaced with

[196] 88 FR 27960 at 28013.

[197] *https://www.cms.gov/medicare/payment/fee-schedules.*

''Medicaid fee-for-service fee schedule payment rates'' for clarity and consistency. Therefore, in (b)(1) we state that, the State agency is required to publish all Medicaid FFS fee schedule payment rates. Further, in § 447.203(b)(1)(i), we specify that, ''for purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.''

We would like to clarify which Medicaid FFS fee schedule payment rates are subject to the payment rate transparency provisions in § 447.203(b). Medicaid FFS fee schedule payment rates are payment amounts made to a provider, known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. A fee schedule is a list, table, or similar presentation of covered services and associated payment amounts that are generally determined at the State's discretion. We also consider a State to use a fee schedule when the State has not yet organized its payment amounts into such a straightforward list, table, or similar presentation, but under the State's approved payment methodology, the State determines payment rates based on the application of a mathematical formula to another fee schedule or other reference rate stated as an amount certain. In other words, a fee schedule that utilizes a formula, but has not yet been organized into a list, table, or similar presentation of covered services and associated payment amounts, is included in the scope of fee schedules subject to the payment rate transparency provisions. For example, a Medicaid payment methodology that provides for payment at 80 percent of the corresponding Medicare PFS rate would constitute a Medicaid fee schedule payment methodology because it applies a formula to a fee schedule to produce a fee schedule payment rate that is known in advance of a provider delivering the service. This formula reflects that the State's fee schedule payment methodology starts with the Medicare PFS fee schedule, then reduces the fee schedule amount to 80 percent of the Medicare PFS amount to arrive at the Medicaid fee schedule payment rate. States that utilize the previously described formula-based methodology that may not currently publish these payment rates on a fee schedule will be required to publish the actual payment amounts as determined by their formula in the payment rate transparency publication under this final rule. This final rule focuses on ensuring transparency of Medicaid FFS fee schedule payment rates so that they are ''. . . organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service,'' as stated in the proposed regulatory language in § 447.203(b)(1), which we are finalizing in § 447.203(b)(1)(iii) of this final rule with a slight modification to replace ''the service'' with ''a given service.'' Merely publishing the mathematical formula that a member of the public would need to use to calculate each payment rate the State has set for a particular service would not meet this requirement of this final rule. To summarize, fee schedule payment methodologies that utilize a formula applied to another fee schedule are included in the scope of fee schedules, and the payment rate transparency publication must reflect the actual fee schedule payment rate amounts.

Certain bundled payment rates (as discussed later in this comment response) and PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are considered fee schedules payment rates subject to the payment rate transparency publication because these payment amounts are also known in advance of a provider delivering a service to a beneficiary and are stated (or can readily be stated) as a list, table, or similar presentation.

We recognize that PPS rates are utilized in different contexts in Medicaid to pay for various services (including for services of FQHCs, RHCs, inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities) and can be calculated differently, depending on the service. PPS rates in Medicaid used to pay for services provided by inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities would be included. In the context of payment rates to hospitals and nursing facilities, the term ''encounter rate'' or ''per diem rate'' can also be used to describe the PPS rate received by these providers. This term generally describes a daily payment rate that is paid to a hospital or nursing facility during a patient's admission to a hospital or nursing facility. In this situation, the PPS payment methodology typically makes payment based on a predetermined, fixed amount. States often use or model their payment methodologies after Medicare's prospective payment systems to pay for outpatient hospital, inpatient hospital, and nursing facility services. In these situations, under Medicare's prospective payment systems, Medicare typically pays providers for a particular service an amount derived based on the services expected to be received during a visit or course of treatment (for more complex conditions). For example, under the Medicare IPPS, payment is made based on the Diagnosis Related Group (DRG) to which the patient discharge is assigned. States also often use other grouping systems, such as Medicare's PDPM for nursing facilities, Ambulatory Payment Classifications under Medicare's hospital outpatient PPS for hospital outpatient services items, or Medicare's End Stage Renal Disease PPS for facilities or hospital-based providers that furnish dialysis services and supplies. These PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are paid to most hospitals and nursing facilities and are typically known in advance of a health care provider delivering a service to a beneficiary. Therefore, these types of PPS rates would be subject to the payment rate transparency publication in this final rule.

In contrast, FQHCs and RHCs are paid PPS rates that are developed under a methodology that is statutorily mandated under section 1902(bb) of the Act, which generally requires that FQHCs and RHCs receive a per visit, or encounter, rate that is provider-specific and must be based on a health center's unique cost and visit data.[198] This requirement creates a payment rate floor where FQHC and RHCs cannot be paid less than the PPS rate developed under this statutorily mandated methodology. Because this statutory payment floor is set by Congress, FQHC and RHC payment rates are uniquely situated in a manner that does not exist for other Medicaid payment rates under State discretion.[199] Although States must comply with section 1902(a)(30)(A) of the Act, this statutory provision does

[198] In the context of payment rates to FQHCs and RHCs, the terms ''encounter rate,'' ''per visit rate,'' and ''provider-specific rate'' can also be used to describe the PPS payment rate.

[199] We acknowledge that Medicaid payment rates for hospice services also have a statutorily mandated payment floor: the Medicaid hospice payment rates are calculated based on the annual hospice rates established under Medicare. These rates are authorized by section 1814(i)(1)(C)(ii) of the Act, which also provides for an annual increase in payment rates for hospice care services. However, we do not believe these rates would be burdensome on States to include because they are paid to all Medicaid participating hospice providers and are therefore not carving them out of this requirement.

not set a specific payment rate floor. Therefore, because of the unique provider-specific payment floor mandated by Congress for FQHCs and RHCs, we believe access concerns related to payment rates for FQHCs and RHCs are attenuated and as such, we are not including FQHC and RHC PPS rates in the payment rate transparency publication requirement. Furthermore, because the FQHC and RHC PPS rates are provider-specific based on an individual provider's costs and scope of service and required to be paid by States as a floor set by Congress, we generally do not believe that publication of the individual providers' payment rates as part of the payment rate transparency provision finalized in this rule would not result in actionable information for CMS to consider in ensuring compliance with section 1902(a)(30)(A) of the Act as intended through this final rule at this time.

In addition, if we were to require States to also publish FQHC and RHC PPS rates, we would expect a significant increase in burden on States in meeting this requirement. FQHC and RHC PPS rates are unique to each FQHC and RHC in a State (rather than a single fee schedule rate that Medicaid would pay for a given service to any provider in a State) and, therefore, publicizing the FQHC and RHC rates would represent a sharp increase in States' efforts for rates that are less concerning to CMS due to the statutory payment floor in section 1902(bb) of the Act. We do not believe the increase in burden is justifiable given our aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act with this final rule. Finally, and as discussed in detail in an earlier response to comments in this section, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC and RHC services are subject to the access analyses in § 447.203(c) for proposed rate reductions and restructuring.

Certain FFS VBP payment methodologies are also fee schedule payment methodologies, even if the exact dollar amount that a particular provider will receive for a given service is not known in advance because of the need to adjust for metric-based performance. In such a case, a State might have an approved FFS VBP payment methodology in the State plan that includes a 2 percent withhold of the fee schedule payment amount and the potential for an additional 3 percent bonus to the provider based on the provider's performance for the year on certain quality measures. Assuming the State's payment methodology starts with a base payment of 80 percent of the Medicare PFS payment amount, the provider's minimum payment for the service would be .98 * (PFS * .80), and the maximum payment (achieved through a retrospective true-up payment based on final quality performance for the year) would be 1.03 * (PFS * .80). The provider's minimum and maximum possible payment amounts are known in advance (2 percent less than the Medicaid fee schedule amount, and 3 percent more, respectively) and are based on the application of a formula to a fee schedule. We also consider this type of FFS VBP arrangement to constitute a fee schedule payment methodology, because although the State does not know in advance the final payment amount a given provider will receive for a particular service (since the provider's quality performance is not known in advance), the minimum payment amount is calculable in advance based on the application of a mathematical formula to a fee schedule amount. We expect the State to use the minimum payment amount for purposes of the requirements of § 447.203(b), because this is the amount that a provider is assured to receive for furnishing the service. At State option, the State could also include information on the maximum payment amount the provider might receive under the FFS VBP payment methodology.

We would also like to clarify what payments are not subject to the payment rate transparency publication provision. Payment rates that are not subject to the transparency provisions include those where the minimum fee schedule payment is not known in advance of a provider delivering a service to a beneficiary because certain variables required for the payment calculation are unknown until after the provider has delivered the service. For example, cost-based and reconciled cost payment methodologies (including those that involve interim payments) are not subject to the payment rate transparency provisions because actual cost is unknown until the end of the provider's reporting period. As another example, FFS supplemental payment methodologies are not subject to the payment rate transparency publication provision because these methodologies often utilize variables, such as claims volume or number of qualifying providers, for dividing up a pre-determined payment pool, and actual supplemental payment amounts are unknown until the end of the provider's (or providers') reporting period.

While a relatively simple FFS VBP payment methodology (such as the one discussed earlier in this response, with a bonus and withhold percentage added to or subtracted from a fee schedule rate based on provider performance) is considered to result in a fee schedule payment rate subject to the payment rate publication requirement, we acknowledge that some States already utilize more complex FFS VBP payment methodologies (including episodes of care [200] and integrated care models [201]) that utilize quality and cost measures to determine the provider's unique payment amount. Providers who participate in one of these complex VBP payment arrangements generally report quality and cost data to the State at the end of the provider's reporting period and then the State uses that data to determine the provider's payment amount after the provider has furnished services. Excluding complex VBP payment methodologies from the payment rate transparency publication balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to publish payment rates determined by complex FFS VBP payment methodologies, it would be burdensome on States, as these payment rates are

[200] We consider episodes of care to be a complex VBP because the payment methodology determines the total payment by comparing the provider's cost of care for an episode to the State determined thresholds for how much the State expects a provider to spend on an episode. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider and episode to episode. Therefore, the unknown amount of a provider's cost of care for an episode relative to the State's threshold affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

[201] We consider integrated care models to be a complex VBP because the payment methodologies used in these models, for example, shared savings methodologies, determine the total payment by comparing the provider's cost of care to the State determined total cost of care benchmark for how much the State expects a provider to spend. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider. Additionally, States can apply risk and gain-sharing arrangements that decreases or increases provider's payment rate based on their performance in meeting specific quality goals. Therefore, the unknown amount of a provider's cost of care relative to the State's total cost of care benchmark and additional decreases or increases to payment rates based on performance meeting quality goals affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

unique to the provider and are determined using variables (the provider's quality performance and cost of furnishing services) that are unknown until after a provider's reporting period has ended. As these measures are generally unknown until after the provider's reporting period has ended, the State does not know a provider's payment in advance. Therefore, complex VBP payment methodologies as previously described are not fee schedule payment methodologies within the meaning of this final rule that are subject to the payment rate transparency provision.

We also recognize that an advanced payment methodology, as described in SMDL 20–004, could utilize fee schedule payments within the meaning of this final rule.[202] For example, a State could calculate an advanced payment of $10,000 for a provider that is expected to furnish 1,000 services and each service is paid at a fee schedule payment rate of $10. The advanced payment amount was originally determined by a fee schedule payment rate, which is known in advance of a provider delivering a service to a beneficiary, and therefore these rates would appear to be covered by this requirement. However, there are also features of certain advanced payment methodologies that could place them outside the scope of this requirement. For example, an advanced payment methodology that permits States to include risk adjustments and quality performance adjustments to the advanced payment amount, and/or requires the State to perform a reconciliation to the actual number of claims, could mean that the Medicaid payment amount that the provider could expect to receive could not be known in advance. At the time of publication of this final rule, there are no approved SPAs that utilize an advanced payment methodology as discussed in SMDL 20–004, so we are unable to state definitively whether any advanced payment methodology that may be used in FFS Medicaid pursuant to a future SPA would be subject to the payment rate transparency publication requirement. Without implementation experience of advanced payment methodologies, we will review future advanced payment methodologies on a case-by-case basis to determine if the methodology uses a fee schedule payment methodology within the meaning of this final rule. We encourage States that propose advanced payment methodology after finalization of this rule to reach out to CMS for technical assistance on determining whether advanced payment amounts are subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to ''manually priced items'' to mean a provider payment rate that the State determines after a service or item has been delivered to a beneficiary and the provider has billed for it. For example, certain durable medical equipment items that are infrequently furnished to beneficiaries may be paid at the manufacturer's suggested retail price minus a percentage. This is described in the approved State plan, and when such an item is furnished to a beneficiary, the State must manually adjust the amount paid for the claim to equal the manufacturer's suggested retail price minus the percentage listed in the State plan, rather than pay a particular Medicaid FFS fee schedule payment rate. Because these services and items are infrequently furnished and States manually price each service and item as they are delivered to the beneficiary, we understand that it would be impractical and burdensome on States to maintain current lists of the manufacturer's suggested retail price for all potential items or services a beneficiary might require and a provider may bill for, and that States often source these items and services from multiple manufacturers. Therefore, for the purposes of the payment rate transparency publication, we consider manually priced payment methodologies that utilize the manufacturer's suggested retail price to result in a payment amount that is not known in advance of a provider delivering a service or item to a beneficiary, and thus not to be a fee schedule payment methodology subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to ''negotiated rates'' to mean a provider payment rate where the individual provider's final payment rate is agreed upon through negotiation with the State Medicaid agency. For example, negotiated rates may be offered by a State when a particular service has very low utilization, a custom item is required (for example, certain wheelchairs), or the State does not have information needed to establish a payment rate under an approved State plan payment methodology (for example, information from other payers, such as Medicare or the State's employee health insurance on how much they pay for the service or item) to establish a fixed payment rate. In these instances, generally, the State has not developed a rate prior to service delivery; payment for the service or item on a case-by-case-basis in the circumstances does not constitute a fee schedule payment methodology. Additionally, DSH payments and supplemental payments are not subject to the payment rate transparency publication requirement because they do not fall into the description of Medicaid FFS fee schedule payment rates for purposes of the payment rate transparency provision in § 447.203(b)(1). Finally, SDPs in Medicaid managed care delivery systems are outside the scope of § 447.203(b)(1)(i), which is specific to the FFS delivery system.

We invite States to reach out to CMS for technical assistance if they have a FFS payment rate or methodology that may not clearly align with the previous descriptions and examples of Medicaid FFS fee schedule payment rates that are subject to the payment rate transparency publication provision, and other payment methodologies that are not.

We disagree with commenters that that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service. To clarify, we did not intend for the payment rate transparency publication to reflect the entire universe of payments a provider may receive. Setting the scope of the publication to Medicaid FFS fee schedule payment rates, as previously discussed in this response to commenters, balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to also include DSH payments and supplemental payments along with the Medicaid FFS fee schedule payment rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for furnishing the service to a Medicaid beneficiary, as DSH payments and supplemental payments are generally paid on a provider-level basis rather than a service-level basis, and not all providers of a given service will qualify for these payments.

Comment: One commenter requested clarification regarding whether payment rates paid to the direct support workforce are subject to the payment rate transparency publication requirements. Another commenter questioned if self-directed service payment rates should be published

[202] *https://www.medicaid.gov/sites/default/files/2020-09/smd20004.pdf.*

separately from agency model personal care services.

Response: We interpret the commenter's reference to ''the direct support workforce'' to generally mean the direct support workers or direct support professionals that provide hands-on and in-person Medicaid services to beneficiaries. To the extent a State's payment rates to direct support workforce utilize Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail in an earlier response to comments in this section, those payment rates would be subject to payment rate transparency requirements under § 447.203(b)(1).

Regarding self-directed service payment rates being separately published from agency model personal care services, we assume the commenter was referring to self-directed models with service budget and agency-provider models authorized under 42 CFR 441.545. We would like to clarify that, to the extent a State pays an agency-provider a Medicaid FFS fee schedule payment rate as discussed in detail in an earlier response to comments in this section, then those payment rates are subject to the payment rate transparency requirements in § 447.203(b)(1). Self-directed models with service budget [203] are not subject to the payment rate transparency publication requirement in § 447.203(b)(1). As previously stated, payment rates that are not subject to the payment rate transparency publication requirement include those that that are not known in advance of a provider delivering a service to a beneficiary. Under the self-directed model with service budget, the State only sets the beneficiary's overall service budget, and the beneficiary negotiates the payment rate with the direct support worker; therefore, the State is not setting the payment rate and does not know in advance what rate the direct service worker will be paid for furnishing services to the beneficiary. This does not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, and as such these types of payment rates are excluded from the publication requirement. We further clarify that we do not expect States to list each beneficiary's individual self-directed service budget in the payment rate transparency publication.

Comment: One commenter expressed concern that requiring States to publish all Medicaid FFS payment rates online could have unintended consequences, such as beneficiary confusion about how much their copayment amount would be if it was included on the State's fee schedule which typically lists the amount allowed for the service, as well as State burden from increased documentation on the State's website. The commenter recommended CMS permit States to provide easily accessible links where the fee schedules are located to copayment information already available to providers and clients in a clear and concise manner.

Response: We understand commenters' concerns about the effects of the payment rate transparency publication in practice. Regarding commenters' concerns about beneficiary confusion, we want to clarify that the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments, as discussed earlier in a response to comments this section. We encourage States, as part of transparency efforts, to include in the payment rate transparency publication a link to the page on the website where existing beneficiary cost sharing information is located so beneficiaries and other interested parties will be able to easily access this existing source of information about beneficiary cost sharing obligations. Additionally, regarding commenters' concerns about burden from increased documentation on the State's website, as documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. With the finalization of the provisions in this rule, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same). As previously stated, States also have the flexibility to utilize contractors or other third-party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule).

Comment: One commenter requested clarification on the 1-month update requirement for the payment rate transparency requirement. The commenter stated that there are instances where SPAs are submitted with prospective effective dates or where States may face a delayed operationalization in their claims system that includes approved rate changes. The commenter noted that, in both instances under the proposed regulatory language for the payment rate transparency requirement, a State would be expected to publish rates that are not yet in effect or not currently being paid to providers. The commenter suggested revising the regulatory language to require States update rate changes in the payment rate transparency publication within 1 month of CMS approval of a SPA, the effective date of payment rate changes, or the date system changes are operationalized by a State, whichever date occurs latest. Additionally, one commenter suggested extending the requirement for updates to the payment rate transparency publication to 2 months instead of 1 month as proposed.

Response: In response to comments, we have revised the regulatory language to account for SPAs with prospective effective dates. As finalized in this rule, § 447.203(b)(1)(vi) now states, ''[t]he agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment.'' We are adding this language as a technical change to account for States submitting SPAs with prospective effective dates as the proposed regulatory language would have required State to publish payment rates in the payment rate transparency publication that were approved, but not yet effective. We thank the commenter for pointing out this possibility, and we believe this change will ensure a State's payment rate transparency publication is as current as possible, and accurate once published.

[203] Self-directed services are paid for using an individualized budget. States are required to describe the method for calculating the dollar values of individual budgets based on reliable costs and service utilization, define a process for making adjustments to the budget when changes in participants' person-centered service plans occur, and define a procedure to evaluate participants' expenditures. *https://www.medicaid.gov/medicaid/long-term-services-supports/self-directed-services/index.html.*

However, we have not included regulatory language to account for system changes with a delayed operationalization date as suggested by this commenter. In accordance with §§ 430.10 and 430.20 and part 447, subpart B, States are required to pay the approved State plan payment rates in their State plan effective on or after the approved effective date. Therefore, payment of any rate outside of the approved State plan would result in a State plan compliance issue, and non-compliance is not a circumstance we would accommodate in regulations. We have also not extended the timeframe from 1 month to 2 months for States to update their payment rate transparency publications after a payment rate change. States are aware that a payment rate change is forthcoming and its requested effective date when they submit a SPA, and as such, we believe 1 month is more than sufficient to update the payment rate transparency publication. We invite States to reach out to CMS for technical guidance regarding any technological or operational limitations that may impact a State's compliance with the payment rate transparency publication requirement.

Comment: We received a few comments expressing concern about which bundled payment rates would be subject to the payment rate transparency publication as well as concern about the burden imposed on States from operational challenges to break down bundled payment rates into constituent services and rates allocated to each constituent service in the bundle. These commenters also requested clarification on how States will be required to publish bundled payment rates in the payment rate transparency publication. Commenters requested clarification regarding the following instances where bundled payment rates are used by States: team-based services, provider-specific rates (for example, PPS rates typically paid for FQHC and RHC services or an encounter rate typically paid to clinics for clinic services (we assume commenters meant clinic services as defined in § 440.90) and CCBHC services), and per diem rates paid for facility or institutional (that is, hospital and nursing facility) services. These commenters stated that this requirement would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist or bundled rates are established on a provider-specific basis using provider-specific historical cost data and inflationary adjustments. These commenters requested further clarification regarding a definition of constituent services, how States should unbundle rates and services from a bundled rate, as well as additional explanation of the value CMS believes this requirement will contribute to the Medicaid program. They encouraged CMS to explicitly exempt facility and institutional providers from the payment rate transparency publication requirements.

Response: Bundled payments are a versatile payment methodology that States can utilize within and across numerous Medicaid benefit categories. Bundled payments are generally developed using State-specific assumptions about the type, quantity, and intensity of services included in the bundle, and generally are based on the payment rates for the individual constituent services when they are furnished outside the bundled rate.

In this final rule, we clarify bundled payment rates that are subject to the requirement in the payment rate transparency publication provision that States identify how much of the bundled fee schedule payment rate is allocated to each constituent service under the State's payment methodology. In the case of a bundled payment methodology, the State must publish the Medicaid FFS bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

To explain further, the bundled payment rates that are subject to this requirement are State-developed payment rates that provide a single payment rate for furnishing a bundle of services, including multiple units of service, multiple services within a single benefit category, or multiple services across multiple benefit categories. In any of these instances, multiple providers and provider types could contribute to a bundle of services, which is what we interpret the comment about team-based services to mean. Bundled payment rates that are based on fee schedule payment rates for each constituent service are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

States can develop bundled payment rates for multiple units of a single service, for example, by setting a daily rate for up to 4 hours of personal care services a day that includes multiple 15-minute units of personal care services for which there is a fee schedule payment rate. States can also develop a bundled payment rate for multiple services within a single benefit category. For example, within the rehabilitative services Medicaid benefit, a daily rate for assertive community treatment, which can include constituent services set at fee schedule payment rates for assessments, care coordination, crisis intervention, therapy, and medication management, is considered a bundled rate. Finally, States can also develop a bundled payment rate for one or more services across multiple benefit categories. For example, a daily rate that includes constituent services set at fee schedule payment rates for up to 2 hours of personal care services, up to 2 hours of targeted case management services, and 1 hour of physical therapy services is considered a bundled rate. As all of these examples describe bundled payment rates comprised of constituent services that are based on fee schedule payment rates, they are subject to the bundled rate breakdown requirement in the payment rate transparency provision. Later in this response, we will discuss how States are required to allocate the bundled payment rate to each constituent service under the State's methodology.

Within a bundled payment rate, a constituent service is a Medicaid-covered service included in a bundle of multiple units of service and/or multiple services. These constituent services within the bundled payment rate must correspond to service descriptions in section 3.1–A of the State plan, which describes covered services. When initially adding a bundled payment rate to the State plan, States are required to separately list out each constituent service included in the bundle to ensure that non-covered services are not included in the bundled rate.[204] For example, a bundle for assertive community treatment covered under the rehabilitative services State plan benefit should not include room and board, as rehabilitative services are not covered in institutional settings. Therefore, ''room and board'' is a non-covered service under the rehabilitative services benefit and would not be a constituent service in the bundled payment rate.

We also clarify payment rates that pay for various services and could be considered a bundled payment rate that

[204] *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

are not subject to the requirement in the payment rate transparency publication provision. For purposes of the requirement of this final rule, this bundled payment rate breakdown requirement only applies to bundled payment rates that are based on fee schedule payment rates for each constituent service. Payment rate methodologies that do not utilize fee schedule payment rates for each constituent service to create a single State-developed bundled payment rate to pay for a combination of services, including multiple units of the same service, multiple services within a single benefit category, or multiple services across multiple benefit categories, are not subject to the bundled rate breakdown requirement in the payment rate transparency publication provision. For example, prospective payment system rates that States use to pay for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are not subject to the bundled rate breakdown requirement, because these PPS rates (as previously mentioned, in the context of payment rates to hospitals and nursing facilities, the terms ''encounter rate'' or ''per diem rate'' can also be used to describe the prospective payment system rate received by these providers) do not utilize fee schedule payment rates to create a single payment rate to pay for a bundle of services. These PPS payment methodologies generally pay providers an amount derived based on a formula that accounts for the resources required to treat a patient, such as the patient's condition (that is, illness severity or clinical diagnosis), the provider's operating costs (that is, labor, supplies, insurance), and adjustment factors (that is, cost of living, case-mix, State determined factors), such as when an individual has an inpatient hospital stay for knee replacement surgery. While these PPS rates generally are subject to the payment rate transparency publication requirement in this final rule because they are typically known in advance of a provider delivering a service to a beneficiary, they are not subject to the breakdown requirement to the extent they do not utilize exclusively fee schedule payment rates to create a single payment rate for the bundle of services. Therefore, if we were to require States to also break down PPS rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for the furnishing the services to a Medicaid beneficiary, as PPS rates are generally not determined based only on payment rates for constituent services within the meaning of this final rule. We believe a fee schedule payment rate for each constituent service is needed to enable the State to perform a straightforward and reliable allocation of the bundled payment rate to each included service. Therefore, because PPS rates are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule, States do not need to identify each constituent service included within a PPS rate and how much of the PPS rate is allocated to each constituent service under the State's methodology. In response to the comment asking about FQHC and RHC PPS rates, please see the discussion earlier in this section explaining why these rates are carved out of this requirement due to the statutory floor for rates and consideration of potentially undue burden on States.

Regarding whether payment rates for CCBHC services are subject to the bundled payment rate breakdown requirement, PPS rates for CCBHC demonstration services authorized under section 223 of the Protecting Access to Medicare Act of 2014 are not subject to the payment rate transparency publication requirement, including the bundled rate breakdown requirement, because these payments rates are outside of Medicaid FFS State plan authority. For CCBHC services covered and paid for under Medicaid FFS State plan authority, States that use Medicaid FFS fee schedule rates within the meaning of this rule to pay for CCBHC services must include these payment rates in the payment rate transparency provisions. Additionally, Medicaid FFS fee schedule rates that are bundled payment rates within the meaning of this rule paid to clinics (as defined in § 440.90), are subject to the bundled rate breakdown requirement.

Based on this, if a State determines a bundled payment rate is subject to the bundled payment rate breakdown requirement, we will now discuss how to allocate the bundled payment rate to each constituent service under the State's methodology. States have flexibility in determining the assumptions regarding the type, quantity, intensity, and price of the constituent services that they factor into the initial development of a bundled rate.[205] When States establish the payment rate for a bundle, States may include the current fee schedule payment rates for the constituent services to determine the total bundled rate. For example, a State might pay a $480 bundled rate for assertive community treatment, based on the application of a small discount factor to the fee schedule payment rates for all of the constituent services (assessments, care coordination, crisis intervention, therapy, and medication management). In this scenario, the State's fee schedule payment rates might be $50 for an assessment, $30 for care coordination, $200 for crisis intervention, $200 for 2 hours of individual therapy, and $20 for medication management. Separately, the State would pay a total of $500 for all of these services; however, the State might determine that a provider likely would realize efficiencies from providing the services together in a coordinated fashion, and so might reduce the bundled payment rate by 4 percent to account for these expected savings. Thus, the State's bundled payment rate would be $480, which would be allocated as follows: $480 * ($50/$500) = $48 for assessment; $480 * ($30/$500) = $28.80 for care coordination; $480 * ($200/$500) = $192 for crisis intervention; $480 * ($200/$500) = $192 for 2 hours of individual therapy; and $480 * ($20/$500) = $19.20 for medication management. In this example, the State would identify each of these constituent services and use these allocation amounts to meet the requirements finalized in paragraph (b)(1)(iv).

In response to commenters' request for an explanation of the value CMS believes the bundled payment rate breakdown requirement will contribute to the Medicaid program, our rationale is the same as for this payment rate publication requirement generally. Bundled rates are not inherently transparent, and in order to achieve the same goal of transparency in service of ensuring adequate access to covered care and services, it is important for interested parties to know what is covered in a bundled rate and how much of the bundle is attributable to each constituent service, which provides information relevant to whether the bundled rate is adequate in relation to its constituent services and enables comparison to how the constituent services are paid when

[205] For new bundled rates, CMS requests information on how States developed the rates, including: assumptions regarding the type, quantity, intensity, and price of the component services typically provided to support the economy and efficiency of the rate. *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

furnished outside the bundle. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

In response to commenters' concerns that the bundled payment rate breakdown provision would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist, we are providing guidance on how States are expected to address these circumstances. We acknowledge there are instances where States may have bundled payment rates that have been in place for many years, even decades, and the State currently does not have available information about how the payment rates were developed. Therefore, the State may lack historical data to perform a reasonable allocation of the bundled payment rate to constituent services. We also recognize there are instances where States utilizing bundled payment rates do not permit providers to bill for the constituent services separately. In this instance, States may no longer regularly update the fee schedule amounts for the constituent services included in the bundled payment rate because the bundle is primarily how the services are delivered and billed by providers. Therefore, the current fee schedule payment rates for the constituent services do not reflect how the State would pay for the constituent services outside of the bundle.

States have flexibility in determining how best to allocate the bundled payment rate to each constituent service in these scenarios. Should a State not have certain historical data about the bundled payment rate available, we are offering a few solutions for the State to consider. If a State can reasonably calculate missing rates, we expect them to do so for the purposes of completing the bundled payment rate allocation. For example, a State may have a bundled payment rate that includes five constituent services, which the State knows was calculated by summing the undiscounted fee schedule payment rates for each of the five constituent services. Today, the State may be unable to locate the fee schedule amount for one of the constituent services. In this instance, we would expect the State to reasonably deduce the allocated rate for the fifth constituent service by summing the four known rates for the four constituent services and subtracting that amount from the total bundled payment rate. If a State cannot calculate a missing portion of a bundled payment rate, they may use current fee schedule rates. For example, a State may have a bundled payment rate, but it does not have historical information about how the bundled payment rate was originally calculated from the constituent services. In this instance, we would expect the State to use the current fee schedule rates for the constituent services included in the bundle to allocate the bundled payment rate for the payment rate transparency publication. Regardless of the approach States utilize to allocate the bundled payment rate to the constituent services, we expect States to include a description of how the bundled payment rate was allocated in the payment rate transparency publication to ensure that a member of the public can readily determine the amount that Medicaid would pay for the bundled service and understand how the State has accomplished a reasonable allocation of this amount to each constituent service included in the bundle, as required in § 447.203(b)(1)(iii).

In situations where the State cannot reasonably deduce how to allocate the bundled payment rate to the constituent services included in the bundle or the current fee schedule rates for the constituent services do not serve as a reasonable proxy to determine the allocation of the bundled payment rate to its constituent services, we invite States to reach out to us for technical assistance on how to comply with § 447.203(b)(1)(iv) on a case-by-case basis. We expect this guidance to provide States with relief from burden associated with allocating the bundled payment rate to constituent services when historical information is unavailable, including in certain situations raised by commenters where individual historical rates for constituent services within the bundle are no longer available. Regardless of how a State chooses to address a lack of data related to a bundled payment rate, we expect the State to update the payment rate transparency publication with an accurate allocation information following the effective date or CMS approval date of a SPA, a section 1915(c) HCBS waiver amendment, or similar amendment amending the bundled payment rate in question in accordance with § 447.203(b)(1)(vi). These processes require the State to provide information about the fee schedule payment rates for the constituent services included in the bundle, therefore making available the necessary data to perform an allocation for the payment rate transparency publication.

We also invite States to contact CMS for technical assistance if they have a bundled payment methodology that does not clearly align with the previous descriptions and examples of bundled payment rates that are and are not subject to the bundled payment rate breakdown requirement. We also encourage States to review our existing Bundled Rate Payment Methodology resource on Medicaid.gov for more information about bundled payment methodologies.[206]

Regarding commenters' concerns about burden on States to break down institutional services bundled payment rates into constituent services in the payment rate transparency publication, we understand these concerns were primarily about operational challenges States would face if rates paid to hospitals and nursing facilities, as well as cost-based rates generally, were subject to this provision. As previously discussed in this response, PPS rates that are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv); however, PPS rates generally are considered Medicaid FFS fee schedule payment rates in the context of this rule and are required to be published in the payment rate transparency publication under § 447.203(b)(1) as finalized in this rule. Also previously discussed in this response, PPS rates for FQHCs and RHCs are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv) because these payment rates are not subject to the payment rate transparency publication requirement under § 447.203(b)(1).

In this final rule, we are revising the regulatory language to make clear what bundled payment rates are subject to the constituent service allocation, or breakdown, requirement. We proposed in § 447.203(b)(1) to provide that the State must, ''. . . in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and

[206] *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

how much of the bundled payment rate is allocated to each constituent service under the State's methodology.'' We are finalizing § 447.203(b)(1)(iv) to state, ''In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' (new language identified in bold). We also deleted ''or similar'' from ''In the case of a bundled payment methodology . . .'' because we determined that this language is unnecessary and potentially confusing; instead, in this final rule, we are clarifying specifically which bundled payment rates are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.

Comment: Several commenters offered suggestions and recommendations for the proposed payment rate transparency requirements. These suggestions and recommendations include linking together FFS and managed care plan web pages for full transparency, allowing State contractors to publish the State's payment rates, requiring the published format of the payment rates be ready for data analysis, requiring States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses) as well as the frequency and processes for rate reviews, and requiring States publish additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency).

Response: We appreciate commenters' suggestions and recommendations for the payment rate transparency publication requirement. While the transparency provisions in the Managed Care final rule (as published elsewhere in this **Federal Register**) and this final rule share a similar goal, we are not incorporating the suggestion to require States to link together FFS and managed care plan web pages for full transparency because there is often no relationship between FFS Medicaid payment rates and managed care plan provider rates, as the rates are determined through different processes, subject to different Federal requirements, and States, managed care plans, and CMS assess access to care differently for FFS and managed care. Therefore, we believe that requiring States link their FFS payment rate transparency publication websites with managed care plan web pages would not provide beneficiaries, providers, CMS, and other interested parties with relevant payment information for the purposes of assessing access to care issues to better ensure compliance of FFS payment rates with section 1902(a)(30)(A) of the Act.

As discussed in an earlier response to comments in this section, we have revised the regulatory language in § 447.203(b)(1) from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. Specifically, in § 447.203(b)(1), we deleted the language requiring that the website where Medicaid fee-for-service fee schedule payment rates be published be ''developed and maintained by the single State agency.'' As finalized, § 447.203(b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' We continue to require that ''The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.'' in § 447.203(b)(1)(ii).

We are not incorporating the suggestion to require the format of the payment rate transparency publication be ready for any particular form of data analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Transparency will provide us and other interested parties with information necessary that is not currently available at all or not available in a clear and accessible format for us to ensure the payment rates for consistency with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. The payment rate transparency publication is the first step in ensuring payment rate data is transparent, then the comparative payment rate analysis is the next step in analyzing the payment rate data relative to Medicare as a benchmark. Additionally, given the requirements that the payment rate transparency publications be publicly available, clear, and accessible, we anticipate that various interested parties will be able to adapt the published information manually or through technological means so that it is suited to any analysis they wish to perform.

We are not incorporating the suggestion to require States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses), the frequency and processes for rate reviews, or additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency), because we want our initial focus to be on establishing the new payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While the payment rate transparency publication does not require additional granular data outside of payment rate variations by population (pediatric and adult), provider type, and geographical location, we would like to note that utilization in the form of the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service is required to be included in the comparative payment rate analysis and payment rate disclosure; however, these requirements do not include dental services. We acknowledge that the commenters' suggestions would add relevant and beneficial context to the payment rate information required to be published by States in this final rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with

this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. While we are not adopting all of these suggestions and recommendations, we note that States have the flexibility to add the elements described to their payment rate transparency publications if they so choose.

We believe that there are minimal qualities that the website containing the payment rate transparency publication necessarily must include, such as being able to function quickly and as an average user would expect; requiring minimal, logical navigation steps; taking reasonable steps to provide meaningful access to individuals with limited English proficiency; and ensuring accessibility for persons with disabilities in accordance with section 504 of the Rehabilitation Act and Title II of the ADA. An example of this includes a single web page clearly listing the names of the State's published fee schedules (such as Physician Fee Schedule, Rehabilitation Services Fee Schedule, etc.)) as links that transport the user to the relevant State fee schedule file, which file should be in a commonly accessible file format that generally can be viewed within a web browser without requiring the user to download a file for viewing in separate software. In this example, there is no unnecessary burden (including requiring payment (paywall)) creation of an account and/or password to view the web page, or need to install additional software to view the files) on the individual to trying to view the published fee schedules. We invite States to reach out to CMS for technical guidance regarding compliance with the payment rate transparency publication requirement. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant payment rate transparency publication might look like, that we will issue prior to the effective date of this final rule.

Comment: A few commenters suggested narrowing the scope of the payment rate transparency requirement. Commenters recommended narrowing the scope by requiring publication of payment rate transparency information only about a representative subset of services, a State's most common provider types and covered services, or the same CMS-published list of E/M codes that we proposed for the comparative payment rate analysis requirement. A subset of these commenters suggested that, once States have acclimated to the requirements of payment rate transparency, then CMS could expand the requirement gradually to include all Medicaid FFS payment rates, to ease burden on States.

Response: We appreciate the commenters' suggestions on narrowing the scope of the payment rate transparency requirement; however, we are not changing the scope in this final rule. As previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. While we understand the broad scope of included rates will require some work for many States to implement, we believe the time between the effective date of this final rule and the applicability date of July 1, 2026, for the first publication of payment rate transparency information is sufficient for these requirements. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter suggested requiring States identify an additional level of payment rate variation within the population (pediatric and adult) where, within the pediatric population, Medicaid and CHIP pay different rates, which should be disclosed separately in the payment rate transparency publication.

Response: We appreciate the commenter's suggestion; however, we are not including a requirement that States break down payment rates to include separate Medicaid and CHIP payment rate information within the pediatric population payment rate reporting. Regulations applicable to CHIP under 42 CFR part 457 and relevant guidance are beyond the scope of this rulemaking. After obtaining implementation experience with these new policies, we will consider proposing to require States to identify additional levels of payment rate variations in the Medicaid FFS payment rate transparency publication through future rulemaking.

Comment: One commenter suggested applying the payment rate transparency requirements to all Medicaid HCBS programs.

Response: To the extent a State's Medicaid HCBS program utilizes Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail earlier in this section, those payment rates would be subject to payment rate transparency publication requirements described in § 447.203(b)(1). Additionally, we are finalizing a similar provision to the Medicaid FFS fee schedule payment rate transparency requirement for HCBS direct care worker compensation elsewhere in this final rule. The HCBS Payment Adequacy and Reporting requirements in this final rule require that States report annually, in the aggregate for each service, on the percent of payments for homemaker, home health aide, personal care, and habilitation services that are spent on compensation for direct care workers, and separately report on payments for such services when they are self-directed and facility-based.

Comment: One commenter suggested collecting provider-level data on all payments, not just fee schedule payment rates, as well as the source(s) of non-Federal share for payments, to determine net Medicaid payments (total Medicaid provider payments received minus the provider's contributions to the non-Federal share through mechanisms including provider-related donations, health care-related taxes, intergovernmental transfers, and certified public expenditures) to each provider.

Response: Existing UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the Consolidated Appropriations Act, 2021 (CAA) (Pub L. 116–260),) already require States to submit provider-level payment data for certain services to CMS. Therefore, we are not incorporating the suggestion to collect provider-level data on all payments because this would be duplicative of existing requirements and because that is not the intention of the payment rate transparency publication requirement. While we do collect information about the non-Federal share through SPA reviews, regulatory requirements regarding collection of non-Federal share data are beyond the scope of this rulemaking.

Comment: A couple of commenters stated that dually eligible beneficiaries and their providers face unique issues when accessing and delivering Medicaid services (such as beneficiaries facing worse outcomes and having complex needs that require providers to coordinate and deliver specialized care) and requested CMS include additional provisions in the payment rate transparency publication requirements specifically for this group. One commenter suggested CMS require the

payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage. Another commenter suggested requiring that the payment rates be disaggregated for the purposes of comparing providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries to ensure differences in access to care and payment rates are documented. The commenter also recommended the payment rate transparency publication identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies (that is, for dually eligible Qualified Medicare Beneficiaries, States are obligated to pay Medicare providers for deductibles and co-insurance after Medicare has paid; however, States limit those payments to the lesser of the Medicaid rate for the service or the Medicare co-insurance amount).

Response: We appreciate the commenters' concern for and suggestions on how we might evaluate access to care for dually eligible beneficiaries. We are not incorporating the suggestion to require the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage because these provisions focus on requiring States to publish and analyze quantitative data (such as, payment rates, claims volume, beneficiary counts) to assess access to care, rather than qualitive data (such as, surveys on beneficiary experience). We are also not incorporating the suggestion to identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies in the payment rate transparency publication because we remain focused on the transparency of States' payment rates, rather than States' payment policies, as a method of assessing consistency with section 1902(a)(30)(A) of the Act. Additionally, we are not incorporating the suggestion to require States disaggregate their Medicaid FFS fee schedule payment rates for providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Monitoring access to care is an ongoing priority of the agency and we will continue to work with States and other interested parties as we seek to expand access monitoring in the future, including potentially through future rulemaking. However, we remain focused on maintaining a balance in Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

Comment: A couple of commenters recommended that the payment rate transparency requirements under § 447.203(b) be applied to payment rates for services delivered to beneficiaries through managed care to ensure managed care plan rates are published publicly.

Response: While we appreciate the value in transparency of provider payment rates in managed care delivery systems, regulations applicable to managed care under 42 CFR parts 438 and 457 are beyond the scope of this rulemaking.

Comment: One commenter requested CMS work with States to correct deficient payment rates once identified by the transparency requirements.

Response: To clarify, the provisions in this final rule do not require States to change their provider payment rates. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all Medicaid FFS fee schedule payment rates can be easily located and understood.

Transparency, particularly the requirement that States must publicly publish their Medicaid FFS fee schedule payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We will utilize the information in the payment rate transparency publication during SPA reviews and other situations when States are proposing provider payment rate changes for services included in the publication and when the public process in § 447.204 is used to raise access to care issues related to possible deficient payment rates for services included in the publication.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(1) as proposed, apart from the following changes:

- Updated the organizational structure of (b)(1) to add romanettes.
- Added clarifying language to the proposed language stating what Medicaid FFS payment rates need to be published.

++ In paragraph (b)(1), the proposed language was revised from ''The State agency is required to publish all Medicaid fee-for-service payment rates . . .'' to finalize the language as ''The State agency is required to publish all Medicaid fee-for-service **fee schedule** payment rates . . .'' (new language identified in bold)

++ In paragraph (b)(1)(i), the proposed language was revised from ''Published Medicaid fee-for-service payment rates include fee schedule payment rates . . .'' to finalize the language as ''**For purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are** Medicaid fee-for-service payment rates . . .'' (new language identified in bold)

- Deleted the proposed language specifying that the payment rate transparency must be developed and maintained on the State Medicaid agency's website. The proposed language was revised from ''The State agency is required to publish all Medicaid fee-for-service payment rates on a website developed and maintained by the single State agency that is accessible to the general public'' to finalize the language as ''The State agency is required to publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public.'' in paragraph (b)(1).
- Revised the proposed language about a member of the public being able to readily determine the payment amount for a service from ''Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service'' to finalize the language as

''Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service.'' in paragraph (b)(1)(iii). (new language identified in bold)

- Revised the proposed language about bundled payment rates from ''. . . in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology'' to:

++ Delete ''or similar'' from ''In the case of a bundled or similar payment methodology . . .''

++ Add ''the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must . . .''

The language is finalized as ''In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' in paragraph (b)(1)(iv). (new language identified in bold)

- Revised the applicability date for this section from the proposed January 1, 2026, to require that the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026, in paragraph (b)(1)(vi).
- Revised the proposed language about updating the publication after SPA approval from ''The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology.'' to finalize the language as ''The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment.'' in paragraph (b)(1)(vi). (new language identified in bold)

b. Comparative Payment Rate Analysis and Payment Rate Disclosure § 447.203(b)(2) Through (5)

In paragraph (b)(2), we proposed to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain specified services, and a payment rate disclosure for certain HCBS. We specified the categories of services that States would be required to include in a comparative payment rate analysis and payment rate disclosure of Medicaid payment rates. Specifically, we proposed that for each of the categories of services in paragraphs (b)(2)(i) through (iii), each State agency would be required to develop and publish a comparative payment rate analysis of Medicaid payment rates as specified in proposed § 447.203(b)(3). We also proposed that for each of the categories of services in paragraph (b)(2)(iv), each State agency would be required to develop and publish a payment rate disclosure of Medicaid payment rates as specified in proposed § 447.203(b)(3). We proposed for both the comparative payment rate analysis and payment rate disclosure that, if the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The categories of services listed in paragraph (b)(2) include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

In paragraph (b)(2), we proposed to require States separately identify the payment rates in the comparative payment rate analysis and payment rate disclosure, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. These proposed breakdowns of the Medicaid payment rates, similar to how we proposed payment rates would be broken down in the payment rate transparency publication under proposed § 447.203(b)(1), would apply to all proposed categories of services listed in paragraph (b)(2): primary care services, obstetrical and gynecological services, outpatient mental health and substance use disorder services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

We acknowledged that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we have included language ''if the rates vary'' and ''as applicable'' in the proposed regulatory text. We included this language in the proposed regulatory text to ensure the comparative payment rate analysis and payment rate disclosure capture all Medicaid payment rates, including when States pay varied payment rates by population (pediatric and adult), provider type, and geographical location. We also included proposed regulatory text for the payment rate disclosure to ensure that the average hourly payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary, as later discussed in connection with § 447.203(b)(3)(ii). For States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location and pay a single Statewide payment rate for a single service, then the comparative payment rate analysis and payment rate disclosure would only need to include the State's single Statewide payment rate.

We proposed to include a breakdown of Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, on the Medicaid side of the comparative payment rate analysis in paragraph (b)(2) to align with the proposed payment rate transparency provision, to account for State Medicaid programs that pay variable Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, and to help ensure the State's comparative payment rate analyses accurately align with Medicare. Following the initial year that the proposed provisions proposed would be in effect, these provisions would align with and build on the payment rate transparency requirements described in § 447.203(b)(1), because States could source the codes and their corresponding Medicaid payment rates that the State already would publish to meet the payment rate transparency requirements.

We explained that these proposed provisions are intended to help ensure that the State's comparative payment rate analysis contains the highest level of granularity in each proposed aspect by considering and accounting for any variation in Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as previously required in the AMRP process under § 447.203(b)(1)(iv) and (v), and (b)(3). Additionally, Medicare varies payment rates for certain NPPs (nurse practitioners, physician assistants, and clinical nurse specialists) by paying them 85 percent of the full Medicare PFS amount and varies their payment rates by geographical location through calculated adjustments to the pricing amounts to reflect the variation in practice costs from one geographical location to another; therefore, we explained that the comparative payment rate analysis accounting for these payment rate variations is crucial to ensuring the Medicaid FFS payment rates accurately align with FFS Medicare PFS rates.[207] Medicare payment variations for provider type and geographical location would be directly compared with State Medicaid payment rates that also apply the same payment variations, in addition to payment variation by population (pediatric and adult) which is unique to Medicaid, yet an important payment variation to take into consideration when striving for transparency of Medicaid payment rates. For States that do not pay varied payment rates by population (pediatric and adult), provider type, or geographical location and pay a single Statewide payment rate for a single service, Medicare payment variations for provider type and geographical location would be considered by calculating a Statewide average of Medicare PFS rates which is later discussed in this final rule.

Similar to the payment rate transparency publication, we acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication and the comparative payment rate analysis include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' payment rates vary based on these groupings. However, we believe that any approach to requiring a comparative payment rate analysis would involve some level of burden that is greater for States that choose to employ these payment rate differentials, since any comparison methodology would need to take account—through a separate comparison, weighted average, or other mathematically reasonable approach—of all rates paid under the Medicaid program for a given service. In all events, we believe this proposal would create an additional level of granularity in the analysis that is important for ensuring compliance with section 1902(a)(30)(A) of the Act. We noted that multiple types of providers, for example, physicians, physician assistants, and nurse practitioners, are delivering similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each State.

Section 1902(a)(30)(A) requires ''. . . that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,'' and we noted our belief that having sufficient access to a variety of provider types is important to ensuring access for Medicaid beneficiaries meets this statutory standard. For example, a targeted payment rate reduction to nurse practitioners, who are often paid less than 100 percent of the State's physician fee schedule rate, could have a negative impact on access to care for services provided by nurse practitioners, but this reduction would not directly impact physicians or their willingness to participate in Medicaid and furnish services to beneficiaries. By proposing that the comparative payment rate analysis include a breakdown by provider type, where States distinguish payment rates for a service by provider type, we explained that the analysis would capture this payment rate variation among providers of the same services and provide us with a granular level of information to aid in determining if access to care is sufficient, particularly in cases where beneficiaries depend to a large extent on the particular provider type(s) that would be affected by the proposed rate change for the covered service(s).

We identified payment rate variation by population (pediatric and adult), provider type, and geographical location as the most commonly applied adjustments to payment rates that overlap between FFS Medicaid and Medicare and could be readily broken down into separately identified payment rates for comparison in the comparative payment rate analysis. For transparency purposes and to help to ensure the comparative payment rate analysis is conducted at a granular level of analysis, we explained our belief that it is important for the State to separately identify their rates, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. We solicited comments on the proposal to require the comparative payment rate analysis to include, if the rates vary, separate identification of payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the comparative payment rate analysis in proposed § 447.203(b)(2).

We acknowledged that States may apply additional payment adjustments or factors, for example, the Consumer Price Index, Medicare Economic Index, or State-determined inflationary factors or budget neutrality factors, to their Medicaid payment rates other than population (pediatric and adult), provider type, and geographical location. We stated that we expect any other additional payment adjustments and factors to already be included in the State's published Medicaid fee schedule rate or calculable from the State plan, because § 430.10 requires the State plan to be a ''comprehensive written statement . . . contain[ing] all information necessary for CMS to determine whether the plan can be approved to serve as a basis for . . . FFP . . .'' Therefore, for States paying for services with a fee schedule payment rate, the Medicaid fee schedule is the sole source of information for providers to locate their final payment rate for Medicaid services provided to Medicaid beneficiaries under a FFS delivery system. For States with a rate-setting methodology where the approved State plan describes how rates are set based upon a fee schedule (for example, payment for NPPs are set a percentage of a certain published Medicaid fee schedule), the Medicaid fee schedule would again be the source of information for providers to identify the relevant starting payment rate and apply the rate-setting methodology described in the State plan to ascertain their Medicaid payment.[208] We solicited comments on any additional types of payment adjustments or factors States make to their Medicaid payment rates as listed on their State fee schedules that should be identified in the comparative payment rate analysis that we have not

[207] *https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.*

[208] *https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/fed-req-pymt-methodologies.docx.*

already discussed in § 447.203(b)(i)(B) of this final rule, and how the inclusion of any such additional adjustments or factors should be considered in the development of the Medicare PFS rate to compare Medicaid payment rates to, as later described in § 447.203(b)(3)(i)(C), of this final rule.

In paragraphs (b)(2)(i) through (iv), we proposed that primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be subject to a comparative payment rate analysis of Medicaid payment rates and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be subject to a payment rate disclosure of Medicaid payment rates. We begin with a discussion about the importance of primary care services, obstetrical and gynecological services, and outpatient behavioral health services as proposed in § 447.203(b)(2)(i) through (iii), and the reason for their inclusion in this proposed requirement. Then, we will discuss the importance and justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as proposed in § 447.203(b)(2)(iv).

In § 447.203(b)(2)(i) through (iii), we proposed to require primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services be included in the comparative payment rate analysis, because we believe that these categories of services are critical preventive, routine, and acute medical services in and of themselves, and that they often serve as gateways to access to other needed medical services, including specialist services, laboratory and x-ray services, prescription drugs, and other mandatory and optional Medicaid benefits that States cover. Including these categories of services in the comparative payment rate analysis would require States to closely examine their Medicaid FFS payment rates to comply with section 1902(a)(30)(A) of the Act. As described in the recent key findings from public comments on the February 2022 RFI that we published, payment rates are a key driver of provider participation in the Medicaid program.[209] By proposing that States compare their Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services to Medicare payment rates, States would be required to analyze if and how their payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In the proposed rule, we noted our belief that Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to a beneficiary because Medicare delivers services through a FFS delivery system across all geographical regions of the US and historically, the vast majority of physicians accept new Medicare patients, with extremely low rates of physicians opting out of the Medicare program, suggesting that Medicare's payment rates are generally consistent with a high level of physician willingness to accept new Medicare patients.[210] Additionally, Medicare payment rates are publicly published in an accessible and consistent format by CMS making Medicare payment rates an available and reliable comparison point for States, rather than private payer data which typically is considered proprietary information and not generally available to the public. Therefore, we explained that the proposed requirement that States develop and publish a comparative payment rate analysis would enable States, CMS, and other interested parties to closely examine the relationship between State Medicaid FFS payment rates and those paid by Medicare. This analysis would continually help States to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our belief that the comparative payment rate analysis would provide States, CMS, and other interested parties with clear and concise information for identifying when there is a potential access to care issue, such as Medicaid payment rates not keeping pace with changes in corresponding Medicare rates and decreases in claims volume and beneficiary utilization of services. As discussed later in this section, numerous studies have found a relationship between Medicaid payment rates and provider participation in the Medicaid program and, given the statutory standard of ensuring access for Medicaid beneficiaries, a comparison of Medicaid payment rates to other payer rates, particularly Medicare payment rates as justified later in this rule, is an important barometer of whether State payment rates and policies are sufficient for meeting the statutory access standard under section 1902(a)(30)(A) of the Act.

We proposed to focus on these particular services because they are critical medical services and of great importance to overall beneficiary health. Beginning with primary care, these services provide access to preventative services and facilitate the development of crucial doctor-patient relationships. Primary care providers often deliver preventive health care services, including immunizations, screenings for common chronic and infectious diseases and cancers, clinical and behavioral interventions to manage chronic disease and reduce associated risks, and counseling to support healthy living and self-management of chronic diseases; Medicaid coverage of preventative health care services promotes disease prevention which is critical to helping people live longer, healthier lives.[211] Accessing primary care services can often result in beneficiaries receiving referrals or recommendations to schedule an appointment with physician specialists, such as gastroenterologists or neurologists, that they would not be able to obtain without the referral or recommendation by the primary care physician. Additionally, primary care physicians provide beneficiaries with orders for laboratory and x-ray services as well as prescriptions for necessary medications that a beneficiary would not be able to access without the primary care physician. Research over the last century has shown that the impact of the doctor-patient relationship on

[209] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

[210] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

[211] *https://www.medicaid.gov/medicaid/benefits/prevention/index.html.*

patient's health care experience, health outcomes, and health care costs exists [212] and more recent studies have shown that the quality of the physician-patient relationship is positively associated with functional health among patients.[213] Another study found that higher primary care payment rates reduced mental illness and substance use disorders among non-elderly adult Medicaid enrollees, suggesting that positive spillover from increasing primary care rates also positively impacted behavioral health outcomes.[214] Lastly, research has shown that a reduction in barriers to accessing primary care services has been associated with helping reduce health disparities and the risk of poor health outcomes.[215] [216] These examples illustrate how crucial access to primary care services is for overall beneficiary health and to enable access to other medical services. We solicited comments on primary care services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i).

Similar to primary care services, both obstetrical and gynecological services and outpatient behavioral health services provide access to preventive and screening services unique to each respective field. A well-woman visit to an obstetrician–gynecologist often provides access to screenings for cervical and breast cancer; screenings for Rh(D) incompatibility, syphilis infection, and hepatitis B virus infection in pregnant persons; monitoring for healthy weight and weight gain in pregnancy; immunization against the human papillomavirus infection; and perinatal depression screenings among other recommended preventive services.[217] [218] Behavioral health care promotes mental health, resilience, and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities. Outpatient behavioral health services can overlap with preventative primary care and obstetrical and gynecological services, for example screening for depression in adults and perinatal depression screenings, but also provide unique preventive and screening services such as screenings for unhealthy alcohol use in adolescents and adults, anxiety in children and adolescents, and eating disorders in adolescents and adults, among other recommended preventive services.[219]

The US is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and outpatient behavioral health services, respectively, at the forefront.[220] [221] According to Medicaid and CHIP Payment and Access Commission (MACPAC), ''Medicaid plays a key role in providing maternity-related services for pregnant women, paying for slightly less than half of all births nationally in 2018.'' [222] Given Medicaid's significant role in maternal health during a time when maternal mortality rates in the US continue to worsen and the racial disparities among mothers continues to widen,[223] [224] accessing obstetrical and gynecological care, including care before, during, and after pregnancy is crucial to positive maternal and infant outcomes.[225] We solicited comments on obstetrical and gynecological services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(ii).

Improving access to behavioral health services is a critical, national issue facing all payors, particularly for Medicaid which plays a crucial role in mental health care access as the single largest payer of services and has a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to behavioral health services.[226] [227] Several studies have found an association between reducing the uninsured rate through increased Medicaid enrollment and improved and expanded access to critically needed behavioral health services.[228] Numerous studies have found positive outcomes associated with Medicaid expansion: increases in the insured rate and access to care and medications for adults with depression, increases in coverage rates and a greater likelihood of being diagnosed with a mental health condition as well as the use of prescription medications for a mental health condition for college students from disadvantaged backgrounds,[229] and a decrease in delayed or forgone necessary care in a nationally representative sample of non-elderly adults with serious psychological distress.[230] While individuals who are covered by Medicaid have better access to behavioral health services compared to people who are uninsured, some coverage gaps remain in access to behavioral health care for many people, including those with Medicaid.

In the proposed rule, we noted that some of the barriers to accessing

[212] Cockerham, W.C. (2021). *The Wiley Blackwell Companion to Medical Sociology* (1st ed.). John Wiley & Sons.

[213] Olaisen, R.H., Schluchter, M.D., Flocke, S.A., Smyth, K.A., Koroukian, S.M., & Stange, K.C. (2020). Assessing the longitudinal impact of physician-patient relationship on Functional Health. *The Annals of Family Medicine, 18*(5), 422–429. *https://doi.org/10.1370/afm.2554*.

[214] Maclean, Johanna Catherine, McCleallan, Chandler, Pesko, Michael F., and Polsky, Daniel. (2023). Medicaid reimbursement rates for primary care services and behavioral health outcomes. Health economics, 1–37. *https://doi.org/10.1002/hec.4646*.

[215] Starfield, B., Shi, L., & Macinko, J. (2005). Contribution of primary care to health systems and health. The Milbank quarterly, 83(3), 457–502. *https://doi.org/10.1111/j.1468-0009.2005.00409.x*.

[216] *https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care*.

[217] Rh(D) incompatibility is a preventable pregnancy compilation where a woman who is Rh negative is carrying a fetus that is Rh positive (Rh factor is a protein that can be found on the surface of red blood cells). When the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers. Her body will try to destroy it by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn. Prevention of Rh(D) incompatibility requires screening for Rh negative early in pregnancy (or before pregnancy) and, if needed, giving a medication to prevent antibodies from forming.

[218] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/10/well-woman-visit*.

[219] *https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P*.

[220] *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf*.

[221] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/*.

[222] *https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf*.

[223] *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm*.

[224] *https://www.nytimes.com/2022/02/23/health/maternal-deaths-pandemic.html?smid=url-share*.

[225] *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf*.

[226] *https://www.medicaid.gov/medicaid/access-care/downloads/coverage-and-behavioral-health-data-spotlight.pdf*.

[227] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html*.

[228] *https://www.cbpp.org/research/health/to-improve-behavioral-health-start-by-closing-the-medicaid-coverage-gap*.

[229] Cowan, Benjamin W. & Hao, Zhuang. (2021). Medicaid expansion and the mental health of college students. Health economics, 30(6), 1306–1327. *https://www.nber.org/system/files/working_papers/w27306/w27306.pdf*.

[230] Novak, P., Anderson, A.C., & Chen, J. (2018). Changes in Health Insurance Coverage and Barriers to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act. Administration and policy in mental health, 45(6), 924–932. *https://doi.org/10.1007/s10488-018-0875-9*.

behavioral health treatment in Medicaid reflect larger system-wide access problems: overall shortage of behavioral health providers in the United States and relatively small number of psychiatrists who accept any form of insurance or participate in health coverage programs.[231] Particularly for outpatient behavioral health services for Medicaid beneficiaries, one reason physicians are unwilling to accept Medicaid patients is because of low Medicaid payment rates.[232] One study found evidence of low Medicaid payment rates by examining outpatient Medicaid claims data from 2014 in 11 States with a primary behavioral health diagnosis and an evaluation and management (E/M) procedure code of 99213 (Established patient office visit, 20–29 minutes) or 99214 (Established patient office visit, 30–39 minutes) and found that psychiatrists in nine States were paid less, on average, than primary care physicians.[233] These pieces of research and data about the importance of outpatient behavioral health services and the existing challenges beneficiaries face in trying to access outpatient behavioral health services underscore how crucial access to outpatient behavioral health services is, and that adequate Medicaid payment rates for these services is likely to be an important driver of access for beneficiaries. We solicited comments on outpatient behavioral health services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(iii) which we are finalizing as ''Outpatient mental health and substance use disorder services.''

In § 447.203(b)(2)(iv), we proposed to require personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in the payment rate disclosure requirements proposed in § 447.203(b)(3)(ii). We noted that many HCBS providers nationwide are facing workforce shortages and high staff turnover that have been exacerbated by the COVID–19 pandemic, and these issues and related difficulty accessing HCBS can lead to higher rates of costly, institutional stays for beneficiaries.[234] As with any covered service, the supply of HCBS providers has a direct and immediate impact on beneficiaries' ability to access high quality HCBS, therefore, we included special considerations for LTSS, specifically HCBS, through two proposed provisions in § 447.203. The first provision in proposed paragraph (b)(2)(iv) would require States to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency to be included in the payment rate disclosure in proposed paragraph (b)(3)(ii). The second provision in paragraph (b)(6), discussed in the next section, would require States to establish an interested parties' advisory committee to advise and consult on rates paid to certain HCBS providers. We explained that this provision is intended to help contextualize lived experience of direct care workers and beneficiaries who receive the services they deliver by providing direct care workers, beneficiaries and their authorized representatives, and other interested parties with the ability to make recommendations to the State Medicaid agency regarding the sufficiency of Medicaid payment rates for these specified services to help ensure sufficient provider participation so that these HCBS are accessible to beneficiaries consistent with section 1902(a)(30)(A) of the Act.

The proposed payment rate disclosure would require States to publish the average hourly payment rates made to individual providers and to providers employed by an agency, separately, if the rates vary, for each category of services specified in § 447.203(b)(2)(iv). No comparison to Medicare payment rates would be required in recognition that Medicare generally does not cover and pay for these services, and when these services are covered and paid for by Medicare, the services are very limited and provided on a short-term basis, rather than long-term basis as with Medicaid HCBS. While Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance), Medicare does not cover personal care or homemaker services.[235]

We proposed to require these services be subject to a payment rate disclosure because this rule aims to standardize data and monitoring across service delivery systems with the goal of improving access to care. To remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e), where we proposed to require annual State reporting on access and payment adequacy metrics for homemaker, home health aide, and personal care services, we proposed to include these services, provided by individual providers and providers employed by an agency in the FFS payment rate disclosure proposed in 447.203(b)(2). We explained that we selected these specific services because we expect them to be most commonly conducted in individuals' homes and general community settings and, therefore, constitute the vast majority of FFS payments for direct care workers delivering services under FFS. We acknowledged that the proposed analyses required of States in the HCBS provisions at § 441.311(d)(2) and (e) and in the FFS provisions at § 447.203(b)(2) are different, although, unique to assessing access in each program and delivery system. We proposed to include personal care, home health aide, and homemaker services for consistency with HCBS access and payment adequacy provisions, and also to include these services in the proposed provisions of § 447.203(b)(2) to require States to conduct and publish a payment rate disclosure. We noted our belief the latter proposal is important because the payment rate disclosure of personal care, home health aide, and homemaker services would provide CMS with sufficient information, including average hourly payment rates, claims volume, and number of Medicaid enrolled beneficiaries who received a service as specified in proposed § 447.203(b)(3)(ii), from States for ensuring compliance with section 1902(a)(30)(A) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Additionally, we explained that this proposal to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency is

[231] *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/.*

[232] *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/.*

[233] Mark, Tami L., Parish, William, Zarkin, Gary A., and Weber, Ellen (2020). Comparison of Medicaid Reimbursements for Psychiatrists and Primary Care Physicians. Psychiatry services 71(9), 947–950. *https://doi.org/10.1176/appi.ps.202000062.*

[234] *https://www.kff.org/coronavirus-covid-19/event/march-30-web-event-unsung-heroes-the-crucial-role-and-tenuous-circumstances-of-home-health-aides-during-the-pandemic/; https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[235] *https://www.medicare.gov/coverage/home-health-services.*

supported by the statutory mandate at section 2402(a) of the Affordable Care Act. Among other things, section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that ensure that there is an adequate number of qualified direct care workers to provide self-directed services. We solicited comments on personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the payment rate disclosure requirements in proposed § 447.203(b)(2)(iv).

After discussing our proposed categories of services for the comparative payment rate analysis and payment rate disclosure requirements, we discussed the similarities and differences between the proposed rule and services previously included in the AMRP requirements. We explained that while the proposed rule would eliminate the previous triennial AMRP process, there are some similarities between the service categories for which we proposed to require a comparative payment rate analysis or payment rate disclosure in § 447.203(b)(2) and those subject to the previous AMRP requirements under § 447.203(b)(5)(ii). Specifically, § 447.203(b)(5)(ii)(A) previous required the State agency to use data collected through the previous AMRP process to provide a separate analysis for each provider type and site of service for primary care services (including those provided by a physician, FQHC, clinic, or dental care). We proposed the comparative payment rate analysis include primary care services, without any parenthetical description. We explained our belief this is appropriate because the proposed rule includes a comparative payment rate analysis that is at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, the specifics for which are discussed later in this section. This approach requires States to perform less sub-categorization of the data analysis, and as discussed later, the analysis would exclude FQHCs and clinics.

We explained that the previous AMRP process also includes in § 447.203(b)(5)(ii)(C) behavioral health services (including mental health and substance use disorder); however, we proposed that the comparative payment rate analysis only would include outpatient behavioral health services to narrow the scope of the analysis by excluding inpatient behavioral health services (including inpatient behavioral health services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals). While we acknowledged that behavioral health services encompass a broad range of services provided in a wide variety of settings, from outpatient screenings in a physician's office to inpatient hospital treatment, we proposed to narrow the scope of behavioral health services to outpatient services only to focus the comparative payment rate analysis on ambulatory care provided by practitioners in an office-based setting without duplicating existing requirements, or analysis that must be completed to satisfy existing requirements, for upper payment limits (UPL) and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the CAA, 2021.

The proposed categories of services are delivered as ambulatory care where the patient does not need to be hospitalized to receive the service being delivered. Particularly for behavioral health services, we proposed to narrow the scope to outpatient behavioral health services to maintain consistency within the categories of service included in the proposed comparative payment rate analysis and payment rate disclosure all being classified as ambulatory care. Additionally, as discussed further in this section of the final rule, we proposed that the comparative payment rate analysis would be conducted on a CPT/HCPCS code level, focusing on E/M codes. By narrowing the comparative payment rate analysis to E/M CPT/HCPCS codes, we proposed States' analyses includes a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii). To balance State administrative burden with our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act, we also proposed to limit the services to those delivered primarily by physicians and NPPs in an office-based setting for primary care, obstetrical and gynecological, and outpatient behavioral health services. By excluding facility-based services, particularly inpatient behavioral health services, we explained our intent to ensure the same E/M CPT/HCPCS code-level methodology could be used for all categories of services included in the proposed comparative payment rate analysis, including the use of E/M CPT/HCPCS codes used for outpatient behavioral health services. Rather than fee schedule rates, States often pay for inpatient behavioral health services using prospective payment rate methodologies, such as DRGs, or interim payment methodologies that are reconciled to actual cost.[236] These methodologies pay for a variety of services delivered by multiple providers that a patient receives during an inpatient hospital stay, rather than a single ambulatory service billed by a single provider using a single CPT/HCPCS code. Variations in these payment methodologies and what is included in the rate could complicate the proposed comparison to FFS Medicare rates for the services identified in paragraphs (b)(2)(i) through (iii) and could frustrate comparisons between States and sometimes even within a single State. Therefore, we explained that we do not believe the E/M CPT/HCPCS code level methodology proposed for the comparative payment rate analysis would be feasible for inpatient behavioral health services or other inpatient and facility-based services in general.

While we considered including inpatient behavioral health services as one of the proposed categories of services in the comparative payment rate analysis, we ultimately did not because we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL and supplemental payment reporting requirements under section 1903(bb) of the Act. SMDL 13–003 discusses the annual submission of State UPL demonstrations for inpatient hospital services, among other services, including a complete data set of payments to Medicaid providers and a reasonable estimate of what Medicare would have paid for the same services.[237] [238] UPL requirements go beyond the proposed requirements by requiring States to annually submit the following data for all inpatient hospital services, depending on the State's UPL methodology, on a provider level basis:

[236] *https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf.*

[237] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[238] If a State's payment methodology describes payment at no more than 100 percent of the Medicare rate for the period covered by the UPL, then the State does not need to submit a demonstration. See FAQ ID: 92201. *https://www.medicaid.gov/faq/index.html?search_api_fulltext=ID%3A92201&sort_by=field_faq_date&sort_order=DESC.*

Medicaid charges, Medicaid base payments, Medicaid supplemental payments, Medicaid discharges, Medicaid case mix index, Medicaid inflation factors, other adjustments to Medicaid payments, Medicaid days, Medicare costs, Medicare payments, Medicare discharges, Medicare case mix index, Medicare days, UPL inflation factors, Medicaid provider tax cost, and other adjustments to the UPL amount. If we proposed and finalized inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis, then this final rule would require States to biennially submit the following data for only inpatient behavioral health services on a CPT/HCPCS code level basis: base Medicaid FFS fee schedule payment rate for select E/M CPT/HCPCS codes (accounting for rate variation based on population (pediatric and adult), provider type, and geographical location, as applicable), the corresponding Medicare payment rates, Medicaid base payment rate as a percentage of Medicare payment rate, and the number of Medicaid-paid claims. While the UPL requires aggregated total payment and cost data at the provider level and the proposed comparative payment rate analysis calls for more granular base payment data at the CPT/HCPCS code level, the UPL overall requires aggregate Medicaid provider payment data for both base and supplemental payments as well as more detailed data for calculating what Medicare would have paid as the upper payment amount. Therefore, we explained that proposing to require States include Medicaid and Medicare payment rate data for inpatient behavioral health services in the comparative payment rate analysis would be duplicative of existing UPL requirements that are inclusive of and more comprehensive than the payment information proposed in the comparative payment rate analysis.

Additionally, section 1903(bb) of the Act requires us to establish a Medicaid supplemental payment reporting system that collects detailed information on State Medicaid supplemental payments, including total quarterly supplemental payment expenditures per provider; information on base payments made to providers that have received a supplemental payment; and narrative information describing the methodology used to calculate a provider's payment, criteria used to determine which providers qualify to receive a payment, and explanation describing how the supplemental payments comply with section 1902(a)(30)(A) of the Act. Section 1903(bb)(1)(C) of the Act requires us to make State-reported supplemental payment information publicly available. For States making or wishing to make supplemental payments, including for inpatient behavioral health services, States must report supplemental payment information to us, and we must make that information public and, therefore, transparent. Although the proposed rule sought to increase transparency, with the proposed provisions under § 447.203(b)(1) through (5) focusing on transparency of FFS base Medicaid FFS fee schedule payment rate, including inpatient behavioral health services as a category of service in § 447.203(b)(2) subject to the comparative payment rate analysis would be duplicative of the existing upper payment limit and supplemental payment reporting requirements, which capture and make transparent base and supplemental payment information for inpatient behavioral health services. However, we solicited comments regarding our decision not to include inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2) in the final rule, should we finalize the comparative payment rate analysis proposal.

The AMRP process also previously included in § 447.203(b)(5)(ii)(D) pre- and post-natal obstetric services including labor and delivery; we proposed to include these services in the comparative payment rate analysis requirements under proposed § 447.203(b)(2)(ii), but we explained in the proposed rule that we intended to broaden the scope of this category of services to include both obstetrical and gynecological services. This expanded proposed provision would capture a wider array of services, both obstetrical and gynecological services, for States and CMS to assess and ensure access to care in Medicaid FFS is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required by with section 1902(a)(30)(A) of the Act. Lastly, similar to previous § 447.203(b)(5)(ii)(E), which specifies that home health services were included in the previous AMRP process, we proposed to include personal care, home health aide, and homemaker services, provided by individual providers and providers employed by an agency. This refined proposed provision would help ensure a more standardized effort to monitor access across Medicaid delivery systems, including for Medicaid-covered LTSS. We explained our belief that this proposal also would address public comments received in response to the February 2022 RFI.[239] Many commenters highlighted the workforce crisis among direct care workers and the impact on HCBS. Specifically, commenters indicated that direct care workers receive low payment rates, and for agency-employed direct care workers, home health agencies often cite low Medicaid payment as a barrier to raising wages for workers. Commenters suggested that States should be collecting and reporting to CMS the average of direct care worker wages while emphasizing the importance of data transparency and timeliness. We explained that we were responding to these public comments by proposing to require States to transparently publish a payment rate disclosure that collects and reports the average hourly rate paid to individual providers and providers employed by an agency for services provided by certain direct care workers (personal care, home health aide, and homemaker services).

In public comments that we received during the public comment period for the 2015 final rule with comment period, many commenters requested that we require States to publish access to care analyses for pediatric services, including pediatric primary care, behavioral health, and dental care. At the time, we responded that pediatric services did not need to be specified in the required service categories because States were already required through § 447.203(b)(1)(iv) to consider the characteristics of the beneficiary population, ''including . . . payment variations for pediatric and adult populations,'' within the previous AMRPs.[240] Although we proposed to eliminate the previous AMRP requirements, we noted that the proposed rule would continue to include special considerations for pediatric populations that are addressed in the discussion of proposed § 447.203(b)(2).

We proposed to eliminate the following from the previous AMRP process without replacement in the comparative payment rate analysis requirement, § 447.203(b)(5)(ii)(F): Any additional types of services for which a review is required under previous § 447.203(b)(6); § 447.203(b)(5)(ii)(G): Additional types of services for which

[239] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

[240] 80 CFR 67576 at 67592.

the State or CMS has received a significantly higher than usual volume of beneficiary, provider or other interested party access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with previous § 447.203(b)(7); and § 447.203(b)(5)(ii)(H): Additional types of services selected by the State.

We proposed to eliminate § 447.203(b)(5)(ii)(F) and (G) without a direct replacement because the proposed State Analysis Procedures for Rate Reduction or Restructuring described in § 447.203(c) are inclusive of and more refined than the previous AMRP requirements for additional types of services for which a review is required under previous § 447.203(b)(6). Specifically, as discussed later in this section, we proposed in § 447.203(c)(1) that States seeking to reduce provider payment rates or restructure provider payments would be required to provide written assurance and relevant supporting documentation that three conditions are met to qualify for a streamlined SPA review process, including that required public processes yielded no significant access to care concerns for beneficiaries, providers, or other interested parties, or if such processes did yield concerns, that the State can reasonably respond to or mitigate them, as appropriate. If the State is unable to meet all three of the proposed conditions for streamlined SPA review, including the absence of or ability to appropriately address any access concern raised through public processes, then the State would be required to submit additional information to support that its SPA is consistent with the access requirement in section 1902(a)(30)(A) of the Act, as proposed in § 447.203(c)(2). We proposed to modify this aspect of the previous AMRP process, because our implementation experience since the 2017 SMDL has shown that States typically have been able to work directly with the public (including beneficiaries and beneficiary advocacy groups, and providers) to resolve access concerns, which emphasizes that public feedback continues to be a valuable source of knowledge regarding access in Medicaid. We explained our belief that this experience demonstrates that public processes that occur before the submission of a payment SPA to CMS often resolve initial access concerns, and where concerns persist, they will be addressed through the SPA submission and our review process, as provided in proposed § 447.203(c). Rather than services affected by proposed provider rate reductions or restructurings (previous § 447.203(b)(5)(ii)(F)) and services for which the State or CMS received significantly higher than usual volume of complaints (previous § 447.203(b)(5)(ii)(G)) being addressed through the previous AMRP process, these services subject to rate reductions or restructurings and services where a high volume of complaints have been expressed would now be addressed by the State analysis procedures in proposed § 447.203(c). We noted our belief that this approach would ensure public feedback is fully considered in the context of a payment SPA, without the need to specifically require a comparative payment rate analysis for the service(s) subject to payment rate reduction or restructuring under proposed § 447.203(b)(2).

Lastly, we proposed to eliminate previous § 447.203(b)(5)(ii)(H), requiring the previous AMRP process to include analysis regarding ''Additional types of services selected by the State,'' without a direct replacement because our implementation experience has shown that the majority of States did not select additional types of service to include in their previous AMRPs beyond the required services § 447.203(b)(5)(ii)(A) through (G). When assessing which services to include in the proposed rule, we determined that the absence of an open-ended type of service option, similar to § 447.203(b)(5)(ii)(H) is unlikely to affect the quality of the analysis we proposed to require and therefore, we did not include it in the proposed set of services for the comparative payment rate analysis. These proposed shifts in policy were informed by our implementation experience and our consideration of State concerns about the burden and value of the previous AMRP process.

In paragraph (b)(3), we proposed that the State agency would be required to develop and publish, consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data, a comparative payment rate analysis and payment rate disclosure. This comparative payment rate analysis is divided into two sections based on the categories of services and the organization of each analysis or disclosure. Paragraph (b)(3)(i) describes the comparative payment rate analysis for the categories of services described in paragraphs (b)(2)(i) through (iii): primary care services, obstetrical and gynecological services, and outpatient behavioral health services. Paragraph (b)(3)(ii) describes the payment rate disclosure for the categories of service described in paragraphs (b)(2)(iv): personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

Specifically, in paragraph (b)(3)(i), we proposed that for the categories of service described in paragraphs (b)(2)(i) through (iii), the State's analysis would compare the State's Medicaid FFS payment rates to the most recently published Medicare payment rates effective for the same time period for the E/M CPT/HCPCS codes applicable to the category of service. The proposed comparative payment rate analysis of FFS Medicaid payment rates to FFS Medicare payment rates would be conducted on a code-by-code basis at the CPT/HCPCS code level using the most current set of codes published by us. We explained that this proposal is intended to provide an understanding of how Medicaid payment rates compare to the payment rates established and updated under the FFS Medicare program.

We stated that we would expect to publish the E/M CPT/HCPCS codes to be used for the comparative payment rate analysis in subregulatory guidance along with the final rule, if this proposal is finalized. We proposed that we would identify E/M CPT/HCPCS codes to be included in the comparative payment rate analysis based on the following criteria: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount for the same time period of the comparative payment rate analysis.[241] [242] [243]

The CMS-published list of E/M CPT/HCPCS codes subject to the comparative

[241] *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management.*

[242] *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system.*

[243] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched.*

payment rate analysis would classify each E/M CPT/HCPCS code into a corresponding category of service as described in proposed § 447.203(b)(2)(i) through (iii). As previously discussed, by narrowing the comparative payment rate analysis to CMS-specified E/M CPT/HCPCS codes, we proposed States' analyses include a broad range of core services that would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii), while also limiting the services to those delivered primarily by physicians and NPPs in an office-based setting. Based on the categories of services specified in proposed § 447.203(b)(2)(i) through (iii), we stated that we would expect the selected E/M CPT/HCPCS codes to fall under mandatory Medicaid benefit categories, and therefore, that all States would cover and pay for the selected E/M CPT/HCPCS codes. To clarify, we did not narrow the list of E/M CPT/HCPCS codes on the basis of Medicare coverage of a particular code. We are cognizant that codes with N (Non-Covered), R (Restricted), or T code statuses have limited or no Medicare coverage; however, Medicare may establish RVUs, and payment amounts for these codes. Therefore, when Medicare does establish RVUs and payment amounts for codes with N (Non-Covered), R (Restricted), or T (Injections) code statuses on the Medicare PFS, we proposed to include these codes in the comparative payment rate analysis to ensure the analysis includes a comprehensive set of codes, for example pediatric services, including well child visits (for example, 99381 through 99384), that are commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii) and delivered primarily by physicians and NPPs in an office-based setting, as previously described.

We proposed that the comparative payment rate analysis would be updated no less than every 2 years. Therefore, prior to the start of the calendar year in which States would be required to update their comparative payment rate analysis, we noted our intent to publish an updated list of E/M CPT/HCPCS codes for States to use for their comparative payment rate analysis updates through subregulatory guidance. The updated list of E/M CPT/HCPCS codes would include changes made by the AMA CPT Editorial Panel (such as additions, removals, or amendments to a code definition where there is a change in the set of codes classified as an E/M CPT/HCPCS code billable for primary care services, obstetrics and gynecological services, or outpatient behavioral services) and changes to the Medicare PFS based on the most recent Medicare PFS final rule (such as changes in code status or creation of Medicare-specific codes).[244]

We explained that we would intend to publish the initial and subsequent updates of the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. We may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes. In this instance, for codes included on our published list of E/M CPT/HCPCS codes that are affected by a correction to the most recent Medicaid PFS final rule, we may add or remove an E/M CPT/HCPCS code from the published list, as appropriate, depending on the change to the Medicare PFS. Alternatively, depending on the nature of the change, we stated that we would expect States to accurately identify which code(s) are used in the Medicaid program during the relevant period that best correspond to the CMS-identified E/M CPT/HCPCS code(s) affected by the Medicare PFS correction. We would expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the proposed requirements in paragraphs (b)(2) through (4).

We acknowledged that there are limitations to relying on E/M CPT/HCPCS codes to select payment rates for comparative payment rate analysis to aid States, CMS, and other interested parties in assessing if payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Providers across the country and within each State deliver a variety of services to patients, including individuals with public and private sources of coverage, and then bill them under a narrow subset of CPT/HCPCS codes that fit into the E/M classification as determined by the AMA CPT Editorial Panel. The actual services delivered can require a wide array of time, skills, and experience of the provider which must be represented by a single five-digit code for billing to receive payment for the services delivered. While there are general principles that guide providers in billing the most representative E/M CPT/HCPCS code for the service they delivered, two providers might perform substantially similar activities when delivering services and yet bill different E/M CPT/HCPCS codes for those activities, or bill the same E/M CPT/HCPCS code for furnishing two very different services. The E/M CPT/HCPCS code itself is not a tool for capturing the exact service that was delivered, but medical documentation helps support the billing of a particular E/M CPT/HCPCS code.

Although they do not encompass all Medicaid services covered and paid for in the Medicaid program which are subject to the requirements in section 1902(a)(30)(A) of the Act, E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. As such, to balance administrative burden on States and our enforcement responsibilities, we proposed to use E/M CPT/HCPCS codes in the comparative payment rate analysis to limit the analysis to how much Medicaid and the FFS Medicare program would pay for services that can be classified into a particular E/M CPT/HCPCS code. We solicited comments on the proposed comparative payment rate analysis requirement in § 447.203(b)(3)(i), including the proposed requirement to conduct the analysis at the CPT/HCPCS code level, the proposed criteria that we would apply in selecting E/M CPT/HCPCS codes for inclusion in the required analysis, and the proposed requirement for States to compare Medicaid payment rates for the selected E/M CPT/HCPCS codes to the most recently published Medicare non-facility payment rate as established in the annual Medicare PFS final rule effective for the same time period, which is discussed in more detail later in this rule when describing the proposed provisions of § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i), we further proposed that the State's comparative payment rate analysis would be required to meet the following requirements: (A) the analysis must be organized by category of service as described in § 447.203(b)(2)(i) through (iii); (B) the analysis must clearly identify the base Medicaid FFS fee

[244] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

schedule payment rate for each E/M CPT/HCPCS code identified by us under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable; (C) the analysis must clearly identify the Medicare PFS non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B); (D) the analysis must specify the Medicaid payment rate identified under paragraph (b)(3)(i)(B) as a percentage of the Medicare payment rate identified under paragraph (b)(3)(i)(C) for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B); and (E) the analysis must specify the number of Medicaid-paid claims within a calendar year for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(i)(A) through (E).

In paragraph (b)(3)(i)(A), we proposed to require States to organize their comparative payment rate analysis by the service categories described in paragraphs (b)(2)(i) through (iii). We explained that this proposed requirement is included to ensure the analysis breaks out the payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services separately for individual analyses of the payment rates for each CMS-selected E/M CPT/HCPCS code, grouped by category of service. We solicited comments on the proposed requirement for States to break out their payment rates at the CPT/HCPCS code level for primary care services, obstetrical and gynecological services, and outpatient behavioral health services, separately, in the comparative payment rate analysis as specified in proposed § 447.203(b)(3)(i)(A).

In paragraph (b)(3)(i)(B), after organizing the analysis by § 447.203(b)(2)(i) through (iii) categories of service and CMS-specified E/M CPT/HCPCS code, we proposed to require States to clearly identify the Medicaid base payment rate for each code, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. We proposed that the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate, that is, the State's Medicaid base rate for each E/M CPT/HCPCS code. By specifying the services included in the comparative payment rate analysis by E/M CPT/HCPCS code, we noted that we would expect the Medicaid base payment rate in the comparative payment rate analysis to only include the State's Medicaid fee schedule rate for that particular E/M CPT/HCPCS code as published on the State's Medicaid fee schedule effective for the same time period covered by the comparative payment rate analysis. As an example, the State's Medicaid fee schedule rate as published on the Medicaid fee schedule effective for the time period of the comparative payment rate analysis for 99202 is listed as $50.00. This rate would be the Medicaid base payment rate in the State's comparative payment rate analysis for comparison to the Medicare non-facility rate, which is discussed later in this section.

Medicaid base payment rates are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.[245] The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is also based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own PFSs, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. States often adjust their payment rates based on provider type, geography, site of services, patient age, and in-State or out-of-State provider status. Additionally, base Medicaid FFS fee schedule payment rate can be paid to physicians in a variety of settings, including clinics, community health centers, and private offices.

We acknowledged that only including Medicaid base payments in the analysis does not necessarily represent all of a provider's revenues that may be related to furnishing services to Medicaid beneficiaries, and that other revenues not included in the proposed comparative analysis may be relevant to a provider's willingness to participate in Medicaid (such as beneficiary cost sharing payments, and supplemental payments). We discussed that public comments we received on the 2011 proposed rule and responded to in the 2015 final rule with comment period regarding the previous AMRPs expressed differing views regarding which provider ''revenues'' should be included within comparisons of Medicaid to Medicare payment rates. One commenter ''noted that the preamble of the 2011 proposed rule refers to 'payments' and 'rates' interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates.'' The commenter stated that if the final rule consider[ed] all Medicaid revenues received by providers, States may be challenged to make any change to the Medicaid program that might reduce provider revenues.'' [246] We proposed to narrow the base Medicaid FFS fee schedule payment rate to the amount listed on the State's fee schedule in order for the comparative payment rate analysis to accurately and analogously compare Medicaid fee schedule rates to Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.

We explained our belief that this approach would represent the best way to create a consistent metric across States against which to evaluate access. Specifically, we did not propose to include supplemental payments in the comparative payment rate analysis. Requiring supplemental payment data be collected and included under this rule would be duplicative of existing requirements. State supplemental payment and DSH payment data are already subject to our review in various forms, such as through DSH audits for DSH payments, and through annual upper payment limits demonstrations, and through supplemental payment reporting under section 1903(bb) of the Act.[247] [248] As such, we explained that

[245] *https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf.*

[246] 80 FR 67576 at 67581.

[247] CMS State Medicaid Director Letter: SMDL 13–003. March 2013. Federal and State Oversight of Medicaid Expenditures. Available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[248] CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

we do not see a need to add additional reporting requirements concerning supplemental payments as part of the proposals in this rulemaking to allow us the opportunity to review the data. Also, supplemental payments are often made for specific Medicaid-covered services and targeted to a subset of Medicaid-participating providers; not all Medicaid-participating providers, and not all providers of a given Medicaid-covered service, may receive supplemental payments in a State. Therefore, including supplemental payments in the comparative payment rate analysis would create additional burden for States without then also providing an accurate benchmark of how payments may affect beneficiary access due to the potentially varied and uneven distribution of supplemental payments. Accordingly, we proposed to require that States conduct the comparative payment rate analysis for only Medicaid base payment rates for selected E/M CPT/HCPCS codes. For each proposed category of service listed in paragraphs (b)(2)(i) through (iii), this would result in a transparent and parallel comparison of Medicaid base payment rates that all Medicaid-participating providers of the service would receive to the payment rates that Medicare would pay for the same E/M CPT/HCPCS codes.

Additionally, in paragraph (b)(3)(i)(B), we proposed that, if the States' payment rates vary, the Medicaid base payment rates must include a breakdown by payment rates paid to providers delivering services to pediatric and adult populations, by provider type, and geographical location, as applicable, to capture this potential variation in the State's payment rates. This proposed provision to breakdown the Medicaid payment rate is first stated in proposed paragraph (b)(2) and carried through in proposed paragraph (b)(3)(i)(B) to provide clarity to States about how the Medicaid payment rate should be reported in the comparative payment rate analysis.

In paragraph (b)(3)(i)(C), we proposed to require States' comparative payment rate analysis clearly identify the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B), including separate identification of the payment rates by provider type. We did not propose to establish a threshold percentage of Medicare non-facility payment rates that States would be required to meet when setting their Medicaid payment rates. Rather, we proposed to use Medicare non-facility payment rates as established in the Medicare PFS final rule for a calendar year as a benchmark to which States would compare their Medicaid payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We explained that benchmarking against FFS Medicare, another of the nation's large public health coverage programs, serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. Similar to Medicaid, Medicare provides health coverage for a significant number of Americans across the country. In December 2023, total Medicaid enrollment was at 77.9 million individuals [249] while total Medicare enrollment was at 66.8 million individuals.[250] [251] Both the Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States. As previously described, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for covered, non-covered, and limited coverage services generally are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. Medicare also ensures that their payment rate data are publicly available in a format that can be analyzed. The accessibility and consistency of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, compared to negotiated private health insurance payment rates that typically are considered proprietary information and, therefore, not generally available to the public, makes Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.

Additionally, Medicare is widely accepted nationwide according to recent findings from the National Electronic Health Records Survey. In 2019, 95 percent of physicians accepting new patients overall, and 89 percent of office-based physicians, were accepting new Medicare patients, and the percentage of office-based physicians accepting new Medicare patients has remained stable since 2011 when the value was 88 percent, with modest fluctuations in the years in between.[252] In regards to physician specialties that align with the categories of services in this rule, 81 percent of general practice/family medicine physicians and 81 percent of physicians specializing in internal medicine were accepting new Medicare patients, 93 percent of physicians specializing obstetrics and gynecology were accepting new Medicare patients, and 60 percent of psychiatrists were accepting new Medicare patients in 2019. Although the percentage of psychiatrists who accept Medicare is lower than other types of physicians providing services included in the comparative payment rate analysis, this circumstance is not unique to Medicare amongst payers. For example, 60 percent of psychiatrists were also accepting new privately insured patients in 2019.[253] Therefore, the decreased rate of acceptance by psychiatrists relative to certain other physician specialists does not make Medicare an inappropriate benchmark when evaluated against other options for comparison.[254]

Historically, Medicare has low rates of physicians formally opting out of the Medicare program with 1 percent of physicians consistently opting out between 2013 and 2019 and of that 1 percent of physicians opting out of Medicare, 42 percent were

[249] *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.*

[250] Total Medicare enrollment equals the Tot_Benes variable in the Medicare Monthly Enrollment Data for December (Month) 2023 (Year) at the national level (Bene_Geo_Lvl). Tot_Benes is a count of all Medicare beneficiaries, including beneficiaries with Original Medicare and beneficiaries with Medicare Advantage and Other Health Plans. We utilized the count of all Medicare beneficiaries because Original Medicare, Medicare Advantage, and other Health Plans offer fee-for-service payments to providers. See the Medicare Monthly Enrollment Data Dictionary for more information about the variables in the Medicare Monthly Enrollment Data: *https://data.cms.gov/sites/default/files/2023-02/1ec24f76-9964-4d00-9e9a-78bd556b7223/Medicare%20Monthly%20Enrollment_Data_Dictionary%2020230131_508.pdf.*

[251] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.*

[252] *https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.*

[253] *https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.*

[254] *https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.*

psychiatrists.[255] This information suggests that Medicare's payment rates generally are consistent with a high level of physician willingness to accept new Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. For the reasons previously described, we proposed to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a national benchmark for States to compare their Medicaid payment rates in the comparative payment rate analysis because we believe that the Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In paragraph (b)(3)(i)(C), we proposed to require States to compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period as the same set of E/M CPT/HCPCS codes paid under Medicaid as specified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. We proposed to require States to compare their payment rates to the corresponding Medicare PFS non-facility rates because we are seeking a payment analysis that compares Medicaid payment rates to Medicare payment rates at comparable location of service delivery (that is, in a non-clinic, non-hospital, ambulatory setting such as a physician's office). States often pay physicians operating in an office based on their Medicaid fee schedule whereas they may pay physicians operating in hospitals or clinics using an encounter rate. The Medicaid fee schedule rate typically reflects payment for an individual service that was rendered, for example, an office visit that is billed as a single CPT/HCPCS code. An encounter rate often reflects reimbursement for total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter. For example, the same encounter rate may be paid for a beneficiary who has an office visit with a physician, a dental examination and cleaning from a dentist, and laboratory tests and for a beneficiary who receives an office visit with a physician and x-rays. Encounter rates are typically paid to facilities, such as hospitals, FQHCs, RHCs, or clinics, many of which function as safety net providers that offer a wide variety of medical services. Within the Medicaid program, encounter rates can vary widely in the rate itself and services paid for through the encounter rate. We explained that States demonstrating the economy and efficiency of their encounter rates would be an entirely different exercise to the fee schedule rate comparison proposed in this rule because encounter rates are often based on costs unique to the provider, and States often require providers to submit cost reports to States for review to support payment of the encounter rate. Comparing cost between the Medicaid and Medicare program would require a different methodology, policies, and oversight than the comparative payment rate analysis requirement that we proposed due to the differences within and between each program. While the Medicare program has a broad, national policy for calculating encounter rates for providers, including prospective payment systems for hospitals, FQHCs, and other types of facilities, Medicare calculates these encounter rates differently than States may calculate analogous rates in Medicaid. Therefore, we explained that disaggregating each of their encounter rates and services covered in each encounter rate to compare to Medicare's encounter rates would be challenging for States.

From that logic, we likewise determined that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would afford the best point of comparison because it is the most accurate and most analogous comparison of a service-based access analysis using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis, as opposed to an encounter rate which could include any number of services or specialties. The Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year is described as ''. . . the fee schedule amount when a physician performs a procedure in a non-facility setting such as the office'' and ''[g]enerally, Medicare gives higher payments to physicians and other health care professionals for procedures performed in their offices [compared to those performed elsewhere] because they must supply clinical staff, supplies, and equipment.'' [256] As such, we stated our belief that the Medicaid fee schedule best represents the payment intended to pay physicians and non-physician practitioners for delivery of individual services in an office (non-facility) setting, and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year represents the best equivalent to that amount and consideration.

For the purposes of the comparative payment rate analysis, we explained in the proposed rule that we would expect States to source the Medicare non-facility payment rate from the published Medicare fee schedule amounts that are established in the annual Medicare PFS final rule through one or both of the following sources: the Physician Fee Schedule Look-Up Tool [257] on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value with Conversion Factor files [258] for the relevant calendar year from *cms.gov.* We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non-facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee

[255] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See 2022 opt-out affidavit data published by the Centers for Medicare & Medicaid services: *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

[256] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

[257] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.*

[258] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first download and review the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. With the publication of this final rule, we have also issued subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis.

Statutory provisions at section 1848 of the Act and regulatory provisions at 42 CFR 414.20 [259] require that most physician services provided in Medicare are paid under the Medicare PFS. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.[260] [261]

For many services, the Medicare PFS also includes separate fee schedule amounts based on the site of service (non-facility versus facility setting). The applicable PFS the rate for a service, facility or non-facility, is based on the setting where the beneficiary received the face-to-face encounter with the billing practitioner, which is indicated on the claim form by a place of service (POS) code. We proposed States use the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in the comparative payment rate analysis. We directed States to the Excel file downloads of the ''PFS Relative Value Files'' which include the RVUs, GPCIs, and the ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file which contains the associated relative value units (RVUs), a fee schedule status indicator, and various payment policy indicators needed for payment adjustment (for example, payment of assistant at surgery, team surgery, or bilateral surgery). We stated that we would expect States to use the formula for the Non-Facility Pricing Amount in ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file to calculate the ''Non-Facility Price'' using the RVUs, GPCIs, and conversion factors for codes not available in the Look-Up Tool.

We explained that Medicaid FFS fee-schedule payment rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, the State's Medicaid base payment rates used for comparison should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to align with the inclusion of expected beneficiary cost sharing in Medicare's non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year.[262]

In paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule must be effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the base Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B). We included this language to ensure the comparative payment rate analysis is as accurate and analogous as possible by proposing that the Medicaid and Medicare payment rates that are effective during the same time period for the same set of E/M CPT/HCPCS codes. As later described in this rule, in paragraph (b)(4), we proposed the initial comparative payment rate analysis and payment rate disclosure of Medicaid payment rates would be a retroactive analysis of payment rates that are in effect as of January 1, 2025, with the analysis and disclosure published no later than January 1, 2026. For example, the first comparative payment rate analysis a State develops and publishes would compare base Medicaid FFS fee schedule payment rate in effect as of January 1, 2025, to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective January 1, 2025, to ensure the Medicare non-facility payment rates are effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B).

Additionally, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule used for the comparison must be for the same geographical location as the Medicaid FFS fee schedule payment rate. For States that pay Medicaid payment rates based on geographical location (for example, payment rates that vary by rural or non-rural location, by zip code, or by metropolitan statistical area), we proposed that States' comparative payment rate analyses would need to use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same geographical location as the Medicaid FFS fee schedule payment rate to achieve an equivalent comparison. We stated that we would expect States to review Medicare's published listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and identify the comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate.[263]

We recognized that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare. For example, a State may use its own State-determined geographical designations, resulting in 5 geographical areas in the State for purposes of Medicaid payment while Medicare recognizes 3 locality areas for the State based on Metropolitan Statistical Area (MSA) delineations determined by the US Office of Management and Budget (OMB) that are the result of the application of published standards to

[259] The Medicare Claims Processing Manual contains additional information about physician service payments in Medicare that are based on the cited statutory and regulatory requirements. *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.*

[260] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.*

[261] *https://www.cms.gov/medicare/physician-fee-schedule/search/overview.*

[262] *According to the Medicare Physician Fee Schedule Guide, for most codes, Medicare pays 80% of the amount listed and the beneficiary is responsible for 20 percent.*

[263] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

Census Bureau data.[264] In this instance, we would expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. Alternatively, as discussed in the next paragraph, the State could determine to use the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our awareness that States may not determine their payment rates by geographical location. For States that do not pay Medicaid payment rates based on geographical location, we proposed that States compare their Medicaid payment rates (separately identified by population, pediatric and adult, and provider type, as applicable) to the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code. The Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code would be calculated as a simple average or arithmetic mean where all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State would be summed and divided by the number of all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State. This calculated Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would be calculated for each CPT/HCPCS code subject to the comparative payment rate analysis using the Non-Facility Price for each locality in the State as established in the annual Medicare PFS final rule for a calendar year. As previously mentioned, Medicare has published a listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area, and we would expect States to use this listing to identify the Medicare locality areas in their State. For example, the Specific Medicare Administrative Contractor (MAC) for Maryland is 12302 and there are two Specific Locality codes, 1230201 for BALTIMORE/SURR. CNTYS and 1230299 for REST OF STATE. After downloading and reviewing the CY 2023 Medicare PFS Relative Value Files to identify the Medicare Non-Facility Price(s) for CY 2023 for 99202 in the Specific MAC locality code for Maryland (12302 MARYLAND), the following information can be obtained: Medicare Non-Facility Price of $77.82 for BALTIMORE/SURR. CNTYS and $74.31 for REST OF STATE.[265] These two Medicare Non-Facility Price(s) would be averaged to obtain a calculated Statewide average for Maryland of $76.07.

For States that do not determine their payment rates by geographical location, we proposed that States would use the Statewide average of the Medicare Non-Facility Price(s) as listed on the PFS, as previously described, because it ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. We explained that this proposal would ensure that all States' comparative payment rate analyses consistently include Medicare geographical payment rate adjustments as proposed in paragraph (b)(3)(i)(C). As previously discussed, we proposed that States that do pay varying rates by geographical location would need to identify the comparable Medicare locality area for the same geographical area as their Medicaid FFS fee schedule payment rate. However, for States that do not pay varying rates by geographical location, at the operational level, the State is effectively paying a Statewide Medicaid payment rate, regardless of geographical location, that cannot be matched to a Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in a comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate. Therefore, to consistently apply the proposed provision that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year must be for the same geographical location as the Medicaid FFS fee schedule payment rate, States that do not pay varying rates by geographical location would be required to calculate a Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to compare the State's Statewide Medicaid payment rate.

Additionally, we proposed that States that do not determine their payment rates by geographical location should use the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to align the implementing regulatory text with the statute's geographic area requirement in section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that Medicaid payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the proposed provisions of this rule, which are implementing section 1902(a)(30)(A) of the Act, must include a method of ensuring we have sufficient information for determining sufficiency of access to care as compared to the general population in the geographic area. As we have

[264] *https://www.census.gov/programs-surveys/metro-micro/about/delineation-files.html.*

[265] *https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=1&H1=99202&C=43&M=5.*

proposed to use Medicare non-facility payment rates as a benchmark for comparing Medicaid FFS fee schedule payment rate, we believe that utilizing a Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for States that do not pay varying rates by geographical location would align the geographic area requirement of section 1902(a)(30)(A) of the Act, treating the entire State (throughout which the Medicaid base payment rate applies uniformly) as the relevant geographic area.

We considered requiring States weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, but we did not propose this due to the additional administrative burden this would create for States complying with the proposed comparative payment rate analysis as well as limited availability of Medicare beneficiary and claims data necessary to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year in this manner. As proposed, States that do not determine their payment rates by geographical location would be required to consider Medicare's geographically determined payment rates by Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. We explained our belief that an additional step to weight the Statewide average by the proportion of the Medicare beneficiary population covered by each rate would not result in a practical version of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for purposes of the comparative payment rate analysis. Additionally, requiring only States that do not determine their payment rates by geographical location to weight Medicare payment rates in this manner would result in additional administrative burden for such States that is not imposed on States that do determine their Medicaid payment rates by geographical location. Additionally, in order to accurately weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, States would likely require Medicare-paid claims data for each code subject to the comparative payment rate analysis, broken down by each of the comparable Medicare locality areas for the same geographical area as the Medicaid FFS fee schedule payment rate that are included in the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. While total Medicare beneficiary enrollment data broken down by State and county level is publicly available on *data.cms.gov,* Medicare-paid claims data broken down by the Medicare locality areas used in the Medicare PFS and by code level is not published by CMS and would be inaccessible for the State to use in weighting the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate. Accordingly, we explained our belief that, for States that do not determine their Medicaid payment rates by geographical location, calculating a simple Statewide average of the Medicare non-facility rates in the State would ensure consistency across all States' comparative payment rate analyses, align with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensure the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analyses accurately reflect how Medicare pays for services. We solicited comments regarding our decision not to propose requiring States that do not pay varying Medicaid rates by geographical location to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the distribution of Medicare beneficiaries in the State.

Furthermore, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule must separately identify the payment rates by provider type. We previously discussed that some States and Medicare pay a percentage less than 100 percent of their fee schedule payment rates to NPPs, including, for example, nurse practitioners, physician assistants, and clinical nurse specialists. To ensure a State's comparative payment rate analysis is as accurate as possible when comparing their Medicaid payment rates to Medicare, we proposed that States include a breakdown of Medicare's non-facility payment rates by provider type. The proposed breakdown of Medicare's payment rates by provider type would be required for all States, regardless of whether or how the State's Medicaid payment rates vary by provider type, because it ensures the comparative payment rate analysis accurately reflects this existing Medicare payment policy on the Medicare side of the analysis. Therefore, every comparative payment rate analysis would include the following Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same set of E/M CPT/HCPCS codes paid under Medicaid as described in § 447.203(b)(3)(i)(B): the non-facility payment rate as established in the annual Medicare PFS rate as the Medicare payment rate for physicians and the non-facility payment rate as listed on Medicare PFS rate multiplied by 0.85 as the Medicare payment rate for NPPs.

As previously mentioned in this final rule, Medicare pays nurse practitioners, physician assistants, and clinical nurse specialists at 85 percent of the Medicare PFS rate. Medicare implements a payment policy where the fee schedule amounts, including the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, are reduced to 85 percent when billed by NPPs, including nurse practitioners, physician assistants, and clinical nurse specialists, whereas physicians are paid 100 percent of the fee schedule amounts Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.[266] As proposed, States' comparative payment rate analysis would need to match their Medicaid payment rates for each provider type to the corresponding Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for each provider type, regardless of the State paying varying or the same payment rates to their providers for the same service. As an example of a State that pays varying rates based on provider type, if a State's Medicaid fee schedule lists a rate of $100.00 when a physician delivers and bills for 99202, then the $100.00 Medicaid base payment rate would be compared to 100 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. If the same State's Medicaid fee schedule lists a rate of $75 when a nurse practitioner delivers and bills for 99202 (or the State's current approved State plan

[266] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

language states that a nurse practitioner is paid 75 percent of the State's Medicaid fee schedule rate), then the $75 Medicaid base payment rate would be compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85. Both Medicare non-facility payments rates would need to account for any applicable geographical variation, including the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for each relevant locality area or the calculated Statewide average of the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for all relevant areas of a State, as previously discussed in this section, for an accurate comparison to the corresponding Medicaid payment rate. Alternatively, if a State pays the same $80 Medicaid base payment rate for the service when delivered by physicians and by nurse practitioners, then the $80 would be listed separately for physicians and nurse practitioners as the Medicaid base payment rate and compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for physicians and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85 for nurse practitioners.

This granular level of comparison provides States with the opportunity to benchmark their Medicaid payment rates against Medicare as part of the State's and our process for ensuring compliance with section 1902(a)(30)(A) of the Act. For example, a State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 80 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 71 percent of the Medicare non-facility payment rate for NPPs, because the State pays a reduced rate to nurse practitioners. Although Medicare also pays a reduced rate to nurse practitioners, the reduced rate the State pays to nurse practitioners compared to Medicare's reduced rate is still a lower percentage than the physician rate. However, another State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 95 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 110 percent of the Medicare non-facility payment rate because the State pays all providers the same Medicaid base payment rate while Medicare pays a reduced rate of 85 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year when the service is furnished by an NPP. By conducting this level of analysis through the comparative payment rate analysis, States would be able to pinpoint where there may be existing or potential future access to care concerns rooted in payment rates. We solicited comments on the proposed requirement for States to compare their Medicaid payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid FFS fee schedule payment rate, that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type, as proposed in § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i)(D), we proposed to require States specify the Medicaid base payment rate identified under proposed § 447.203(b)(3)(i)(B) as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule identified under proposed § 447.203(b)(3)(i)(C) for each of the services for which the Medicaid base payment rate is published under proposed § 447.203(b)(3)(i)(B). For each E/M CPT/HCPCS code that we select, we proposed that States would calculate each Medicaid base payment rate as specified in paragraph (b)(3)(i)(B) as a percentage of the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule specified in paragraph (b)(3)(i)(C). Both rates would be required to be effective for the same time period of the comparative payment rate analysis. As previous components of the proposed comparative payment rate analysis have considered variance in payment rates based on population the service is delivered to (adult or pediatric), provider type, and geographical location to extract the most granular and accurate Medicaid and Medicare payment rate data, we proposed that States would calculate the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis to obtain an informative metric that can be used in the State's and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. As previously discussed, benchmarking against Medicare serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. We proposed that States would calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule because it is a common, simple, and informative statistic that can provide us with a gauge of how Medicaid payment rates compare to Medicare non-facility payment rates in the same geographic area. Initially and over time, States, CMS, and other interested parties would be able to compare the State's Medicaid payment rates as a percentage of Medicare's non-facility payment rates to identify how the percentage changes over time, in view of changes that may take place to the Medicaid and/or the Medicare payment rate. We explained that being able to track and analyze the change in percentage over time would help States and CMS identify possible access concerns that may be related to payment insufficiency.

We noted that the organization and content of the comparative payment rate analysis, including the expression of the Medicaid base payment rate as a percentage of the Medicare payment rate, can provide us with a great deal of information about access in the State. For example, we would be able to identify when and how the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for E/M CPT/HCPCS codes for primary care services may decrease over time if Medicare adjusts its rates and a State does not and use this information to more closely examine for possible access concerns. This type of analysis would provide us with actionable information to help ensure consistency with section 1902(a)(30)(A) of the Act by using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year paid across the same geographical

areas of the State as a point of comparison for payment rate sufficiency as a critical element of beneficiary access to care. When explaining the rationale for proposing to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for comparison earlier in this rule, we emphasized the ability to demonstrate to States that certain Medicaid payment rates have not kept pace with changes to Medicare non-facility payment rates and how the comparative payment rate analysis would help them identify areas where they also might want to consider rate increases that address market changes. We solicited comments on the proposed requirement for States to calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as described in proposed § 447.203(b)(3)(i)(D). We also solicited comments on any challenges States might encounter when comparing their Medicaid payment rates to Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year under proposed § 447.203(b)(3)(i)(D), particularly for any of the proposed categories of service in paragraphs (b)(2)(i) through (iii), as well as suggestions for an alternative comparative analysis that might be more helpful, or less burdensome and equally helpful, for States, CMS, and other interested parties to assess whether a State's Medicaid payment rates are consistent with the access standard in section 1902(a)(30)(A) of the Act.

We noted our awareness in the proposed rule that provider payment rates are an important factor influencing beneficiary access; as expressly indicated in section 1902(a)(30)(A) of the Act, insufficient provider payment rates are not likely to enlist enough providers willing to serve Medicaid beneficiaries to ensure broad access to care; however, there may be situations where access issues are principally due to other causes. For example, even if Medicaid payment rates are generally consistent with amounts paid by Medicare (and those amounts have been sufficient to ensure broad access to services for Medicare beneficiaries), Medicaid beneficiaries may have difficulty scheduling behavioral health care appointments because the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population. Therefore, a State's rates may be consistent with the requirements of section 1902(a)(30)(A) of the Act even when access concerns exist, and States and CMS may need to examine other strategies to improve access to care beyond payment rate increases. By contrast, comparing a State's Medicaid behavioral health payment rates to Medicare may demonstrate that the State's rates fall far below Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, which would likely impede beneficiaries from accessing needed care when the demand already exceeds the supply of providers within a State. In that case, States may need to evaluate budget priorities and take steps to ensure behavioral health rates are consistent with section 1902(a)(30)(A) of the Act.

Lastly, in paragraph (b)(3)(i)(E), we proposed to require States to specify in their comparative payment rate analyses the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B). The previous components of the comparative payment rate analysis focus on the State's payment rate for the E/M CPT/HCPCS code and comparing the Medicaid base payment rate to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for the same code (separately, for each Medicaid base payment rate by population (adult or pediatric), provider type, and geographic area, as applicable). This component examines the Medicaid-paid claims volume of each E/M CPT/HCPCS code included in the comparative payment rate analysis relative to the number of Medicaid enrolled beneficiaries receiving each service within a calendar year. We proposed to limit the claims volume data to Medicaid-paid claims, and the number of beneficiaries would be limited to Medicaid-enrolled beneficiaries who received a service in the calendar year of the comparative payment rate analysis, where the service would fall into the list of CMS-identified E/M CPT/HCPCS code(s). In other words, a beneficiary would be counted in the comparative payment rate analysis for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraphs (b)(2)(i) through (iii) for which the State has a Medicaid base payment rate (the number of Medicaid-enrolled beneficiaries who received a service). A claim would be counted in the comparative payment rate analysis for a particular calendar year when that beneficiary had a claim submitted on their behalf by a provider who billed one of the codes from the list of CMS-identified E/M CPT/HCPCS code(s) to the State and the State paid the claim (number of Medicaid-paid claims). With the proposal, we explained that we were seeking to ensure the comparative payment rate analysis reflects actual services received by beneficiaries and paid for by the State or realized access.[267]

We considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We considered this detail in order to identify the unique, or deduplicated, number of beneficiaries who received a service that falls into one of the categories of services described in in paragraph (b)(2)(i) through (iii) in a calendar year. For example, if a beneficiary has 6 visits to their primary care provider in a calendar year and the provider bills 6 claims with 99202 for the same beneficiary, then the beneficiary and claims for 99202 would only be counted as one claim and one beneficiary. Therefore, we chose not to propose this aspect because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. We solicited comments regarding our decision not to propose that States would identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We also considered but did not propose to require States to identify the total Medicaid-enrolled population who could potentially receive a service within a calendar year for each of the services for which the Medicaid base

[267] Andersen, R.M., and P.L. Davidson (2007). Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

payment rate is published under paragraph (b)(3)(i)(B), in addition to the proposed requirement for States to identify the number of Medicaid-enrolled beneficiaries who received a service. This additional data element in the comparative payment rate analysis would reflect the number of Medicaid-enrolled beneficiaries who could have received a service, or potential access, in comparison to the number of Medicaid-enrolled beneficiaries who actually received a service. We did not propose this aspect because this could result in additional administrative burden on the State, as we already collect and publish similar data through Medicaid and CHIP Enrollment Trends Snapshots published on Medicaid.gov. We also solicited comments regarding our decision not to propose that States would identify the total Medicaid-enrolled population who could receive a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We proposed to include beneficiary and claims information in the comparative payment rate analysis to contextualize the payment rates in the analysis, and to be able to identify longitudinal changes in Medicaid service volume in the context of the Medicaid beneficiary population receiving services, since utilization changes could be an indication of an access to care issue. For example, a decrease in the number of Medicaid-paid claims for primary care services furnished to Medicaid beneficiaries in an area (when the number of Medicaid-enrolled beneficiaries who received primary care services in the area is constant or increasing) could be an indication of an access to care issue. Without additional context provided by the number of Medicaid enrolled beneficiaries who received a service, changes in claims volume could be attributed to a variety of changes in the beneficiary population, such as a temporary loss of coverage when enrollees disenroll and then re-enroll within a short period of time.

Further, if the Medicaid base payment rate for the services with decreasing Medicaid service volume has failed to keep pace with the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year over the period of decrease in utilization (as reflected in changes in the Medicaid base payment rate expressed as a percentage of the Medicare non-facility payment rate as required under proposed § 447.203(b)(3)(i)(D)), then we would be concerned and would further scrutinize whether any access to care issue might be caused by insufficient Medicaid payment rates for the relevant services. With each biennial publication of the State's comparative payment rate analysis, as proposed in § 447.203(b)(4), discussed later in this section, States and CMS would be able to compare the number of paid claims in the context of the number of Medicaid enrolled beneficiaries receiving services within a calendar year for the services subject to the comparative payment rate analysis with previous years' comparative payment rate analyses. Collecting and comparing the number of paid claims data in the context of the number of Medicaid enrolled beneficiaries receiving services alongside Medicaid base payment rate data may reveal trends where an increase in the Medicaid base payment rate is correlated with an increase in service volume and utilization, or vice versa with a decrease in the Medicaid base payment rate correlated with a decrease in service volume and utilization. As claims utilization and number of Medicaid enrolled beneficiaries receiving services are only correlating trends, we acknowledge that there may be other contextualizing factors outside of the comparative payment rate analysis that affect changes in service volume and utilization, and we would (and would expect States and other interested parties to) take such additional factors into account in analyzing and ascribing significance to changes in service volume and utilization. We are solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as specified in proposed § 447.203(b)(3)(i)(E).

We noted our belief that the comparative payment rate analysis proposed in paragraph (b)(3) is needed to best enable us to ensure State compliance with the requirement in section 1902(a)(30)(A) of the Act that payments are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. As demonstrated by the findings of Sloan, et al.,[268] which have since been supported and expanded upon by numerous researchers, multiple studies examining the relationship between Medicaid payment and physician participation,[269] [270] at the State level,[271] and among specific provider types,[272] [273] have found a direct, positive association between Medicaid payment rates and provider participation in the Medicaid program. While multiple factors may influence provider enrollment (such as administrative burden), section 1902(a)(30)(A) of the Act specifically concerns the sufficiency of provider payment rates. Given this statutory requirement, a comparison of Medicaid payment rates to other payer rates is an important barometer of whether State payment policies are likely to support the statutory standard of ensuring access for Medicaid beneficiaries such that covered care and services are available to them at least to the extent that the same care and services are available to the general population in the geographic area.

The AMRP requirements previous addressed this standard under section 1902(a)(30)(A) of the Act by requiring States to compare Medicaid payment rates to the payment rates of other public and private payers in current

[268] Sloan, F. et al ''Physician Participation in State Medicaid Programs.'' *The Journal of Human Resources,* Volume 13, Supplement: National Bureau of Economic Research Conference on the Economics of Physician and Patient Behavior, 1978, p. 211–245. *https://www.jstor.org/stable/145253?seq=1#metadata_info_tab_contents.* Accessed August 16, 2022.

[269] Chen, A. ''Do the Poor Benefit from More Generous Medicaid Policies'' SSRN Electronic Journal, January 2014., p. 1–46. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2444286.* Accessed June 16, 2022.

[270] Holgash, K. and Martha Heberlein, ''Physician Acceptance of New Medicaid Patients: What Matters and What Doesn't'' *Health Affairs,* April 10, 2019. *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/#:~:text=Physicians%E2%80%99%20acceptance%20of%20new%20Medicaid%20patients%20is%20only,of%20Medicaid%20patients%20already%20in%20the%20physician%E2%80%99s%20care.* Accessed June 16, 2022.

[271] Fakhraei, H. ''Payments for Physician Services: An analysis of Maryland Medicaid Reimbursement Rates'' *International Journal of Healthcare Technology and Management, Volume 7,* Numbers 1–2, January 2005, p. 129–142. *https://www.researchgate.net/publication/228637758_Payments_for_physician_services_An_analysis_of_Maryland_Medicaid_reimbursement_rates.* Accessed June 16, 2022.

[272] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients,'' *Pediatrics,* Volume 110, Issue 2, August 2002, p. 239–248. *https://publications.aap.org/pediatrics/article-abstract/110/2/239/64380/Factors-That-Influence-the-Willingness-of-Private?redirectedFrom=fulltext?autologincheck=redirected.* Accessed June 16, 2022.

[273] Suk-fong S., Tang, et al ''Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians,'' *Pediatrics,* Volume 141, number 1, January 2018, p. 1–9. *https://publications.aap.org/pediatrics/article/141/1/e20172570/37705/Increased-Medicaid-Payment-and-Participation-by.* Accessed June 16, 2022.

§ 447.203(b)(1)(v) and (b)(3). While we proposed to eliminate the previous AMRP requirements, we noted our belief that our proposal to require States to compare their Medicaid payment rates for services under specified E/M CPT/HCPCS codes against Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same codes, as described in § 447.203(b)(3), would well position States and CMS to continue to meet the statutory access requirement. Some studies examining the relationship between provider payments and various access measures have quantified the relationship between the Medicaid-Medicare payment ratio and access measures. Two studies observed that increases in the Medicaid-Medicare payment ratio is associated with higher physician acceptance rates of new Medicaid patients and with an increased probability of a beneficiary having an office-based physician as the patient's usual source of care.[274] [275] We explained that these studies led us to conclude that Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are likely to be a sufficient benchmark for evaluating access to care, particularly ambulatory physician services, based on provider payment rates.

By comparing FFS Medicaid payment rates to corresponding FFS Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, where Medicare is a public payer with large populations of beneficiaries and participating providers whose payment rates are readily available, we aim to establish a uniform benchmarking approach that allows for more meaningful oversight and transparency and reduces the burden on States and CMS relative to the previous AMRP requirements that do not impose specific methodological standards for comparing payment rates and that contemplate the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. We noted that this aspect of the proposal specifically responds to States' expressed concerns that the previous AMRP requirement to include ''actual or estimated levels of provider payment available from other payers, including other public and private payers'' was challenging to accomplish based on the general unavailability of this information, as discussed elsewhere in this final rule.

Following the 2011 proposed rule, and as addressed by us through public comment response in the 2015 final rule with comment period, States expressed concerns that private payer payment rates were proprietary information and not available to them and that large private plans did not exist within some States so there were no private payer rates to compare to, therefore, the State would need to rely on State employee health plans or non-profit insurer rates.[276] States also expressed that other payer data, including public and private payers, in general may be unsound for comparisons because of a lack of transparency about the payment data States would have compared their Medicaid payment rates to. We discussed how, since 2016, we have learned a great deal from our implementation experience of the previous AMRP process. We have learned that very few States were able to include even limited private payer data in their previous AMRPs. States that were able include private payer data were only able to do so because the State had existing Statewide all payer claiming or rate-setting systems, which gave them access to private payer data in their State, or the State previously based their State plan payment rates off of information about other payers (such as the American Dental Association's Survey of Dental Fees) that gave them access to private payer data.[277] Based on our implementation experience and concerns from States about the previous requirement in § 447.203(b)(1)(v) to obtain private payer data, we proposed to require States only compare their Medicaid payment rates to Medicare's, for which payment data are readily and publicly available.

Next, in paragraph (b)(3)(ii), we proposed that for each category of services described in proposed paragraph (b)(2)(iv), the State agency would be required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates differ. The payment rate disclosure would be required to meet specified requirements. We explained that we intended this proposal to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) and to take specific action regarding direct care workers per Section 2402(a) of the Affordable Care Act. HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we proposed a different analysis of payment rates for providers of these services that does not involve a comparison to Medicare. As previously stated, Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance); however, Medicare does not cover personal care or homemaker services. Therefore, comparing personal care and homemaker services to Medicare, as we proposed in paragraph (b)(3)(i) for other specified categories of services, would not be feasible for States, and a comparison of Medicaid home health aide payment rates to analogous rates for Medicare would be of limited utility given the differences in circumstances when Medicaid and Medicare may pay for such services.

As previously discussed, private payer data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Even if private payer payment rate data were more readily available, like Medicare, many private payers do not cover HCBS as HCBS is unique to the Medicaid program, leaving Medicaid as the largest or the only payer for personal care, home health aide, and homemaker services. Given Medicaid's status as the most important payer for HCBS, we believe that scrutiny of Medicaid HCBS payment rates themselves, rather than a comparison to other payer rates that frequently do not exist, is most important in ascertaining whether such Medicaid payment rates are sufficient to enlist adequate providers so that the specified services are available to Medicaid beneficiaries at least to the same extent as to the general population in the geographic area. We acknowledge that individuals without insurance may self-pay for medical services provided in their home or community; however, similar to private payer data, self-pay data is unlikely to be available to States. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS.

[274] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[275] Cohen, J.W., *Inquiry,* Fall 1993.

[276] Alaska Department of Health and Social Services, Comment Letter on 2011 Proposed Rule (July 7, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0102.*

[277] *https://www.medicaid.gov/sites/default/files/2019-12/co-amrp-2016.pdf, https://www.medicaid.gov/sites/default/files/2019-12/md-amrp-16.pdf, https://www.medicaid.gov/sites/default/files/2019-12/sd-amrp-16.pdf.*

Through the proposed payment rate disclosure, Medicaid payments rates would be transparent and comparable among States and would assist States to analyze if and how their payment rates are compliant with section 1902(a)(30)(A) of the Act.

As noted previously in this section, we proposed to require States to express their rates separately as the average hourly payments made to individual providers and providers employed by an agency, if the rates differ, as applicable for each category of service specified in proposed § 447.203(b)(2)(iv). We noted our belief that expressing the data in this manner would best account for variations in types and levels of payment that may occur in different settings and employment arrangements. Individual providers are often self-employed or contract directly with the State to deliver services as a Medicaid provider while providers employed by an agency are employed by the agency, which works directly with the Medicaid agency to provide Medicaid services. These differences in employment arrangements often include differences in the hourly rate a provider would receive for services delivered, for example, providers employed by an agency typically receive benefits, such as health insurance, and the cost of those benefits is factored into the hourly rate that the State pays for the services delivered by providers employed by an agency (even though the employed provider does not retain the entire amount as direct monetary compensation). However, these benefits are not always available for individual providers who may need to separately purchase a marketplace health plan or be able to opt into the State-employee health plan, for example. Therefore, the provider employed by an agency potentially could receive a higher hourly rate because benefits are factored into the hourly rate they receive for delivering services, whereas the individual provider might be paid a rate that does not reflect employment benefits.

With States expressing their payment rates separately as the average hourly payment rate made to individual and agency employed providers for personal care, home health aide, and homemaker services, States, CMS, and other interested parties would be able to compare payment rates among State Medicaid programs. Such comparisons may be particularly relevant for States in close geographical proximity to each other or that otherwise may compete to attract providers of the services specified in proposed paragraph (b)(2)(iv) or where such providers may experience similar costs or other incentives to provide such services. For example, from reviewing all States' payment rate analyses for personal care, home health aide, and homemaker services, we would be able to learn that two neighboring States have similar hourly rates for providers of these services, but a third neighboring State has much lower hourly rates than both of its neighbors. This information could highlight a potential access issue, since providers in the third State might have an economic incentive to move to one of the two neighboring States where they could receive higher payments for furnishing the same services. Such movement could result in beneficiaries in the third State having difficulty accessing covered services, compared to the general population in the tri-State geographic area.

In paragraph (b)(3)(ii), we proposed that the State's payment rate disclosure must meet the following requirements: (A) the State must organize the payment rate disclosure by category of service as specified in proposed paragraph (b)(2)(iv); (B) the disclosure must identify the average hourly payment rates, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency by population (pediatric and adult), provider type, and geographical location, as applicable; and (C) the disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(ii)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(ii)(A) through (C).

In paragraph (b)(3)(ii)(A), we proposed to require States to organize their payment rate disclosures by each of the categories of services specified in proposed paragraph (b)(2)(iv), that is, to break out the payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency, separately for individual analyses of the payment rates for each category of service and type of employment structure. We solicited comments on the proposed requirement for States to break out their payment rates for personal care, home health aide, and homemaker services separately for individual analyses of the payment rates for each category of service in the comparative payment rate analysis, as described in proposed § 447.203(b)(3)(ii)(A).

In paragraph (b)(3)(ii)(B), we proposed to require States identify in their disclosure the Medicaid average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, as well as by population (pediatric and adult), provider type, and geographical location, as applicable. Given that direct care workers deliver unique services in Medicaid that are often not covered by other payers, we proposed to require a payment rate disclosure, instead of comparative payment rate analysis. To be clear, we did not propose to require a State's payment rate disclosure for personal care, home health aide, and homemaker services be broken down and organized by E/M CPT/HCPCS codes, nor did we propose States compare their Medicaid payment rates to Medicare for these services.

We proposed to require States to calculate their Medicaid average hourly payment rates made to providers of personal care, home health aide, and homemaker services, separately, for each of these categories of services, by provider employment structures (individual providers and agency employed providers). For each of the categories of services in paragraph (b)(3)(ii)(A), one Medicaid average hourly payment rate would be calculated as a simple average (arithmetic mean) where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates. As an example, the State's Medicaid average hourly payment rate for personal care providers may be $10.50 while the average hourly payment rate for a home health aide is $15.00. A more granular analysis may show that within personal care providers receiving a payment rate of $10.50, an individual personal care provider is paid an average hourly payment rate of $9.00, while a personal care provider employed by an agency is paid an average hourly payment rate of $12.00 for the same type of service. Similarly for home health aides, a more granular analysis may show that within home health aides receiving a payment rate of $15.00, an individual home health aide is paid an average hourly payment rate of $13.00, while a home health aide employed by an agency is paid an average hourly payment rate of $17.00.

We explained that we understand that States may set payment rates for personal care, home health aide, and

homemaker services based on a particular unit of time for delivering the service, and that time may not be in hourly increments. For example, different States might pay for personal care services using 15-minute increments, on an hourly basis, through a daily rate, or based on a 24-hour period. By proposing to require States to represent their rates as an hourly payment rate, we would be able to standardize the unit (hourly) and payment rate for comparison across States, rather than comparing to Medicare. To the extent a State pays for personal care, home health aide, or homemaker services on an hourly basis, the State would simply use that hourly rate in its Medicaid average hourly payment rate calculation of each respective category of service. However, if for example a State pays for personal care, home health aide, or homemaker services on a daily basis, we would expect the State to divide that rate by the number of hours covered by the rate.

Additionally, and similar to proposed paragraph (b)(3)(i)(E), we proposed in paragraph (b)(3)(ii)(B), that, if the States' Medicaid average hourly payment rates vary, the rates must separately identify the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable. We included this proposed provision with the intent of ensuring the payment rate disclosure contains the highest level of granularity in each element. As previously discussed, States may pay providers different payment rates for billing the same service based on the population being served, provider type, and geographical location of where the service is delivered. We solicited comments on the proposed requirement for States to calculate the Medicaid average hourly payment rate made separately to individual providers and to agency employed providers, which accounts for variation in payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the payment rate disclosure.

In paragraph (b)(3)(ii)(C), we proposed to require that the State disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid payment rate is published under proposed paragraph (b)(3)(ii)(B), so that States, CMS, and other interested parties would be able to contextualize the previously described payment rate information with information about the volume of paid claims and number of beneficiaries receiving personal care, home health aide, and homemaker services.

We proposed that the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service be reported under the same breakdown as paragraph (b)(3)(ii), where the State provides the number of paid claims and number of beneficiaries receiving services from individual providers versus agency-employed providers of personal care, home health aide services, and homemaker services. As with the comparative payment rate analysis, we proposed the claims volume data would be limited to Medicaid-paid claims and the number of beneficiaries would be limited to Medicaid enrolled beneficiaries who received a service in the calendar year of the payment rate disclosure, where the services fall into the categories of service for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). In other words, the beneficiary would be counted in the payment rate disclosure for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraph (b)(2)(iv) for which the State has calculated average hourly payment rates (the number of Medicaid enrolled beneficiaries who received a service). A claim would be counted when that beneficiary had a claim submitted on their behalf by a provider who billed for one of the categories of services described in paragraph (b)(2)(iv) and the State paid the claim (number of Medicaid-paid claims). We noted we were seeking to ensure the payment rate disclosure reflects actual services received by beneficiaries and paid for by the State, or realized access.[278]

Similar to the comparative payment rate analysis, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). We also considered but did not propose to require States to identify the total Medicaid enrolled population who could receive a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) in addition to proposing States identify the number of Medicaid enrolled beneficiaries who received a service. As discussed in the comparative payment rate discussion, we solicited comments on our decision not to require these levels of detail for the payment rate disclosure.

Also similar to the comparative payment rate analysis requirement under proposed paragraph (b)(3)(i)(E), we explained that this disclosure element would help States, CMS, and other interested parties identify longitudinal changes in Medicaid service volume and beneficiary utilization that may be an indication of an access to care issue. Again, with each biennial publication of the State's comparative payment rate analysis and payment rate disclosure, States and CMS would be able to compare the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for services subject to the payment rate disclosure with previous years' disclosures. Collecting and comparing data on the number of paid claims and number of Medicaid enrolled beneficiaries alongside Medicaid average hourly payment rate data may reveal trends, such as where a provider type that previously delivered a low volume of services to beneficiaries has increased their volume of services delivered after receiving an increase in their payment rate.

We acknowledged that one limitation of using the average hourly payment rate is that the statistic is sensitive to highs and lows, so one provider receiving an increase in their average hourly payment rate would bring up the average overall while other providers may not see an improvement. As these are only correlating trends, we also acknowledged that there may be other contextualizing factors outside of the payment rate disclosure that may affect changes in service volume and utilization. We solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid payment rate is published under paragraph (b)(3)(ii)(B), as specified in proposed § 447.203(b)(3)(ii)(C).

Additionally, in recognition of the importance of services provided to individuals with intellectual or

[278] Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

developmental disabilities and in an effort to remain consistent with the proposed HCBS payment adequacy provisions at § 441.302(k) (discussed in section II.B.5 of this rule), we solicited comments on whether we should propose a similar provision that would require at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers. In this final rule, we want to clarify that this request for comment was distinct from the proposal at § 441.302(k) as discussed in section II.B.5 of this rule. The payment adequacy provision finalized in § 441.302(k) is applicable to rates for certain specified services authorized under section 1915(c) of the Act, as well as sections 1915(j), (k), and (i) of the Act as finalized at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. The request for comment in this section of the rule considered expanding that requirement to Medicaid FFS payments under FFS State plan authority.

In paragraph (b)(4), we proposed to require the State agency to publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payments in effect as of January 1, 2025, as required under § 447.203(b)(2) and (b)(3), by no later than January 1, 2026. Thereafter, the State agency would be required to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data.

As previously discussed in this final rule, we proposed that the Medicaid payment rates included in the initial comparative payment rate analysis and payment rate disclosure would be those in effect as of January 1, 2025. Specifically, for the comparative payment rate analysis, we proposed States would conduct a retrospective analysis to ensure CMS can publish the list of E/M CPT/HCPCS codes for the comparative payment rate analysis and States have timely access to all information required to complete comparative payment rate analysis. As described in paragraph (b)(3)(i)(C), we proposed States would compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, therefore, the Medicare non-facility payment rates as published on the Medicare PFS for the same time period as the State's Medicaid payment rates would need to be available to States in a timely manner for their analysis and disclosure to be conducted and published as described in paragraph (b)(4). Medicare publishes its annual PFS final rule in November of each year and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are effective the following January 1. For example, the 2025 Medicare PFS final rule would be published in November 2024 and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule would be effective January 1, 2025, so States would compare their Medicaid payment rates effective as of January 1, 2025, to the Medicare PFS payment rates effective January 1, 2025, when submitting the initial comparative payment rate analysis that we proposed would be due on January 1, 2026.

Also, previously discussed in this final rule, we noted our intent to publish the initial and subsequent updates to the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. Because the list of E/M CPT/HCPCS codes is derived from the relevant calendar year's Medicare PFS, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule that the State would need to include in their comparative payment rate analysis would also be available to States. We explained that we expect approximately one full calendar year of the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year being available to States would provide the States with sufficient time to develop and publish their comparative payment rate analyses as described in paragraph (b)(4). We considered proposing the same due date and effective time period for Medicaid and Medicare payment rates where the initial publication of the comparative payment rate analysis would be due January 1, 2026, and would contain payment rates effective January 1, 2026; however, we believe a 2-month time period between Medicare publishing its PFS payment rates in November and the PFS payment rates taking effect on January 1 would be an insufficient amount of time for CMS to publish the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis and for States to develop and publish their comparative payment rate analyses by January 1. While the proposed payment rate disclosure would not require a comparison to Medicare, we proposed to use the same due date and effective period of Medicaid payment rates for both the proposed comparative payment rate analysis and payment rate disclosure to maintain consistency.

We noted our expectation the proposed initial publication timeframe would provide sufficient time for States to gather necessary data, perform, and publish the first required comparative payment rate analysis and payment rate disclosure. We determined this timeframe was sufficient based on implementation experience from the previous AMRP process, where we initially proposed a 6-month timeframe between the January 4, 2016, effective date of the 2015 final rule with comment period in the **Federal Register**, and the due date of the first AMRP, July 1, 2016. At the time, we believed that this timeframe would be sufficient for States to conduct their first review for service categories newly subject to ongoing AMRP requirements; however, after receiving several public comments from States on the 2015 final rule with comment period that State agency staff may have difficulty developing and submitting the initial AMRPs within the July 1, 2016 timeframe, we modified the policy as finalized in the 2016 final rule.[279] Specifically, we revised the deadline for submission of the initial AMRP until October 1, 2016 and we made a conforming change to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.[280] We also found that, despite this additional time, some State were still late in submitting their first AMRP to us. Therefore, we noted our belief that a proposed initial publication date of January 1, 2026, thereby providing States with approximately 2 years between the effective date of the final rule and the due date of the first comparative payment rate analysis and payment rate disclosure, would be sufficient. In alignment with the proposed payment rate transparency requirements, we proposed an alternate date if this rule is finalized at a time that

[279] 81 FR 21479 at 21479–21480.

[280] 81 FR 21479 at 21480.

does not allow for States to have a period of 2 years from the effective date of the final rule and the proposed January 1, 2026, date to publish the initial comparative payment rate analysis and payment rate disclosure. We proposed an alternative date of July 1, 2026, for the initial comparative payment rate analysis and payment rate disclosure and for the initial comparative payment rate analysis and payment rate disclosure to include Medicaid payment rates approved as of July 1, 2025, to allow more time for States to comply with the initial comparative payment rate analysis and payment rate disclosure requirements. We acknowledged that the date of the initial comparative payment rate analysis and payment rate disclosure publication would be subject to change based on the final rule publication schedule and effective date. If further adjustment is necessary beyond the July 1, 2026, timeframe to allow more time for States to comply with the payment rate transparency requirements, then we proposed that we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate.

Also, in § 447.203(b)(4), we proposed to require the State agency to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. We proposed that the comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. After publication of the 2011 proposed rule, and as we worked with States to implement the previous AMRP requirements after publication of the 2015 final rule with comment period, many States expressed concerns that the previous requirements of § 447.203, specifically those in previous § 447.203(b)(6) imposed additional analysis and monitoring requirements in the case of provider rate reductions or restructurings that could result in diminished access, were overly burdensome. As described in the 2018 and 2019 proposed rules, ''a number of States expressed concern regarding the administrative burden associated with the requirements of § 447.203, particularly those States with a very high beneficiary enrollment in comprehensive, risk-based managed care and a limited number of beneficiaries receiving care through a FFS delivery system.'' [281] [282] Additionally, from our implementation experience, we learned that the triennial due date for updated AMRPs required by previous § 447.203(b)(5)(ii) was too infrequent for States or CMS to identify and act on access concerns identified by the previous AMRPs. For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), and timely submitted its first AMRP update (the next ongoing AMRP) 3 years later, on October 1, 2019. The 2016 AMRP included data about beneficiary utilization and Medicaid-participating providers accepting new Medicaid patients from 2014 to 2015 (the most recent data available at the time the State was developing the AMRP), while the 2019 AMRP update included similar data for 2016 to 2017 (the most recent data then available). The 2019 AMRP showed that the number of Medicaid-participating providers accepting new Medicaid patients significantly dropped in 2016, and the State received a considerable number of public comments during the 30-day public comment period for the 2019 AMRP update prior to submission to us per the requirements in § 447.203(b) and (b)(2). This data lag between a drop in Medicaid-participating providers accepting new Medicaid patients in 2016 and CMS receiving the next AMRP update with information about related concerns in 2019 illustrates how the infrequency of the triennial due date for the AMRP updates could allow a potential access concern to develop without notice by the State or CMS in between the due dates of the ongoing AMRP updates. Although § 447.203(b)(7) previously required States to have ongoing mechanisms for beneficiary and provider input on access to care, and States are expected to promptly respond to concerns expressed through these mechanisms that cite specific access problems, beneficiaries and providers themselves may not be aware of even widespread access issues if such issues are not noticed before published data reveal them.

We also learned from our previous AMRP implementation experience that the timing of the ongoing AMRP submissions required by previous § 447.203(b)(5)(ii) and access reviews associated with rate reduction or restructuring SPA submissions required by § 447.203(b)(6) have led to confusion about the due date and scope of routine, ongoing AMRP updates and SPA-connected access review submissions, particularly when States were required to submit access reviews within the 3-year period between AMRP updates when proposing a rate reduction or restructuring SPA, per the requirements in previous § 447.203(b)(6). For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), then the State submitted a SPA that proposed to reduce provider payment rates for physical therapy services with an effective date of July 1, 2018, along with an access review for the affected service completed within the prior 12 months, consistent with the requirements in § 447.203(b)(6). The State's access review submission consisted of its 2016 AMRP submission, updated with data from the 12 months prior to this SPA submission, with the addition of physical therapy services for which the SPA proposed to reduce rates. Because the State submitted an updated version of its 2016 AMRP in 2018 in support of the SPA submission, the State was confused whether its next AMRP update submission was due in 2019 (3 years from 2016), or in 2021 (3 years from 2018). Based on the infrequency of a triennial due date for AMRP updates and the numerous instances of similar State confusion during the implementation process for the previous AMRPs, we identified that the triennial timeframe was insufficient for the proposed comparative payment rate analysis and payment rate disclosure.

As we considered a new timeframe for updates to the comparative payment rate analysis and payment rate disclosure to propose in this rulemaking, we initially considered proposing to require annual updates. However, we explained our belief that annual updates would add unnecessary administrative burden as annual updates would be too frequent because many States do not update their Medicaid fee schedule rates for the codes subject to the comparative payment rate analysis and payment rate disclosure on an annual basis. As proposed, the categories of services subject to the proposed comparative payment rate analysis and payment rate disclosure are for office-based visits and, in our experience, the Medicaid payment rates generally do not change much over time due to the nature of an office visit.[283] Office visits primarily

[281] 83 FR 12696 at 12697.

[282] 84 FR 33722 at 33723.

[283] We acknowledged that Medicaid primary care payment increase, a provision in the Patient Protection and Affordable Care Act (ACA, Pub. L. 111–148, as amended), temporarily raised Medicaid

include vital signs being taken and the time a patient meets with a physician or NPP; therefore, States would likely have a considerable amount of historical payment data for supporting the current payment rates for such services. Given the relatively stable nature of payment rates for office visits, our proposal aimed to help ensure the impact of the comparative payment rate analysis is maximized for ensuring compliance with section 1902(a)(30)(A) of the Act while minimizing unnecessary burden on States by holding all States to a proposed update frequency of 2 years to capture all Medicaid (and corresponding Medicare) payment rate changes.

As the proposed rule sought to reduce the amount of administrative burden from the previous AMRP process on States while also fulfilling our oversight responsibilities, we explained our belief that updating the comparative payment rate analysis and payment rate disclosure no less than every 2 years would achieve an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act. We noted our intent for the comparative payment rate analysis and payment rate disclosure States develop and publish to be time-sensitive and useful sources of information and analysis to help ensure compliance with section 1902(a)(30)(A) of the Act. If this proposal is finalized, we stated that both the comparative payment rate analysis and payment rate disclosure would provide the State, CMS, and other interested parties with cross-sectional data of Medicaid payment rates at various points in time. This data could be used to track Medicaid payment rates over time as a raw dollar amount and as a percentage of Medicare non-facility payment as established in the annual Medicare PFS final rule for a calendar year, as well as changes in the number of Medicaid-paid claims volume and number of Medicaid enrolled beneficiaries who receive a service over time. The availability of this data could be used to inform State policy changes, to compare payment rates across States, or for research on Medicaid payment rates and policies. While we noted our belief that the comparative payment rate analysis and payment rate disclosure would provide useful and actionable information to States, we explained that we did not want to overburden States with annual updates to the comparative payment rate analysis and payment rate disclosure. As we proposed to replace the previous triennial AMRP process with less administratively burdensome processes (payment rate transparency publication, comparative payment rate analysis, payment rate disclosure, and State analysis procedures for rate reductions and restructurings) for ensuring compliance with section 1902(a)(30)(A) of the Act, we stated our belief that annual updates to the comparative payment rate analysis and payment rate disclosure would negate at least a portion of the decrease in administrative burden from eliminating the previous AMRP process.

With careful consideration, we stated our belief that our proposal to require updates to the comparative payment rate analysis and payment rate disclosure to occur no less than every 2 years is reasonable. We noted our expectation that the proposed biennial publication requirement for the comparative payment rate analysis and payment rate disclosure after the initial publication date would be feasible for State agencies, provide a straightforward timeline for updates, limit unnecessary State burden, help ensure public payment rate transparency, and enable us to conduct required oversight. We solicited comments on the proposed timeframe for the initial publication and biennial update requirements for the comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(4).

Lastly, we also proposed in paragraph (b)(4) to require States to publish the comparative payment rate analysis and payment rate disclosure consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. Paragraph (b)(1) would require the website developed and maintained by the single State Agency to be accessible to the general public. We proposed States utilize the same website developed and maintained by the single State Agency to publish their Medicaid FFS payment rates and their comparative payment rate analysis and payment rate disclosure. We solicited comments on the proposed required location for States to publish their comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(4).

In § 447.203(b)(5), we proposed a mechanism to ensure compliance with paragraphs (b)(1) through (b)(4). Specifically, we proposed that, if a State fails to comply with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of proposed § 447.203, including requirements for the time and manner of publication, that, under section 1904 of the Act and procedures set forth in regulations at 42 CFR part 430 subparts C and D, future grant awards may be reduced by the amount of FFP we estimate is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of proposed § 447.203 for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. We also proposed that unless otherwise prohibited by law, FFP for deferred expenditures would be released after the State has fully complied with all applicable requirements. We explained that this proposed enforcement mechanism is similar in structure to the mechanism that applies with respect to the Medicaid DSH reporting requirements in § 447.299(e), which specifies that State failure to comply with reporting requirements will lead to future grant award reductions in the amount of FFP CMS estimates is attributable to expenditures made for payments to the DSH hospitals as to which the State has not reported properly. We proposed this long-standing and effective enforcement mechanism because we believed it is proportionate and clear, and to remain consistent with other compliance actions we take for State non-compliance with statutory and regulatory requirements. We solicited comments on the proposed method for ensuring compliance with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements, as specified in proposed § 447.203(b)(5).

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comparative Payment Rate Analysis Comments and Responses

Comment: Among comments received on the comparative payment rate analysis, the majority of commenters generally supported the proposal to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain categories of services. These commenters specifically supported the proposed categories of services, comparing only base payment rates,

physician fees for evaluation and management services (Current Procedural Terminology codes 99201–99499) and vaccine administration services and counseling related to children's vaccines (Current Procedural Terminology codes 90460, 90461, and 90471–90474). This provision expired on December 31, 2014. *https://www.macpac.gov/wp-content/uploads/2015/03/An-Update-on-the-Medicaid-Primary-Care-Payment-Increase.pdf.*

breakdown of Medicaid payment rates by population (pediatric and adult), use of Medicare non-facility rates as a benchmark for comparing Medicaid rates, and number of Medicaid services as a data element in the comparative payment rate analysis. Commenters in support of the comparative payment rate analysis agreed with CMS that the analysis requirement would help to ensure necessary information, specifically Medicaid payment rates and the comparison to Medicare, is available to CMS for ensuring compliance with section 1902(a)(30)(A) of the Act and to interested parties for raising access to care concerns through public processes.

However, a couple of commenters expressed opposition to the proposed comparative payment rate analysis. Commenters in opposition stated the proposed comparative payment rate analysis requirements would be administratively burdensome on States and create challenges for States in benchmarking services to Medicare because Medicare uses a rate setting methodology that is different from each State's Medicaid program. These commenters expressed concerns about the burden associated with the comparative payment rate analysis, specifically about further burden on States that do not use the same procedure/diagnostics codes or same payment methodologies as Medicare, as well as data challenges to stratify State payment rates by population, provider type, and geographic location, and challenges of comparing community mental health center payment rates to the Medicare equivalent.

Response: We appreciate the commenters' support of the comparative payment rate analysis at § 447.203(b)(3)(i). We are finalizing the comparative payment rate analysis provisions as proposed apart from some minor revisions that ensure clarity and consistent terminology throughout § 447.203(b), as well as update the name of ''outpatient behavioral health services'' to ''outpatient mental health and substance use disorder services'' and the compliance timeframe, as discussed earlier in this section. We list and describe the specific revisions we made to the regulatory language for the comparative payment rate analysis provision at § 447.203(b)(2) through (b)(5) at the end of this section of responses to comments.

We disagree with commenters regarding burden of the comparative payment rate analysis and challenges benchmarking services to Medicare. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States have for compliance with this final rule. Specifically for the comparative payment rate analysis, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (2) for the requirement that States break down their payment rates by geographical location, as applicable, States have the flexibility to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. Additionally, we are providing an example list that defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023 and an illustrative example of a compliant comparative payment rate analysis (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We do not expect States to experience excessive burden or challenges in benchmarking services to Medicare because we will issue subregulatory guidance prior to the effective date of this final rule, including a hypothetical example list of the CMS-published list of E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023, where all codes on the CMS-published list of E/M CPT/HCPCS codes have an existing Medicare payment rate. By ensuring there is an existing Medicare payment rate for States to compare their Medicaid payment rate to and providing States with information about where and how to find the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for these codes to include in their analysis (that is, through Excel file downloads of the Medicare PFS Relative Value Files),[284] we do not expect States to face challenges with identifying the applicable Medicare benchmark rates.

Regarding States that do not use same procedure/diagnostics codes as Medicare, as described in the proposed rule, E/M CPT/HCPCS codes are comprised of primarily preventive services which are generally some of the most commonly billed codes in the U.S.,[285] therefore, we do not believe there will be issues with States not using the same procedure/diagnostics codes as Medicare. However, we recognize that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use the exact code included in the CMS-published list of E/M CPT/HCPCS codes, then we expect the State to review the CMS-published list of E/M CPT/HCPCS codes and identify which of their codes are most comparable for purposes of the comparative payment rate analysis. We anticipate States may need to review code descriptions as part of the process of identifying which codes on the CMS-published list of E/M CPT/HCPCS codes are comparable to the codes that States utilizes.

Regarding States that expect to experience challenges benchmarking services to Medicare because they do not use the same payment methodologies as Medicare, while Medicare and State Medicaid agencies may use different methodologies to determine the rate published on their fee schedules, the comparative payment rate analysis only requires the base Medicaid FFS fee schedule payment rates as published on the State's fee schedule and Medicare's rate as published on the PFS for a particular code to be published in the analysis. The methodology to determine the payment rate is not relevant to the comparative payment rate analysis, therefore, having different methodologies to determine the rate does not affect a States' ability to comply with the comparative payment rate analysis requirements. Under the comparative payment rate analysis requirements we are finalizing in this final rule, Medicare rates serve as a benchmark to which States will compare certain of their base Medicaid FFS fee schedule payment rates to

[284] 88 FR 27960 at 28012.

[285] 88 FR 27960 at 28009.

inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act.

Regarding commenters' concerns about data challenges to stratify State payment rates by population, provider type, and geographic location for the comparative payment rate analysis, we acknowledge that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we proposed and are finalizing language noting ''if the rates vary'' and ''as applicable'' in the regulatory text. Therefore, States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location will not need to list varied rates based on factors that the State does not use in its rates. For example, a State that pays different rates by population (pediatric and adult) but does not vary the rates by provider type or geographic location will list separate payment rates for services furnished to a pediatric and to an adult beneficiary, but will not list separate rates based on provider type or geographical location. If the State pays a single Statewide payment rate for a single service, the State will only include the State's single Statewide payment rate in the comparative payment rate analysis. For States that do pay varied payment rates by population (pediatric and adult), provider type, and geographical location, in accordance with § 430.10 and given that States are the stewards of setting and maintaining Medicaid FFS payment rates, States are required to maintain sufficient records about current payment rates, including when payment rates vary, to enable them to meet the comparative payment rate analysis requirements of this final rule.

Regarding the commenter's concerns about comparing community mental health center payments to Medicare rates, we would like to clarify that mental health services provided in a facility-based setting, such as FQHC, RHC, CCBHC, or clinics (as defined in § 440.90) are excluded from the comparative payment rate analysis due to the challenges we expect States to face in disaggregating their rates (including PPS rates paid to FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates and all-inclusive per-visit rates, encounter rates, per visit rates, or provider-specific rates paid to clinics (as defined in § 440.90)) for comparison to Medicare, as discussed in the proposed rule.[286]

[286] 88 FR 27960 at 28011–28012.

Comment: We received a comment requesting clarification about the entity responsible for publishing the comparative payment rate analysis.

Response: The State agency is required to publish a hyperlink where the comparative, as well as the payment rate disclosure and payment rate transparency publication, on the State Medicaid agency's website. As finalized in this rule, § 447.203(b)(3) requires that States' comparative payment rate analysis, as well as payment rate disclosure, must be published consistent with the publication requirements in paragraphs (b)(1) and (b)(1)(ii). Paragraph (b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' As discussed in an earlier response to comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require that ''[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.'' in § 447.203(b)(1)(ii).

Comment: One commenter requested clarification regarding how the comparative payment rate analysis will be organized, particularly if the FFS rates included in the analysis would be organized by CPT code.

Response: As finalized by this rule, § 447.203(b)(3)(i) requires that ''State[s] must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS . . .'' As such, the publication is required to be organized at the CPT level. However, to the extent there are differences in a State's rates based on population (pediatric and adult), provider type, and geographical location, the publication may need to have multiple CPT-level rate comparisons to account for each differing rate.

Comment: One commenter raised concerns regarding the accessibility of the comparative payment rate analysis due to the extensive amount of data, which may be overwhelming and difficult for individuals to understand, for example individuals with disabilities and those who use screen readers. The commenter recommended that CMS require the analysis and disclosure be contained in a designated website, rather than linked from the State Medicaid agency's website to avoid creating potential confusion. They further recommended CMS require States include plain language descriptions of the published payment rate data to ensure the analysis is accessible for individuals with disabilities.

Response: We understand the concern that the amount of data in the analysis could prove overwhelming to some individuals. However, we believe it is important for these data to be easily reached for those interested parties that are trying to locate it. Transparency, particularly the requirement that States must publicly publish their payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties. Therefore, as finalized in this rule, § 447.203(b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' As discussed in an earlier response to comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require at § 447.203(b)(1)(ii) that the website where the State agency publishes its Medicaid FFS payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.

As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. We invite States to reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant comparative payment rate analysis might look like, that will be issued prior to the effective date of this final rule.

Comment: A couple of commenters suggested that the proposed breakdown of the comparative payment rate analysis would result in an

overwhelming volume of information for the average individual viewing the data. One commenter suggested requiring States to report the aggregate fee schedule rate, instead of breaking down a State's payment rates by categories of services in addition to population, provider type and geographic location to ensure data is accessible and meaningful to someone viewing the data.

Response: We understand the commenters' concerns about the potential for the comparative payment rate analysis to contain a large amount of information. However, the level of detail we are requiring will afford States, CMS, and the public the best opportunity to assess individual rates and how they might impact access to certain services. Our hope is that the requirements and guidance around the elements to include, and the consistency this will create across States, will make the data readily navigable and understandable, even though a high volume of information may need to be presented to account for the array of services subject to the comparative payment rate analysis requirement and the potential complexity of the State's payment rate structure.

We assume the commenter who suggested an aggregated fee schedule rate meant we should only require States publish a single Statewide payment rate or a calculated Statewide average Medicaid payment rate if they do have varying payment rates for a service by population (pediatric and adult), provider type, and/or geographic location. We are not adopting this suggestion because only requiring an aggregated fee schedule rate would lose the opportunity for States, CMS, and the public to contextualize payment rates and how they might be impacting access for different populations in different geographical areas, or for beneficiaries seeking services from particular provider types. However, we note that States have the flexibility to add an aggregated fee schedule rate in addition to breaking down a State's payment rates for a given service by population (pediatric and adult), provider type, and geographic location, as applicable, with their comparative payment rate analysis if they so choose. If a State utilizes this flexibility to include this or optional additional information, then required data elements in § 447.203(b)(2) through (3) must be listed first on the State's website to ensure the analysis presents payment rate information in a clear and accurate way, particularly for States that do pay varied rates based on population (pediatric and adult), provider type, and/or geographic location and opted to include an aggregated fee schedule rate (that is, a calculated Statewide average Medicaid payment rate).

The previous AMRP process established a transparent data-driven process to measure access to care in States; however, during the implementation period, we found that States produced varied AMRPs that were difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. With this final rule, we are focusing on payment rate transparency and streamlining information States are required to publish. Therefore, we expect the comparative payment rate analysis to be easier to understand and more consistent across States than the previous AMRPs.

Comment: A few commenters suggested narrowing the scope of the comparative payment rate analysis to a representative subset of services or commonly used services with a Medicare equivalent. On the other hand, one commenter stated that limiting the scope of the comparative payment rate analysis to E/M codes would not be adequate to meaningfully assess access to care for all services under the proposed categories of services.

Response: We appreciate the commenters' suggestions on the scope of the comparative payment rate analysis. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes to be published no later than July 1, 2025, will contain a finite number of E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. While the commenters did not specify their recommendation for what a representative subset of services would include or how they would identify commonly provided services with a Medicare equivalent, we believe the criteria we used to select the E/M CPT/HCPCS codes for the comparative payment rate analysis [287] fulfills these commenters' suggestion for a representative set of commonly provided services with Medicare payment rates for comparison. We believe the categories of services included in the rule (primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services) are a representative subset of Medicaid services available to beneficiaries that are of great importance to overall beneficiary health, as described in the proposed rule.[288] Additionally, E/M CPT/HCPCS codes are some of the most commonly billed codes and one of the criteria in the CMS-published list of the E/M CPT/HCPCS codes is that the Medicare PFS has a payment amount on the fee schedule, therefore, we believe our list of codes includes commonly used services with a Medicare equivalent payment rate.

Also as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the comparative payment rate analysis in paragraph (b)(3)(ii)(B) of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the comparative payment rate analysis. We would also like to clarify that while prospective payment system rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these rates are effectively excluded from the comparative payment rate analysis because of the criteria we discussed in the proposed rule that we used to identify which CPT/HCPCS codes would be subject to the analysis (that is, the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis).[289] Prospective payment system rates are generally used to pay for institutional services (for example, hospitals and nursing facilities) where E/M services are not provided. Prospective payment system rates are also not listed on the Medicare PFS because they do not pay

[287] 88 FR 27960 at 28008.

[288] 88 FR 27960 at 28003.

[289] 88 FR 27960 at 28008.

for a single code, and therefore, they would not have a code or a payment rate on the PFS. Also, as discussed in an earlier response to comments, PPS rates for FQHCs and RHCs are not subject to the payment rate transparency publication requirement under § 447.203(b)(1). Rather than further broadening the services subject to the comparative payment rate analysis requirement, we want our initial focus of this rulemaking to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues.

We disagree with the commenter that our scope of services subject to the comparative payment rate analysis will not provide a meaningful assessment of access. To reemphasize, we believe this list of codes, including primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services, are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.[290] We acknowledge that the code list is limited to services delivered in an ambulatory setting, such as a physician's office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule. Therefore, the code list for the comparative payment rate analysis excludes services delivered in a facility setting and/or services States pay for using a prospective payment system, for example hospitals, nursing facilities, FQHCs, and RHCs; however, we believe these limitations are appropriate to balance administrative burden on States and our enforcement responsibilities. As previously discussed, we believe that asking States to disaggregate their prospective payment system rates for facility-based services to compare to Medicare's prospective payment system rates often would be challenging for States. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters suggested aligning the proposed categories of services with Medicaid service categories as defined in statute and regulation to minimize confusion and ambiguity about the services subject to the comparative payment rate analysis. Another commenter suggested, rather than requiring a specified set of services, that CMS require the comparative payment rate analysis based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program).

Response: We understand commenters' concerns about possible confusion of the categories of services subject to the comparative payment rate analysis that do not align directly with a Medicaid services category. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes actually subject to the comparative payment rate analysis will be published no later than July 1, 2025. We believe this list of codes will eliminate any confusion and ambiguity commenters expressed in response to the proposed rule because it will contain the actual E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. We will only be including codes that satisfy all the defined criteria set forth in this rule. This list will be updated every other year after 2025, that is, July 1, 2027, 2029, so on and so forth. We expect States to review the CMS-published list of the E/M CPT/HCPCS codes to identify the base Medicaid FFS fee schedule payment rate as specified in § 447.203(b)(3)(i)(B) that is required to be included in the comparative payment rate analysis.

We are not adopting the commenter's suggestion to require the comparative payment rate analysis be based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program), rather than requiring a specified set of services. In the comparative payment rate analysis, we are striving for consistency and comparability between States and Medicare, therefore, we have decided to require States use the same categories of services and CMS published list of E/M CPT/HCPCS codes for the analysis.

Comment: A couple of commenters suggested alternative terms for the categories of services in the proposed rule. One commenter recommended using the terms ''substance use disorder and mental health services'' in place of ''behavioral health services'' and requiring the comparative payment rate analysis include separate analyses for each condition. Another commenter suggested using gender-inclusive language such as ''reproductive and sexual health services'' in place of ''obstetrical and gynecological services'' as a category of services in the comparative payment rate analysis.

Response: We appreciate the commenters' suggestions. We understand and appreciate the commenter's request for further granularity in the comparative payment rate analysis by specifying ''substance use disorder and mental health services'' in place of ''behavioral health services.'' We have decided to revise the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalize it as ''Outpatient mental health and substance use disorder services.'' While this revision does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment rate analysis, this revision does ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this **Federal Register**) for consistency across Medicaid FFS and managed care delivery systems and reflects a more granular level of service description as suggested by the commenter.

We agree with the importance of gender-inclusive language, where appropriate. However, current medical and procedural terminology generally still uses the terminology ''obstetrical and gynecological services.'' We determined consistent language would provide interested parties the most clarity. Additionally, we selected obstetrical and gynecological services as a category of service due Medicaid's key role in providing and paying for maternity-related services for pregnant women during a maternal health crisis in the US.[291] We acknowledge that using the term ''reproductive and sexual health services'' would be inclusive of more services, that is, male reproductive services in addition to pregnancy and female reproductive services. However, if we were to utilize the term ''reproductive and sexual health

[290] 88 FR 27960 at 28003.

[291] 88 FR 27960 at 28004.

services'' then this would expand the number of services that would be subject to comparative rate analysis and increase burden on States complying with the analysis. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Therefore, we are finalizing ''obstetrical and gynecological services'' as a category of service in § 447.203(b)(2)(ii) subject to the comparative payment rate analysis. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters raised concerns about inpatient behavioral health services not being a category of service in the comparative payment rate analysis. One of those commenters disagreed with CMS' justification that including inpatient behavioral health services would be duplicative of the information captured through UPL demonstrations because UPL demonstrations do not include the same level of analysis as proposed in the comparative payment rate analysis. In particular, the commenter stated that UPL demonstrations do not ensure hospital base payments are adequate, do not track if Medicaid payments align with Medicare payment rate increases, and the new supplemental payment reporting requirements established by the CAA, 2021 focus on supplemental payments, rather than base payments. Additionally, one commenter recommended that, if inpatient behavioral health services are not subject to the comparative payment rate analysis, CMS take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care.

Response: We understand the commenters' concerns about excluding inpatient behavioral health services from the categories of services subject to the comparative payment rate analysis. We acknowledge the importance of inpatient behavioral health services in the spectrum of behavioral health services for which coverage is available under the Medicaid program. As discussed in the proposed rule, we recognize that Medicaid plays a crucial role in mental health care access as the single largest payer of these services with a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to mental health and substance use disorder services.[292] In this final rule, we are revising the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalizing it as ''Outpatient mental health and substance use disorder services.'' While the scope of the comparative payment rate analysis requirement is limited to outpatient mental health and substance use disorder services, to the extent States pay for inpatient behavioral health services (including inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals) with a Medicaid FFS fee schedule payment rate that falls within the meaning of this rule, as discussed in an earlier response to comments in this section, then those payment rates would be subject to the payment rate transparency publication. In addition to subjecting certain inpatient behavioral health payment rates to the payment rate transparency publication requirement, we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL demonstrations and supplemental payment reporting requirements under section 1903(bb) of the Act. We recognize UPL data are not an exact duplicate of the data required under the policies we are finalizing in this rule. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. Although the UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act represent a different array of data, they still afford us an opportunity for payment oversight. Therefore, we chose to focus on services and rates not covered by those requirements.

We disagree with the commenter that UPL demonstrations do not ensure hospital base payments are adequate and do not track if Medicaid payments align with Medicare payment rate increases. We began requiring annual UPL demonstrations in 2013 to ensure CMS and States have a better understanding of the variables surrounding rate levels, supplemental payments and total providers participating in the Medicare and Medicaid programs and the funding supporting each of the payments subject to UPL demonstrations.[293] UPL demonstrations are a comparison of total Medicaid payments for a particularly benefit category to a reasonable estimate of what Medicare would have paid. Therefore, UPL demonstrations fundamentally track if Medicaid payments align with Medicare payment rates at an aggregate level and provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a payment limit, or ceiling, for economic and efficient. We do acknowledge that the new supplemental payment reporting requirements under section 1903(bb) of the Act focus on supplemental payments, rather than base payments; however, base payment data continues to be collected through UPL demonstrations, providing us, in the aggregate, with detailed information about both base and supplemental payments for hospitals.

Additionally, the comparative payment rate analysis utilizes Medicare rates as a benchmark to which States will compare their Medicaid FFS fee schedule payment rate to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We are not requiring States to meet a threshold percentage of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year or align with Medicare payment rate increases.

We acknowledge the commenter's request for CMS to take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of

[292] 88 FR 27960 at 28004.

[293] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

assessing access to care issues. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are committed to helping States and their providers undertake efforts to improve transitions and improve medical and LTSS coordination by providing technical assistance, resources, and facilitating the exchange of information about promising practices of high quality, high impact, and effective care transition models and processes and we encourage States to review existing resources about improving care transitions on *Medicaid.gov*.[294]

Comment: Some commenters submitted comments about behavioral health services as a category of service in the comparative payment rate analysis. A few commenters suggested particular or additional categories of services for behavioral health services, including inpatient behavioral health services, substance use disorder services, mental health services, intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, and specialist services provided to individuals with chronic diseases and disabilities. These commenters also suggested including codes outside of the E/M category, such as ''H'' HCPCS codes that psychologists, social workers, and marriage and family therapists often bill to ensure a comprehensive analysis of behavioral health services in the comparative payment rate analysis.

Response: We appreciate commenters' suggestion for the comparative payment rate analysis. As stated previously, we are excluding inpatient behavioral health services because existing UPL and supplemental payment reporting requirements under section 1903(bb) of the Act provide for payment oversight for inpatient behavioral health services, and with the provisions of this final rule, we chose to focus on services and payment rates not covered by those requirements. Additionally, we are not considering behavioral health services, now called outpatient mental health and substance use disorder services in this final rule, outside the E/M category as suggested by commenters because E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. If we were to expand outside of E/M category of codes, then it is possible Medicare may not have rates established on the Medicare PFS for States to compare their base Medicaid FFS fee schedule payment rates too in the comparative payment rate analysis. Based on the criteria used to narrow the scope of the comparative payment rate analysis, we are requiting that the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis as well as the code must be included in the BETOS Classification System which only includes Psychotherapy—Group and Psychotherapy—Nongroup (family) under the E/M (category), Behavioral Health Services (subcategory). Psychotherapy is a type of treatment, or service, that can help individuals experiencing a wide array of mental health conditions and emotional challenges, including substance use disorder and mental health.[295] While the CMS published list of E/M CPT/HCPCS codes will not specifically include intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, specialist services provided to individuals with chronic diseases and disabilities, or H codes for Alcohol and Drug Abuse Treatment [296] as suggested by commenters, we believe the services included on the CMS published list of E/M CPT/HCPCS codes are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.[297] As previously discussed, the CMS published list of E/M CPT/HCPCS codes narrows the scope of the comparative payment rate analysis to selected services delivered in an ambulatory setting, such as a physician's office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule to balance administrative burden on States and our enforcement responsibilities. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the exclusion of facility-based services from the comparative payment rate analysis. These commenters requested CMS consider additional provisions for services that are delivered by facility-based providers, which are often paid via an encounter rate, reimbursement of actual cost, or cost-based payment methodologies. One commenter suggested requiring States that pay for behavioral health services using cost-based payment methodologies publish the provider's payment rate compared to provider's actual incurred cost because States are already collecting this information from providers as it is necessary for the State's cost-based payment methodology.

Response: We appreciate the commenter's suggestions. We assume by encounter rate that the commenters were referring more broadly to PPS rates paid to both institutional facilities, such as hospitals and nursing facilities which are often paid encounter or per diem rates, as well as non-institutional facilities, such as FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates, as discussed in detail in an earlier response to comments in this section. We did not propose and are not finalizing in this rule the requirement that States disaggregate each of their PPS rates (including encounter, per diem, per visit, and provider-specific rates) and services covered in each rate to compare to Medicare's prospective payment system rates when Medicare pays a prospective payment system rate for the same service. Likewise, we also did not propose and are not finalizing in this rule the requirement that States publish cost reports or provider's unique cost information when the State's methodology is reimbursement of actual cost or cost-based methodologies and services covered in the reimbursement methodology to compare to actual incurred cost. Therefore, any policies that require States to disaggregate each of their PPS rates and services covered in each PPS rate or publish cost reports or provider's unique cost information in order to compare to Medicare's prospective payment system rates or the commenter's suggestion to compare to actual incurred cost, would be challenging for States because we would require a different methodology, policies, and oversight relative to the comparative payment rate analysis, as

[294] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/improving-care-transitions/index.html.*

[295] *https://www.psychiatry.org/patients-families/psychotherapy.*

[296] *https://www.aapc.com/codes/hcpcs-codes-range/.*

[297] 88 FR 27960 at 28003.

discussed in the proposed rule.[298] As we are seeking an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act, requiring States to publish cost-based Medicaid payments as well as actual, incurred cost for each unique provider would impose more burden on States that was not accounted for in the proposed rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Several commenters recommended changes to the analysis, such as additional categories of services or revisions to the proposed categories of services subject to the comparative payment rate analysis. While some commenters generally recommended expanding the categories of services, including all mandatory Medicaid services, other commenters recommended specific additional categories of services, provider types, or costs such as supplies. Those recommendations included: physician specialist services and specialty/specialist care (for example, cancer care); subspecialty services (for example, pediatric ophthalmology); services provided by NPPs; services delivered in clinics and other settings; prosthetic supplies (for example, ostomy and urological supplies), home health services (for example, homemaker and home health aide), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.); dental and oral health services (including pediatric dentistry), ground emergency medical transportation services; cell and gene therapies; hospital and emergency department services; vaccine administration services; and habilitation and rehabilitation services provided by physical therapists. Commenters also suggested processes to add services when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified.

Response: We thank the commenters for the many recommendations for additional or alternate categories of service. In order to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same), we are finalizing this rule with a narrow scope of categories of services subject to the comparative payment rate analysis and not including additional categories of services suggested by commenters. As discussed in the proposed rule, we chose primary care services, obstetrical and gynecological services, and outpatient behavioral health services (which we are finalizing as outpatient mental health and substance use disorder services) because they are critical medical services and of great importance to overall beneficiary health.[299] Primary care providers often deliver preventative health care services, write referrals or recommendations to schedule an appointment with physician specialists, and write orders for lab and x-ray services and prescriptions that a beneficiary would not be able to access without the primary care provider, therefore, access to a primary care provider is often a gateway to accessing other care. Obstetrical and gynecological providers and behavioral health providers also deliver preventive services respective to their field, such as well-woman visits and screenings for behavioral health conditions (such as alcohol disorders, anxiety, and eating disorders), respectively. As described in the proposed rule, the U.S. is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and mental health and substance use disorder services at the forefront.[300]

We clarify that we did propose to include in the comparative payment rate analysis a couple of the services commenters suggested: care delivered by NPPs, and sexual and reproductive health services (to the extent these are included within the category of obstetrical and gynecological services). If a State's base Medicaid FFS fee schedule payment rate varies by provider type for a particular code subject to the comparative payment rate analysis, then the payment rates must be separately identified by provider type, including, but not limited to, physician, nurse practitioner, and physician assistant, as specified in § 447.203(b)(3)(i)(B). While we are not including the broader category of sexual and reproductive health services, obstetrical and gynecological services are one of the categories of services subject to the analysis. Lastly, homemaker and home health aide services are subject to the payment rate disclosure, but not the comparative payment rate analysis because of a lack of comparable Medicare payment rate.

Finally, we are not including the following services suggested by commenters in the comparative payment rate analysis: services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.) to the extent these are not included within the category of obstetrical and gynecological services, hospital and emergency department services, and medical supplies. Our current access strategy focuses broadly on Medicaid FFS fee schedule payment rates for outpatient practitioner services. As described in the proposed rule, encounter rates (generally based on total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter) are typically paid to facilities, such as hospitals, FQHCs, RHCs, and clinics, and proposing States demonstrate the economy and efficiency of their encounter rates would be an entirely different exercise to the comparative payment rate analysis.[301] Therefore, we are not including services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)) or hospital and emergency department services in the comparative payment rate analysis. As previously stated, obstetrical and gynecological services are one of the categories of services subject to the analysis, but we are not including the broader category of sexual and reproductive health services because our focus in this rule is ensuring access to care to services that can most directly respond to the maternal health crisis occurring the U.S. As Medicaid plays a key role in providing and paying for maternity-related services for pregnant women, obstetrical and gynecological services generally represent the services received before, during, and after pregnancy.[302]

[298] 88 FR 27960 at 28012.

[299] 88 FR 27960 at 28003.

[300] 88 FR 27960 at 28004.

[301] 88 FR 27960 at 28012.

[302] 88 FR 27960 at 28004.

We note that one of the criteria used to narrow the CMS published list of E/M CPT/HCPCS codes requires that the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for obstetrics and gynecological services; this includes prostate cancer screenings (G0102). Additionally, our current access strategy focuses on Medicaid FFS fee schedule payment rates for the provision of outpatient practitioner services, rather than medical supplies.

We are also not including the suggestion to create processes to add services to the comparative payment rate analysis when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified, because these situations will generally trigger the processes in § 447.203(c) which include similar requirements to the comparative payment rate analysis (that is, requiring State publish or submit information to CMS about Medicaid payment rates, number of Medicaid beneficiaries receiving services, and number of Medicaid services furnished/paid claims). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters submitted specific CPT/HCPCS codes and services for CMS' consideration when developing the CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis. These codes and services included specific obstetric codes including surgical procedures billed by providers of obstetric-gynecological services, reproductive care codes, pediatric ophthalmology codes including surgical procedures and clinical evaluations, vaccine administration, and other E/M codes. We also received requests to require analysis of the most frequently billed surgical codes for obstetrical-gynecological services, as well as behavioral health services that do not have E/M codes or a Medicare analog.

Response: We appreciate the commenters' suggestions. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. Several of the commenter's suggested codes are included in the example list; however, this list is subject to change when the first CMS-published list of the E/M CPT/HCPCS codes subject to the comparative payment rate analysis for CY 2025 is published no later than July 1, 2025. Of the specific codes suggested by commenters, we can confirm that the following codes would be included in the CMS published list of E/M CPT/HCPCS codes subject to the analysis, if it were in effect for CY 2023: CPT 59400–59612, 58300–58301, 59120–59160, 59812–59857, 99401–99404, 90832–90853, 90791–90792, 96158, and 96165. Because of the criteria outlined in the proposed rule intended to narrow the scope of codes subject to the comparative payment rate analysis, CPT 59852 and 59857, peer support services, psychosocial rehab, and assertive community treatment, as well as vaccine administration codes are excluded from the comparative payment rate analysis due to their classification outside of the BETOS Classification System as E/M codes that are primary care, obstetrical and gynecological services, or outpatient mental health and substance use disorder services. Additionally, pediatric ophthalmology surgical procedures and the top 10 surgical codes billed by obstetrician-gynecologists to the Medicaid program are excluded from the analysis because one of the criteria used to narrow the scope of the comparative payment rate analysis was that for a code to be included on the CMS published list of E/M CPT/HCPCS codes, the code has to be included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule). E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. Therefore, we narrowed the scope of codes to just E/M codes and surgical codes fall outside of this scope. As described in the proposed rule, the following criteria were used to identify the E/M CPT/HCPCS codes to be included in the comparative payment rate analysis: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis. As discussed in an earlier response to comments in this section, the revision from outpatient behavioral services to outpatient mental health and substance use disorder services does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment rate analysis. While the payment rate transparency publication does not require a comparison to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, it does require transparency of Medicaid payment rates by requiring States publicly publish all Medicaid FFS fee schedule payment rates, which will often include a number of the services requested by commenters to be subject to the comparative payment rate analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Given that our work to better ensure access in the Medicaid program is

ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters suggested additional data elements and analyses for the comparative payment rate analysis. A couple of commenters suggested data elements specifically for comparing FQHC and non-FQHC settings: number of primary care claims provided in FQHC and non-FQHC settings, number of patients served in FQHC and non-FQHC settings, total spending in FQHC and non-FQHC settings. Commenters also suggested data elements specifically for nursing facility payments, such as comparing payments to total cost of care, examining the relationship between payments and quality of care and health disparities in nursing facilities, and trend data on medical inflation and practice costs.

Response: We appreciate commenters' suggestions for the comparative payment rate analysis. As described in the proposed rule, we excluded encounter rates often paid for facility-based services, including FQHC and nursing facility services, from the comparative payment rate analysis due to the challenges we expect States to face in disaggregating encounter rates for comparison to Medicare. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their comparative payment rate analysis if they so choose. We would encourage any State choosing to disclose additional comparative payment rate analysis for facility-based services also to publish detailed information about the State's methodology for disaggregating its payment rates, as applicable, and identifying analogous Medicare payment rates for comparison.

Comment: We received a few comments in response to our consideration of requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We received one comment that opposed requiring the unique number of claims and beneficiaries while a few commenters encouraged CMS to require this data element to improve the collection and quality of data on Medicaid service utilization.

Response: We appreciate the commenters' feedback. As described in the proposed rule, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year.[303] Upon further review, we determined the request regarding unique beneficiaries was inaccurately framed, as a beneficiary would not duplicate. Nevertheless, we decided not to require States to identify the number of Medicaid-paid claims (bold added to highlight the difference between data element we considered and the data element we are finalizing in this rule). Instead, we are finalizing the comparative payment rate analysis to require States to include the number of Medicaid-paid claims (which may duplicate codes) and the number of Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid FFS fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section, as proposed. Although we do see value in obtaining unique, or deduplicated, claims counts, we did not propose this data element because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. To illustrate, and to correct the example provided in the proposed rule, for a beneficiary with 6 visits to their primary care provider in a calendar year where the provider bills 6 claims with CPT code 99202 for the same beneficiary, the State is required to report 6 claims for CPT code 99202. The beneficiary count would remain 1. If 6 separate beneficiaries each received a service and the provider bills CPT code 99202 for all of them, the claims count would still be 6, but the beneficiary count would also be 6. Given that our access work is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

Comment: One commenter recommended CMS allow States to have a 6-month period to account for lags in claims reporting by providers and States paying providers' claims for codes required to be in the comparative payment rate analysis.

Response: We believe the commenter was referring to the claims run out period where a State may not have received all of their providers' claims for the codes subject to the comparative payment rate analysis by the time the analysis is due, which could result in an undercount of both claims for services furnished and beneficiaries who received a service during the year. In response to comments and based on the timing of this final rule, we have revised the timeframes for the comparative payment rate analysis. The regulatory language finalized in this rule at paragraph (b)(4) now states the following, ''[t]he State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.'' Therefore, for the initial comparative payment rate analysis, States will need to include their claims and beneficiary data required in paragraph (b)(3)(i)(E) for CY 2025 in the analysis to be published no later than July 1, 2026. This timing provides a 6-month period for claims run out, as requested by the commenter.

Comment: One commenter raised concerns regarding the requirement to separately identify the base Medicaid FFS fee schedule payment rate by provider type without the inclusion of an additional analysis to assess whether the State's rate setting process complies with the Mental Health Parity and Addiction Equity Act (MHPAEA or the Parity Act).

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. Parity requirements do not apply to MH or SUD benefits for enrollees who receive only Medicaid non-ABP FFS State plan coverage; however, CMS encourages States to comply with parity for all Medicaid beneficiaries.[304] [305] Congress has not extended MHPAEA requirements to non-ABP Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid agency

[303] 88 FR 27960 at 28016.

[304] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/parity/index.html.*

[305] *https://www.medicaid.gov/sites/default/files/2023–09/cmcs-mental-health-parity-092023.pdf.*

partners to ensure their non-ABP FFS benefits voluntarily comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with overarching requirements under section 1902(a)(30)(A) of the Social Security Act ''to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.'' This review thus helps promote the fundamental objective of MHPAEA to ensure access to mental health and substance use disorder treatment services.

Comment: One commenter requested clarification about the Medicare rate to be used in the comparative payment rate analysis.

Response: As finalized by this rule, § 447.203(b)(3)(i)(C) requires States to compare their base Medicaid FFS fee schedule payment rate to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the base Medicaid FFS fee schedule payment rate rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. That is, States are required to compare their base Medicaid FFS fee schedule payment rates to the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. As described in the proposed rule, we expected States to source the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year from the published Medicare fee schedule amounts on the Medicare PFS through one or both of the following sources: the Physician Fee Schedule Look-Up Tool [306] on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value Files [307] for the relevant calendar year from *cms.gov*. We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first by downloading and reviewing the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non facility payment rates. Prior to the effective date of this final rule, we will issue subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis. Therefore, for the initial comparative payment rate analysis, after Medicare's publication of the CY 2025 Physician Fee Schedule rate by November 2024, we encourage States to begin sourcing Medicare non-facility payment rates as established in the annual Medicare PFS final rule for CY 2025 by downloading and reviewing the CY 2025 Medicare PFS Relative Value with Conversion Factor File from cms.gov.[308]

Comment: While we received overwhelming support from commenters for proposing to use Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis, some commenters expressed concerns or suggested alternative comparison points. Many commenters stated that Medicare payment rates are low and have not kept up with inflation; therefore, these commenters stated that Medicare is not an appropriate comparison point for payment rates for many services, including dental, anesthesiology, and physical therapy. Some commenters stated that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations (for example, Medicare's limited coverage of pediatric services, behavioral health services (including substance use disorder and mental health care), and dental care) which results in fundamentally different payment rate methodologies. A few commenters expressed that Medicare is not a perfect comparator and should not be used as the standard for adequacy of Medicaid payment rates, but agreed it was a useful starting place because Medicare rates are publicly available. One commenter stated that States aligning Medicaid payment rates with Medicare rates for psychiatrist services as well as decreasing administrative burden could help encourage more providers to enroll in Medicaid.

Many commenters who opposed using Medicare non-facility rates for the comparative payment rate analysis offered alternative suggestions for States to compare their payment rates to. Several commenters suggested private payer rates. One commenter suggested Medicaid rates from geographically similar States that CMS identifies for States. A few commenters suggested rates from Federal or State employee dental plans. Two commenters suggested FAIR Health data [309] (particularly for dental services). One commenter suggested Medicare Advantage for dental, vision, and hearing services. We also received a comment suggesting CMS develop an alternative to Medicare as a point of comparison in the comparative payment rate analysis, particularly for inpatient administered therapies that are paid using DRGs.

Response: We thank the commenters for their support of using the Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis. We understand the commenters' concerns about using Medicare as a benchmark for Medicaid rates to be compared to in the comparative payment rate analysis; however, we do not agree that Medicare payment rates are low and have not kept up with inflation. As described in the proposed rule, Medicare PFS payment rates are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT),) using resource-based inputs to establish RVUs in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.[310] The Medicare PFS is revised annually by CMS ensure that our payment systems are updated to reflect changes in medical practice and the

[306] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.*

[307] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

[308] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

[309] We assume the commenter was referring to *https://www.fairhealth.org/.*

[310] 88 FR 27960 at 28012. Note this language has been revised for accuracy in this final rule,

relative value of services, as well as changes in the statute.[311]

With regard to commenters who raised concerns about using Medicare as a point of comparison, we disagree with the commenter that differences in coverage and populations limits comparability between Medicare and Medicaid in any way that would make Medicare an inappropriate comparator. As described in the proposed rule, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are utilized in this rule as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis.[312] Medicare PFS payment rates simply serve as a point of comparison for CMS to consider in assessing if Medicaid payments are consistent with section 1902(a)(30)(A) of the Act. Differences in the methodology that Medicare uses and States use to determine their FFS fee schedule payment rates does not compromise the value of Medicare as a reliable benchmark for assessing payment rate sufficiency for enlisting providers to furnish services to an individual, as required by section 1902(a)(30)(A) of the Act. As described in the proposed rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.[313] Also as described in the proposed rule, base Medicaid FFS fee schedule payment rate are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.[314] The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own fee schedules, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. Again, one of the criteria for including codes on the CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis is that there must be a payment rate on the Medicare PFS so States have a Medicare payment rate to compare their Medicaid base payment to.

We also disagree with commenters that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations. We acknowledge that Medicare and Medicaid vary in terms of covered services and populations served; however, the Medicare PFS includes payment rates for covered, non-covered, and limited coverage services and applies the same resource-based formula to ensure all PFS rates are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. As described in the proposed rule, Medicare PFS non-facility rates serves as a reliable benchmark for assessing the level of payment sufficiency to enlist providers to furnish the relevant services to an individual for the following reasons.[315] As we have narrowed the scope of the comparative payment rate analysis to E/M CPT/HCPCS codes, Medicare PFS non-facility payment rates are comparable to Medicaid FFS fee schedule payment rates because both fee schedule rates are generally for services provided in a physician's office and specify the rate paid to a provider for delivering an individual service (that is, a single FFS payment for a single service, rather than an encounter rate paying for any number for services). The accessibility and consistent format of the published Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year makes these rates an available and reliable comparison point for States to use in the comparative payment rate analysis for the foreseeable future as the Medicare PFS is free to the public, updated on an annual basis, and posted online on an easily located website, relative to private payer rates that States would need to request access to and perhaps pay for the information. Medicare also has a low rate of physicians formally opting out of the program, suggesting that Medicare's payment rates generally are consistent with a high level of physician willingness to furnish services to Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. Additionally, Medicare is another of the nation's large public health coverage programs which serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency.

We appreciate commenters' alternative suggestions to using Medicare as a benchmark in the comparative payment rate analysis; however, we are not incorporating these suggestions due to the following reasons. As discussed in the proposed rule, we learned from our implementation experience with the previous AMRP process that very few States were able to include even limited private payer data in their AMRPs due to the payment data being proprietary or unsound due to a lack of transparency about the construction of the payment data or because States did not have large private plans in their State so there were no private payer rates to compare to. This resulted in States being unable fully to comply with the previous AMRP regulations, to the extent they required an analysis that included private payer rate information.[316] Without this final rule, requiring States to compare their Medicaid rates to geographically similar States would not be possible because not all States currently post their Medicaid FFS fee schedule payment rates in a transparent and consistent format that would permit data analysis among States. While some States were able to compare their payment rates to other States' rates in their previous AMRPs, this was inconsistent across AMRPs and risked a subjective comparison where States selected which rates and States they compared themselves to. Requiring a comparison to Medicare ensures all States are using the same consistent data point to compare their rates to. Regarding the suggestion that CMS could identify the geographically similar States for States to compare their payment rates to, this would require a different approach than what we proposed due to the variation across State Medicaid programs and would require careful consideration and policy development to ensure that any proposal would be consistent with the statutory requirement in section

[311] *https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other.*

[312] 88 FR 27960 at 28012.

[313] 88 FR 27960 at 28011.

[314] 88 FR 27960 at 28010.

[315] 88 FR 27960 at 28011.

[316] 88 FR 27960 at 28018.

1902(a)(30)(A) of the Act that looks to the ''geographic area'' in determining whether payment rates are sufficient. Similarly, we would also not require States compare their rates to rates from Federal or State employee dental plans because this information might not be generally available to State Medicaid agencies.

At this time and for the purposes of the comparative payment rate analysis, we are not advocating or requiring States source payment rate information from any particular data source other than the State's own Medicaid agency (who is responsible for setting and paying the payment rates required in the analysis and, therefore has direct access to base Medicaid FFS fee schedule payment rates required in the analysis) and publicly available Medicare fee schedule rates (which we have previously described as an available and reliable comparison point for States to use in the comparative payment rate analysis). Therefore, we are not requiring States compare their rates to FAIR Health data because this data source is outside of the State agency and Medicare's publicly available fee schedule rates. We would also not require States compare their rates to Medicare Advantage for dental, vision, and hearing services because these are not categories of services subject to the comparative payment rate analysis. As previously stated, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. The list does not include dental, anesthesiology, physical therapy, vision, and hearing services and these services, among others not on the CMS-published list of E/M CPT/HCPCS codes, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

For the previously stated reasons, we believe the Medicare payment rates for the categories of services subject to the comparative payment rate analysis are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. Therefore, we are finalizing this rule with the requirement that States use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as the comparison point for States to compare their Medicaid payment rates to in the comparative payment rate analysis.

We would also like to clarify that the provisions in this final rule do not require States to change their payment rates, including requiring States to align their Medicaid payment rates with Medicare rates for psychiatrist services. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions, for example), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Comment: Some commenters were concerned about how States would be expected to conduct the comparative payment rate analysis for services that Medicaid pays for, but Medicare does not. A few commenters suggested CMS develop a methodology for calculating a proxy rate for Medicaid services with no equivalent Medicare rate or Medicaid services that are provided very infrequently in Medicare, so Medicare rates are not a reliable comparison. Two commenters suggested working with MedPAC or MACPAC to set appropriate comparison points for services that are not covered by Medicare, for example contraceptive and pregnancy-related services.

Response: To clarify, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. All codes on this list have an existing Medicare payment rate, therefore, the development of a proxy rate is unnecessary. Codes outside of this list, including services that Medicaid pays for, but Medicare does not, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenter that Medicare rates are not a reliable comparison when services are provided infrequently to Medicare beneficiaries. As previously described, Medicare PFS payment rates are computed using a resource-based formula made up of three components of a procedure's RVU: physician work, practice expense, and malpractice as well as geographical differences in each locality area of the country.[317] The Medicare PFS is revised annually by CMS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.[318] Despite a service being covered and paid for infrequently by Medicare, the payment rates on the Medicare PFS are consistently updated with relevant data on a frequent, annual basis.

Comment: A few commenters suggested alternative update frequencies for the comparative payment rate analysis. Commenter suggestions included updates annually, every 3 years, and every 4 years. Commenters' justification ranged from more frequent than 2 years due to the need for timely publication of Medicaid data to less frequent to align with the State's existing rate study schedule or because they did not believe rates would change significantly during a 2-year period. Additionally, one commenter suggested CMS require States to document when rates have not changed between comparative payment rate analysis biennial publications.

Response: We are finalizing the payment rate transparency requirements, including the comparative payment rate analysis, with an applicability date of July 1, 2026; however, we are not changing the proposed timeframe of 2 years for States to update their publications. We believe requiring updates to the comparative payment rate analysis every 2 years balances State burden with maintaining up-to-date information. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter expressed concerns about cross walking a State's geographical areas to Medicare in the comparative payment rate analysis. The commenter stated that States may define a geographical region differently than Medicare and result in a complex and confusing analysis that would be contrary to CMS' transparency goals.

Response: As discussed in the proposed rule, we recognize that States

[317] 88 FR 27960 at 28012.

[318] *https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other.*

that make Medicaid payment based on geographical location may not use the same locality areas as Medicare.[319] We expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in a calendar year in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. States could also calculate the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. While States have flexibility in mapping their geographical areas to Medicare's for the comparative payment rate analysis, we invite States to reach out to CMS for technical assistance.

Comment: A few commenters stated that other factors besides rates impact access to care. Commenters suggested CMS consider regional cost differences, provider shortages (including number of providers and their location), and the unique needs of specific populations (such as dually eligible beneficiaries, or beneficiaries in rural areas of a State) as factors that impact access to care.

Response: We agree with commenters that other factors besides rates impact access to care.[320] After considering feedback received from States and other interested parties about the previous AMRP process issued through the 2015 final rule with comment period, as well as our obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are finalizing a streamlined and standardized process to assess access to care that focuses on payment rate transparency. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the privacy of beneficiary information when it comes to the requirement that the comparative payment rate analysis and payment rate disclosure must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service. Commenters suggested CMS provide an exception when the volume of claims or beneficiaries is small.

Response: We take privacy and our obligations to protect beneficiary information very seriously. We remind States of their obligations to comply with applicable Federal and State privacy laws with respect to such information, such as the HIPAA Privacy Rule and Federal Medicaid requirements in section 1902(a)(7) of the Social Security Act and 42 CFR part 431, subpart F. We are not requiring States to publish any beneficiary-identifiable information in the comparative payment rate analysis or payment rate disclosure. We expect States will ensure that any claims and Medicaid beneficiary data made publicly available under these requirements have been de-identified in accordance with the HIPAA Privacy Rule at 45 CFR 164.514(b).

We strongly encourage States to have policies to ensure that all information, particularly claims and beneficiary data, published in their comparative payment rate analysis and payment rate disclosure is de-identified prior to publishing on July 1, 2026. Such policies should address circumstances in which the number of Medicaid-paid claims and/or Medicaid enrolled beneficiaries is small. For example, States may consider implementing a small cell size suppression policy for publishing data on the State's website, similar to CMS' cell size suppression policy that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly.[321] We invite States to reach out to CMS regarding any data privacy concerns that may impact a States' compliance with the comparative payment rate analysis or payment rate disclosure requirements.

Additionally, to address privacy concerns at the individual level, we would like to share the following resources for filing civil rights and HIPAA complaints with the Office for Civil Rights:

- Filing a civil rights complaint;[322] and
- Filing a health information privacy or security complaint.[323]

Comment: A commenter raised concerns that the comparative payment rate analysis would incentivize States to raise payment rates for the categories of services subject to the analysis, but might also lead or contribute to rate cuts for other services, since the proposed rule would not provide that States may not cut some rates to make funds available to raise other rates.

Response: We understand the commenter's concerns about the effects of the comparative payment rate analysis in practice. We emphasize that the comparative payment rate analysis will afford more transparency to CMS and the public about rates for primary care, obstetrical and gynecological, and outpatient mental health and substance use disorder services, and will also provide States with an opportunity to identify where existing rates could create an access issue for the services subject to the comparative payment rate analysis requirement. If a State chooses to raise payment rates for the categories of services subject to the analysis, and in order to do so seeks to reduce rates for other services, then the State would be required to follow the State Analysis Procedures for Rate Reduction or Restructuring in § 447.203(c) to ensure the proposed rate reductions do not reduce access to care to the services for which payment rates would be reduced below the statutory standard. A public input process to raise access concerns with States is described in § 447.203(c)(4) of this final rule. We are confident our policies finalized in this rule will work in conjunction with each other to ensure ongoing and improved access to care.

Comment: A couple of commenters requested clarification regarding the circumstance whereby a comparative payment rate analysis reveals that a State's Medicaid payment rates are significantly below Medicare rates. One commenter suggested requiring States to submit a corrective action plan in those instances.

Response: Transparency, particularly the requirement that States must publicly publish their payment rates and compare their payment rates to Medicare, helps to ensure that interested parties have basic

[319] 88 FR 27960 at 28013

[320] 88 FR 27960 at 28016–28017.

[321] *https://resdac.org/articles/cms-cell-size-suppression-policy.*

[322] *https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

[323] *https://www.hhs.gov/hipaa/filing-a-complaint/complaint-process/index.html.*

information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We intend to utilize the information published by States in their payment rate transparency publication and comparative payment rate analysis whenever the provisions of § 447.203(c) are invoked, when a State submits a SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access. We did not propose and are not requiring States to submit a corrective action plan when Medicaid payment rates included in the comparative payment rate analysis are lower than Medicare payment rates. While the results of a comparative payment rate analysis would not themselves require a corrective action plan, § 447.203(c)(5) does require a State to submit a corrective action plan to remedy an access deficiency within 90 days from when it is identified to the State.

Comment: One commenter requested that CMS make UPL demonstration data and methodologies publicly available for purposes of data analysis, particularly for inpatient behavioral health services as CMS did not propose to include these services in the comparative payment rate analysis.

Response: While the comparative payment rate analysis is limited in scope to base Medicaid FFS fee schedule payment rates, the payment rate transparency publication does include PPS rates that are considered fee schedules payment rates within the meaning of this final rule, including for inpatient hospital, outpatient hospital, and nursing facility services. The PPS rates, which are generally the base payment for these services, and reported through UPLs, will be publicly available through the payment rate transparency publication. We acknowledge that supplemental payments as well as UPL data and methodologies typically are not publicly available currently. Nevertheless, UPL demonstrations provide us with an opportunity for payment oversight and we consider UPL demonstrations in assessing State compliance with the access requirement in section 1902(a)(30)(A) of the Act.[324] As previously discussed in an earlier response to comments, we stated that UPL demonstrations provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a payment limit, or ceiling, for economic and efficient. Requiring supplemental payments as well as UPL data and methodologies be publicly available would contribute to our transparency efforts; however, the current reporting format of UPL data would not align with § 447.203(b)(1)(iii) which requires Medicaid FFS fee schedule payment rates be published and organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Therefore, we would need to develop a different methodology, policies, and oversight than what is being finalized in this rule to ensure UPL data is transparent. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues.

Payment Rate Disclosure Comments and Responses

Comment: We received general support for our proposal to require States to develop and publish a payment rate disclosure for certain HCBS. Commenters specifically expressed support for the proposed categories of services and calculation of the average hourly payment rate.

However, a couple of comments expressed opposition of the payment rate disclosure provision. Commenters in opposition stated the proposed payment rate disclosure requirements would be administratively burdensome for States and that it was unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes.

Response: We appreciate the commenters' support of the payment rate disclosure provision at § 447.203(b)(3)(ii). We are finalizing the payment rate disclosure provisions with an additional category of service, habilitation, a few minor revisions for clarification purposes and consistent terminology usage within § 447.203(b), and an update to the compliance timeframe, the latter of which was discussed earlier in this section. The addition of habilitation services to the payment rate disclosure is further discussed in a later response to comments in this section. In this final rule, we are revising the regulatory language to clarify which services and payment rates are subject to this requirement. We proposed in § 447.203(b)(3)(ii) that the State would be required to publish the ''average hourly payment rate, separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary'' for each category of service specified in paragraph (b)(2)(iv). We are finalizing in § 447.203(b)(3)(ii) that States are required to publish the ''average hourly **Medicaid fee-for-service fee schedule** payment rates, separately identified for payments made to individual providers and **provider agencies,** if the rates vary.'' (new language identified in bold). We proposed in § 447.203(b)(3)(ii)(B) that the State would be required to ''identify the average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable.'' We are finalizing in § 447.203(b)(3)(ii)(B) that the States are required to ''identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' (new language identified in bold). For clarification and consistent terminology usage of ''Medicaid fee-for-service fee schedule payment rates,'' similar revisions were made in § 447.203(b)(2)(iv) and (b)(3)(ii)(B) and (C) and described in detail at the end of responses to comments in this section. We utilized the term ''average hourly Medicaid fee-for-service fee schedule payment rates'' in the payment rate disclosure for

[324] 88 FR 27960 at 28006.

consistency throughout § 447.203(b) where the term Medicaid FFS fee schedule payment rates is used to describe what payment rates are subject to the payment rate transparency publication in § 447.203(b)(1)(i). Additionally, we are incorporating the term ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published. Lastly, we added the requirement that payments that include facility-related costs must be separately identified to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs. Additional information about these regulatory language changes is discussed in later responses to comments in this section.

We disagree with the commenters regarding administrative burden of the payment rate disclosure. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule. Specifically for the payment rate disclosure, and as discussed in a later response to comments, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate disclosure on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule), (2) format and organize the payment rate disclosure how they chose (that is, we are not requiring certain codes be included as required in the comparative payment rate analysis) (however, we remind States that the disclosure is still subject to the publication requirements described in proposed paragraphs (b)(1) and (b)(1)(ii) for payment rate transparency data), and (3) calculate the average hourly Medicaid FFS fee schedule payment rate as a simple average or arithmetic mean where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates, rather than a weighted average which would impose more burden on States to calculate. Additionally, we are providing an illustrative example of a compliant payment rate disclosure (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We are not identifying codes for the categories of services subject to the payment rate disclosure. We are providing States with flexibility in determining which codes to include in the calculated average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure because States may use a wide variety of codes to bill and pay for personal care, home health aide, homemaker, and habilitation services, such as HCPCS codes T1019–T1022 and/or CPT codes 99500- 99602. For example, HCPCS codes T1019–T1022 for home health services includes T1019 (personal care services that are part of the individualized plan of treatment, per 15 minutes), T1020 (personal care services that are part of the individualized plan of treatment, per diem), T1021 (home health aide or certified nurse assistant, per visit), and T1022 (contracted home health agency services, all services provided under contract, per day). One State may use T1019 or T1020 depending on the unit (daily or per diem), a second State may only use T1021, and a third State may use none of these codes. We expect States to review their Medicaid FFS fee schedule payment rates for the payment rate and unit the State uses to pay for each of category of service and calculate the Medicaid average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, separately by service and provider employment structure as well as for payments that include facility-related costs, as provided in this final rule and discussed in later responses to comments in this section.

Additionally, the list of possible codes States may pay for personal care, home health aide, homemaker, and habilitation services is already limited by the available CPT/HCPCS codes, so we did not see a need to narrow the codes with a CMS-published list of E/M CPT/HCPCS like the comparative payment rate analysis. As previously discussed, we recognize that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use CPT or HCPCS codes as published by AMA and CMS, then we expect the State to review the published lists of CPT or HCPCS codes and identify which of their codes are most comparable for purposes of the payment rate disclosure. We anticipate States may need to review code descriptions of CPT and HCPCS codes for personal care, home health aide, homemaker, and habilitation services as part of the process of identifying which CPT and HCPCS codes are comparable to the codes that States utilizes. We want to ensure the full scope of personal care, home health aide, homemaker, and habilitation services, and providers of these services, are included in the payment rate disclosure for transparency purposes, rather than narrowing the scope to certain codes and/or provider types, which would result in a limited disclosure of provider payment rates.

Regarding commenters that were unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes, we are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). Calculating an average hourly Medicaid FFS fee schedule payment rate for categories of services subject to the payment rate disclosure will ensure a standardized unit and permit States, CMS, and other interested parties to compare payment rates among State Medicaid programs. As discussed in the proposed rule, HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we are proposing a different disclosure of payment rates for providers of these services that does not involve a comparison to Medicare. Additionally, private payer data and self-pay data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS that is covered by a third-party payer.[325]

[325] 88 FR 27960 at 28019

Comment: Some commenters requested CMS clarify and add to the proposed categories of services included in the payment rate disclosure requirements. A few commenters requested clarification regarding whether services covered under waiver authority or State plan authority are subject to the disclosure requirements. A couple of commenters suggested adding regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure. Another couple of commenters requested clarification specifically about self-directed services when an individual has budget authority and residential services. A few commenters encouraged CMS to require States to report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority) due to States varying rates for the same service furnished to different targeted populations under different coverage authorities.

A few commenters recommended additional categories of services to the proposed categories of services subject to the payment rate disclosure. While some commenters recommended expanding the categories of services generally, a number of commenters specifically recommended expanding the categories of service to include habilitation services (including residential habilitation services, day habilitation services, and home-based habilitation services).

Response: Personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority are subject to the payment rate disclosure described in § 447.203(b)(3)(ii). We are clarifying that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or identify as not applicable one or more of the requirements as part of the approval of the demonstration project. Please see section II.B for additional information on the inclusion of section 1115 demonstrations under the provisions of this final rule. While we appreciate the commenters' suggestion to add regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure, we are not incorporating this suggestion as we previously provided clarification on which authorities are subject to the disclosure.

As previously discussed, self-directed services delivery models under which an individual beneficiary has budget authority do not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, as well as the payment rate disclosure. Generally, under such self-directed services delivery models, the individual beneficiary determines a reasonable payment rate for the service in the State-authorized budget for that beneficiary. As such, these types of payment rates are excluded from the disclosure requirement. Regarding commenters' request for clarification about residential services being subject to the disclosure, as discussed in a later response to comments, personal care, home health aide, homemaker, and habilitation services, are inherently delivered in a home or community setting, outside of an institutional or residential facility. However, we acknowledge that the addition of habilitation services to the disclosure would now include residential habilitation services and we further address this in the later portion of this comment response.

We appreciate commenters' suggestion to require States report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority). However, that level of detailed reporting is beyond the scope of what we are seeking to implement in this current rulemaking, and would represent additional burden to States. We are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by various factors that we believe will provide beneficial insights into these rates.

As stated in the proposed rule, we intend to standardize data and monitoring across service delivery systems with the goal of improving access to care, to the extent possible, and particularly for the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii), we intend to remain consistent with the HCBS provisions we are finalizing at § 441.311(d)(2) and (e).[326] Given the addition of habilitation services to these HCBS provisions in this final rule as well as the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) and after consideration of comments, we are adding habilitation services, including residential habilitation, day habilitation, and home-based habilitation services, to the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii). Specifically, the regulatory language finalized in this rule at § 447.203(b)(2)(iv) requires States to publish the average hourly Medicaid FFS payment rate for personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6) in the payment rate disclosure. We note that § 447.203(b)(2)(iv) refers to ''habilitation'' services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. As previously discussed in section II.B., these categories will be further described in subregulatory guidance. As discussed in a later response to comments in this section, we also adding a requirement in the payment rate disclosure that States must separately identify the Medicaid FFS fee schedule payment rates for services that include facility-related costs. We believe this distinction will generally only arise for habilitation service rates, but we are applying it across all four service categories to remain consistent with the amended provisions at § 441.311(e)(2), and for consistency in reporting across all four services within the payment rate disclosure.

As discussed in the proposed rule, we initially proposed to include in the payment rate disclosure requirement only personal care, home health aide, and homemaker services because they are most commonly conducted in beneficiaries' homes and general community settings and, therefore, constituted the majority of FFS payments for direct care workers delivering services under FFS.[327] However, and as previously stated, we agree with commenters' recommendation that the payment rate disclosure should include payment rates for habilitation services. As such, and to remain consistent with the HCBS provisions at § 441.311(d)(2) and (e) finalized in this rule, we are adding habilitation services as a category of service subject to the payment rate disclosure.

We acknowledge that habilitation services are also generally high-volume,

[326] 88 FR 27960 at 28005.

[327] 88 FR 27960 at 28005.

high-cost services particularly in States where individuals with intellectual or developmental disabilities receive personal care services through habilitation. In other words, we acknowledge that some States design the delivery of and payment rates for habilitation services to include personal care services in these instances. If we were to exclude habilitation services from the payment rate disclosure provisions, then we would effectively exclude an important component of personal care services provided to individuals with intellectual or developmental disabilities from the payment rate disclosure, which would not align with our intent to ensure transparency of payment rates of personal care services within this provision. In instances where States combine the delivery and payment of habilitation services with personal care services, requiring reporting on both services supports our goal of enhancing the transparency of payment rates that support the delivery of personal care services while accommodating the potential variation in classification a State utilizes. We want to note a State has the option to indicate when a habilitation service rate includes personal care services or otherwise provide further data nuances while meeting the requirements of this final rule. In addition, this change provides clarity to States that might have reported on habilitation services under the personal care category of services in the payment rate disclosure were it not for this revision to the disclosure. Given the variation in how States deliver and pay for habilitation services, separately identifying habilitation as a category of service supports our payment rate transparency goals to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

As previously discussed in detail in an earlier response to comments in section II. of this final rule, including habilitation services in HCBS reporting requirements at § 441.311(d)(2) and (e), as well as the payment rate disclosure at § 447.203(b)(2) and (3)(ii), will ensure that services of particular importance to certain beneficiary populations, namely individuals with intellectual or developmental disabilities, are not excluded from our efforts to promote payment rate transparency in the interest of ensuring adequate access to care. As previously stated, in accordance with commenters' recommendation, and to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) as stated in the proposed rule,[328] we are adding habilitation services to the payment rate disclosure to ensure transparency of rates that disproportionately affect access to services required by a unique population, individuals with intellectual or developmental disabilities.

Comment: A few commenters expressed concern over certain terms used in the proposed rule. Two commenters noted the terms ''rates,'' ''payments,'' ''wage,'' and ''compensation'' were used throughout the rule and were concerned about potential confusion about complying with the payment rate disclosure with the terms not clearly defined. One commenter was concerned the payment rate disclosure required States to request detailed financial records and information from provider organizations/agencies, which are often private businesses. Another couple of commenters requested a Federal-level definition or description of ''provider type'' and ''geographical location'' in the context of the payment rate disclosure.

Response: The payment rate disclosure requires States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). We are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In section II.C. of this final rule, wage is only mentioned while summarizing comments received on the February 2022 RFI.[329] Likewise, compensation is only mentioned in section II.C. of this final rule while describing the difference between individual providers and provider agencies and when requesting public comments on whether we should have proposed a provision similar to the HCBS provisions we proposed at § 441.302(k)(3)(i) (where we proposed to require at least 80 percent of all Medicaid FFS payments for certain services be spent on compensation for direct care workers). Therefore, we are not requiring that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation that the provider agency pays to its employee in the payment rate disclosure provisions at § 447.203(b)(3)(ii). We consistently used average hourly payment rate to refer to the payment rate that States are required to publish in the payment rate disclosure. As finalized in this rule, we are replacing the term ''average hourly payment rate'' with ''average hourly Medicaid FFS fee schedule payment rate'' for clarity and consistency throughout § 447.203(b).

We are not specifying a Federal definition for provider type because of the variety of provider types a State could license and pay for delivering Medicaid services. States are responsible for licensing providers in their State and have the flexibility to license a wide variety of provider types for personal care, home health aide, homemaker, and habilitation services, including, but not limited to, personal care attendants, home health aides, certified nursing assistants, or registered nurses. We would like to ensure the full scope of providers of personal care, home health aide, homemaker, and habilitation services across States are included in the payment rate disclosure for transparency purposes.

Finally, we also are not providing a Federal definition of geographical location. Because the payment rate disclosure does not involve a comparison to Medicare (or other payer), the data need only reflect the State's specific circumstances. Different States have different methods of assigning payment rates to particular regions and are therefore best situated to determine how rates must reflect their State-determined geographical designations.

Comment: A few commenters requested clarification regarding what CMS meant by ''individual providers'' and ''providers employed by an agency'' in the payment rate disclosure. Commenters were generally unsure if States are required to publish the average hourly payment rate paid to the agency or the compensation the agency pays to its employee. One commenter

[328] 88 FR 27960 at 28005.

[329] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

requested clarification on what CMS considers ''payments made to individual providers'' and ''payments made. . .to providers employed by an agency.'' Another commenter noted an example where agencies have multiple direct care workers as employees and was unsure from the language in the proposed rule (''providers employed by agency'') what CMS considered to be the payment rate, either total compensation (including benefits) divided by total hours, or the hourly base wage of the direct care workers. One commenter specifically noted the use of the terms ''direct care worker'' and ''provider'' are both used in 42 CFR 447.203(b)(3)(ii) and stated these terms are often misaligned. The commenter explains that ''direct care worker'' or ''home care worker'' refers to personal care aides and home health aides, who provide hands-on services to those in need while ''providers'' are the agencies that employ direct care workers, train and screen them (health status and background checks), supervise them, schedule their services, reimburse their travel expenses, and support their professional development as well as liaise with service recipients and their families, handle all service billing, prepare for and respond to emergencies, and ensure day-to-day compliance with State and Federal standards.

Response: We appreciate the commenters' examples to illustrate the requested areas of clarification in the rule. As previously stated, in this final rule, we are revising the language ''to providers employed by an agency'' in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing the language as ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published which is discussed shortly in this response to comments. To clarify, in the payment rate disclosure, we are requiring States to calculate and publish the average hourly Medicaid FFS fee schedule payment rate that States pay to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs. As described in the proposed rule and this final rule, individual providers in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to individuals that are direct care workers and often self-employed or contract directly with the State to deliver services as a Medicaid provide; additionally, the individual provider bills the States directly and is paid directly by the State for services provided. To clarify, individual providers does not refer to providers delivering services through self-directed models with service budget authorized under 42 CFR 441.545, as these are not considered Medicaid FFS fee schedule payment rates for the purposes of the payment rate transparency publication, as well as the payment rate disclosure at § 447.203(b)(3)(ii), which was discussed in an earlier response to commenters.

Provider agency in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to the agency contracted or enrolled with the State to deliver Medicaid services and the agency in turn employs or contracts with direct care workers as employees of the agency that works directly with the Medicaid agency to provide Medicaid services; additionally, the agency bills the State directly and is paid directly by the State for services their employees or contractors provide. Also, as previously stated, to the extent a State pays a provider agency a Medicaid FFS fee schedule payment rate (as discussed in detail in an earlier response to comments in this section), then those payment rates are subject to the payment rate disclosure requirements at § 447.203(b)(3)(ii).

As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation the provider agency pays to its employee. While the comment focuses on the daily work of a ''direct care worker'' and the functions of a ''provider'' to distinguish these terms, for the purposes of this rule, we focused on the type of employment structure (that is, individual provider or provider agency) to best account for variations in types and levels of payment that may occur for different provider types. We clarify that the codified regulation text for § 447.203(b)(3)(ii) does not include the phrase ''direct care worker.''

Comment: Many commenters raised concerns and requested clarification regarding CMS requiring the payment rate being an hourly unit in the payment rate disclosure. A few commenters requested CMS clearly define what to include in the average hourly payment rate (for example, wages or benefits) to ensure the average hourly payment rates are comparable across States. A couple of commenters requested clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly payment rate while one commenter requested CMS permit States to publish an average payment rate in the unit the State pays to ease burden on States. Lastly, one commenter stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates.

Response: For personal care, home health aide, homemaker, or habilitation services under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority, this final rule requires States to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid FFS fee schedule payment rates, separately identified for payments made to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs, as applicable. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service and, therefore, States currently pay for these services in a wide range of units, from minutes to hourly to daily to monthly units. As described in the proposed rule, because of Medicaid's status as the most important payer for HCBS and lack of other points of comparison (that is, Medicare, private payers, self-pay), transparency and comparability among States is most important for assessing compliance with section 1902(a)(30)(A) of the Act. To ensure the payment rate disclosure supports our transparency efforts to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties, we are requiring States publish their payment rates in a uniform and comparable format, that is, an average hourly Medicaid FFS fee schedule payment rate. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

Regarding commenters requesting clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly

payment rate, we would like to clarify that States that pay for the categories of services specified in paragraph (b)(2)(iv) in a unit other than an hourly payment rate are expected to calculate an hourly payment rate using the unit of the rate the State pays for the service and the number of hours covered by that unit. For example, if a State provides home health aide services as a half day or on a per diem (daily) or per visit basis, then the State would be expected to divide their payment rate for a half day, day, or visit by the number of hours covered by the rate, such as 8 hours for a full day, to calculate an average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service. We expect States have a maximum number of hours factored into their payment rate for services set on a per diem or per visit basis and States should use that maximum number in calculating the average hourly Medicaid FFS fee schedule payment rate, which is a simple average (arithmetic mean) where all payment rates are summed, then divided by the number of all hourly payment rates. Regarding commenters who stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates, we are not incorporating this suggestion into the final rule as we would expect States to use the previously described process to calculate an hourly payment rate from a per diem (daily) rate.

As previously mentioned in an earlier response to comments, this final rule adds habilitation services to the categories of services subject to the payment rate disclosure. This final rule is also adding a requirement that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate for services includes facility-related costs in § 447.203(b)(2) and (3)(ii)(B) to remain consistent with HCBS provisions finalized in this rule at § 441.311(e)(2). We recognize that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services; as such, payment rates for habilitation services generally may include facility-related costs, as in the case of residential or day habilitation services delivered in a residential group home or day center, whereas home-based habilitation would not include facility-related costs.[330] We remind States that we proposed an ''as applicable'' clause in § 447.203(b)(3)(ii)(B) that applies to the ways payment rates can vary (that is, by employment structure, population (pediatric and adult), provider type, geographical location). The requirement to identify whether a payment rate includes facility-related costs would also be covered by the ''as applicable'' clause. As such, we would not expect States to identify facility-related costs for personal care, home health aide, homemaker, and habilitation service payment rates when they are delivered in a home-based setting. While § 447.203(b)(2) and (3)(ii)(B) requires that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate includes facility-related costs may not apply to all services and delivery sites (that is, in home or community settings), we believe this provision will help to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs.

Comment: One commenter requested clarification regarding individually negotiated rates and bundled rates being included in the average hourly payment rate calculation in the payment rate disclosure.

Response: As previously described in detail in an earlier response to comments in this section, we interpret the commenter's reference to ''negotiated rates'' to mean a provider payment rate where the individual provider's final payment rate is agreed upon through negotiation with the State Medicaid agency. For consistency with the payment rate transparency publication requirement, negotiated rates are not subject to the payment rate disclosure provision because these payment rates are not subject to the payment rate transparency publication as negotiated rates are not Medicaid FFS fee schedule payment rates that are known in advance of a provider delivering a service to a beneficiary.

Also, as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the payment rate disclosure in paragraph (b)(3)(ii)(B) of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the payment rate disclosure.

We also clarify that while PPS rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these PPS rates are effectively excluded from the payment rate disclosure because the categories of services specified in § 447.203(b)(2)(iv), personal care, home health aide, homemaker, and habilitation services, inherently delivered in a home or community setting, outside of an institutional facility.

Comment: Many commenters suggested additional data elements and levels of analysis for the payment rate disclosure. A couple of commenters suggested additional breakdowns of the average hourly payment rates, including when a State pays different rates for higher level of need or complexity (such as paying tiered rates for a single service when provided on nights, weekends, or in a particular geographical area), demographic information (such as gender and race of the direct care worker), and type of service provided. Another commenter suggested CMS require States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure to enable easier comparison of compensation between individual providers and to providers employed by an agency. One commenter suggested requiring States to publish the rates that provider agencies pay their employees to ensure payment rates are fully disclosed at the State and provider levels. One commenter suggested additional data elements be reported by States in the payment rate disclosure: Medicaid-authorized payment rates; minimum base wages that would be paid to direct care workers if the proposed 80 percent requirement is met; average Medicaid payment rates and average direct care worker wages; the minimum, maximum, and median rates of wages; and number of direct care workers employed by the agency.

[330] We remind States that room and board is generally only coverable and payable to an individual who has been admitted to a medical institution as an ''inpatient'' as defined in 42 CFR 440.2 and 435.1010. Therefore, room and board in a facility setting that provides residential or day habilitation service must be excluded from the average hourly Medicaid FFS fee schedule payment rate for habilitation services.

Response: We appreciate commenters' suggestions for the payment rate disclosure. As previously discussed in an earlier response to commenters, in this final rule, we are revising the proposed language ''to providers employed by an agency'' in in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing it as ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published, that is, the payment rate the State pays a provider agency for services its employees have delivered. While the commenters did not provide additional explanation or examples of what they meant by requiring an additional break down of the average hourly payment rate by ''type of service provided,'' we clarify that the payment rate disclosure requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, which are types of services, separately. Additionally, while we are not explicitly requiring States break down their payment rates by higher level of need or complexity, we did propose and are finalizing the requirement to break down the average hourly Medicaid FFS fee schedule payment rate by geographical location, which was one of the examples of additional criteria the commenter provided for suggested further breakdown.

However, we are not incorporating the other suggestions to require the other, additional breakdowns of the average hourly payments rates as suggested by commenters or to require additional data elements be reported by States in the payment rate disclosure, to remain consistent across provisions of this final rule. If we were to include these suggestions only for the payment rate disclosure, then the payment rate breakdowns would be inconsistent with the payment rate transparency publication and comparative payment rate analysis in terms of requiring, for example, demographic information about the direct care worker. During the initial compliance period of this final rule and in consideration of the numerous, concurrent regulatory changes States are facing, we believe consistency, where possible, across provisions will contribute to our goal to standardize data and monitoring across service delivery systems with the goal of improving access to care.

Likewise, we are not incorporating the suggestion to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure. While the suggestion aligns with the intent of HCBS provisions we are finalizing in this rule at § 441.302(k) as discussed in section II.B.5 of this rule, we did not propose to require 80 percent of all payments with respect to services at § 440.180(b)(2) through (4) must be spent on compensation for direct care workers within the payment rate disclosure, as discussed in a later response to comments in this section. As we remain focused on consistency, because we are not requiring a certain percentage of all payments be spent on compensation for direct care workers, we are also not requiring at § 447.203(b)(3)(ii) that States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker.

We are also not incorporating the suggestion to require States publish the rates that provider agencies pay their employees because, similar to private payer data as a point of rate comparison, rates that provider agencies pay their employees is generally considered proprietary and this information may not be available to States. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their payment rate disclosure publication if they so choose. We will also review how our finalized policies work in conjunction with other policies finalized in this rule to identify any potential areas for future enhancements suggested by the commenters.

Comment: One commenter suggested CMS could ease burden on States by collecting State payment rates from Dual Special Needs Plans (D–SNPs) through Medicare Advantage, rather than requiring States to calculate and publish their average hourly payment rate for the payment rate disclosure.

Response: We appreciate the commenters' suggestion; however, D–SNPs do not provide us with the specific data elements (that is, State Medicaid payment rates, number of Medicaid-paid claims, and number of Medicaid enrolled beneficiaries) we are requiring in this rule. Some D–SNPs only cover Medicare services and do not directly pay for Medicaid services. Other D–SNPs do cover Medicaid services (either directly or through an affiliated Medicaid managed care plan), but this rule only applies to Medicaid FFS payment rates. Therefore, as D–SNPs do not collect or provide us with Medicaid payment rate information that is relevant to this rule, we will not be incorporating this suggestion. Additionally, we believe that the States, as stewards of Medicaid payment rates in the Medicaid program, would be the party best situated to publish and analyze their own payment rate information for the payment rate transparency requirements finalized in this rule, including the payment rate disclosure. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures.

Comment: A few commenters suggested alternative timelines for States updating their payment rate disclosures. One commenter suggested extending the requirement for updates to the payment rate disclosure to every 3 years, instead of the proposed 2 years, to align with the State's existing data publication cycle. However, another commenter suggested the update frequency of the payment rate disclosure be every year.

Response: We are finalizing the payment rate transparency requirements, including the payment rate disclosure, with an applicability date of July 1, 2026; however, we are not changing the proposed timeframe of 2 years for States to update their payment rate disclosure. We believe requiring updates to the payment rate disclosure every 2 years appropriately balances State burden and maintaining up-to-date information in the payment rate disclosure.

Comment: Most commenters were supportive in response to our request for public comment on whether we should propose a provision to what we proposed at § 441.302(k) (where we proposed to require that at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care

workers) in § 447.203(b) on the basis that this provision would help address the direct care workforce crisis and access issues. One commenter suggested that if such a provision were proposed and implemented, then CMS should implement an accountability requirement where States would be required to validate that direct care workers are receiving 80 percent of all Medicaid FFS payments.

Some commenters opposed this consideration and suggested that, if this provision is finalized, the requirement would negatively affect access to care. These commenters aligned with those in opposition to the proposed HCBS provisions at § 441.302(k), as discussed in section II.B.5 of this rule. These commenters opposed this because the policy does not consider that given low levels of payment for relevant services, the remaining 20 percent of the payment rate would be insufficient for the administrative costs (that is, staff, technology, training, travel, oversight) of running a business, provider agencies are already challenged by worker shortages, providers would withdraw from the Medicaid program or stop serving Medicaid beneficiaries, and the requirement would be ineffective without supportive policies in place to implement standards for determining sufficient Medicaid payment rates that provide competitive wages, promote quality services, and ensure compliance with all State and Federal regulations. Commenters in opposition recommended alternatives including: a lower percentage than 80 percent of all Medicaid FFS payments going to compensation for direct care workers, establishing quality outcome metrics, and focusing on wage review and transparency.

Response: We thank commenters for their input and suggestions. We also understand the commenters' concerns. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, particularly from the HCBS provisions finalized in this rule at § 441.302(k) as discussed in section II.B.5, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Many commenters expressed concerns about requiring States to publish the average hourly payment rate that States pay for personal care, home health aide, and homemaker services. These commenters were generally concerned that requiring States to publish this information could result in unintended consequences or be ineffective for assessing and improving access to care. The unintended consequences commenters were primarily concerned about included contributing to providers leaving areas where there are low Medicaid payment rates which could create or exacerbate access to care issues in that area and misunderstandings of the required average hourly payment rate without additional context about employee benefits (for example, paid time off, health insurance, pension, employee assistance program) that are not easily disaggregated from an hourly Medicaid service payment rate. Regarding commenter concerns that publishing the average hourly rate would be ineffective, one commenter stated that their State already publishes provider rates, and it has not resolved issues with low and unequal payment rates among providers employed by agencies.

Response: We understand commenters' concerns about the effects of the payment rate disclosure in practice. Regarding commenters' concerns that providers could leave an area where there are low Medicaid payment rates, we would like to emphasize that the payment rate disclosure requirements will afford more transparency to CMS and the public about rates for HCBS, but they will also provide States with an opportunity to identify where existing rates could create an access issue. If the difference in rates between two areas enlists more providers to one area over another, States may need to consider revisions to their payment rates to comply with section 1902(a)(30)(A) of the Act to ''assure that payments . . . are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Therefore, if the transparency created by the payment rate disclosure requirements induces providers to switch locations, affecting access to care, we would expect States to address the rate disparities that the commenter has correctly identified are negatively impacting access.

Regarding commenters' concerns that there could be misunderstandings of the published average hourly payment rate without additional context about employee benefits, the payment rate disclosure provisions at § 447.203(b)(3)(ii) requires States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In other words, we are focused on payment rate transparency for personal care, home health aide, homemaker, and habilitation services rather than what the providers of these services does with their payment rate (that is, pay for employee benefits). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenters that publishing the average hourly Medicaid FFS fee schedule payment rate of personal care, home health aide, homemaker, and habilitation providers through the payment rate disclosure requirement will be ineffective, including because one commenter's State already publishes this information, and the commenter has not seen improvement in low and unequal payment rates among providers employed by agencies. We believe a broad requirement for all States that provide personal care, home health aide, homemaker, and habilitation services through the FFS delivery system will help ensure consistency across delivery systems in monitoring and ensuring access to care, particularly with the HCBS provisions at § 441.311(d)(2) and (e), which require annual State reporting on access and payment adequacy metrics for the same set of services as the payment rate disclosure as well as with the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) for Medicaid to require a payment analysis of the total amount paid for homemaker services, home health aide services, and personal care services and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same claims. While the commenter did not provide additional details about

their State's publication of payment rates, we believe that with a broad rate transparency requirement across delivery systems, we can reasonably expect that States, CMS, and interested parties will have transparent payment rate information available to them across delivery systems. Transparency would continually help States and CMS to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Transparency also helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

Comment: Several commenters expressed concern over low payment rates in Medicaid, particularly for HCBS, dental services, and behavioral health care, and the negative impact on access to care. Many commenters suggested that the primary causes of these low payment rates in Medicaid are stagnant and insufficient payment rates left unadjusted for rising costs, inflation, new regulatory requirements, and increased service expectations over time, particularly for the HCBS direct care workforce.

A few of these commenters suggested CMS could address these issues directly by requiring States conduct regular rate reviews (for example, annual, biennial, triennial, or when a programmatic change occurs), publish the results, and update their payment rates, when necessary, based on criteria that CMS sets. One commenter suggested this could be achieved thorough regular SPA and waiver reviews where CMS could prevent stagnant and insufficient rates from being maintained. Particularly for HCBS, one commenter recommended setting a national standard base pay rate for direct care workers as determined by the States' cost of living index or requiring States have parity for all State payment rates, regardless of geographic location, but allow differences in payment rates for services provided to pediatric and adult populations.

Response: We appreciate the commenters' suggestions. However, we are limited in our authority to directly address the commenters' concerns regarding stagnant and insufficient payment rates. With limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), we do not have the authority to require States update their payment rates to a particular level. Section 1902(a)(30)(A) of the Act requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under the statutory authority at section 1902(a)(30)(A) of the Act and through this final rule, we are requiring States to develop and publish a payment rate transparency publication, comparative payment rate analysis of certain services, and payment rate disclosure for certain HCBS, which are directed at helping the States and CMS ensure that State payment rates are consistent with the payment standards under section 1902(a)(30)(A) of the Act.

While we are not explicitly requiring that States update their payment rates to a particular level or regularly submit SPAs and/or waivers (except where desired by the State to implement a programmatic change, consistent with existing requirements) waivers in this rulemaking, we believe there are three requirements within our statutory authority and finalized by this rule that effectively address the concerns raised by commenters. First, this final rule requires States to review their payment rates during the development and publication of their payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Specifically, the payment rate transparency publication requires States to regularly review their rates in the course of publishing them and maintaining the current accuracy of the publication, including publishing the date the payment rate publication website was last updated, which will reveal any rates that may be stagnant and potentially insufficient. States must also ensure the data in the publication is kept current (that is, updates must be made within 1 month of a rate change). With this final rule, we focused on transparency to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We acknowledge the provisions finalized in this rule do not specifically require rate reviews to ensure payment rates are adjusted for rising costs, inflation, new regulatory requirements, and increased service expectations that commenters suggested are factors contributing to a crisis in the HCBS direct care workforce. However, this provision creates a process to help validate that payment rates are compliant with section 1902(a)(30)(A) of the Act.

Second, this final rule requires States to establish an advisory group for interested parties to advise and consult on certain current and proposed Medicaid provider payment rates to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area. We strongly encourage States to use this group as part of a process to conduct rate reviews and encourage eligible participants (including direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State) to join their State's interested parties advisory group once established to bring their concerns directly to States that are setting the payment rates for HCBS.

Third, this final rule establishes a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. However, meeting the three criteria described in the first tier does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. The second tier of this approach, § 447.203(c)(2) requires the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. We believe this two-tiered approach, in

combination with updated public process requirements in § 447.203(c)(4) (which this final rule relocates from § 447.203(b)(7)) will help us ensure that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(2) to (4) as proposed, apart from the following changes.

• Deleted the word ''following'' in two places in the following sentence in § 447.203(b)(2) ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the **following** categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the **following** categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.'' The finalized language now states ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.'' (bold added to emphasize the deleted word).

• Replaced ''Medicaid payment rates'' with ''Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(2) with regard to the comparative payment rate analysis. The finalized language now states ''. . . publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates. . .'' for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''Medicaid payment rates'' with ''average hourly Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(2) with regard to the payment rate disclosure. The finalized language now states ''. . . [publish] . . . payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates'' for clarification and consistent terminology usage within § 447.203(b).

• Revised sentence structure organization and added clarifying language to the proposed language stating how the Medicaid FFS payment rates published in the comparative payment rate analysis and the payment rate disclosure need to be listed, if the rates vary. The proposed language in § 447.203(b)(2) stated ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the following categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the following categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.''

++ Added the following sentence to address payment rate variation for the comparative payment rate analysis: ''If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.'' in § 447.203(b)(2).

++ Revised the following sentence to add payment rate variation related to facility-related costs for the payment rate disclosure: ''If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' (new language identified in bold).

The language is finalized as ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. **If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish** a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' in paragraph (b)(2). (new language identified in bold).

• Updated ''Outpatient behavioral health services'' as a category of service in § 447.203(b)(2)(iii) to ''Outpatient mental health and substance use disorder services.''

• Added ''habilitation'' as a category of service in the payment rate disclosure described in § 447.203(b)(2)(iv) and added a reference to § 440.180(b)(6). The finalized language now states ''Personal care, home health aide, homemaker, **and habilitation** services, as specified in § 440.180(b)(2) through (4) and (6), provided by individual providers and provider agencies (new language identified in bold).

• Clarified which publication requirements apply to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(3) and (b)(4) to align with a previously described update to the organizational structure of paragraph (b)(1) to add romanettes to specify the ''publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section.'' (new language identified in bold).

• Replaced ''Medicaid base payment rates'' with ''base Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(3)(i)(B) through (E) for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''Medicare non-facility payment rate'' with ''Medicare non-facility payment rate as established in the annual Medicare Physician Fee Schedule final rule'' in § 447.203(b)(3)(i)(C) and (D) for clarification.

• Added ''and whether the payment rate includes facility-related costs'' in § 447.203(b)(3)(ii)(B) to account for facility-related costs in habilitation settings, particularly residential habilitation or day habilitation. The finalized language now states, ''[t]he disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable in § 447.203(b)(3)(ii)(B) (new language identified in bold).

• Replaced ''average hourly payment rate'' with ''average hourly Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(3)(ii) and (ii)(B) and (C) for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''to providers employed by an agency'' with ''provider agencies''

in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) for clarification.

- Replaced ''Medicaid payment rates'' with ''Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(4) for clarification and consistent terminology usage within § 447.203(b).
- Updated the applicability date in § 447.203(b)(4) from January 1, 2026 and effective date of the Medicaid payment rates subject to the comparative payment rate analysis and payment rate disclosure from January 1, 2025 to read: ''The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.''

c. Interested Parties Advisory Group § 447.203(b)(6)

In the proposed rule, we noted that a fundamental element of ensuring access to covered services is the sufficiency of a provider network.[331] As discussed elsewhere in this rule, the HCBS direct care workforce is currently experiencing notable worker shortages.[332] A robust workforce providing HCBS allows more beneficiaries to obtain necessary services in home and community-based settings. We proposed to use data-driven benchmarks in requiring comparative payment rate analyses relative to Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the categories of service specified in proposed § 447.203(b)(2)(i) through (iii), but Medicare non-facility payment rates are generally not relevant in the context of HCBS, as discussed earlier in this section. Furthermore, data alone cannot replace the lived experience of direct care workers and recipients of the services they provide.

Understanding how Medicaid payment rates compare in different geographic areas of a State and across State programs is also an important access to care data point for covered benefits where Medicaid is a predominant payer of services, as in the case of HCBS. In the absence of HCBS coverage and a lack of available payment rate and claims utilization data from other health payers, such as Medicare or private insurers, and with the significant burden and potential infeasibility associated with gathering payment data for individuals who pay out of pocket (that is, self-pay), we noted our belief that it would be a reasonable standard for States to compare their rates to geographically similar State Medicaid program payment rates as a basis for understanding compliance with section 1902(a)(30)(A) of the Act for those services. In addition, even for services where other payers establish payment rates, comparisons to rates paid by other geographically similar States could be important to understanding compliance with section 1902(a)(30)(A) of the Act since Medicaid beneficiaries may have unique health care needs that are not typical of the general population in particular geographic areas.

Section 2402(a) of the Affordable Care Act directs the Secretary to issue regulations ensuring that all States develop service systems that, among other things, improve coordination and regulation of providers of HCBS to oversee and monitor functions, including a complaint system, and ensure that there are an adequate number of qualified direct care workers to provide self-directed services. This statutory mandate, coupled with the workforce shortages exacerbated by the COVID–19 pandemic, necessitates action specific to direct care workers. As such, we proposed to require States to establish an interested parties advisory group to advise and consult on FFS rates paid to direct care workers providing self-directed and agency-directed HCBS, at a minimum for personal care, home health aide, and homemaker services as described in § 440.180(b)(2) through (4), and States may choose to include other HCBS.

We proposed the definition of direct care workers under § 441.302(k)(1)(ii), which is being finalized under § 441.311(e)(1)(ii) in this final rule. We proposed to use that definition to consider a direct care worker a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving HCBS; a licensed nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; a direct support professional; a personal care attendant; a home health aide; or other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living directly to Medicaid-eligible individuals receiving HCBS available under part 441, subpart G. A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

We proposed that the group would consult on rates for service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to individual providers or providers employed by an agency for, at a minimum, the previously described types of services, including for personal care, home health aide, and homemaker services provided under sections 1905(a), 1915(i), 1915(j), and 1915(k) State plan authorities, and section 1915(c) waivers. These proposed requirements also would extend to rates for HCBS provided under section 1115 demonstrations, as is typical for rules pertaining to HCBS authorized using demonstration authority. We proposed that the interested parties advisory group may consult on other HCBS, at the State's discretion.

In this final rule, we are adding an additional service to the group's purview, habilitation services as found under § 440.180(b)(6). In the proposed rule, we proposed an alignment of services subject to the requirements between the HCBS payment adequacy and access to care metrics requirements, and the payment rate disclosure and interested parties advisory group provisions. Within the payment adequacy and access to care metrics provisions of the proposed rule, we requested comment on whether to expand services subject to those requirements to include habilitation services from the proposed personal care, home health aide, and homemaker services. In this final rule, we are adding habilitation services to the reporting requirements for direct care worker compensation data under § 441.311(e) and access to care metrics under § 441.311(d)(2), and therefore are adding habilitation services to the interested parties' advisory group's purview (and, as previously discussed, to the payment rate disclosure requirements). This addition will create consistency between HCBS-related provisions of this final rule. It will also simplify the process for States to provide the relevant materials to members of the interested parties advisory group, and avoid any confusion on the scope of review. We also want to note the point made in earlier provisions of this final

[331] 88 FR 27960 at 28023.

[332] *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

rule, that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services. All three types are included within the ''habilitation services'' we are adding to this provision.

In § 447.203(b)(6), we proposed that the State agency would be required to establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4). In this final rule, as noted, we are adding habilitation services as found at § 440.180(b)(6). The interested parties advisory group would be required to include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. We explained that ''authorized representatives'' refers to individuals authorized to act on the behalf of the beneficiary, and other interested parties may include beneficiary family members and advocacy organizations. To the extent a State's MAC established under proposed § 431.12, if finalized, meets these requirements of this regulation, we proposed that the State could use that committee for this purpose. However, we noted the roles of the MAC under proposed § 431.12 and the interested parties advisory group under proposed § 447.203(b)(6) would be distinct, and the existence or absence of one committee or group (for example, if one of these proposals is not finalized) would not affect the requirements with respect to the other as established in a final rule.

We further proposed in § 447.203(b)(6)(iii) that the interested parties advisory group would advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services. We want to clarify that the group would not be required to advise and consult on the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), until such a time as those data are available under the newly established requirements. We also want to note again here that we are expanding the service categories to include habilitation services as found at § 440.180(b)(6).

In § 447.203(b)(6)(iv), we proposed that the interested parties' advisory group would meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency would be required to ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics for HCBS as described in § 441.311(d)(2) to produce these recommendations. These materials would be required to be made be available with sufficient time for the advisory group to consider them, formulate recommendations, and transmit those recommendations to the State. If the State has asked the group to consider a proposed rate change, the State would need to provide the group with sufficient time to review and produce a recommendation within the State's intended rate adjustment schedule. We noted that this would be necessary because the group's recommendation would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze. The interested parties advisory group would make recommendations to the Medicaid agency on the sufficiency of the established and proposed State plan, section 1915(c) waiver and demonstration payment rates, as applicable. In other words, the group would provide information to the State regarding whether, based on the group's knowledge and experience, current payment rates are sufficient to enlist a sufficiently large work force to ensure beneficiary access to services, and whether a proposed rate change would be consistent with a sufficiently large work force or would disincentivize participation in the work force in a manner that might compromise beneficiary access. We clarify here, as well that the State would not be required to make available the HCBS provider payment adequacy minimum performance and reporting standards under § 441.311(e), and applicable access to care metrics for HCBS under § 441.311(d)(2), until such a time as those data are available per the applicable applicability dates of those respective provisions in this final rule.

We proposed to require States to convene this interested parties' advisory group every 2 years, at a minimum, to advise and consult on current and suggested payment rates and the sufficiency of these rates to ensure access to HCBS for beneficiaries consistent with section 1902(a)(30)(A) of the Act. This timing aligns with the comparative payment rate analysis and payment rate disclosure publication requirements proposed in § 447.203(b)(4), although we noted that this would be a minimum requirement and a State may find that more frequent meetings would be necessary or helpful for the advisory group to provide meaningful and actionable feedback. We further proposed that the process by which the State selects its advisory group members and convenes meetings would be required to be made publicly available, but other matters, such as the tenure of members, would be left to the State's discretion. We want to note that the 2-year cadence could require the group to convene its first meeting and produce a recommendation before the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), will be available. We do not expect the State to furnish information to the group that is not yet available or for the group to comment on those topics for which the State has not yet provided data. We nevertheless are maintaining the 2-year cadence that would require a recommendation 2 years from the effective date of this final rule, as we believe the benefits to the State and group in convening that initial time, even with a limited availability of data for the first meeting, will be beneficial for getting the group to be operational. States have the flexibility to convene the group within a shorter timeframe to adjust the future cadence to align with other publication schedules, if desired.

Finally, in § 447.203(b)(6)(v), we proposed that the Medicaid agency would be required to publish the recommendations of the interested parties' advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency. We intend that States would consider, but not be required to adopt, the recommendations of the advisory group. Under this proposal, the work of the

advisory group would be regarded as an element of the State's overall rate-setting process. Additionally, the feedback of this advisory group would not be required for rate changes. That is to say, should a State need or want to adjust rates and it is not feasible to obtain a recommendation from the advisory group in a particular instance, the State would still be permitted to submit its rate change SPA to CMS. However, to the extent the group comments on proposed rate changes, its feedback would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze, and submit such analysis to us, in connection with any SPA submission that proposes to reduce or restructure Medicaid service payment rates. In addition, by way of clarification, we noted our intent that the advisory group would be permitted to suggest alternate rates besides those proposed by the State for consideration.

We solicited comments on the proposed interested parties' advisory group and about whether other categories of services should be included in the requirement for States to consult with the interested parties advisory group. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing general support for the establishment of the interested parties advisory group. Commenters agreed that individuals with lived experience would provide invaluable insight into appropriate rates for direct care services, including both beneficiaries and direct care workers, which the proposed group would include. Commenters also pointed to a number of anticipated benefits, such as helping to increase pay for these valuable workers, giving beneficiaries a voice on decisions that impact them, providing additional insights into a unique area of the healthcare market, identifying what can attract workers, and addressing an area of critical concern for staffing, which is necessary for the stability of access to HCBS. Multiple commenters stated it was important to have payment rate decisions focus on community needs rather than be determined solely by a State's budget, and thus better meeting the needs of beneficiaries. One commenter stated this group would be valuable for staying abreast of the day-to-day provision of services as it relates to current pay rates, while another noted how it is important to focus on rates in a service area for which there is no Medicare comparison. Another stated this proposal should be used as the template for group feedback and reporting for all provider payment systems in a State.

Some commenters also chose to specifically highlight aspects of the proposals for this group they agreed with. These include having a group to advise on wages, the cadence of group meetings, the publication requirements, the composition of the group members, and allowing States to set the tenure for members. One commenter also pointed out how this group will complement payment adequacy requirements by identifying rates that may meet a set threshold for direct compensation but remains low generally.

Response: We thank commenters for taking the time to express support for the provision and for highlighting many of the areas where we expect this group will add value. We are finalizing the provisions related to the interested parties' advisory group as proposed, with the addition of habilitation services. The shortage of direct care workers demands special attention, and we hope that finalizing these requirements will be one of several steps contained in this final rule toward addressing those concerns.

Comment: A very large proportion of commenters on these provisions had recommendations for changes or enhancements to the interested parties advisory group. A number of those comments related to the composition of the group, with commenters requesting certain proportions for types of members, or specific member positions be added generally or defined as an interested party. Specifically, various commenters recommended a required composition of 25 percent beneficiary representation, 25 percent direct care workers, and 25 percent provider employers, such as representatives from an agency providing HCBS and employing direct care workers. Some commenters expressed similar sentiments without precise numbers, instead recommending representation by various individuals: agency-based model providers; consumer-directed model providers; union representatives; patient advocates; program administrators; politicians; or members of the general public. Some commenters recommended that a majority of members be beneficiaries, unpaid beneficiary caregivers, and advocacy organizations. These commenters had concerns about the possibility that certain key voices could be silenced if not sufficiently represented within the overall composition of the group.

A number of commenters stated that the regulations should require other specific member types without defining in what proportion. There were multiple requests to require members from unions, worker advocacy organizations, consumer advocates, and representatives from provider agencies and provider State associations. These commenters wanted to ensure certain technical expertise would be available amongst the group members. For example, a qualified consumer advocate may have knowledge of technical program aspects that other members may not.

One commenter requested nurses be included in the group, and another requested physician anesthesiologists, noting that they are subject to a uniquely structured payment system. Several commenters stated the group should bar employees of the State agency to ensure independence in developing the recommendations.

Finally, a few commenters requested members who were already among those included in the proposed regulation. Specifically, one commenter stated the group should include paid direct service workers, while another stated HCBS providers should be included.

Response: As stated, we are finalizing the interested party advisory group requirement as proposed apart from the addition of habilitation services, and that includes the provisions defining the membership of the group without specifying particular proportions of required membership. We agree generally that additional types of members such as those suggested by commenters could bring unique perspectives or expertise to the group. Nevertheless, we are finalizing as proposed the membership requirements, because we intentionally proposed a great deal of flexibility for States in recognition of the unique circumstances of State Medicaid programs. We also want to ensure States can meaningfully implement the requirements for this group, and every additional member or type of member presents additional considerations for recruitment needed to set up the group, as well as logistical considerations for coordinating meetings. We believe a limited but inclusive list, with considerable State flexibility in determining the composition of the group, will ensure that interested parties' voices are heard and not silenced, but as with any new policy, we will monitor implementation to identify if adjustments may be needed through future rulemaking.

As the proposed rule contained many changes to existing requirements and processes, we were mindful at every

step of the burden this would place on States, and balanced potential State burden against the proposal's potential to help ensure and improve access. After careful consideration, we determined it was more important to implement a basic framework for the interested party advisory group and leave many details of its precise composition and operation to the States. Our access work is ongoing, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

We would encourage States, when recruiting members, to consider the composition of members that would best satisfy the goals of this group and identify where there is a need for technical expertise, sufficient representation, etc., and work to establish the group in a manner that promotes its efficient functioning and meaningful contribution to Medicaid policies in the State. The inclusion of ''other interested parties'' affords States the flexibility to do so. We believe the lived experiences of the members of this group when coupled with the requirements for States to provide relevant documents and reports for the group's consideration, will be adequate to provide the type of perspective on rates we are seeking through this group.

Finally, we want to clarify which members States are required to include as part of the interested parties advisory group. States are required to include direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the rates in question, as determined by the State, which may include beneficiary family members (other than those who may be authorized representatives for beneficiaries) and advocacy organizations. Representation from each type of individual specified on this list is required. As such, the group could not be solely beneficiaries, or solely direct care workers, or solely other individuals meeting neither of those criteria but whom a State would deem an interested party.

Comment: Another area where many commenters made suggestions was with respect to the scope of the group's work and the requirements related to consideration of the group's recommendations. Many commenters recommended that CMS require States to consult with the group for any rate or payment methodology changes, highlighting the value of the group's input, and to require a written, public response to the recommendation of the group, with evidence and rationale, where the final rates differ from what the group recommended. One commenter also requested a public comment process for the group's recommendations. Some emphasized the importance of transparency of this process, and one suggested recommendations and responses be made public for a minimum of 30 days prior to the effective date of a new rate. Several commenters, noting the proposal made the group advisory in nature, recommended that States be required to justify when they choose to go against the recommendation of the group, with some of those commenters offering that at a minimum the State must engage again with the group when intending to finalize rates that differ from the group's recommendation, including meaningful negotiations with the providers represented on the group, perhaps with steps defined by CMS to reach consensus. One commenter wanted the public process regulations at § 447.204(a)(2) updated to explicitly include obtaining and considering the interested parties advisory group's input. The importance of the group's recommendation came up in multiple comments, with one stating it is not enough merely to require the State to receive, and provide a written response to, the advisory groups' input, but that we should ensure the group has authority to shape policy.

Some commenters had detailed recommendations for additional requirements related to the group's output. One suggested a structured and routine process for regular review and approval of new rates or changes, with meaningful input from beneficiaries. The commenter requested the structured process to be coupled with a requirement for States to explain the roles and responsibilities of a rate review advisory body. Another wanted CMS to require States to clearly delineate how a proposed rate change has factored in inflation and any unfunded mandates on providers. One commenter stated that the group's recommendations should go to the State Medicaid director, as well as to the governor, the State legislature, and HHS. Like other commenters, this commenter wanted the State to communicate acceptance or denial of recommendations to the group, with explanations of the State's decisions in writing, but also stressed that CMS must monitor the State advisory committees as part of accountability and transparency and provide feedback to the State.

Some comments also contained other, related recommendations for the group's purview. Two commenters recommended the group be allowed to advise and comment on a broad range of HCBS provider rates, with one suggesting CMS consider leveraging the group for feedback on HCBS access issues more broadly. That commenter stressed the importance to the Medicaid program to evaluate rates and access for HCBS, especially considering the unique market power of Medicaid for HCBS infrastructure. A commenter requested the group's rate review consider the experience of individuals dually eligible for Medicare and Medicaid and factors related to Medicare coverage. One commenter stated the group should advocate for creating a sustainable wage program to attract and retain staff to benefit both recipients and providers of the specified services. Another commenter recommended that the group should review and comment on provider payment rates in managed care delivery systems. One commenter, in response for our request for comment on the services under review, stated the group should focus on direct care work across all waiver categories. Finally, a couple commenters sought clarity on how States must acknowledge or respond to the group's recommendations.

Response: We are finalizing as proposed the advisory nature of the interested parties advisory group. We agree that the group's input will be valuable in setting rates, assessing payment adequacy and applicable access to care metrics, and may provide a perspective on rates and access that could be lacking in existing processes. As one commenter noted, Medicaid has an important and large role in the market for HCBS. However, we believe the policies as we are finalizing them strike the right balance of accountability and flexibility for a wholly new rate advisory group process. The State will be required to publish the recommendations of the interested parties advisory group for transparency, under § 447.203(b)(6)(v). In addition, when the group has a recommendation on a proposed rate change, the State will be required to consider and respond to that recommendation as it would be deemed part of the input of interested parties described in §§ 447.203(c)(4) and 447.204(b)(3). In light of the public notice and public input requirements already in place when a State proposes a rate change, and treatment of the recommendation as public input to which a State is required to consider and address under these requirements, we are not establishing any specific, new public notice or comment process requirements for the recommendations

of the interested parties advisory group. The group could recommend a sustainable wage program, but we are not adding a requirement to develop one. We intend for the group to have broad discretion, within their remit, to make recommendations to the State, which could thereby result in such recommendations. We encourage the group to provide feedback to assist the State in implementing a sustainable HCBS program.

By keeping the group's recommendations recommendation advisory only (that is, non-binding on the State), we intend for the State to give serious consideration to the group's recommendations while avoiding the imposition of policy strictures on the State that could require sudden shifts in budget priorities or create conflicts, for example, with the State legislature. Fundamentally, the single State Medicaid agency must maintain ultimate responsibility to operate the State's Medicaid program. Also, because the group is advisory only, we are not including requirements for the State to negotiate with providers or the group on rate changes, or justify when a rate change is made that is not consistent with the recommendation of the group. However, we remind States that the group's recommendation, to the extent it has commented on rates included in a SPA, would be considered part of the public feedback to which the State must respond, under §§ 447.203(c)(4) and 447.204.

As part of the requirement to establish the interested parties' advisory group in this final rule, States will be responsible for giving appropriate guidance to the group so that it understands its role and responsibilities in producing recommendations. We defer to States on how to best communicate this information to the group. We also want to emphasize for States that the information they provide the group can be expected to shape the nature of the group's recommendations. As such, although we are not requiring the State to explain if and how inflation has factored in to a proposed rate, for example, or provide information to the group on costs imposed on providers beyond what is required under the payment adequacy metrics required under 441.311(e), it would benefit a State to provide as much context as possible to the group so that it can produce the strongest, best-informed, most useful recommendations. Because the group's recommendations must be published publicly, interested parties such as State legislators and HHS will be able to see and review any recommendations.

In addition, with the meeting cadence we are finalizing (at least every 2 years), and with recent examples of when a rate change may be needed to be enacted quickly (for example, to address urgent programmatic needs in connection with the COVID–19 pandemic and public health emergency), it is not feasible to require consultation with the group for every possible rate change. We also note that the mandate of the group and the minimum required meeting cadence should not be viewed as limitations, and States have flexibility to rely on this group in ways that will best help to enhance HCBS or Medicaid more broadly. States may have the group review broader HCBS issues or rates if it so chooses; we merely focused the required scope on the most frequently used HCBS. They can also have the group advise on provider payment rates in managed care delivery systems even though that was not our prioritized focus in this new requirement, under the flexibility States have to direct the work of the group. We also note that although we are not requiring dually eligible beneficiaries specifically in the group to maximize the available pool for recruiting beneficiary members of the group, the majority of HCBS recipients are dually eligible. Finally, we appreciate the many recommendations and suggestions that we will consider if and when we examine the regulations for this group for potential changes through future rulemaking as part of our ongoing access work.

Comment: Several commenters had recommendations for the nature of materials, data, explanations, and information the group should have access to, to ensure the group's input could be fully informed by data, both public and internal to the agency, as to how any rates were calculated. These comments included advice on what materials the group should have access to or suggestions of sources the group should be required to review and consider. Specifically, a couple of commenters wanted the group to be required to consult any analyses performed pursuant to the requirements we are finalizing in § 447.203(c), since those analyses would include valuable data on the number of home care claims, the number of enrollees receiving home care services, and the number of providers furnishing such services. Another commenter recommended the group to be required to consult wage data, such as data from the Bureau of Labor Statistics or from unions, to use as a basis of rate recommendations. Another commenter encouraged CMS to partner with the Department of Labor to provide States with data on competitive wages for other occupations with similar low entry level requirements, to avoid putting burden on States while providing the advisory group with State-level economic data to assess the competitiveness of direct care worker wages.

One commenter provided a detailed recommendation for data to provide the group, including explanations and supporting information on how any proposed rates were calculated, in addition to the metrics required under the payment adequacy and reporting requirements provisions of this final rule. Specifically, the commenter stated this information should include clear, consistent definitions of the cost elements that are considered in establishing a rate, noting that if the definitions of cost components such as employee travel or training are not clear and the bases for these calculations are not shared with sufficient granularity, then the advisory group will not be able to meaningfully comment. Similarly, a commenter urged CMS to ensure that the interested parties advisory group have access to both public-facing reports that States are required to produce and publish described in payment transparency provisions of this rule, and to the underlying data that States use to prepare these reports, which may allow the interested parties advisory group to identify trends or access issues that are not readily apparent in the public reports. One commenter recommended that States be required, through a phase-in, to both collect and provide to the group data on turnover and vacancy rates for direct care workers. The commenter explained that tools currently used by States, such as the National Core Indicators-Intellectual and Developmental Disabilities Staff Stability Survey, or the National Core Indicators-Aging and Physical Disabilities tool currently being piloted, only provide data for agency-directed workers, and as such, more information was needed about independent providers in self-directed programs. The commenter noted these are important data elements to assess the adequacy of wages and compensation.

Finally, a few commenters stated that States should make compensation, including information on median wages and historic trends in compensation, available to all members of the public, for transparency and to assist current or future members of the group itself.

Response: We are finalizing as proposed, apart from the addition of habilitation services, the regulation requiring that the group will advise and consult on current and proposed

payment rates, HCBS provider payment adequacy reporting information under § 441.311(e),), and applicable access to care metrics under § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6). The responsibility for the group to advise and consult on these matters necessarily implies that the State must ensure that the group is provided access to current and proposed rate information, HCBS provider payment adequacy data, and applicable access to care metrics. We believe that these requirements, coupled with requirements we are finalizing for payment rate disclosures for HCBS at § 447.203(b)(2) through (3), will provide the group with sufficient data to develop and support their recommendations, and we also believe those additional finalized provisions will provide reassurance to commenters interested in more publicly available data. We further note that certain data, such as certain BLS wage data, are already publicly available and can be used by the group. We remind States that they are not limited to the requirements we are finalizing and are free to consider and provide as much data that the State considers relevant and reasonably available to support the group in its work.

We did not propose and are not finalizing any data collection requirements specifically with respect to the interested parties' advisory group to inform their consideration of Medicaid payment rates for certain HCBS, although we understand that currently available tools and data may have some gaps. In view of the otherwise existing information sources just discussed, we do not believe the value of requiring States to identify or develop and make available additional data sources, such as reporting on independent providers in self-directed programs, would outweigh the added burden of a new data collection. We are similarly not taking on any additional data collection to support these efforts, again noting that we think the policies in this final rule will be sufficient, but as with any new or existing policy we will work with our State partners to assist them in establishing these groups and identifying where we can support State efforts that may extend beyond the requirements in this final rule.

Comment: We received a number of comments around various administrative aspects of § 447.203(b)(6), from member recruitment to the meeting cadence. Several commenters stated that the State should publicly recruit members and requested States to publicly disclose the process of how those members are recruited and the process to convene meetings. A few commenters recommended the members have term-limits, coupled with the protection to only be removed for cause during a term, in order to protect the individuals and the group from reprisal or disbandment.

Comments about the meeting cadence varied. A few recommended the group should meet for every rate change proposed by the State, one agreed with a biannual cadence, while another suggested to increase the cadence to annually in addition to meeting for every rate change. Another commenter supported annual meetings and noted that issues impacting the lives of beneficiaries and workers that should be addressed by rates can happen at a more frequent rate than biannual State budget cycles. One commenter stated the meeting cadence should be every 6 months.

A few commenters suggested a number of additional recommendations such as the regulation should include a requirement of recordkeeping, and the regulation should focus on the distinction between independent and agency-employed workers. Finally, one commenter suggested a name change for the group, ''direct care workforce payment advisory committee,'' to clarify the role and importance of the group.

Response: We appreciate the feedback about the specifics of the administration of the interested parties advisory group. We are finalizing these aspects as proposed. The meeting cadence, as noted by the commenter, is intended to align with usual State budgetary cycles. While other factors may impact the needs of beneficiaries, providers and direct care workers, the State budget creates the framework in which decisions and recommendations can be made, and we believe aligning with that cycle appropriately balances the value gained from the interested parties advisory group's recommendations with burden on States. Similarly, we are finalizing the ability of States to determine the tenure of members, as States are best situated to assess their beneficiaries' and workers' ability to participate in an advisory group and for what length of time. Term limits and removal for cause will be at the State's discretion to ensure the effective operation of the group. We note that the regulation does specify that the process by which the State selects interested parties advisory group members and convenes its meetings must be made publicly available, which aligns with recommendations from some commenters.

States have requirements to maintain records of public input under § 447.203(c)(4)(iii), and as stated we would regard the recommendation of the group a form of public input to the extent the group comments on proposed rates.

With respect to individual and agency-employed providers, the payment rate disclosure requirements under § 447.203(b)(3)(ii2)(iv) require States to publish average hourly Medicaid FFS fee schedule payment rates for individual providers and provider agencies separately to the extent they differ, creating a new method through which the State, CMS, and the public can scrutinize any rate difference between individual providers and provider agencies. We are not adding additional requirements for the group to examine further distinctions between individual and provider agencies, but as the group will be reviewing current and proposed rates, they will have the opportunity to see where such rates differ and make recommendations accordingly.

Finally, we appreciate the suggestion to change the name of the group, but we want to remind that the purview of this group is not solely payments for HCBS, although that is the primary focus. The work includes access metrics, specifically HCBS payment adequacy data as required at § 441.311(e), and access to care metrics under § 441.311(d)(2). We understand the name is rather generic, and we will make every effort to ensure any materials or communications are clear about when an ''interested parties advisory group'' is in reference to § 447.203(b)(6).

Comment: We received some comments in opposition to an interested parties advisory group. A primary, recurring element of these comments was related to the burden of establishing this group relative to the value the commenters thought the group would add. One commenter stated this group would be duplicative of other State efforts, without adding value. Another was concerned that the group would establish a pattern for more, similar groups to be created, resulting in significant State burden. Another stated the group would create undue interference in a State's ability to manage its Medicaid program. One commenter stated that limiting the group's purview to three services would create disjointedness in discussions about HCBS or broader rates in general.

One commenter stated that their MCAC (or, following the effective date of this final rule, their MAC), already performs the same functions as the

proposed interested parties advisory group. Another requested an exception to the requirement for States that already have a group established for similar topics. Two commenters in opposition to the requirement had recommendations for adjustments. One commenter stated that the group should not include members who have a conflict of interest because they stand to receive a financial benefit from the decisions of the group, or that the scope of the group's recommendations should exclude payment rates if group members have financial conflicts of interest. Another commenter, who thought the group was unworkable and likely would not be productive, indicated it would be more productive to require States to establish a separate advisory group for each rate setting activity they undertake and to include both industry and consumer (beneficiary) representatives.

Response: We understand that there will be costs and work for States to set up a new advisory group. We do not take lightly the decision to finalize this policy. However, the circumstance of HCBS and the direct care workforce shortage described earlier in this section demand immediate action. We kept the required scope of the group's remit narrow to allow States that need to minimize the work of the group the ability to focus most acutely on certain services and certain topics around rates, access, and payment adequacy. However, we also wrote into these regulations a great deal of flexibility for States. We understand the burden our requirements put on States, which is why we take steps to create and highlight flexibility for States to minimize the burden of new requirements and help ensure that States are able to comply with new requirements in a manner likely to result in the greatest benefit given the particular circumstances of the State and its provider and beneficiary communities. We make these assessments with every rulemaking proposal. The creation of this group does not mean that we necessarily will propose to require the formation of additional similar, discrete groups in the future; we are mindful that any such proposal would be likely to involve additional burden on States, and analysis of that burden would inform any future proposal.

If a State believes the group, in the form which we are finalizing in this final rule, will not add value, there is room to expand and enhance the group to a point where that State realizes value to its program. The group's purview includes the requirement to examine rates for three services, but States can always have the group advise on more. In addition, the group will not be in a position to unduly influence the State's Medicaid program, as its role is only advisory in nature and the single State agency will maintain full responsibility to administer the State's Medicaid program. We also want to remind States what we included in the proposed rule, that to the extent a State's MAC established under § 431.12 meets the requirements of this regulation, the State could utilize that committee for this purpose, thereby eliminating duplication between these entities. Furthermore, while we are unaware of specific examples, if a State has another, extant group that meets the requirements of § 447.203(b)(6), then we expect the State could use that group for this purpose as well, similar to what we indicated for MACs. Finally, we do not agree that having members in the group with a financial interest, such as the direct care workers whose wages may be impacted, and advising on rates creates a problematic conflict of interest. Rather, in the case of direct care workers, we believe their lived experience will supply a valuable perspective, and their input on rates specifically could be useful to the State agency that (although operating under a fiduciary obligation to administer the Medicaid program in the best interest of beneficiaries under section 1902(a)(19) of the Act) also has a fiscal interest in a proposed rate change. This final rule leaves States free to establish conflict of interest policies applicable to the members of the interested parties' advisory group, which we expect States will do in a manner that protects the integrity of the group while not unduly restricting input from individuals with perspectives the final rule is intended to ensure are heard.

Comment: Several commenters responded to language included in the proposed rule that, to the extent a State's MAC established under proposed § 431.12 also meets the requirements of this advisory group regulation, the State could utilize that committee for this purpose. The majority of those comments recommended keeping the MAC separate. These commenters explained that the work involved merits two groups and any overlap of membership between the groups would be acceptable and potentially beneficial. One of those commenters stated that the work of the interested parties' advisory group was much more specialized than that of the MAC. One suggested the interested parties' advisory group be a subgroup of the MAC, similar to the BAG. Finally, one commenter suggested that the MAC and interested parties' advisory group meetings be kept separate, or the MAC could have a dedicated subgroup responsible for HCBS, to ensure adequate attention to the topic. There were a few commenters who appreciated the flexibility to allow for the MAC to serve this dual purpose of meeting both the MAC requirements and the interested parties' advisory group requirements, and one expected some States may pursue this flexibility.

Response: When we were developing the proposed rule, which included proposals under § 431.12 to reconfigure the MCAC as the MAC and BAG (now BAC), we noted that the membership and scope of the MAC could potentially align with what we were proposing for the interested parties' advisory group. While we agree that the work of each is distinct and important, deserving of dedicated time and focus, we also seek to avoid duplication where possible. If a MAC has membership that includes direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services and rates of focus in the interested parties' advisory group, then we believe it would be unnecessarily duplicative to require a separate group and deny the State the ability to include the remit of the interested parties' advisory group in the work of the MAC under the flexibility given to States and their MACs under § 431.12(g)(8), which we are finalizing to include in the MAC's scope ''[o]ther issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.'' States potentially also could establish the interested parties' advisory group as a subgroup of the MAC, similar to the BAC, consistent with the requirements of this final rule. States will have the discretion to determine if the groups and/or their meetings need to be kept distinct in order best to fulfil the obligations of each.

However, we caution States that this flexibility is not creating any type of exception. The cadence of required meetings, focus, and work products of the interested parties advisory group are distinct, and States wishing to utilize their MAC will need to take adequate steps to ensure the MAC is meeting the regulatory requirements for both entities. Some States may find keeping the interested parties group distinct will allow for easier recruitment, retention, and focus on the relevant subject matter. We also want to highlight the concerns expressed by commenters requesting the groups be kept distinct and emphasizing

the specialized work of this interested parties advisory group. Although we did not elect to add requirements to keep the groups or meetings distinct, States should do so if combining the groups or their meetings would hinder the work of either the MAC or interested parties advisory group.

Comment: A few commenters requested additional clarity about what support would be available for States to establish the advisory group. A couple of commenters requested CMS confirm that States can claim FFP for activities related to establishing and running this group, similar to the confirmation provided in the MAC/BAG provisions explicitly saying FFP would be available.[333] Others requested CMS make States aware of any available funding streams or opportunities for enhanced match.

Response: In the proposed rule, we specified that ''FFP would be available for expenditures that might be necessary to implement the activities States would need to undertake to comply with the provisions of the proposed rule, if finalized.''[334] As we are finalizing the requirements related to this advisory group, FFP will be available for States claiming qualifying expenditures for related activities. We note that generally, the applicable matching rate will be the general 50 percent administrative matching rate, but to the extent a State incurs expenditures it believes qualify for a higher match rate, higher statutory matching rates potentially could be available to the extent the expenditures meet applicable Federal requirements. There is not a separate, unique funding source for this provision of the final rule.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(6) with the following changes:

- Added a regulatory reference for habilitation services as a category of service in § 447.203(b)(6)(i). The finalized language now states ''. . . for the self-directed or agency-directed services found at § 440.180(b)(2) through (4) **and (6)**.'' (new language identified in bold).
- Added a regulatory reference for habilitation services and ''habilitation'' as a category of service in § 447.203(b)(6)(iii). The finalized language now states ''. . . associated with services found at § 440.180(b)(2) through (4) **and (6)**, to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and **habilitation** services'' (new language identified in bold).
- Added language to clarify the ''. . . publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section . . .'' (new language identified in bold).
- Minor technical changes to wording.

3. State Analysis Procedures for Rate Reduction or Restructuring (§ 447.203(c))

As stated previously, the Supreme Court's Armstrong decision underscored the importance of CMS' administrative review of Medicaid payment rates to ensure compliance with section 1902(a)(30)(A) of the Act. CMS' oversight role is particularly important when States propose to reduce provider payment rates or restructure provider payments, since provider payment rates can affect provider participation in Medicaid, and therefore, beneficiary access to care. In § 447.203(c), we proposed a process for State access analyses that would be required whenever a State submits a SPA proposing to reduce provider payment rates or restructure provider payments.

As noted previously, the 2015 final rule with comment period required that, for any SPA proposing to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, States must submit a detailed analysis of access to care under previous §§ 447.203(b)(1) and (b)(6) and 447.204(b)(1). This analysis includes, under previous § 447.203(b)(1), the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Previously, this information was required for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, regardless of the provider payment rates or levels of access to care before the proposed reduction or restructuring.

Following the implementation of the 2015 final rule with comment period, as we worked with States to implement the previous AMRP requirements, many States expressed concerns that the requirements that accompany proposed rate reductions or restructurings are overly burdensome. Specifically, States pointed to instances where proposed reductions or restructurings are nominal, or where rate changes are made via the application of a previously approved rate methodology, such as when the State's approved rate methodology ties Medicaid payment rates to a Medicare fee schedule and the Medicare payment rate is reduced. We acknowledged these concerns through previous proposed rulemaking. In the 2018 proposed rule, we agreed that our experience implementing the previous AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when proposed rate changes include nominal rate reductions or restructurings that are unlikely to result in diminished access to care.[335]

We did not finalize the 2018 proposed rule; instead, in response to feedback, we proposed a rescission of the previous AMRP process in the 2019 proposed rule.[336] In that proposed rule, we indicated that future guidance would be forthcoming to provide information on the required data and analysis that States might submit with rate reduction or restructuring SPAs in place of the previous AMRP process to support compliance with section 1902(a)(30)(A) of the Act.[337] We did not finalize the rescission proposed in the 2019 proposed rule. Although we were concerned that the previous AMRP process was overly burdensome for States and CMS in relation to the benefit obtained in helping ensure compliance with the access requirement in section 1902(a)(30)(A) of the Act, our 2018 and 2019 proposed rules did not adequately consider our need for information and analysis from States seeking to reduce provider payment rates or restructure provider payments to enable us to determine that the statutory access requirement is met when making SPA approval decisions.

To improve the efficiency of our administrative procedures and better inform our SPA approval decisions, we proposed to establish standard information that States would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when

[333] 88 FR 27960 at 27967.

[334] 88 FR 27960 at 27962.

[335] 83 FR 12696 at 12697.

[336] 84 FR 3372.2.

[337] Id at 33723.

the changes could result in diminished access, including a streamlined set of data when the reductions or restructurings are nominal, the State rates are above a certain percentage of Medicare payment rates, and there are no evident access concerns raised through public processes; and an additional set of data elements that would be required when States propose FFS provider payment rate reductions or restructurings in circumstances when the changes could result in diminished access and these criteria are not met. For both sets of required or potentially required elements, we proposed to standardize the data and information States would be required to submit with rate reduction or restructuring SPAs. Although the previous AMRP process has helped to improve our administrative reviews and helped us make informed SPA approval determinations, we explained that the proposed procedures would provide us with similar information in a manner that reduces State burden. Additionally, the proposed procedures would provide States increased flexibility to make program changes with submission of streamlined supporting data to us when current Medicaid rates and proposed changes fall within specified criteria that create a reasonable presumption that proposed reductions or restructuring would not reduce beneficiary access to care in a manner inconsistent with section 1902(a)(30)(A) of the Act.

This final rule seeks to achieve a more appropriate balance between reducing unnecessary burden for States and CMS and ensuring that we have the information necessary to make appropriate determinations for whether a rate reduction or restructuring SPA might result in beneficiary access to covered services failing to meet the standard in section 1902(a)(30)(A) of the Act. In § 447.203(c), we proposed to establish analyses that States would be required to perform, document, and submit concurrently with the submission of rate reduction and rate restructuring SPAs, with additional analyses required in certain circumstances due to potentially increased access to care concerns.

We proposed a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, proposed at § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. The State agency would be required to provide written assurance and relevant supporting documentation that the three criteria specified in those paragraphs are met, as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act. As explained in more detail later in this section, these criteria proposed in § 447.203(c)(1) represent thresholds we believe would be strong indicators that Medicaid payment rates would continue to be sufficient following the change to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted that, in the course of our review of a payment SPA that meets these criteria, as with any SPA review, we may need to request additional information to ensure that all Federal SPA requirements are met. We also note that meeting the three criteria described in proposed § 447.203(c)(1) does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. Furthermore, if any criterion in the first tier is not met, we proposed a second tier in § 447.203(c)(2), which would require the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. A detailed discussion of the second tier follows the details of the first tier in this section.

Under proposed § 447.203(c)(1)(i), the State would be required to provide a supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

In proposed § 447.203(c)(1)(i), we explained that we mean for ''benefit category'' to refer to all individual services under a category of services described in section 1905(a) of the Act for which the State is proposing a payment rate reduction or restructuring. Comparing the payment rates in the aggregate would involve first performing a comparison of the Medicaid to the Medicare payment rate on a code-by-code basis, meaning CPT, CDT, or HCPCS as applicable, to derive a ratio for individual constituent services, and then the ratios for all codes within the benefit category would be averaged by summing the individual ratios then dividing the sum by the number of ratios. For example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates. For supplemental payments, we are relying upon the definition of supplemental payments in section 1903(bb)(2) of the Act, which defines supplemental payments as ''a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority . . . [b]ut such term does not include a disproportionate share hospital payment made under section 1923 [of the Act].'' With the inclusion of supplemental payments, States would need to aggregate the supplemental payments paid to qualifying providers during the State fiscal year and divide by all providers' total service volume (including service volume of providers that do not qualify for the supplemental payment) to establish an aggregate, per-service supplemental payment amount, then add that amount to the State's fee schedule rate to compare the aggregate Medicaid payment rate to the corresponding Medicare payment rate. As this supported assurance in proposed § 447.203I(1)(i) is expected to be provided with an accompanying

SPA, we noted that CMS may ask the State to explain how the analysis was conducted if additional information is needed as part of the analysis of the SPA. We solicited comments on the proposed § 447.203I(1)(i) supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services should include a weighted average of the payment rate analysis by service volume, number of beneficiaries receiving the service, and total amount paid by Medicaid for the code in a year using State's Medicaid utilization data from the MMIS claims system rather than using a straight code-by-code analysis.

We explained that we understand this approach may have a smoothing effect on the demonstrated overall levels of Medicaid payment within a benefit category under the State plan. In many circumstances, only a subset of providers are recipients of Medicaid supplemental payments with the rest of the providers within the benefit category simply receiving the State plan fee schedule amount. This could result in a demonstration showing the Medicaid payments being high relative to Medicare, but the actual payments to a large portion of the providers would be less than the overall demonstration would suggest. As an alternative, we considered whether to adopt separate comparisons for providers who do and who do not receive supplemental payments, where a State makes supplemental payments for a service to some but not all providers of that service. We solicited comments on the proposed approach and this alternative.

We selected FFS Medicare, as opposed to Medicare Advantage, as the proposed payer for comparison for a number of reasons. A threshold issue is payment rate data availability: private payer data may be proprietary or otherwise limited in its availability for use by States. In addition, Medicare sets its prices rather than negotiating them through contracts with providers, and is held to many similar statutory standards as Medicaid with respect to those prices, such as efficiency, access, and quality.[338] For example, section 1848(g)(7) of the Act directs the Secretary of HHS to monitor utilization and access for Medicare beneficiaries provided through the Medicare fee schedule rates, and directs that the Medicare Payment Advisory Commission (MedPAC) shall comment on the Secretary's recommendations. In developing its comments, MedPAC convenes and consults a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care. In a March 2001 report, MedPAC summarized its evaluation of Medicare rates, stating ''Medicare buys health care products and services from providers who compete for resources in private markets. To ensure beneficiaries' access to high-quality care, Medicare's payment systems therefore must set payment rates for health care products and services that are: high enough to stimulate adequate numbers of providers to offer services to beneficiaries, sufficient to enable efficient providers to supply high-quality services, given the trade-offs between cost and quality that exist with current technology and local supply conditions for labor and capital, and low enough to avoid imposing unnecessary burdens on taxpayers and beneficiaries through the taxes and premiums they pay to finance program spending.'' [339] Medicare's programmatic focus on beneficiary access aligns with the requirements of section 1902(a)(30)(A) of the Act.

In addition, Medicare PFS fee schedule rates are stratified by geographic areas within the States, which we seek to consider as well to ensure that payment rates are consistent with section 1902(a)(30)(A) of the Act. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT),) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average. The current Medicare PFS locality structure was implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). Under the current locality structure, there are 112 total PFS localities.[340]

When considering geography in their rate analyses, we noted that we expect States to conduct a code-by-code analysis of the ratios of Medicaid-to-Medicare provider payment rates for all applicable codes within the benefit category, either for each of the GPCIs within the State, or by calculating an average Medicare rate across the GPCIs within the State (such as in cases where a State does not vary its rates by region). In cases where a State does vary its Medicaid rates based on geography, but that variation does not align with the Medicare GPCI, we explained that the State should utilize the Medicare payment rates as published by Medicare for the same geographical location as the base Medicaid FFS fee schedule payment rate to achieve an equivalent comparison and align the Medicare GPCI to the locality of the Medicaid payment rates, using the county and locality information provided by Medicare for the GPCIs, for purposes of creating a reasonable comparison of the payment rates.[341] To conduct such an analysis that meets the requirements of proposed § 447.203(c)(1)(i), States may compare the Medicaid payment rates applicable to the same Medicare GPCI to each Medicare rate by GPCI individually, and then aggregate that comparison into an average rate comparison for the benefit category. To the extent that Medicaid payment rates do not vary by geographic locality within the State, the State may also calculate a Statewide average Medicare rate based upon all of the rates applicable to the GPCIs within that State and compare that average Medicare rate

[338] *https://www.healthcarevaluehub.org/advocate-resources/publications/medicare-rates-benchmark-too-much-too-little-or-just-right.*

[339] MedPAC. Report to the Congress: Medicare Payment Policy, March 2001. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar01Ch1.pdf.* Accessed December 20, 2022.

[340] Section 220(b) of PAMA 204 added section 1848(e)(6) of the Act, which requires that, for services furnished on or after January 1, 2017, the locality definitions for California, which has the most unique locality structure, be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California's locality structure increased its number of localities from 9 under the previous structure to 27 under the MSA-based locality structure (operational note: for the purposes of payment the actual number of localities under the MSA-based locality structure is 32). Of the 112 total PFS localities, 34 localities are Statewide areas (that is, only one locality for the entire State). There are 75 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 112 localities. Medicare PFS Locality Configuration. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.* Accessed December 21, 2022.

[341] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

to the average Medicaid rate for the benefit category.

Once we decided to propose using Medicare payment rates as a point of comparison, we needed to decide what threshold ratio of proposed Medicaid to Medicare payment rates should trigger additional consideration and review for potential access issues. First, we considered how current levels of Medicaid payment compares to the Medicare payment for the same services. In a 2021 *Health Affairs* article, Zuckerman, et al, found that ''Medicaid physician fees were 72 percent of Medicare physician fees for twenty-seven common procedures in 2019.'' [342] This ratio varied by service type. For example, ''the 2019 Medicaid-to-Medicare fee index was lower for primary care (0.67) than for obstetric care (0.80) or for other services (0.78).'' The authors also found that ''between 2008 and 2019 Medicare and Medicaid fees both increased (23.6 percent for Medicare fees and 19.9 percent for Medicaid fees), leaving the fee ratios similar.'' [343]

Next, considering that Medicaid rates are generally lower than Medicare, we wanted to examine the relationship between these rates and a beneficiary's ability to access covered services. This led us to first look into a comparison of physician new patient acceptance rates based on a prospective new patient's payer. In a June 2021 fact sheet, MACPAC found ''in 2017 (the most recent year available), physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent).'' [344] MACPAC found this to be true ''regardless of physician demographic characteristics (age, sex, region of the country); and type and size of practice.'' [345]

We then wanted to confirm whether this was related to the rates themselves. In a 2019 *Health Affairs* article, the authors found that, ''higher payment continues to be associated with higher rates of accepting new Medicaid patients. . .physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid.'' [346] The study found that physicians in States that pay above the median Medicaid-to-Medicare fee ratio accepted new Medicaid patients at higher rates than those in States that pay below the median, with acceptance rates increasing by nearly 1 percentage point (0.78) for every percentage point increase in the fee ratio.[347]

Similarly, in a 2020 study published by the *National Bureau of Economic Research,* researchers found that there was a positive association between increasing Medicaid physician fees and increased likelihood of having a usual source of care, improved access to specialty doctor care, and large improvements in caregivers' satisfaction with the adequacy of health coverage, among children with special health care needs with a public source of health coverage.[348] Further, Berman, et al, focused on pediatricians and looked at Medicaid-Medicare fee ratio quartiles, finding that the percent of pediatricians accepting all Medicaid patients and relative pediatrician participation in Medicaid increased at each quartile, but improvement was most significant up to the third quartile.[349] According to the Kaiser Family Foundation, in 2016, following the expiration of section 1202 of the Affordable Care Act (Pub. L. 111–148), which amended section 1902(a)(13) of the Act to implement a temporary payment floor for certain Medicaid primary care physician services, the third quartile of States had Medicaid-Medicare fee ratios of between 79 and 86 percent for all services provided under all State Medicaid FFS programs.[350] Importantly, considering the proposed requirements at paragraph (c) would pertain to proposed payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access, multiple recent studies have also shown that the association between Medicaid physician fees and measures of beneficiary access are consistent whether physician payments are increased or decreased to reach a particular level at which access is assessed.[351]

The Kaiser Family Foundation found that 23 States have Medicaid-to-Medicare fee ratios of at least 80 percent for all services, 17 States have fee ratios of 80 percent for primary care services, 32 States have fee ratios of 80 percent for obstetric care, and 27 States have fee ratios of 80 percent for other services.[352] Additional studies support the Holgash and Heberlein findings that physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid, showing that States with a Medicaid to Medicare fee ratio at or above 80 percent show improved access for children to a regular source of care,[353] and decreased use of hospital-based facilities, versus States with a lower Medicaid to Medicare fee ratio.

We noted our concern that higher rates of acceptance by some providers of new patients with payers other than Medicaid (specifically, Medicare and private coverage), and indications by some providers that low Medicaid payments are a primary reason for not accepting new Medicaid patients, may suggest that some beneficiaries could have a more difficult time accessing covered services than other individuals in the same geographic area. We are encouraged by findings that suggest that some increases in Medicaid payment rates may drive increases in provider acceptance of new Medicaid patients, with one study finding that new Medicaid patient acceptance rates increased by 0.78 percent for every percentage point increase in the Medicaid-to-Medicare fee ratio, for certain providers for certain States above the median Medicaid-to-Medicare fee ratio.[354] [355] In line with the Berman

[342] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611 (accessed December 23, 2022).*

[343] Id.

[344] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf* (accessed December 23, 2023).

[345] Id.

[346] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[347] Id.

[348] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Medicaid Physician Fees and Access to Care among Children with Special Health Care Needs | NBER. Accessed June 16, 2022.

[349] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[350] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[351] Candon, M., et al. ''Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients'' *JAMA Internal Medicine,* Volume 178, Number 1, January 2018, p. 145–146. Available at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663253.* Accessed June 16, 2022.

[352] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[353] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Available at *https://www.nber.org/papers/w26769.* Accessed August 16, 2022.

[354] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/*

Continued

study, which found that increases in the percentage of pediatricians participating in Medicaid and of pediatricians accepting new Medicaid patients occurred with Medicaid payment rate increases at each quartile of the Medicaid-to-Medicare fee ratio but were most significant up to the third quartile, we believe that beneficiaries in States that provide this level of Medicaid payment generally may be less likely to encounter access to care issues at rates higher than the general population.[356] In line with the Kaiser Family Foundation reporting of the Medicaid-to-Medicare fee ratio third quartile as ranging from 79 to 86 percent in 2016, depending on the service, we stated our belief that a minimum 80 percent Medicaid-to-Medicare fee ratio is a reasonable threshold to propose in § 447.203(c)(1)(i) as one of three criteria State proposals to reduce or restructure provider payments would be required to meet to qualify for the proposed streamlined documentation process.[357] As documented by the Kaiser Family Foundation, many States currently satisfy this ratio for many Medicaid-covered services, and according to findings by Zuckerman, et al. in *Health Affairs,* in 2019, the average nationwide fee ratio for obstetric care met this proposed threshold.[358] [359] We proposed that this percentage would hold across benefit categories, because we did not find any indication that a lower threshold would be adequate, or that a higher threshold would be strictly necessary, to support a level of access to covered services for Medicaid beneficiaries at least as great as for the general population in the geographic area. We noted that the disparities in provider participation for some provider types may be larger than this overview suggests, as such we proposed a uniform standard in the interest of administrative simplicity but cautioned that States must meet all three of the criteria in proposed paragraph (c)(1) to qualify for the streamlined analysis process; otherwise, the additional analysis specified in proposed paragraph (c)(2) would be required.

Given the results of this literature review, and by proposing this provision as only one part of a three-part assessment of the likely effect of a proposed payment rate reduction or payment restructuring on access to care, as further discussed in this section, we proposed 80 percent of the most recently published Medicare payment rates, as identified on the applicable Medicare fee schedule for the same or a comparable set of Medicare-covered services, as a benchmark for the level of Medicaid payment for benefit categories that are subject to proposed provider payment reductions or restructurings that is likely to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent as to the general population in the geographic area, where the additional tests in proposed § 447.203(c)(1) also are met. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

We explained that the published Medicare payment rates means the amount per applicable procedure code identified on the Medicare fee schedule. The established Medicare fee schedule rate includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient. Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, State fee schedules should be inclusive of total base payments from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to include expected beneficiary cost sharing to align with Medicare's fee schedule.

We noted that Medicaid benefits that do not have a reasonably comparable Medicare-covered analogue, and for which a State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access, would be subject to the expanded review criteria proposed in § 447.203(c)(2), because the State would be unable to demonstrate its Medicaid payment rates are at or above 80 percent of Medicare payment rates for the same or a comparable set of Medicare-covered services after the payment rate reduction or payment restructuring. For identifying a comparable set of Medicare-covered services, we stated that we would expect to see services that bear a reasonable relationship to each other. For example, the clinic benefit in Medicaid does not have a directly analogous clinic benefit in Medicare. In Medicaid, clinic services generally are defined in § 440.90, as ''preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.'' This can include a number of primary care services otherwise available through physician practices and other primary care providers, such as nurse practitioners. Therefore, in seeking to construct a comparable set of Medicare-covered services to which the State could compare its proposed Medicaid payment rates, the State reasonably could include Medicare payment rates for practitioner services, such as physician and nurse practitioner services, or payments for facility-based services that bear a reasonable similarity to clinic services, potentially including those provided in Ambulatory Surgical Centers. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for

uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf (accessed December 23, 2023).

[355] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[356] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[357] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[358] Id.

[359] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611* (accessed December 23, 2022).

constructing the Medicare rate to compare to Medicaid payment rates.

In § 447.203(c)(1)(ii), we proposed that the State would be required to provide a supported assurance that the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the State fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a single State fiscal year. We explained that the documentation will need to show the change stated as a percentage reduction in aggregate FFS Medicaid expenditures for each affected benefit category. We recognized that the effects of payment rate reductions and payment restructurings on beneficiary access generally cannot be determined through any single measure, and applying a 4 percent threshold without sufficient additional safeguards would not be prudent. Therefore, we proposed to limit the 4 percent threshold as the cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. We proposed the cumulative application of the threshold to State plan actions taken within a State fiscal year as opposed to a SPA-specific application to avoid circumstances where a State may propose rate reductions or restructurings that cumulatively exceed the 4 percent threshold across multiple SPAs without providing additional analysis.

For example, if a State proposed to reduce payment rates for a broad set of obstetric services by 3 percent in State fiscal year 2023 and had not proposed any other payment changes affecting the benefit category of obstetric care during the same State fiscal year, that payment change would meet the criterion proposed in § 447.203(c)(1)(ii) because it would be expected to result in no more than a 3 percent reduction in aggregate Medicaid expenditures for obstetric care within a State fiscal year. However, if the State had received approval earlier in the State fiscal year to revise its obstetric care payment methodology to include value-based arrangements expected to reduce overall Medicaid expenditures for obstetric care by 2 percent per State fiscal year, then it is likely that the cumulative effect of the proposal to reduce payment rates for a broad set of obstetric services by 3 percent and the Medicaid obstetric care expenditure reductions under the earlier-approved payment restructuring would result in an aggregate reduction to FFS Medicaid expenditures for obstetric services of more than 4 percent in a State fiscal year. If so, the State's proposal would not meet the criterion proposed in § 447.203(c)(1)(ii), and the proposal would be subject to the additional review criteria proposed in § 447.203(c)(2). The State would need to document for our review whether the three percent payment rate reduction proposal for the particular subset of obstetric services would be likely to result in a greater than 2 percent further reduction in aggregate FFS Medicaid expenditures for obstetric care as compared to the expected expenditures for such services for the State fiscal year before any payment rate reduction or payment restructuring; if this expected aggregate reduction is demonstrated to be 2 percent or less, then the proposal still could meet the criterion proposed in § 447.203(c)(1)(ii).

We proposed to codify a 4 percent reduction threshold for aggregate FFS Medicaid expenditures in each benefit category affected by a proposed payment rate reduction or payment restructuring within a State fiscal year. This threshold is consistent with one we proposed in the 2018 proposed rule, which proposed to require the States to submit an AMRP with any SPA that proposed to reduce provider payments by greater than 4 percent in overall service category spending in a State fiscal year or greater than 6 percent across 2 consecutive State fiscal years, or restructure provider payments in circumstances when the changes could result in diminished access.[360] The proposed rule received positive feedback from States regarding its potential for mitigating administrative burden, and providing States with flexibility to administer their programs and make provider payment rate changes. Some States and national organizations requested that we increase the rate reduction threshold to 5 percent and increase the consecutive year threshold to 8 percent.[361] [362] Non-State commenters cautioned CMS against providing too much administrative flexibility and to not abandon the Medicaid access analysis the previous AMRP regulations required. Commenters also raised that 4 and 6 percent may seem nominal for larger medical practices and health care settings, but for certain physician practices or direct care workers a 6 percent reduction in payment could be considerable.[363] This feedback has been essential in considering how we proceed with this rulemaking, in which we emphasize that the size of the rate reduction threshold proposed in § 447.203(c)(1)(ii) would operate in conjunction with the two other proposed elements in § 447.203(c)(1)(i) and (iii) to qualify the State for a streamlined analysis process and would not exempt the proposal from scrutiny for compliance with section 1902(a)(30)(A) of the Act.

We proposed a 4 percent threshold on cumulative provider payment rate reductions throughout a single State fiscal year as one of the criteria of the streamlined process in proposed paragraph (c)(1), and therefore, emphasizing that while we believe this payment threshold to be nominal and unlikely to diminish access to care, we proposed to include paragraph (c)(1)(i) to require States to review current levels of provider payment in relation to Medicare and proposed to include paragraph (c)(1)(iii) to require that States rely on the public process to inform the determination on the sufficiency of the proposed payment rates after reduction or restructuring, with consideration for providers and practice types that may be disproportionately impacted by the State's proposed rate reductions or restructurings.

As previously noted, we would not consider any payment rate reduction or payment rate restructuring proposal to qualify for the streamlined analysis process in the proposed paragraph (c)(1) unless all three of the proposed paragraph (c)(1) criteria are met. Using information from the Kaiser Family Foundation's Medicaid-to-Medicare fee index [364] as an example, only 15 States could have reduced primary care service provider payment rates by up to 4 percent in 2019 and continued to meet the 80 percent of Medicare threshold in proposed paragraph (c)(1). Even those 15 States with rates above the 80 percent of Medicare threshold would be subject to proposed paragraph (c)(2) requirements if the State received significant public feedback that the proposed payment reduction or restructuring would result in an access

[360] 83 FR 12696 at 12698.

[361] Connecticut Department of Social Services. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf*.

[362] National Association of Medicaid Directors. Comment Letter on 2018 Proposed rule (June 1, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0115/attachment_1.pdf*.

[363] American Academy of Family Physicians, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0017/attachment_1.pdf*.

[364] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/*.

to care concern, if the State were unable to reasonably respond to or mitigate such concerns. All States with primary care service payment rates below the 80 percent of Medicare threshold, no matter the size of the payment rate reduction or restructuring and no matter whether interested parties expressed access concerns through available public processes, would have to conduct an additional access analysis required under proposed paragraph (c)(2).

We issued SMDL #17–004 to provide States with guidance on complying with regulatory requirements to help States avoid unnecessary burden when seeking approval of and implementing payment changes, because States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule.[365]

In instances where States submitted payment rate reduction SPAs after the publication of SMDL #17–004, we routinely have asked the State for an explanation of the purpose of the proposed change, whether the FFS Medicaid expenditure impact for the service category would be within a 4 percent reduction threshold, and for an analysis of public comments received on the proposed change, and approved those SPAs to the extent that the State was able to resolve any potential access to care issues and determined that access would remain consistent for the Medicaid population. For example, in the proposed rule, we stated that, of the 849 SPAs approved in 2019, there were 557 State payment rate changes. Of those, 39 were classified as payment rate reductions or methodology changes that resulted in a reduction in overall provider payment. Within those 39, there were 18 SPAs that sought to reduce payments by less than 4 percent of overall spending within the benefit category, most of which were decreases related to changes in Medicare payment formulas. Sixteen of the remaining 21 SPAs fell into an area discussed in SMDL #17–004 as being unlikely to result in diminished access to covered services, where with the State's analytical support, we were able to determine that the payment rates would continue to comply with section 1902(a)(30)(A) of the Act without the State submitting an AMRP with the SPA. Six of these SPAs represented rate freezes meant to continue forward a prior year's rates or eliminate an inflation adjustment. Six SPAs reduced a payment rate to comply with Federal requirements, such as the Medicaid UPLs in §§ 447.272 and 447.321, the Medicaid DME FFP limit in section 1903(i)(27) of the Act, or the Medicaid hospice rate, per section 1902(a)(13)(B) of the Act. Four SPAs contained reductions that resulted from programmatic changes such as the elimination of a Medicaid benefit or shifting the delivery system for a benefit to coverage by a pre-paid ambulatory health plan. Finally, we identified five SPAs for which States were required to submit AMRPs. In each instance, the SPAs were approved by CMS, with three of the SPAs being submitted to us in 2017 and updated for 2019 with the appropriate AMRP data submission required by the 2015 final rule with comment period. Overall, our review of SPAs revealed that smaller reductions may often be a result of elements or other requirements that may be outside of the State's control, such as Federal payment limits or changes in the Medicare payment rate that might be included in a State's proposed payment methodology (such as where some Medicare payment rates for certain services increased and others decreased as a result of the Medicare payment formulas, which may disproportionately impact one benefit category), or coding changes that might affect the amount of payment related to the unit of service. We determined, using this information, that it is necessary to provide States with some degree of flexibility in making changes, even if that change is a reduction in provider payment. For example, if a State submits a SPA to reduce or restructure inpatient hospital base or supplemental payments, where inaction on the State's part would result in the State exceeding the applicable UPL, the State will need to reduce inpatient hospital payments or risk a compliance action against the State for violating Medicaid UPL requirements authorized under section 1902(a)(30)(A) of the Act and implementing regulations in 42 CFR 447 subparts C and F. We recognized that this flexibility does not eliminate the need to monitor or consider access to care when making payment rate decisions, but also recognized the need to provide some relief in circumstances where the State must take a rate action to address an issue of compliance with another statutory or regulatory requirement.

Accordingly, we proposed that, where a State has provided the information required under proposed paragraphs (c)(1)(i) through (iii), we would consider that the proposed reduction would result in a nominal payment adjustment unlikely to diminish access below the level consistent with section 1902(a)(30)(A) of the Act and would approve the SPA, provided all other criteria for approval also are met, without requiring the additional analysis that otherwise would be required under proposed § 447.203(c)(2).

Finally, in § 447.203(c)(1)(iii), we proposed that the State would be required to provide a supported assurance that the public processes described in § 447.203(c)(4) yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate, as documented in the analysis provided by the State under § 447.204(b)(3). The State's response to any access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us.

We noted that the proposed requirement in § 447.203(c)(4) would not duplicate the requirements in previous § 447.204(a)(2), as the previous § 447.204(a)(2) required States to consider provider and beneficiary input as part of the information that States are required to consider prior to the submission of any SPA that proposes to

[365] See, for example: Indiana Family and Social Services Administration. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0055/attachment_1.pdf;* Colorado Department of Health Care Policy and Financing. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0087/attachment_1.pdf;* The Commonwealth of Massachusetts Executive Office of Health and Human Services Office of Medicaid. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0020/attachment_1.pdf.*

reduce or restructure Medicaid service payment rates. The proposed § 447.203(c)(4) describes material that States would be required to include with any SPA submission that proposes to reduce or restructure provider payment rates. As discussed in the CMCS informational bulletin dated June 24, 2016,[366] before submitting SPAs to us, States were required under previous § 447.204(a)(2) to make information available so that beneficiaries, providers, and other interested parties may provide input on beneficiary access to the affected services and the impact that the proposed payment change would have, if any, on continued service access. We explained that States are expected to obtain input from beneficiaries, providers, and other interested parties, and analyze the input to identify and address access to care concerns. States must obtain this information prior to submitting a SPA to us and maintain a record of the public input and how the agency responded to the input. When a State submits the SPA to us, § 447.204(b)(3) requires the State to also submit a specific analysis of the information and concerns expressed in input from affected interested parties. We would rely on this and other documentation submitted by the State, including under proposed § 447.203(c)(1)(iii), (c)(2)(vi), and (c)(4), to inform our SPA approval decisions.

In addition, we noted that States are required to use the applicable public process required under section 1902(a)(13) of the Act, as applicable, and follow the public notice requirement in § 447.205, as well as any other public processes required by State law (for example, State-specified budgetary process requirements), in setting payment rates and methodologies in view of potential access to care concerns. States have an important role in identifying access to care concerns, including through ongoing and collaborative efforts with beneficiaries, providers, and other interested parties. We acknowledged that not every concern would be easily resolvable, but we anticipate that States would be meaningfully engaged with their beneficiary, provider, and other interested party communities to identify and mitigate issues as they arise. We explained that we would consider information about access concerns raised by beneficiaries, providers, and other interested parties when States propose SPAs to reduce Medicaid payment rates or restructure Medicaid payments and would not approve proposals that do not comport with all applicable requirements, including the access standard in section 1902(a)(30)(A) of the Act.

In feedback received regarding implementation of the previous AMRP requirements in the 2015 final rule with comment period, States expressed concern about burdensome requirements to draft, solicit public input on, and update their AMRPs after receiving beneficiary or provider complaints that were later resolved by the State's engagement with beneficiaries and the provider community. we explained that our proposal to require access review procedures specific to State proposals to reduce payment rates or restructure payments would provide an opportunity for the State meaningfully to address and respond to interested parties' input, and seeks to balance State burden concerns with the clear need to understand the perspectives of the interested parties most likely to be affected by a Medicaid payment rate reduction or payment restructuring. Previously, § 447.203(b)(7) requires States to have ongoing mechanisms for beneficiary and provider input on access to care through various mechanisms, and to maintain a record of data on public input and how the State responded to such input, which must be made available to us upon request. We proposed to retain this important mechanism and to relocate it to § 447.203(c)(4). Through the cross reference to proposed § 447.203(c)(4) in proposed § 447.203(c)(1)(iii), we would require States to use the ongoing beneficiary and provider feedback mechanisms to aid in identifying and assessing any access to care issues in cooperation with their interested parties' communities, as a component of the streamlined access analysis criteria in proposed § 447.203(c)(1).

Together, we stated our belief that the proposed criteria of § 447.203(c)(1)(i) through (iii), where all are met, would establish that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. Importantly, as noted above, proposed § 447.203(c)(4) (proposed to be relocated from previous § 447.203(b)(7)) would ensure that States have ongoing procedures for compliance monitoring independent of any approved Medicaid payment changes.

We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. We did not propose to codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. However, as a possible addition to the proposed streamlined access analysis criteria in proposed § 447.203(c)(1), we solicited comments on whether this list of circumstances discussed in SMDL #17–004 should be included in a new paragraph under proposed § 447.203(c)(1) and, if one or more of these circumstances were applicable, the State's proposal would be considered to qualify for the streamlined analysis process under proposed § 447.203(c)(1) notwithstanding the other criteria in proposed paragraph(c)(1).

In proposed paragraph (c)(1), we specified the full set of written assurances and relevant supporting documentation that States would be required to submit with a proposed payment rate reduction or payment restructuring SPA in circumstances when the changes could result in diminished access, where the requirements in proposed paragraphs (c)(1)(i) through (c)(1)(iii) are met. The inclusion of documentation that confirms all criteria proposed in paragraph (c)(1) are met would exempt the State from the requirements in proposed § 447.203(c)(2), discussed later in this section; however, it would not guarantee SPA approval. Proposed payment rate reduction SPAs and payment rate restructuring SPAs meeting the requirements in proposed § 447.203(c)(1) would still be subject to CMS' standard review requirements for all proposed SPAs to ensure compliance with section 1902(a) of the Act, including implementing regulations in part 430. Specifically, and without limitation, we noted that this includes compliance with section 1902(a)(2) of the Act, requiring financial participation

[366] CMCS Informational Bulletin, ''Federal public notice and public process requirements for changes to Medicaid payment rates.'' Published June 24, 2016. *https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf.* Accessed November 3, 2022.

by the State in payments authorized under section 1903 of the Act. We review SPAs involving payments to ensure that the State has identified an adequate source of non-Federal share financing for payments under the SPA so that section 1902(a)(2) of the Act is satisfied; in particular, section 1903(w) of the Act and its implementing regulations establish requirements for certain non-Federal share financing sources that CMS must ensure are met. We further noted that a proposed SPA's failure to meet the criteria in proposed paragraph (c)(1) would not result in automatic SPA disapproval; rather, such proposals would be subject to additional documentation and review requirements, as specified in proposed § 447.203(c)(2).

In paragraph (c)(2), we proposed the additional, more rigorous State access analysis that States would be required to submit where the State proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) are not met. We explained our belief that this more rigorous access analysis should be required where the State is unable to demonstrate that the proposed paragraph (c)(1) criteria are met, because more scrutiny then is needed to ensure that the proposed payment rates and structure would be sufficient to enlist enough providers so that covered services would be available to beneficiaries at least to the same extent as to the general population in the geographic area. Accordingly, we proposed in § 447.203(c)(2) to have States document current and recent historical levels of access to care, including a demonstration of counts and trends of actively participating providers, counts and trends of FFS Medicaid beneficiaries who receive the services subject to the proposed payment rate reduction or payment restructuring; and service utilization trends, all for the 3-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA, as a condition for approval. As with the previous AMRP process, the information provided by the State would serve as a baseline of understanding current access to care within the State's program, from which the State's payment rate reduction or payment restructuring proposal would be scrutinized.

The 2015 final rule with comment period included requirements that the previous AMRP process include data on the following topics, in previous § 447.203(b)(1)(i) through (v): the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The usefulness of the previous ongoing AMRP data was directly related to the quality of particular data measures that States selected to use in their AMRPs, and one of the biggest concerns we heard about the process was that States were not always certain that they were providing us with the relevant data that we needed to make informed decisions about Medicaid access to care because the 2015 final rule provided States with a considerable amount of flexibility in determining the type of data that may be provided in support of the State's access analysis included in their AMRP. In addition, States were required to consult with the State's medical advisory committees and publish the draft AMRP for no less than 30 days for public review and comment, per § 447.203(b). Therefore, the final AMRP, so long as the base data elements were met and supported the State's conclusion that access to care in the Medicaid program met the requirements of section 1902(a)(30)(A) of the Act, then the AMRP was accepted by us. As a result, the previous AMRPs were often very long and complex documents that sometimes included data that was not necessarily useful for understanding the extent of beneficiary access to services in the State or for making administrative decisions about SPAs. In an effort to promote standardization of data measures and limit State submissions to materials likely to assist in ensuring consistency of payment rates with the requirements of section 1902(a)(30)(A) of the Act, we proposed to maintain a number of the previously required data elements from the previous AMRP process but to be more precise about the type of information that would be required.

In § 447.203(c)(2), we proposed that, for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, where the requirements in paragraphs (c)(1)(i) through (iii) are not met, the State would be required to also provide specified information to us as part of the SPA submission as a condition of approval, in addition to the information required under paragraph (c)(1), in a format prescribed by us. Specifically, in § 447.203(c)(2)(i), we proposed to require States to provide a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year. We proposed to collect this information for SPAs that require a § 447.203(c)(2) analysis, but for those that meet the criteria proposed under § 447.203(c)(1), we did not proposed to require a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change beyond that which is already provided as part of a normal State plan submission or as may be requested by CMS through the normal State plan review process; we solicited comments whether these elements should apply to both proposed § 447.203(c)(1) and (c)(2) equally.

In § 447.203(c)(2)(ii), we proposed to require the State to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We noted that this proposed element is similar to the previous § 447.203(b)(1)(v) rate comparison requirement, which required the previous AMRPs to include ''[a]ctual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.'' However, the proposed analysis specifically would require an aggregate comparison including Medicaid base and supplemental

payments, as applicable, before and after the proposed reduction or restructuring are implemented, compared to the most recently published Medicare payment rates for the same or comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We found that, first, States struggled with obtaining and providing private payer data as contemplated by the 2015 final rule with comment period, and second, States were confused about how to compare Medicaid rates to Medicare rates where there were no comparable services between Medicare and Medicaid. We wanted to acknowledge the feedback we received from States during the previous AMRP process and modify the requirements in the final rule by focusing on the more readily available Medicare payment data as the most relevant payment comparison for Medicaid, as discussed in detail above. We explained that the E/M CPT/HCPCS code comparison methodology included in the proposed § 447.203(b)(3)(i) and the payment rate disclosure in proposed § 447.203(b)(3)(ii) could serve, at a minimum, as frameworks for States that struggled to compare Medicaid rates to Medicare where there may be no other comparable services between the two programs. Otherwise, where comparable services exist, States would be required to compare all applicable Medicaid payment rates within the benefit category to the Medicare rates for the same or comparable services under proposed § 447.203(c)(2)(ii). For reasons mentioned previously in this section, Medicare through MedPAC engages in substantial analysis of access to care as it reviews payment rates for services, so we noted our belief that this is a sufficient benchmark for the Medicaid payment rate analysis.

In § 447.203(c)(2)(iii), we proposed to require States to provide information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, we stated that an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State would be required to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of actively participating providers in each geographic area over this period. The State could provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area. This data element is similar to previous § 447.203(b)(1)(ii), under which States must analyze the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service, in the previous AMRP process; however, the proposal would require specific quantitative information describing the number of providers, by geographic area, provider type, and site of service available to furnish services to Medicaid beneficiaries and would leave less discretion to the States on specific data measures. With all of the data elements included in proposed paragraph (c)(2), we proposed that the data come from the 3 years immediately preceding the State plan amendment submission date, as this would provide us with the most recent data and would allow for considerations for data anomalies that might otherwise distort a demonstration of access to care if only 1 year of data was used.

In § 447.203(c)(2)(iv), we proposed to require States to provide information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish). The State would be required to document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State would be required to provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We explained that this proposed provision is a combination of previous § 447.203(b)(1)(i) and (iv), which require States to provide an analysis of the extent to which beneficiary needs are met, and the characteristics of the beneficiary population (including considerations for care, service, and payment variations for pediatric and adult populations and for individuals with disabilities). Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we proposed to require current information on the number of beneficiaries currently receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this beneficiary data is relevant because it provides information about the recipients of Medicaid services and where, geographically, these populations reside to ensure that the statutory access standard is met.

In § 447.203(c)(2)(v), we proposed to require information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment

changes may affect access to care and service delivery. The State would be required to provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We noted that this proposed data element was similar to that previously required in § 447.203(b)(1)(iii), which required an analysis of changes in beneficiary utilization of covered services in each geographic area. However, as stated earlier, the difference here is that this proposed analysis would be limited to the beneficiary populations impacted by the rate reduction or restructuring, for a narrower set of data points, rather than requiring the State to conduct a full review of the Medicaid beneficiary population every 3 years on an ongoing basis. Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we proposed to require current information on the number and types of Medicaid services being delivered to Medicaid beneficiaries through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this data is relevant because it provides information about the actual distribution of care received by Medicaid beneficiaries and where, geographically, these services are provided to ensure that the statutory access standard is met.

Finally, in § 447.203(c)(2)(vi), we proposed to require a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). We noted that this proposed requirement mirrors the requirement in § 447.204(b)(3), which requires that for any SPA submission that proposes to reduce or restructure Medicaid service payment rates, a specific analysis of the information and concerns expressed in input from affected interested parties must be provided at the time of the SPA submission. The new proposed § 447.203(c)(2)(vi) would require the same analysis while providing more detail as to what we expect the State to provide. Proposed § 447.203(c)(2)(vi) would require information about concerns and complaints from beneficiaries and providers specifically, as well as from other interested parties, and would underscore that the required analysis would be required to include the State's responses.

Where any of the previously discussed proposed data elements requires an analysis of data over a 3-year period, we proposed this time span to smooth statistical anomalies, and so that data variations can be understood. For example, any 3-year period look-back that includes portions of time during a public health emergency, such as that for the COVID–19 pandemic, might include much more variation in the access to care measures than periods before or after the public health emergency. By using a 3-year period, it is more likely that the State, CMS, and other interested parties would be able to identify and appropriately account for short term disruptions in access-related measures, for example, when the number of services performed dropped precipitously in 2020 as elective visits and procedures were postponed or canceled due to the public health emergency.[367] If the proposed rule only included a 12-month period, for example, it might not be clear that the data represent an accurate reflection of access to care at the time of the proposed reduction or restructuring. For example, a State may see variation in service utilization if there have been programmatic changes that are introduced over time, such as a move to increase care provided through a managed care delivery system in the State through which the FFS utilization declines steadily until managed care enrollment targets are achieved, but a one-time review of that FFS utilization capturing just a 12-month period might not capture data most reflective of the current FFS utilization demonstrating access to care consistent with section 1902(a)(30)(A) of the Act. We solicited comments on the proposed use of a 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2). We also solicited comments on the data elements required in § 447.203(c)(2) as additional State rate analysis.

Proposed paragraph (c)(2) would require that States conduct and provide to us a rigorous analysis of a proposed payment rate reduction's or payment restructuring's potential to affect beneficiary access to care. However, by limiting these analyses to only those proposed payment rate reductions and payment restructurings in circumstances when the changes could result in diminished access that do not meet the criteria in proposed paragraph (c)(1), we believe that the requirements proposed in paragraph (c)(2) would help to enable us to determine whether the proposed State Medicaid payment rates and payment methodologies are consistent with section 1902(a)(30)(A) of the Act while minimizing State and Federal administrative burden, to the extent possible. We would use this State-provided information and analysis to help us understand the current levels of access to care in the State's program, and determine, considering the provider, beneficiary, and other interested party input collected through proposed § 447.203(c)(4), whether the proposed payment rate reduction or payment restructuring likely would maintain access to care for the particular service(s) consistent with the statutory standard in section 1902(a)(30)(A) of the Act. If we approve the State's proposal, the data provided would serve as a baseline for prospective monitoring of access to care within the State.

We explained that the proposed analysis and documentation requirements in paragraph (c)(2) draw, in part, from the requirements of the previous AMRP process in the previous § 447.203(b)(1) and reflect the diverse methods and measures that are and can be used to monitor access to care. We also drew on some of the comments received on the 2011 proposed rule, as discussed in the 2015 final rule with comment period, where several commenters recommended that CMS consider identifying a set of uniform measures that States must collect data on or that CMS weighs more heavily in its analysis.[368] We proposed to provide more specificity on the types of uniform data elements in § 447.203(c) than is provided under previous § 447.203(b)(1). States have shown that they have access to the data listed in the proposed § 447.203(c)(2) when we have requested it during SPA reviews and through the previous AMRP process, and through this proposed rule, we proposed to specify the type of data that we would expect States to provide with rate reduction or restructuring SPAs that do not meet the proposed criteria for streamlined analysis under § 447.203(c)(1). As noted elsewhere in the preamble, the ongoing AMRP requirements previously presented an administratively burdensome process for States to follow every 3 years,

[367] Stuart, B. ''How The COVID–19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead.'' *Health Affairs,* October 8, 2020. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20201006.263687* (accessed February 27, 2023).

[368] 80 FR 67576 at 67590.

particularly where we did not provide States with the specific direction on the types of data elements we preferred for States to include. However, the data elements involved in the previous AMRP process in § 447.203(b)(1) can provide useful information about beneficiary access to care in previous § 447.203(b)(1)(i), (iii), and (iv); Medicaid provider availability in previous § 447.203(b)(1)(ii); and about payment rates available from other payers, which may affect Medicaid beneficiaries' relative ability to access care, in previous § 447.203(b)(1)(v). We found that the previous AMRPs were most relevant when updated to accompany a submission of rate reduction or restructuring SPAs as specified in the previous § 447.203(b)(6); accordingly, to better balance ongoing State and Federal administrative burden with our need to obtain access-related information to inform our approval decisions for payment rate reduction or restructuring SPAs, we proposed to end the ongoing AMRP requirement but maintain a requirement that States include similar data elements when submitting such SPAs to us that do not qualify for the proposed streamlined analysis process under § 447.203(c)(1).

We explained that the proposed analyses in paragraph (c)(2) would enable us to focus our review of Medicaid access to care on proposals that are at highest risk to result in diminished access to care, enabling us to more substantively review a proposed rate reduction's or restructuring's potential impact on access (for example, counts of participating providers), realized access (for example, service utilization trends), and the beneficiary experience of care (for example, characteristics of the beneficiary population, beneficiary utilization data, and information related to feedback from beneficiaries and other interested parties collected during the public process and through ongoing beneficiary feedback mechanisms, along with the State's responses to that feedback), while also being able to more quickly work through a review of nominal rate reduction SPAs for which States have demonstrated certain levels of payment and for which the public process did not generate access to care concerns. By including information on provider type and site of service, we believe States would be able to demonstrate access to the services provided under a specific benefit category within a number of different settings across the Medicaid program, such as the availability of physician services delivered in a physician practice, clinic setting, FQHC or RHC, or even in a hospital-based office setting. We noted our belief that defining specific data elements that must be provided to support a payment rate reduction SPA would create a more predictable process for States and for CMS in conducting the SPA review than under the previous AMRP process in § 447.203(b)(6).

Furthermore, data elements proposed to be required under proposed § 447.203(c)(2) would be based on State-specified geographic stratifications, to help ensure we can perform access review consistent with the requirements of section 1902(a)(30)(A) of the Act. We expect that States would have readily available access to geographically differential beneficiary and provider data. We observed that some of this information is available through CMS-maintained resources, such as the Transformed Medicaid Statistical Information System (T–MSIS), and other data is available through the National Plan and Provider Enumeration System (NPPES), but States should have their own data systems that would allow them to generate the most up-to-date beneficiary utilization and provider enrollment data, stratified by geographic areas within the State. States should use the most recent complete data available for each of the proposed data elements, and each would be required to be demonstrated to CMS by State-specified geographic area. We noted our belief that the geographic stratification would enable CMS to establish a baseline for Medicaid access to care within the geographic areas so that we can determine if current levels of access to care are consistent with section 1902(a)(30)(A) of the Act and can make future determinations if access is diminished subsequently within the geographic area. For all of the data elements in proposed § 447.203(c)(2), we stated that the more geographic differentiation that can be provided (that is, the smaller and more numerous the distinct geographic areas of the State that are selected for separate analysis), the more we believe that the State can meaningfully demonstrate that the proposed rate changes are consistent with the access standard in section 1902(a)(30)(A) of the Act, which requires that States assure that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

If finalized, we stated that we would anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis Timeframe* proposed in § 447.203(b)(4). In the intervening period, we would anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

In § 447.203(c)(3), we proposed mechanisms for ensuring compliance with requirements for State analysis for rate reduction or restructuring, as specified in proposed paragraphs (c)(1) and (c)(2), as applicable. We proposed that a State that submits a SPA that proposes to reduce provider payments or restructure provider payments that fails to provide the required information and analysis to support approval as specified in proposed paragraphs (c)(1) and (2), as applicable, may be subject to SPA disapproval under § 430.15(c). Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed SPA, including any raised by CMS in our review of the proposal and any raised through the public process as specified in proposed paragraph (c)(4) of this section, or under § 447.204(a)(2), may be subject to SPA disapproval under § 430.15(c). Disapproving a SPA means that the State would not have authority to implement the proposed rate reduction or restructuring and would be required to continue to pay providers according to the rate methodology described in the approved State plan. Proposed paragraph (c)(3) would further provide that if, after approval of a proposed rate reduction or restructuring, State monitoring of beneficiary access shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in the number of beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, we may take a compliance action. As described in § 447.204(d), compliance actions would be carried out using the procedures described in § 430.35.

As discussed in the prior section, we proposed to move previous § 447.203(b)(7) to § 447.203(c)(4) as finalized in this rule. We did not propose any changes to the public process described in paragraph (b)(7). We proposed that if the other provisions of the proposed rule are finalized, we would redesignate paragraph (b)(7) as paragraph (c)(4). The ability for

providers and beneficiaries to provide ongoing feedback to the State regarding access to care and a beneficiary's ability to access Medicaid services is essential to the Medicaid program in that it provides the primary interested parties the opportunity to communicate with the State and for the State to track and take account of those interactions in a meaningful way. We stated that the ongoing mechanisms for provider and beneficiary feedback must be retained, as this process serves an important role in determining whether or not the public has raised concerns regarding access to Medicaid-covered services, which would inform the State's approach to ongoing Medicaid provider payment rates and methodologies, and whether related proposals would be approvable.

We proposed to move previous § 447.203(b)(8) to § 447.203(c)(5), as finalized in this rule, to better organize § 447.203 to reflect the policies in the proposed rule. We did not propose any changes to the methods for addressing access questions and remediation of inadequate access to care, as described in paragraph (b)(8). We proposed that if the other provisions of the proposed rule are finalized, we would redesignate paragraph (b)(8) as paragraph (c)(5). We stated that it is important to retain this provision because we acknowledge that there may be access issues that come about apart from a specific State payment rate action, and there must be mechanisms through which those issues can be identified, and corrective action taken.

Finally, we proposed to move previous § 447.204(d) to proposed § 447.203(c)(6). We noted our belief that the subject matter, of compliance actions for an access deficiency, is better aligned to the proposed changes in § 447.203. We did not propose any changes to the remedy for the identification of an unresolved access deficiency, as described in § 447.204(d). We proposed that if the other provisions of this proposed rule are finalized, we would redesignate § 447.204(d) as paragraph (c)(6).

We solicited public comment on our proposed procedures and requirements for State analysis when submitting payment rate reduction or payment restructuring SPAs. We received public comments on these proposals. The following is a summary of the comments we received and our responses, organized by regulatory section.

a. General Comments

Comment: Many commenters supported the approaches to reviewing rate changes. Specifically, a number of commenters noted support for the two-tiered process to provide specific levels of information and data with a request to reduce or restructure payment rates in circumstances where such changes could result in diminished access to care, with some commenters specifically supporting the inclusion of concerns raised during the public comment process. Other commenters noted general support for requiring State justification for rate reductions and restructurings as it would provide greater transparency and accountability into State justifications for potentially harmful rate reductions. A couple commenters noted support for CMS' administrative review of rate changes to ensure continued access. One commenter was encouraged that CMS proposed to include protections to mitigate the risk that payment reductions will translate into reduced access. Another commenter agreed with CMS that additional scrutiny is warranted when a rate reduction is more than nominal, and when public concerns are raised regarding the rate. Finally, one commenter expressed appreciation for CMS' detailed review and summary of the literature on the impact of payment rates for providers on access to care for beneficiaries.

Response: We appreciate the support of the commenters on both our overall approach and for certain specific aspects of our proposed policies, which we are finalizing as proposed. We agree that the public process is an important component of Medicaid program changes.

Comment: One commenter supported requiring States to demonstrate that a reduction in payment rates will not adversely impact access to care. The commenter stated that the effort required for States to make such a showing will guard against rate reductions that would be detrimental to Medicaid recipients' ability to access care.

Response: We appreciate the support of the commenter. We believe there will be States, in certain circumstances, that will be able to meet the requirements of the streamlined access process under § 447.203(c)(1). The intention of the § 447.203(c) provisions is to balance the requirement that State's ensure compliance with section 1902(a)(30)(A) of the Act with reducing unnecessary burden in the State's administration of their Medicaid programs. We believe that the streamlined process under § 447.203(c)(1) is itself consistent with the statutory access standard, because the policies in this final rule ensure that only rate reductions or restructurings that are likely to be consistent with that standard will be approvable under this streamlined process.

Comment: One commenter stated that in some States, there is high potential for interruption in access due to delays created by the SPA process. The commenter was concerned that long delays caused by the SPA process can interrupt access to the latest standard of care. They stated that clarification on CMS regulations for SPAs for changes that increase access to the standard of care could reduce the risk of care interruptions.

Similarly, another commenter recommended that CMS give States the flexibility to increase rates to 100 percent of the equivalent Medicare rate without a SPA, and to make midyear adjustments to rates without a SPA. The commenter also indicated SPAs should only be required beyond specified thresholds.

Response: We appreciate the concern of the commenter related to any delays in the approval of SPAs. We are interested in approving approvable SPAs as expeditiously as possible, which is one of the reasons for issuing this final rule with an included template. SPAs generally may be effective no earlier than the first day of the quarter in which they are submitted per 42 CFR 430.20. The policies in this final rule and the template process provide States with clear documentation requirements for SPAs proposing to reduce or restructure provider payment rates. Without exception, our policy, as set forth in § 447.201(b), is that States must receive approval through the SPA process to modify Medicaid payment methodologies. CMS approval ensures that the changes in service payment methodologies comply with all applicable regulatory and statutory requirements and that resulting State expenditures are eligible for FFP. Changes to these requirements are beyond the scope of this rulemaking. In addition, regardless of this final rule, all SPAs are reviewed using the criteria and timeframes outlined in 42 CFR part 430 subpart B.

Comment: One commenter requested that CMS clarify how the § 447.203(c) provisions would apply to performance-based incentives, withholds, and alternative payment models, indicating that States should not be penalized for moving away from a FFS model that is not tied to performance.

Response: Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes,

while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.[369]

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve down-side risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: A few commenters expressed concern that the provisions of § 447.203(c) appear to be operating under the assumption that current payment rates are adequate, with some commenters focusing on HCBS service payment, and concern that there is no express requirement to regularly review the payment methodology to account for inflationary updates. For example, one commenter indicated that there would be no analysis required by a State that today pays less than the cost of delivering care and does not increase rates for the next 5 years, but also does not propose any rate reductions. Another indicated that the new rate review process requires no accountability from a State that may currently have rates below the cost of care or where rates remain static for several years. These commenters strongly encouraged CMS to include provisions that would require States to review current payment rates for adequacy and update payment rates immediately and on an ongoing basis either annually or up to every 2 years to account for inflation, new regulatory requirements that impose costs on providers, and other changes that may impact the cost of doing business.

Response: We agree with the commenter on the importance of States having adequate rates, even when they are not proposing to reduce or restructure those provider payment rates. We direct the commenter to the other provisions of this final rule, including the payment rate transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before July 1, 2026) are adequate. We also note that beneficiaries and providers have opportunities to raise access to care concerns to the State through the State's mechanisms for ongoing beneficiary and provider input described in § 447.203(c)(4). This final rule addresses how States can demonstrate sufficient access to care as required by section 1902(a)(30)(A) of the Act when submitting SPAs that propose to reduce or restructure provider payment rates. Neither provider cost nor inflation is a required review element in meeting the requirements of the final rule. States may certainly consider these elements when engaging in rate setting or conducting rate reviews, but it is not a required component of this final rule.

Comment: Two commenters supported the proposal to revamp previous requirements in effect for SPAs that propose to reduce rate or restructure payments and strongly urged CMS to consider changes to the final rule to ensure the new proposed structure does not permit States to alter rates in ways that negatively impact beneficiary access.

[369] 80 FR 67578 and 67579.

Response: We appreciate the commenters' support. We are finalizing the provisions as proposed. The final rule provides CMS with an administrative process through which States can demonstrate that they have considered access to care and responded to public concerns in the implementation of payment rate reduction or restructuring SPAs. We are confident these steps will ensure rate changes do not impact access in a manner inconsistent with section 1902(a)(30)(A) of the Act.

Comment: Some commenters supported efforts to bring more transparency to the rate-setting process but did not support CMS' proposed change to replace the current rate reduction review process for one that examines proposed rate reductions on a State fiscal year basis. One commenter expressed concern that the proposal to establish an across-the-board threshold for provider payment rate reductions subject to the access review process fails to recognize the need for variable rate assumptions consistent with the characteristics of different Medicaid eligibility groups. The commenters expressed concern that it is not always appropriate to use the same assumptions for all populations or providers serving these eligibility groups, especially for complex populations, and noted that this proposal fails to recognize the impact individual provider rate reductions may have on a class of providers, noting that it is not appropriate to aggregate the impact of provider rate reductions, particularly for services provided to complex populations served under the Temporary Aid for Needy Families; Aged, Blind, and Disabled; and LTSS eligibility groups.

Response: We understand the commenters' concerns. States, under the finalized § 447.203(c)(1) and (2), as applicable, will be required to analyze the impact on provider payments based on the affected benefit category, but we acknowledge that particular services within a benefit category may be provided across different provider classes or settings. For example, physicians may provide services in an office setting, a hospital setting, or a clinic setting. The provider may receive a different payment rate for physician services depending upon the setting where services are performed as a result of differences between facility and non-facility payment rate types, which account for the difference in provider overhead cost assumptions based on the setting where the services occur.

We also note, as the commenter specifically raised concerns regarding complex populations and eligibility groups, that CMS policy has long established policy, consistent with statutory requirements for comparability in amount, duration, or scope of medical assistance, that States may not establish differential rates based upon an individual's eligibility category. States are able to set rates based on a patient's acuity, service complexity, or other service-related consideration, but to set different rates for different eligibility categories could promote inequity across the Medicaid program if providers were offered greater financial incentives to furnish services to beneficiaries in some eligibility groups than others. Such differentiation of payment rates would also not be considered economic and efficient in a manner consistent with section 1902(a)(30)(A) of the Act because some payment rates would be higher than necessary considering relevant service-related factors, for example, if rates were higher for certain eligibility groups than others in relation to the Federal matching rate available for expenditures for the respective groups.

Comment: One commenter recommended CMS clarify that FQHC services are included in protections for payment rate reductions in § 477.203(c).

Response: The requirements in § 447.203(c) are applicable to all Medicaid FFS services under the Medicaid State plan, including services furnished by FQHCs.

Comment: One of the commenters recommended that CMS consider proposals to address stagnant and insufficient Medicaid payment rates that are not high enough to support paying competitive wages. One commenter recommended that CMS require States to perform a one-time rate review analysis (requiring States to submit the data described in paragraph (c)(1) and, if not all three of the requirements are met, (c)(2)) upon implementation of this rule to ensure payment adequacy necessary to support access to quality care.

Response: We understand the commenters' concerns regarding stagnant provider payment rates and rates that may not support competitive wages. We encourage providers to engage with their State Medicaid programs through forums available to them, such as the interested parties advisory group and the mechanisms for ongoing beneficiary and provider input, described in § 447.203(c)(4). In addition, we direct the commenter to the other provisions of this final rule, including the payment rate transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before 7/1/26) are adequate.

We explained in the proposed rule that our primary objective was to replace the previous AMRP process with something that could better assess access while decreasing burden on States. Requiring the analysis described by the commenters would represent an enormous one-time burden on States. We note that we are finalizing the rate transparency and analysis requirements proposed under § 447.203(b), which we expect will provide greater insight into rates relative to access issues, while maintaining a scope that seeks to minimize unnecessary burden on States.

Comment: A few commenters noted how CMS indicated in the preamble of the proposed rule that the term ''benefit category'' under § 447.203(c) would refer to services under a category of services as described in section 1905(a) of the Act. One commenter stated that CMS has declined to define ''benefit category'' in a meaningful way and requested clarification. The commenter was concerned that extremely large swaths of services can be grouped together for the purposes of conducting the analysis, which could circumvent the analysis of real-world impact of payment cuts on specific provider types. Another commenter requested that CMS clarify that the required analyses apply to both home care services (that is, personal care and home health services) provided under section 1905(a) of the Act and to services provided under 1915 authorities. However, rather than treating (for example) personal care services as a single benefit category across all authorities for the purpose of the required analysis, the commenter suggested that CMS view 1905(a) PCS as one benefit and treat the set of HCBS coverable under 1915 and other authorities as a separate single benefit.

Response: Reiterating the definition in the preamble, we mean for ''benefit category'' to refer to all individual services under a category of services described in the Medicaid State plan for which the State is proposing a payment rate reduction or restructuring. Just as with our review of Medicaid payment rates, we do not review the inclusion of individual services within a benefit category unless the intention of a SPA is to specifically add or remove coverage for a particular service from the State plan. Further, we have concerns about the usefulness of information that

would inform our SPA review as the relevant unit of analysis becomes smaller (from benefit category to individual service level). For example, it is unclear that a reduction in the number of group occupational therapy services furnished by therapy providers during a given time frame would indicate that there is an issue with provider payment rates being insufficient to support adequate beneficiary access, or if the reduction merely represented a data anomaly that is unrelated to the rate of payment. We believe that the higher level of review of payment rate sufficiency at the benefit category level is consistent with the requirement in section 1902(a)(30)(A) of the Act that rates be sufficient to ensure that ''care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.''

That being said, if a State proposes to group together services together that are not reasonably considered to be within the same benefit category (including where the grouping is not consistent with how the State covers and/or pays for the services under the State plan) to attempt to meet the paragraph (c)(1) thresholds and avoid the need to submit additional analysis under paragraph (c)(2), we will request additional information from the State including demonstrations that the paragraph (c)(1) criteria are met using a reasonable benefit category definition, or the additional analysis required under paragraph (c)(2), to support SPA approval.

Finally, in response to the commenter that requested that CMS clarify that the required analyses apply to home care services (including personal care and home health services) under section 1905(a) of the Act and to those covered under section 1915 authorities, we affirm that the analyses apply to both types of home care services under State plan, section 1915(c) waiver and demonstration payment rates, as applicable. To the extent that it is applicable, the 1905(a) PCS is one benefit category and the set of HCBS coverable PCS under 1915 and other authorities are considered as individual benefits as the payment methodologies for these services of often distinct methodologies across the different State plan or waiver authorities.

Comment: One commenter suggested CMS provide a template for the code-by-code analysis level to support the State analysis procedures for rate reductions or restructurings.

Response: We produced and are finalizing a template for States to ease the administration of the requirements of this final rule, including a code-by-code analysis to the support the payment analysis. The template will assist the States with meeting the § 447.203(c)(1)(i) and (c)(2)(ii) requirements for an aggregate analysis of Medicaid base and supplemental payments relative to Medicare, but it is important for us to clarify that these provisions do not necessarily require submission to CMS of a code-by-code analysis as suggested by the commenter. Section 447.203(c)(1)(i) requires States to provide written assurance and relevant supporting documentation that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. Section 447.203(c)(2)(ii) requires States to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. In each case, the analysis performed would be an aggregate comparison of the State's proposed Medicaid rates to Medicare; however, CMS may request that the State provide supporting documentation, for example, where CMS has concerns with the accuracy of the analysis performed.

Comment: One commenter stated that, while imperfect as a point of comparison, Medicare is at least a reliable source of data that utilizes cost studies and other factors in its own rate setting processes. The commenter stated that if Medicare is retained as the benchmark, they would endorse use of an aggregate, as opposed to code-by-code, comparison with Medicaid rates. They explained that a code-by-code analysis would be extremely difficult, as CMS would need to define a methodology to determine if there is a one-to-one match between service descriptions and procedural codes in Medicare and Medicaid; Medicaid agencies report significant variation in codes and service descriptions.

Response: We agree with the commenter and note that the final rule in § 447.203(c)(1)(i), and the similar provision in § 447.203(c)(2)(ii), require that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring be compared to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. For this purpose, the Medicare services selected for comparison should align reasonably with the Medicaid services covered by the State within the affected Medicaid benefit category. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the comparison of Medicaid to Medicare payment rates.

Comment: A few commenters opposed the two-tiered approach, believing that this approach is insufficient to ensure access. Those commenters urged CMS to only use the tier two (§ 447.203(c)(2)) analysis on any SPA that proposes to reduce or restructure provider payment rates. One of the commenters opposed the two-tiered system on the basis that it would result in States implementing significant cuts to Medicaid rates without scrutiny for prolonged periods of time as long as they are exempt from second-tier analysis.

Response: We appreciate the commenters' viewpoints, but we are finalizing the two-tiered analysis as proposed. We do not agree that the two-tiered system would result in States implementing significant cuts to Medicaid without scrutiny for prolonged periods of time. We are finalizing § 447.203(c)(1) to require that all three provisions of § 447.203(c)(1) must be met in order for the SPA to qualify for the streamlined analysis provision of the final rule. In our view, the streamlined review for qualifying SPAs under § 447.203(c)(1) is sufficient because the State's payment rates would remain at or above 80 percent of the Medicare rate; the proposed reduction or restructuring would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by

proposed reduction or restructuring within a State fiscal year; and the public process yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate. Taken together, the streamlined State analysis provides safeguards to mitigate the impact of State rate reductions while also providing protection for compounding reductions that could occur over a prolonged period of time. We anticipate that compounding rate reductions or restructurings would lower the possibility that a State's payment rates remain at or above 80 percent of Medicare and the public input process would generate significant provider and beneficiary feedback in the event that such reductions are taken at 4 percent per State fiscal year which would disqualify a State Plan rate reduction or restructuring proposal from meeting the requirements for the streamlined § 447.203(c)(1) process. We included this aspect of the analysis, in part, to protect against a large reduction spread over time through smaller reductions that pass initial scrutiny having an unacceptable negative impact on beneficiary access. As noted above, we anticipate that any State that is making significant cuts to provider payment rates over time will have a significant challenge in meeting the requirements for the initial State analysis in § 447.203(c)(1).

Comment: One commenter noted that the proposed rule would require States to provide additional information to justify their requests for reduced or restructured payment rates in SPAs, but the commenter noted that CMS does not commit to denying the requests where the State proposes payment rates below 80 percent of Medicare and did not agree with CMS's lack of commitment to disapprove such requested rate actions. The commenter did not believe this would sufficiently dissuade rate reductions, and that the language indicating CMS might not approve such proposed payment rate reduction or restructuring SPAs would just generate confusion, as well as attempts by States to ''game the system'' to try to figure out what language they should submit to win approval of their applications.

Response: Much like the previous AMRP process from the 2015 final rule with comment period, the access provisions contained in § 447.203(c) are intended to create a baseline measurement from which the State rate reduction or restructuring proposals may be evaluated. CMS has not taken the position that State payment rate proposals that set provider payment rates below 80 percent of Medicare are to be automatically disapproved, but instead we are committing States to a process by which they demonstrate that access is sufficient in their State so the agency can properly evaluate these State proposals under the section 1902(a)(30)(A) of the Act requirements. SPAs that fail to include the information required under the applicable provisions of § 447.203(c) will be disapproved by CMS. For proposals that do not meet the streamlined State analysis requirements under § 447.203(c)(1), States are required to provide the following with all payment rate reduction or restructuring SPAs: a summary of the proposed change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed, as required under § 447.204(a)(2). In addition to being used to establish a baseline, as mentioned above, CMS will use the information in determining whether access is sufficient based on the State's submission of the required data and analysis, including of Medicaid provider enrollment, service utilization, and number of beneficiaries receiving affected services (including observed trends). We expect State proposals to be accompanied by documentation of meaningful engagement with providers, beneficiaries, and potentially other interested parties, to ensure that the proposed payment rate reductions or restructurings will not reduce access to care for Medicaid beneficiaries below the standard set in section 1902(a)(30)(A) of the Act. However, we acknowledge that the individual circumstances of the SPA proposal will inform the precise information required to be submitted under this final rule. We are confident that the provisions of the final rule are clear and outline a process which States will be required to follow when reducing or restructuring provider payment rates which CMS will review on a case-by-case basis, but we are confident that the documentation requirements will not allow States to game the system, as the commenter contends.

Comment: One commenter urged CMS to take an approach that is more straightforward than the two-tiered proposal to better monitor provider payment adequacy. For example, the commenter stated that payment reductions in excess of 5 percent for any given service or CPT code should be reviewed by CMS to determine if beneficiary access is at risk. Another commenter was concerned that CMS' proposed ''aggregate'' standard, reviewing rates across a benefit category rather than at the service-specific level, could mean that some Medicaid services may be paid well below the percentage threshold even if the overall benefit category achieves the threshold. They recommended setting the threshold on a disaggregated basis to protect access to key services and avoid permitting States to obscure low payment rates.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule

would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan. For example, if the State uses the Medicare fee schedule for items of DME under the Medicaid State plan but decides to alter the payment rate for the oxygen codes (E0441, for example) to set Medicaid-specific rates, we will review those individual payment rate changes as they fall outside of the State's payment rate setting methodology under the State plan. Further, the payment rate transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

b. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Comment: One commenter stated their general support for the streamlined initial review process, noting it provides States with clear safe harbor guidelines.

Response: We appreciate the support of the commenter. However, we note that section 447.203(c)(1) does not necessarily provide a ''safe harbor'' guaranteeing approval of a SPA. All applicable Federal requirements must be met for SPA approval. And even where paragraph (c)(1)(i) and (ii) are met because the aggregate Medicaid payment rates for the benefit category after reduction or restructuring would be at or above 80 percent of the most recently published Medicare rates for the same or a comparable set of Medicare-covered services, and the cumulative effect of all reductions or restructurings throughout the current State fiscal year would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for the benefit category, paragraph (c)(1)(iii) still must be met. That is to say, even when the quantitative standards of the first two prongs of the (c)(1) test are satisfied, we will carefully review the information the State provides to us under section 447.204(b)(3) specifically analyzing any information and concerns expressed in input from affected interested parties in connection with the proposed SPA. As specified in section 447.203(c)(1)(iii), there must be no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if public processes did yield such concerns, the State must be able to reasonably respond to or mitigate them, as appropriate.

Comment: One commenter noted their support of CMS' first-tier proposal for handling rate reductions. However, they recommended that CMS establish a process for granting States flexibility from the requirements under unique circumstances. For example, a reduction may occur as the result of a decrease in CMS' RVUs or Medicare payment schedules. Some State fee schedules are indirectly tied to CMS RVUs or other Medicare payment schedules, and decreases occurring there are likely to also occur on the State's fee schedule. The commenter stated that an exemption from rate reduction requirements would be justified in this circumstance.

Response: For States that have set their approved State plan payment methodology at the current Medicare RVU prices, CMS would interpret such a methodology as accounting for changes that Medicare makes to components of their RVU-based methodology without the need for additional SPA action on the State's part. This would only include scenarios where the State has specifically indicated that the payment rates for Medicaid services are set at the current Medicare price for the State plan services and would not apply to circumstances where the State creates a static fee schedule that simply relies on a particular snapshot of Medicare prices to inform a State fee schedule, or for methodologies that rely upon a prior iteration of the Medicare prices for the current Medicaid payment rates.

Comment: One commenter suggested that provider associations and participant representatives be part of reviewing and analyzing the impacts on rate reductions and access that would be required under § 447.203(c)(1) and (2).

Response: Section 447.203(c)(4) as finalized in this final rule provides that States must have ongoing mechanisms for beneficiary and provider input (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), through which interested parties can raise concerns about access, including payment sufficiency. Provider associations and participant representatives, which we understand to be representatives of beneficiaries that may be under the age of 21, are able to participate in public engagement through these mechanisms, related to State actions that could result in a reduction or restructuring of State plan payment rates. To be clear, the public process in § 447.203(c)(4) serves as a means for the State to receive feedback on real-time access to care issues that may be addressed on an ad hoc basis; interested parties do not need to wait for the State to develop a payment SPA to raise access to care issues through mechanisms under § 447.203(c)(4). This input, as well as input collected through the public input process under § 447.204, will be considered under § 447.203(c)(1)(iii) and used to determine whether or not the proposed reduction or restructuring SPA is consistent with section 1902(a)(30)(A) of the Act.

Comment: A few commenters suggested CMS use its authority to encourage States toward a national floor for rates, with some stating the Medicaid-to-Medicare fee ratio threshold proposed in § 447.203(c)(1)(i) should become a Federal floor for all SPA and waiver approvals. For example, they recommended that CMS could phase-in an explicit regulatory floor or implement standards tying improvements in Medicaid rates to approvals of related Medicaid flexibilities, such as section 1115 approvals, SDPs, etc. One commenter pointed out that some States have rates well below Medicare levels and change rates infrequently. This means that, assuming a State does nothing, currently inadequate rates could simply persist for decades more under CMS' approach, and in fact regress relative to inflation. Another commenter specifically recommended that CMS require both an initial in-depth analysis of access metrics as well as an analysis over time for any State that implements payment rates lower than Medicare.

Response: Unless explicitly authorized by statute, CMS does not have the authority to establish a national floor for Medicaid payment rates. Refusing to approve any payment rate reductions or restructurings that do not specifically meet the thresholds in § 447.203(c)(1)(i) could be construed as setting a national floor for rates. We understand that some States may infrequently update their payment rates, but section 1902(a)(30)(A) of the Act provides States with flexibility to establish payment rates in a manner that

balances consideration of State budgetary needs and restrictions with the obligation to provide medical assistance under the State plan in accordance with Federal requirements. With the policies finalized throughout this final rule, we hope that both States and the public will more closely examine existing rates. Our policies around rate transparency and adequacy will enhance opportunities to determine where an existing rate may negatively impact access to care and identify for States where a need should be addressed by providing beneficiaries, providers, other and interested parties with easier access to State plan payment rates through payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries and providers opportunities to engage with States where existing payment rates may have an impact on beneficiaries' access to care.

The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process under the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements.

We note that the policies finalized in § 447.203(c)(2) do include an analysis of data that looks back at a 3-year period of time to help ascertain whether access to care for the relevant services is consistent with the statutory access standard. Further, the rule includes a requirement for ongoing access monitoring to the extent that access issues are identified that require State intervention, as provided in § 447.203(c)(5), which requires the State to take corrective action resulting in measurable and sustainable access improvements.

Comment: One commenter recommended that CMS amend § 447.203(c)(1) and (2) to require States to demonstrate compliance with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as applicable, for any proposed rate reduction or restructuring and provide technical assistance to States on compliance with this provision that would include guidance on the required comparative analysis both for the standard as written and in operation.

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. We did not specifically require that States demonstrate compliance with the MHPAEA as part of this final rule, as the final rule focuses on payment rates established by the State Medicaid agencies to pay for allowable Medicaid services under the Medicaid State plan through FFS. Congress has not extended MHPAEA requirements to Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid and CHIP agency partners to ensure their FFS benefits comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with the requirements of section 1902(a)(30)(A) of the Social Security Act ''to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.'' This review thus includes the fundamental objective of MHPAEA—to ensure access to mental health and substance use disorder treatment.

Comment: One commenter requested further information on what circumstances CMS would expect to result in diminished access for a SPA that would restructure, but not reduce, rates.

Response: We acknowledge that there may be any number of payment methodology changes that could harm access to care even when there is a restructuring but not reduction in rates, and unfortunately, we are unable to identify all such circumstances in advance. However, as discussed previously, one common type of restructuring is a change in the targeting of supplemental payments. States may alter payments, including in ways that are budget neutral for a benefit category as a whole (that is, they do not decrease overall Medicaid spending for the benefit category), but the changes would reduce payments for some providers, potentially harming beneficiary access.

Comment: One commenter requested that CMS clarify what is meant by ''restructure'' and confirm that this would not include any type of rate increase.

Response: A rate restructuring is a payment action where a State amends its methodology for an interrelated set of rates whereby individual rates may increase, decrease, or remain the same, which the State typically undertakes to achieve some programmatic purpose, such as achieving more efficient payment for services that frequently are furnished together. While a rate restructuring potentially could include rate increases, if increasing rates is the only effect of the rate restructuring, then we generally would not expect these to be circumstances when the changes could result in diminished access, and the requirements of § 447.203(c)(1) through (3) would not have to be met. Although we cannot set forth an exhaustive list of rate restructurings, one common type of restructuring is a change in the targeting of supplemental payments, under which the set of providers qualifying for a supplemental payment might change and/or the amounts received by each provider might increase or decrease. States may use a methodology to identify amounts that a provider would receive, which would not require a SPA to initiate a change in the amounts providers receive. For example, a State sets up supplemental payment pools of $10 million for trauma care centers in the State and that payment pool is distributed based upon a provider's pro rata share of Medicaid services. The amounts paid to providers eligible for that pool may vary from year to year based upon each providers' relative Medicaid utilization within the State, but the total amount of available funds remains the same. If that State submits a SPA to change the distribution methodology or to add more qualifying providers to the payment methodology,

but not change the $10 million pool, then this change would be considered a payment restructuring. If the State were to reduce the total pool from $10 million to $8 million, then that would be considered a reduction. A change in supplemental payments that reduces the total amounts that providers receive or shifts funds from one provider to another could result in access to care issues and is one example of a potential payment restructuring that could negatively impact access to care. Where there is uncertainty, we will work with States to help identify situations where a rate restructuring could diminish access to care such that the processes under § 447.203(c)(1) through (3) will apply.

Comment: One commenter suggested streamlined approval should apply to any rate reduction that meets any one of the three criteria listed in the proposed rule. The commenter specifically recommended providing streamlined approval for rate reductions that result in the rates being 100 percent or higher of the comparable Medicare rate regardless of the reduction in overall expenditures for the benefit category (otherwise stated, without the application of § 447.203(c)(1)(ii)).). Another commenter recommended that CMS' primary goal should be to encourage increasing rates to Medicare levels and generating feedback through processes with interested parties.

Response: To the extent a State proposes a payment rate reduction or restructuring which results in payment rates at or above 100 percent of Medicare, it would certainly meet one of the three criteria in § 447.203(c)(1) for the initial State analysis for rate reduction or restructuring, but would still require that the other two criteria in § 447.203(c)(1) be met. We are requiring all three criteria in § 447.203(c)(1) be satisfied for the State to qualify for the streamlined process, to protect access across varied circumstances. For example, a proposed rate may be 100 percent of Medicare, but if the currently approved Medicaid payment rate is higher such that the change represents a payment reduction, then the proposed rate reduction still could harm beneficiary access to the relevant services and potentially reduce access to below the statutory standard.

Although we generally believe that setting rate thresholds at a level recommended by the commenter (100 percent of the corresponding Medicare rate, or higher) could help support adequate access to care for Medicaid beneficiaries, we believe there are circumstances where balancing State budgetary considerations, and the willingness of providers to accept a given level of payment for services provided to the Medicaid population, will suggest a Medicaid payment rate that diverges from a corresponding Medicare rate but is still consistent with the access requirement under section 1902(a)(30)(A) of the Act.

Comment: One commenter requested that CMS provide additional guidance about how to conduct the Medicaid to Medicare comparison required under § 447.203(c)(1) and (2).

Response: As part of the proposed rule PRA process, we proposed a template for States to use to complete the analyses under § 447.203(c). The template includes detailed instructions for how States should complete each tier and component of the analysis, as applicable. We are finalizing that template as proposed.

Comment: Several commenters inquired about whether the guidance provided in SMDL #17–004 [370] would remain applicable under the new proposals, wherein CMS determined that there were circumstances unlikely to diminish access, and as such, would not invoke the requirements of § 447.203(b)(6) of the 2015 final rule with comment period: reductions necessary to implement CMS Federal Medicaid payment requirements (for example, Federal upper payment limits and financial participation limits), but only in circumstances under which the State is not exercising discretion as to how the requirement is implemented in rates; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology (For example, modifications to diagnostic related groups and the resource based relative value scale, adoption of new Medicare payment systems, consistency with value-based purchasing initiatives, etc.). One commenter specifically inquired about circumstances where payment rates would be below the threshold of 100 percent of the most recently published Medicare rates for the same or comparable services in the impacted benefit area before and after the proposed restructuring. A few other commenters encouraged CMS to allow a tier 1 review for rate reductions in circumstances where rate reductions: (1) are necessary to implement CMS Medicaid payment requirements (for example, UPL); (2) result in payment rates that remain at or above Medicare or average commercial rate amounts; or (3) are prompted by a change in Medicare payment rates when the State's rate methodology adheres to Medicare methodology. One commenter specifically recommended that the exemptions provided under SMDL #17–004 be included in the exemptions under § 447.203(c)(1), specifically citing circumstances in the SMDL where Medicaid payment rate reductions generally would not be expected to diminish access, such as: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology.

Response: We did specifically request comment on whether and how the policies discussed in SMDL #17–004 should be included in the final rule, and we thank the commenters for their helpful suggestions. As stated, we are finalizing § 447.203(c)(1) as proposed, and we are not finalizing any exceptions to the tier 1 (or tier 2) analysis. We believe the analysis is warranted under any rate reduction or restructuring. The three circumstances described by commenters from SMDL #17–004 are either inapplicable to this final rule or already accounted for. Specifically, in the first circumstance, where Federal Medicaid payment requirements are otherwise established in statute or regulation, we recognize that States often have multiple ways of complying with multiple Federal requirements that may bear upon payment rates, and the review required in this final rule in § 447.203(c) is necessary to ensure that the State's programmatic decisions are consistent with all applicable Federal requirements including that they ensure sufficient beneficiary access to care. In the third circumstance, reductions that result from changes implemented through the Medicare program, where such a change does not require a SPA to implement would also fall outside of § 447.203(c)(1) through (3), which are only applicable when a State must submit a SPA. The final rule provisions only apply to the extent that a SPA is

[370] SMDL #17–004. November 16, 2017. *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17004.pdf.*

needed to implement the proposed reduction or restructuring.

The second circumstance is the only one subject to the provisions of this final rule, for reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates. These reductions or restructurings would need to meet all of the requirements of § 447.203(c)(1) in order to be eligible for the streamlined access review criteria. We decided not to include this criterion from SMDL #17–004 in this final rule because we received a number of comments on this final rule that suggested that providers and beneficiaries should have input where non-nominal rate reductions or restructurings may occur, regardless of the current or proposed payment level. Including this particular provision could provide a State with a means to significantly reduce provider payment rates without needing to engage with the provider and beneficiary community on the impact such a reduction might have on access to care.

Comment: One commenter expressed concern that CMS' proposals would slow or in some cases prevent altogether the adoption of VBP arrangements or other alternative payment models. Under these models, the commenter stated that it is common for some providers to experience increases in payment reflective of outcomes attributable to those providers, and it is also common for some providers to experience decreases in payment, including when aggregate levels of payment are increasing for a relevant service or services. Given that any SPA proposing to implement or substantially modify a VBP payment arrangement could reasonably be considered a proposal to ''restructure'' payments, the commenter was concerned that the proposed rule essentially would treat all VBP payment arrangements as inherently suspect and as requiring additional scrutiny and administrative burden. The commenter encouraged CMS to continue to identify ways to support and encourage the adoption of VBP models in Medicaid, noting that CMS should not adopt rules that create additional obstacles for States seeking to implement VBP models. A few other commenters suggested that streamlined review should be available in situations where rate reductions are used to implement VBPs through a withhold payment rate restructuring that does not reduce the total payments within the overall service category, because the withheld amounts subsequently are paid out based on performance.

Response: We agree with the commenter that VBP arrangements can be useful tools to promote high-quality services for Medicaid beneficiaries while promoting efficient and economic care delivery, fully consistent with beneficiary access to covered services that meets the statutory standard. Although a proposed SPA seeking to implement or significantly modify a VBP arrangement likely may be considered a payment rate restructuring, nothing in the final rule would prohibit or is intended to discourage States from adopting such structures. Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes, while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.[371]

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve down-side risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect

[371] 80 FR 67578–67579.

States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: One commenter strongly suggested that the State rate analysis be required on an annual basis, not only upon rate reductions or restructuring, and further suggested that any rate examinations by CMS should also include rates paid in managed care, noting the volume of HCBS provided under managed care, and as such, focusing only on FFS rates is a disservice to much of the industry.

Response: We intend for the payment rate transparency provisions in § 447.203(b) to provide interested parties with insight into State plan payment rates relative to the Medicare payment rates for the same services. While these payment analyses will be updated every other year, as opposed to annually as mentioned by the commenter, the § 447.203(b) analysis will be available for CMS and for interested parties to review, while the § 447.203(c) analysis will apply only to SPA submissions that propose to reduce or restructure provider payment rates. The § 447.203(c) provisions of this final rule concern SPAs proposing to reduce or restructure payment rates in Medicaid FFS. Other components of this final rule address payment rate adequacy and transparency for HCBS specifically, and access to care in managed care is being addressed through the Managed Care final rule (as published elsewhere in this **Federal Register**).

Comment: One commenter stated that SPAs that would result in Medicaid payments that are at or above 80 percent of Medicare rates for the same or comparable services should be approvable without resorting to the larger access analysis described in proposed § 447.203(c)(2). The commenter noted that it is common for Medicaid to pay a percentage of Medicare rates (for example, 85 percent of Medicare) and stated that a proposed payment methodology should not have to result in Medicaid payments that are exactly the same as Medicare rates to avoid access concerns.

Response: This final rule does not require that the proposed payment methodology result in payments that are exactly the same as Medicare rates, or any specific percentage of the Medicare rates for the same or a comparable set of services. States that have rates at or above 80 percent of Medicare in the aggregate, including base and supplemental payments, can qualify for the streamlined initial State analysis for rate reduction or restructuring in § 447.203(c)(1) of the final rule, provided that the other criteria of § 447.203(c)(1) are met. As discussed in an earlier response to comment in this final rule; however, we do not agree that State payment proposals that meet the 80 percent of Medicare threshold should be exempt from the other qualification criteria specified in § 447.203(c)(1)(ii) and (iii), nor the additional analysis elements in § 447.203(c)(2) if all the criteria for the streamlined process are not met.

Comment: One commenter commended CMS for moving towards more clear and transparent processes for rate analyses associated with State-proposed payment changes. However, the commenter indicated that the first tier's streamlined requirements are unlikely to ever be met, as the commenter noted that there are rarely any changes in rates that are proposed that do not elicit complaints and/or concerns about impacts to access from the public and/or interested parties, even in such circumstances as rate increases. The commenter suggested that CMS reconsider the tier guidelines to make it more feasible for a State to meet the requirements of the initial, streamlined tier.

Response: We disagree that the streamlined requirements are unlikely to ever be met. We discussed a State's ability to meet the streamlined criteria in the preamble, and direct the commenter to sections II.C.3 and III.C.11.d.i. of the final rule, which discusses the overall impact of this policy on State proposals to reduce or restructure provider payment rates. Similar to our experience after the issuance of SMDL #17–004, as discussed in the above referenced sections of the final rule, we anticipate that there will be States that propose rate reductions or restructurings that will be able to demonstrate compliance with § 447.203(c)(1). The final rule provides that significant access concerns can be raised, and the proposal can still meet the (c)(1) threshold, provided that the State can reasonably respond to or mitigate the concerns, as appropriate. States should be working with their provider and beneficiary communities and engaging with constructive criticism and complaints, and provide justification to those interested parties as to why the reductions are necessary, and discuss alternatives considered. An important purpose of § 447.203(c)(1)(iii) is to encourage meaningful engagement between States and s interested parties.

Comment: Multiple commenters recommended that CMS increase the proposed threshold to qualify for the streamlined payment SPA analysis proposed at § 447.203(c)(1)(i) from 80 percent of Medicare, with some commenters suggesting that the threshold be changed to 100 percent of Medicare to make the streamlined process more meaningful. These commenters noted that, although Medicare FFS pays physicians considerably more, on average, than Medicaid, it is not competitive in markets with a large percent of commercial payers and Medicare Advantage plans, which typically pay more than traditional Medicare. Therefore, these commenters stated that setting a benchmark at 80 percent of a rate that is not competitive in many parts of the country would undermine efforts to ensure Medicaid payments comply with section 1902(a)(30)(A) of the Act. Another commenter stated that many people cannot access Medicaid acute-care services of the types that Medicare pays for because States do not pay providers adequate rates to induce them to accept Medicaid as payment, and the commenter noted that this problem has existed for a very long time, and it is not related to whether a State wants to reduce or restructure rates from their current levels. One commenter noted that many providers are already paid at 80 percent of Medicare and thus recommended that it seems appropriate to select a higher standard by which to assess whether a reduction would diminish access. Further, a couple of commenters suggested that if access problems persist after a State has achieved the 80 percent threshold for a suitable period of time, and those problems can be traced to inadequate rates, then the State should be required to raise those rates to 85 percent, then 90 percent and so on until the rates reach 100 percent of the Medicare rate. One commenter suggested that such a graduated approach to the § 447.203(c)(1)(i) threshold should be included regardless of whether there are persistent documented access to care issues. Some commenters had similar recommendations to increase the threshold without recommending a specific number, noting that Medicare payments are often low relative to provider costs, and one of these

commenters also recommended a phase-in approach.

Some commenters suggested that CMS take a different approach for different services where the commenters suggested that Medicare may undervalue a service, such as mental health, or where certain service providers do not take insurance, which leads to higher charges in the private market. One specifically suggested a 100 percent threshold for behavioral health, for these reasons.

Response: We appreciate the viewpoints and suggestions of the commenters. First, where the commenters suggested raising the 80 percent threshold to a higher level, such as a 100 percent threshold, to make the streamlined process more protective of beneficiary access, we believe the 80 percent threshold continues to present a meaningful threshold, particularly as it is coupled with the other standards in § 447.203(c)(1). As we discussed in the preamble, after careful review of the literature, we determined that 80 percent of Medicare would be a reasonable payment rate threshold to aid States' and our assessment of compliance with section 1902(a)(30)(A) of the Act. Based on a review of evidence discuss elsewhere in the proposed rule and preamble of this final rule, we do not currently have evidence that a ratio higher than 80 percent is necessary to ensure compliance with the statutory access standard.[372] However, we are committed to monitoring implementation and would consider proposing a sliding percentage threshold for the Streamlined analysis required under § 447.203(c)(1) through future rulemaking, if it is determined that such a change would be appropriate. The threshold is not a level set for approval (or disapproval) of a SPA, but merely to inform the level of analysis would be required. Additionally, the other commenter's assertion that many providers are already paid at 80 percent of Medicare does not, in our view, indicate a need for stricter thresholds, but rather provides that some States may simply be able to meet the § 447.203(c)(1)(i) threshold. If these providers, the beneficiaries they serve, and/or other interested parties have access-related concerns about current or proposed payment rates in their State, they may raise those concerns to the State through the various available forms of public process, which the State would need to address consistent with § 447.203(c)(1)(iii) to qualify for the streamlined analysis process in the event of a payment SPA that would reduce or restructure rates in circumstances that could result in diminished access. We note that, in general, there is no requirement that payment rates for Medicaid services include explicit consideration of a provider's cost of care. The level of payment rates in relation to provider costs is not necessarily the only or the decisive factor in ensuring access to care consistent with the statutory standard, and we do not require that States establish that rates are sufficient to ensure access by reviewing the relationship of payment rates to provider costs.

Second, we agree that Medicare payment rates are typically higher than Medicaid, but do not agree the fact that some private payer rates and Medicare Advantage rates are higher than Medicare FFS rates requires that we select a threshold rate of higher than 80 percent of the Medicare FFS rate to achieve a meaningful comparison that helps ensure that Medicaid rates are adequate to meet the statutory access standard. In addition, regarding the comment that certain providers that do not take insurance, which leads to higher charges, we do not consider a charged amount to be comparable to a payment rate unless the provider actually receives the charged amount as payment amount from a payer (including self-pay individuals). Some providers bill patients on a sliding fee scale, dependent on factors like the individual's income level, even if the provider does not take insurance. This does not mean that using a provider's customary charge is a reasonable proxy for an economic and efficient payment rate or for a payment level that is necessary to support adequate access to care, because not all providers receive payment at their charge rate, even if they bill the patient directly.

We are finalizing the § 447.203(c)(1)(i) threshold at 80 percent of Medicare FFS because we wanted to balance an achievable threshold for States while also establishing a threshold that we believe would be strongly indicative that Medicaid payment rates would be likely to comply with section 1902(a)(30)(A) of the Act. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that a given provider, or a sufficient number of providers, will participate in the Medicaid program, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency of payment rates with section 1902(a)(30)(A) of the Act. Notably, there are other provisions of the final rule that provide opportunities for the public to raise access to care concerns to State agencies and to CMS should Medicaid payment rates be insufficient to ensure adequate provider participation so that the statutory access standard is met, as provided in §§ 447.203(c)(4) and 447.204.

Finally, we acknowledge the commenter that suggested that 80 percent of Medicare does not take into account circumstances in which Medicare may undervalue a service, such as mental health. In the 2024 Medicare PFS final rule, Medicare did finalize an adjustment to the payment for certain timed behavioral health services paid under the PFS.[373] In the same rule, we acknowledged the systemic valuation problem and finalized an adjustment to help mitigate the impact which is scheduled to be phased-in over 4 years. While there are certainly going to be issues within any selected rate comparison approach, do not believe that Medicare payment rates for certain services or in general are insufficient in a manner that would suggest a need to use a threshold higher than 80 percent of the Medicare PFS rate. We acknowledge that the reluctance of some provider types to accept payment from various payers, including public and private payers, is concerning, as this can have a negative effect on access to needed care for Medicaid and Medicare beneficiaries, as well as the public at large, including those who are privately insured. However, to the extent the broader public has difficulty accessing a particular service due to high levels of refusal among providers of that service to accept payment offered by public and private payers, then it is possible that the access standard under section 1902(a)(30)(A) of the Act could be met even if Medicaid beneficiaries are experiencing significant difficultly obtaining services from these providers. Although CMS would encourage States in such circumstances to explore all available options to encourage greater provider participation in Medicaid, we have not seen evidence that leads us to believe this circumstance warrants a different approach to evaluating the sufficiency of payment rates for behavioral health services that is different than the approach for physical health services.

Comment: One commenter recommended that CMS establish a minimum payment threshold that States must adhere to if there are significant, demonstrated access problems, noting

[372] 88 FR 28027 through 28029.

[373] 88 FR 79006.

that States where the 80 percent threshold has been met or exceeded have significantly fewer problems with access to Medicaid services than States where that has not happened. Therefore, the commenter recommended that CMS require States to set all rates under the Medicaid State plan to at least 80 percent of the comparable Medicare rate, unless the State can demonstrate that it does not have a significant access problem with the services for which Medicaid payment rates are below that threshold.

Response: We appreciate the recommendations of the commenters, but the statute does not provide CMS with the authority to establish a floor for Medicaid payment rates as recommended by the commenter, with limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute). We are finalizing the § 447.203(c)(1) and (2) provisions as proposed. Payment rates are not the sole indicators of access to care, and States should pursue any means to improve access to care to the extent that they are able. To the extent that there are significant access issues where the provider payment rates are at least 80 percent of Medicare, the other components of § 447.203(c)(1) would also be reviewed to determine if the payment rate reductions or restructurings meet the § 447.203(c)(1) thresholds. If there are access to care issues, then in following the process described in this final rule, we anticipate that the public processes in paragraph (c)(4) and § 447.204 may yield significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed. We would only consider approving a payment SPA in such circumstances under the streamlined process under § 447.203(c)(1) if the State were able to reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter encouraged CMS to conduct enhanced reviews, consistent with § 447.203(c)(2), of payment rates for States that are already below the 80 percent threshold, even if the State has not submitted a triggering rate reduction SPA.

Response: We appreciate the suggestion of the commenter. The payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements we are finalizing in § 447.203(b) will allow States, CMS, and the public a better insight into rates regardless of whether a SPA is submitted. However, we are not requesting a § 447.203(c)(2) analysis where the State has not submitted a SPA because we are moving away from the previous AMRP process from the 2015 final rule with comment period and replacing that process with the new § 447.203 provisions of this final rule. We will continue in our oversight role of the Medicaid program and note that we can initiate a State plan compliance action if we have evidence that the State's Medicaid payment rates do not meet the access standards in section 1902(a)(30)(A) of the Act, regardless of whether the State is seeking to change them with a SPA.

Comment: For the 80 percent of Medicare analysis, two commenters recommended weighting codes in the analysis by service volume to reflect payment levels more meaningfully across the benefit category. These commenters were concerned that CMS' proposed ''aggregate'' standard, reviewing rates across a benefit category rather than at the service-specific level, will mean that some Medicaid services are paid below 80 percent (including frequently provided services) even if the overall benefit category (including equally weighted but infrequently provided services) achieves the 80 percent threshold. They recommended that CMS set the threshold on a disaggregated basis to avoid permitting States to obscure low payment rates for key services.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted, as determined by the State's public input process, by the payment rate reduction or restructuring proposal. Further, the payment rate transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: One commenter recommended that, for services for which the State does not use a cost-based payment methodology, CMS should require States to transition to a cost-based methodology. Alternatively, they recommended that CMS require Medicaid rates be no less than 80 percent of Medicare, private insurance, private payment (which we interpret to mean self-pay), or rates for State-furnished or paid services or other comparable service rates.

Response: We appreciate the recommendations of the commenter, but with limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), the statute does not provide CMS with the authority to establish a floor or a particular payment methodology for Medicaid payment rates as recommended by the commenter. There is also no statutory requirement to pay providers at the cost of providing services or rates that are equivalent to cost. Prior to 1997, the Omnibus Reconciliation Act of 1980 included the ''Boren Amendment'' which required under then section 1902(a)(13) of the Act that some institutional providers, in particular nursing facilities and intermediate care facilities, receive payments were reasonable and adequate to meet the costs which much be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards. In 1997, through the Balance Budget Act of 1997, the Boren Amendment was repealed and replaced with the current section 1902(a)(13) of Act to instead require States to use a public process to set

institutional provider payment rates. Since these statutory changes have occurred, States are not required to consider the cost of care in the development of provider payment rates, but instead rely on input from those providers in their rate setting, which input also is important under the requirements set forth in this final rule. We are finalizing the § 447.203(c)(1) and (2) provisions as proposed.

Comment: A couple of commenters questioned the use of Medicare rates as the basis for comparison in § 447.203(c), as it is not a significant payor of certain Medicaid-covered services and serves a significantly different population. These commenters suggested that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would ''bear a reasonable similarity'' to the Medicaid-covered services. One commenter expressed concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Specifically, the commenter noted that Medicare Home Health Aides and Medicare in-home skilled nursing services seem like they might be comparable to certain Medicaid HCBS and LTSS, but in practice serve different populations in vastly different volumes and as such are not appropriate comparisons. Commenters urged CMS to issue guidance to States on service categories that would require the submission of additional data under this circumstance. One commenter acknowledged that the aggregate comparison, rather than a rate-by-rate comparison, alleviated some of the challenges of finding a Medicare equivalent for certain services.

Further, one commenter suggested a more nuanced approach to examining payment rates as they relate to access, such as benchmarking against rates for a subset of the highest performing States in terms of access to care for these service categories. That commenter cited recent research from the American Dental Association's Health Policy Institute, which does not suggest a strong relationship between the ratio of Medicaid-to-private payer rates and dental provider participation in Medicaid, meaning that a comparison to private payer rates is not necessarily instructive for all services in the absence of Medicare comparator rates.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. The regulations account for circumstances where Medicare does not cover comparable services, by requiring States to compare, ''as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services, ''which comparison is required even if it is impossible to compare'' to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists. We also agree with the commenter who pointed out that the aggregate comparison at the level of the benefit category makes it more feasible to find a reasonable Medicare comparison. While the regulations allow States some flexibility in determining how to perform the required comparison in developing and submitting their SPA analysis, all State-submitted information will be reviewed by CMS through the SPA process, and we reserve the right to request any additional information necessary to further understand the SPA or the accompanying analysis, which may include a request for additional rate comparison information.

Although we appreciate the concern of the commenter about circumstances where neither Medicare nor private payer rates provide a reasonable analog to assess access to care, we have to balance our requirements against the feasibility of obtaining data for comparison. Although the rate transparency requirements we are finalizing in this rule will increase the availability of State rate data, determining the highest performing States for use as the commenter suggested would require additional burden on both States and the Federal Government to determine which States would be benchmark States for which services. In addition, it is not necessarily clear that this approach would be appropriate to ensure compliance with the statutory access standard, which looks to whether beneficiaries have access to covered services at least as great as that enjoyed by the general population in the same geographic area. We believe the policies we are finalizing strike an appropriate balance that reasonably considers availability of data and State burden, as well as the need to ensure sufficient beneficiary access.

We acknowledge the commenters' concern that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would ''bear a reasonable similarity'' to the Medicaid-covered services, and the concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Particularly for facility-based services, we recognize that Medicare and Medicaid provider types may not be identical in certain cases. However, often, facility-based services furnished by a provider type enrolled in one program are covered when furnished in a different setting or by a provider with a different enrollment type in the other program. In such cases, States should look to the nature of the service rather than, for example, the enrollment type of the provider, to identify a reasonably similar set of Medicare-covered services for comparison. We acknowledge that Medicare also establishes payment rates for certain services for which Medicare seldom pays; however, States still should consider these rates when constructing their comparisons to Medicare in accordance with the provisions of this final rule.

Comment: Some commenters requested that CMS remove the 4 percent threshold under 447.203(c)(1), noting that a 4 percent, or even lower, standard would in most cases be reducing a rate which is already far below Medicare levels. One commenter suggested that if a 1 or 2 percent threshold is not feasible for every State, then CMS should use this standard (that is, 1 or 2 percent, instead of 4 percent) for States whose aggregate Medicaid FFS payments average less than the national average of 72 percent for the most common E/M services.

One of these commenters supported CMS' proposal to assess such rate reductions on a cumulative basis over the course of a State fiscal year. Another commenter urged CMS to consider designing a limit to ensure that States could not implement a large cut (for example, 20 percent) to payments for a particular service, which the commenter perceived as a risk due to our proposal to analyze changes at the benefit category level, where we proposed to examine whether aggregate payment rate changes for the benefit category as a whole would exceed the 4 percent threshold. The commenter also suggested that CMS could also consider disaggregating service analysis in future rulemaking.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. As discussed previously, the 4 percent threshold is one of three criteria identified in § 447.203(c)(1), which, if not met, will require the State to submit additional information required under § 447.203(c)(2). Where a State's payment rates are already below 80 percent of the Medicare FFS payment rate for the same or a comparable set of services, then any rate reductions from that State would be subject to the requirements of

§ 447.203(c)(2). This feature will ensure States with rates already below 80 percent of comparable Medicare FFS rate levels will have to take additional steps to establish that the rate change will not result in access below the level required under section 1902(a)(30)(A) of the Act. We declined to include a lower threshold because we believe that the 4 percent is sufficient based upon our experience with State proposals received after the publication of SMDL #17–004. State proposals that included a reduction less than or equal to 4 percent of the aggregate FFS Medicaid expenditures for each benefit category impacted by the reduction or restructuring generally did not result in access to care issues for affected services.

Comment: Multiple commenters were concerned that the 4 percent reduction criterion is not nominal, as CMS had described it. These commenters urged CMS to re-assess the appropriateness of the 4 percent threshold.

Response: As discussed in the proposed rule, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly.[374] We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004 six years ago, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule, as well as in response to the proposed rule in this rulemaking. The provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17–004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter noted that the 4 percent reduction threshold is consistent with the 2018 proposed rule, but suggested that CMS assess any rate reduction compared to broader trends in the economy, particularly when considering rising medical cost and adjusting for inflation, a 4 percent payment cut should not be considered nominal, especially in States where Medicaid payments are already low. Furthermore, the accumulating effect of yearly cuts to provider payments, which could still meet the thresholds of the rule, would be extremely detrimental to access for beneficiaries in the Medicaid program. For example, the Medicare Economic Index (MEI) measures the impact of inflation faced by physicians with respect to practice costs and general wage levels, and as such show the year-over-year change in cost of providing the same basket of services. The commenter stated that rate reductions should be compared against this type of measure rather than against an arbitrary percentage. The commenter also noted that the 4 percent rate reduction threshold would operate in conjunction with the other criteria in § 447.203(c)(1), and therefore not exempt a State proposal from compliance with the broader access framework in the rule, but expressed concern about the disproportionate impact a 4 percent reduction can have on certain practice types, such as pediatric.

Response: We appreciate the suggestion of the commenter. We are finalizing § 447.203(c)(1)(ii) as proposed. We did not want to rely upon the MEI to supply an inflation factor that must be considered in examining the approvability of payment rate changes or restructurings because we wanted to provide flexibility for States within their budgetary constraints. We also note that the comparison of State payment rates to Medicare would accomplish a similar goal to that stated by the commenter. By requiring State rate actions be compared to the most recently published Medicare rate, which are trended forward annually, the (c)(1)(i) threshold does take into account inflation that may occur in the health care industry.

We reiterate the statement of the commenter that the provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17–004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably

[374] 88 FR 28030.

respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

We disagree that 4 percent is an arbitrary threshold. As noted in a prior response, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule and the proposed rule in this rulemaking. In addition, we did not receive comments indicating that specific State rate reductions that were less than 4 percent had an impact on beneficiary access to care in their State Medicaid programs. In addition, the 4 percent threshold is then a measure to ensure that payment rates are not reduced by too significant of an amount over a single State fiscal year. The two quantitative thresholds in paragraphs (c)(1)(i) and (ii), taken together with the public input requirements in paragraph (c)(1)(iii), work in conjunction to ensure that State payment rates are consistent with section 1902(a)(30)(A) of the Act.

Comment: One commenter suggested where States make changes to a cost-related payment methodology that may result in diminished access (for example, by placing a new cap on administrative costs, requiring a ''rebase,'' or otherwise altering cost-reporting procedures), it may be challenging to determine whether the change would result in a 4 percent or more decrease in payment.

Response: We understand the commenter's concern and note that the 4 percent threshold is a cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. During the SPA process, States are required to estimate the amount of the financial impact on their CMS form 179 and in their public notice as required by § 447.205(c)(2), which states that the public notice must ''give an estimate of any expected increase or decrease in annual aggregate expenditures.'' Where States are unsure how they should demonstrate whether the proposed change meets the 4 percent threshold in § 447.203(c)(1)(ii), they should look to existing criteria and methodologies used to estimate financial impacts for the CMS form 179 and public notice under § 447.205.

Comment: One commenter noted that § 447.203(c)(1)(iii) requires an assessment of ''significant concerns'' from providers and others, and requested additional detail regarding the definition of ''significant concern,'' and what the State's response to significant concerns must entail. A couple of commenters stated that requiring States to demonstrate that no concerns were raised or to ''address'' concerns raised in public comment would be a difficult requirement to meet, noting that any proposed rate reduction is likely to result in significant public comment. One of these commenters stated it is unclear what level of concern or complaint would shift a State from one tier (that is, the streamlined process under § 447.203(c)(1)) to the next (that is, to requiring the additional analysis under § 447.203(c)(2)). The other of these commenters added that, as CMS does not define the term ''address'' in the rule, it is concerning that a State must meet all of the criteria in § 447.203(c)(1) to qualify for the streamlined analysis.

Response: The term ''significant'' can be dependent upon the circumstances, but we generally consider ''significant concerns'' to mean those that are not easily resolvable through engagement with beneficiaries, providers, and other interested parties. We also note that the regulation does not actually use the word ''address'' but rather requires that, to the extent that States received public input on their proposed SPA to reduce or restructure payment rates that ''yielded . . . significant access to care concerns from beneficiaries, providers, or other interested parties,'' the State must demonstrate that it is able to ''respond to or mitigate the concerns, as appropriate.'' For example, a State may receive a large number of public comments on a proposed rate change, but if all the comments merely seek to clarify an aspect of the change, this situation, despite the high volume of comments, would not be a significant concern, because no concern has been raised other than a request for clarification of the proposal As an alternative example, where providers are raising concerns about the level of payment they would receive under a State's new payment rate proposal, the State could discuss with interested parties other legislative initiatives underway or programmatic goals that might be considered as offsetting any decrease in provider payments that might be expected from the proposed rate action. This is common with value-based purchasing initiatives in States. Section 447.203(c)(4), where we are recodifying § 447.203(b)(7) as finalized in the 2015 final rule with comment period, continues to require that ''States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.'' Furthermore, § 447.203(c)(4)(ii) provides that ''States should promptly respond to public input through these mechanisms . . . with an appropriate investigation, analysis, and response,'' and ''States must maintain a record of data on public input and how the State responded to this input,'' which record the State must make available to us upon request. If the State is not able to demonstrate that its proposal will not decrease access below the statutory standard, including by credibly refuting any reasonable, supported concern raised in public comments that it will harm access excessively, then the proposed rate reduction or restructuring will not meet the requirements for the streamlined (c)(1) process and will be subject to the tier 2 process in paragraph (c)(2), where additional data and analysis will be required to be submitted. In all cases, we will review to ensure that statutory access standard and all other applicable Federal requirements are met.

Comment: A few commenters commended CMS for including the third criterion, which centers the importance of public concerns about rate reductions or restructuring, but these commenters opposed CMS implementing any threshold for rate reduction or restructuring SPAs under § 447.203(c)(1).

Response: We appreciate the support of the commenters. With respect to the inclusion of this criterion as one of three

requirements needed to qualify for a streamlined access analysis and in response to the commenters' opposition to implementing any threshold for rate reductions or restructuring SPAs under § 447.203(c)(1), we note that the intention of this final rule is to balance the administrative burden on the States associated with rate reduction or restructuring SPAs with the need to have sufficient information to make an administrative decision on State payment rate proposals, and whether they satisfy the access standard in section 1902(a)(30)(A) of the Act, while also providing providers, beneficiaries, and interested parties to raise concerns directly to the State through the mechanisms for ongoing beneficiary and provider feedback in § 447.203(c)(4) of the final rule.

Comment: A few commenters strongly supported the public input process provision in § 447.203(c), particularly in § 447.203(c)(1)(iii), since developing robust mechanisms for States to hear feedback from providers and interested parties about access concerns will be critical to assuring that access analysis in connection with payment SPAs has its intended effect. One commenter suggested that CMS should further consider formalizing a specific role for the MAC/BAG in this process.

Response: We appreciate the support of the commenters and note that the public input processes defined in § 447.203(c)(4), where we are recodifying requirements previously located in § 447.203(b)(7), requires that States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204. We did not specifically provide a defined role for the MAC or BAC in the regulatory rate reduction or restructuring process, but States are not prohibited from including such entities in their public input process to the extent that they believe it would be valuable. However, if the MAC/BAC under § 431.12 of this final rule, or the interested parties' advisory group under § 447.203(b)(6) produces a comment on a State proposal to reduce or restructure payment rates, then the State would be required to consider and respond to it as public input under § 447.204.

Comment: A few commenters stated that providers that receive Medicaid payments always raise concerns about any proposed rate reduction or restructuring. These concerns are typically framed as concerns about access. While one commenter reiterated the value of the input of providers and other interested parties in the rate-setting process, a requirement to conduct an access analysis any time a provider voices concerns during the public input process is a de facto requirement to conduct an access analysis for all SPAs. The commenter stated that this will increase the administrative burden for States and CMS and undermine the two-tiered level of analysis envisioned by CMS.

Response: We understand the viewpoint of the commenter and can affirm that the mere existence of one or more comments is not in and of itself a measure of whether the comments have raised a significant access to care concern or whether the State is able to respond to and mitigate any significant concern, as appropriate. If comments received do not raise any significant access to care concern, or if they do but the State documents a reasonable response to all significant concerns that demonstrates that the proposal will not reduce access below the statutory standard notwithstanding the concerns, or that mitigations identified by the State will prevent such a degradation of access, then the proposed reduction or restructuring will qualify for the streamlined initial State analysis under § 447.203(c)(1). We also point out that the requirement that States provide adequate notice and consider public comment for payment rate changes is a long-standing requirement of the Medicaid program in 42 CFR part 447, subpart B.

Comment: One commenter expressed concern that § 447.203(c)(1)(iii), which states as a criterion that ''public feedback yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate,'' presents a dangerous loophole through which States can drastically cut payment for services, including, for example, specialist office visits, without triggering additional regulatory scrutiny. The commenter expressed doubt that the subjective inquiry on whether State efforts might be reasonable coupled with the non-specific activity the State would undertake (''respond'' or ''mitigate'') would provide an actual hurdle to payment cuts, including cuts that could constrict access for beneficiaries with rare and ultra-rare conditions.

Response: We disagree that this provision provides States with a loophole enact drastic cuts for services. First and foremost, the provision in question is just one of three criteria a State must meet in order to perform only a streamlined access analysis under § 447.203(c)(1). Second, qualification for the streamlined analysis does not result in automatic approval of the SPA. We will still review both the SPA itself and the streamlined analysis as submitted by the State to determine accuracy and whether the State has met all applicable Federal requirements. We fully expect that some States may submit documentation for the streamlined analysis, and CMS will determine that a more extensive analysis under § 447.203(c)(2) is necessary. For example, if we disagreed that a State's streamlined access analysis submission adequately documented that the State had reasonably responded to or mitigated all significant access concerns raised through public processes in connection with a SPA to reduce or restructure payment rates, we would require the State to submit the additional access analysis provided for in this final rule to enable us to verify that the SPA satisfies the access standard in section 1902(a)(30)(A) of the Act.

To be clear, the State's response to any significant access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us. In addition, § 447.203(c)(4), where we are recodifying § 447.203(b)(7), continues to require that ''States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.'' Furthermore, § 447.203(c)(4)(ii) provides that ''States should promptly respond to public input through these mechanisms . . . with an appropriate investigation, analysis, and response,'' and ''States must maintain a record of data on public input and how the State responded to this input,'' which record the State must make available to us upon request. A major benefit and intent of this repeated emphasis on public process is to protect against the situation the commenter describes. Our regulations ensure other parties besides the State have visibility into a proposed rate reduction or restructuring, and are able to voice related concerns, so we do not need to rely solely on a State's assertion that there are no access-related concerns or that all such concerns have been addressed.

c. Additional State Rate Analysis (§ 447.203(c)(2))

Comment: One commenter expressed support for the proposed changes to strengthen and clarify requirements for the analysis required for reductions in rates or restructuring of provider payments under § 447.203(c)(2); however, the commenter raised concerns about comparing Medicaid rates solely to Medicare rates, as Medicare does not have comparable services for every benefit category in Medicaid. As such, the commenter suggested using private pay where no Medicare payment rates are available.

Response: We appreciate the support of the commenter and point out that a comparison to Medicare payment rates is not the sole means of assessing access to care in this final rule. This final rule requires that, for States submitting a proposed rate reduction or restructuring, the proposed reduction or restructuring must meet all three criteria set out in § 447.203(c)(1), which include the 80 percent of Medicare comparison, or else the additional analysis under § 447.203(c)(2) would be required. We also finalized in in § 447.203(c)(2)(ii) to require a comparison of Medicaid payment rates to Medicare ''and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services'' but note that the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. Similarly, under § 447.203(c)(2), a comparison to Medicare rates is just one part of the full, required analysis for States that must complete the tier 2 analysis. The full tier 2 analysis, which we are finalizing as proposed, requires the following in addition to the full tier 1 analysis: a summary of the proposed payment change including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring; an analysis of the Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring and a comparison of each to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or geographic area; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend information; information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and beneficiary population information and anticipated effects; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and service-recipient beneficiary population information and anticipated effects; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates as the State is unable to demonstrate compliance with § 447.203(c)(1). The regulations being finalized in § 447.203(c)(2)(ii) account for circumstances where Medicare does not cover comparable services, by requiring States to compare, ''as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists.

Comment: One commenter expressed concern that, while CMS understandably seeks to clarify which SPAs are subject to heightened scrutiny under the tier 2 analysis requirements in § 447.203(c)(2), the criteria are skewed toward services that are paid for off a fee schedule, and which correspond to Medicare-covered services.

Response: We acknowledge that there is an administrative ease associated with meeting the requirements of § 447.203(c) where States pay according to a fee schedule. However, it is also possible to compare payment amounts where no such fee schedule exists. State UPL demonstrations are a valuable resource in determining level of payment of both base and supplemental payments compared to a reasonable estimate of the amount that Medicare would pay for the same services, and our experience has shown that States are able to make these comparisons on both a provider-specific level and in the aggregate. The methodology States use for required UPL demonstrations would support the analysis required under § 447.203(c) of this final rule, even where the payment methodology is not based on a fee schedule.

Comment: One commenter noted that the proposed first-tier analysis requires States to compare proposed Medicaid rates to Medicare rates, but as CMS acknowledges in the preamble, the absence of a comparable Medicare service for some services would mean the State would need to perform the full two-step access analysis, since they would not be able to meet all three criteria in § 447.203(c)(1). The commenter stated that this expectation is not clearly reflected in proposed § 447.203(c) and suggested that CMS add language clarifying that when there is no comparable set of Medicare services, the State must perform the second tier of analysis under § 447.203(c)(2). Another commenter expressed support for CMS's preamble provision that, for services in which a reasonably comparable Medicare-covered analogue is not available, the State would be obligated to support its rate reduction or restructuring proposal through the submission of additional information under § 447.203(c)(2).

Response: We reiterate that we are finalizing § 447.203(c)(1) and (2) as proposed. In addition, we are finalizing our statement in preamble that for any service for which the State has proposed to reduce or restructure the Medicaid payments in circumstances when the changes could result in diminished access, for which there are no comparable Medicare services that would enable the State to make the showing required under § 447.203(c)(1)(i), the State is required to conduct the secondary analysis required under § 447.203(c)(2). For example, where Medicare does not cover routine dental care, payment rate reductions or restructurings of such services would be subject to § 447.203(c)(2) since comparable Medicare payment information required under § 447.203(c)(1)(i) of the final rule would be unavailable.

Comment: One commenter stated that the information States are required to

collect and examine, especially the number of providers, beneficiaries, and services, will be particularly valuable in assessing the impact of rate changes on access to home care services. One commenter specifically expressed support for the § 447.203(c)(2)(iii) proposal to require States to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area, provider type, and site of service. That commenter acknowledged that this would be valuable information to be made publicly available. Another agreed, saying CMS should require States to publicly post the enhanced analysis, including data submissions, to ensure full transparency.

Response: We appreciate the support of the commenters. At this time, there is no plan for CMS to make the information States provide in these analyses publicly available. Approved SPAs are public facing documents and are posted on Medicaid.gov after they are approved by CMS. Payment rates used to provide the § 447.203(b) and (c) of the final rule should come from these approved SPAs, and these SPAs should help to clarify questions about the State's particular rate model. We further note that the requirements we are finalizing at §§ 447.203(c)(1)(iii), (c)(4), and 447.204 regarding public process and mechanisms for ongoing beneficiary and provider input should provide interested parties opportunity for meaningful input on State rate actions. Otherwise, information may be available upon request from either States or CMS, and we note that some of this information may be subject to Freedom of Information Act (FOIA) disclosure requirements.

Comment: Several commenters expressed that States should be required to provide detailed information described in § 447.203(c)(2)(i) through (vi) about proposed rate reductions or restructuring any time it proposes to reduce rates or restructure rates in a way that could result in diminished access, and not only when the proposed rate fails to meet certain criteria such as those specified in § 447.203(c)(1). These commenters stated concern that the proposed two-tier structure would still permit States to alter rates in ways that harm beneficiary access.

Response: The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1). The commenters' recommendation seems to suggest something closer to a continuation of the previous AMRP process, whereas we believe this final rule strikes a more appropriate balance of easing State burden where SPAs meet the § 447.203(c)(1) criteria (making them unlikely to result in reducing beneficiary access to care to a level inconsistent with section 1902(a)(30)(A) of the Act), and requiring more rigorous data and analysis requirements for SPAs that do not meet the § 447.203(c)(1) criteria and may present more cause for concern related to beneficiary access to care.

Comment: A commenter recommended that, in addition to requiring States to provide summary information about proposed changes, and information about the rates in aggregate in § 447.203(c), CMS should require States to provide the specific range of rates, including any variation in rates (for example, regional differences, or differences based on provider specialty).

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted by the payment rate reduction or restructuring proposal. Further, the payment rate transparency publication in § 447.203(b) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: Several commenters noted appreciation that the additional information that would be required from States that seek to reduce payment rates or restructure payments in a manner that could result in decreased access noting their belief that the § 447.203(c)(2) provision will create important safeguards to prevent decisions that are solely based on State budgetary concerns rather than an actual analysis of the cost of providing services in the Medicaid program. A few commenters noted that they were glad to see that, because of the nature of HCBS, the majority of rate reductions for home care services and supports would always be subject to the provisions mandating greater scrutiny under § 447.203(c)(2), because Medicare rates for the same or a reasonably similar set of services generally will not be available to make such SPAs eligible for the streamlined access review process under § 447.203(c)(1).

Response: We appreciate the support of the commenters, but note for clarity, as discussed earlier in this preamble, there is no requirement in the Medicaid program that payment rates be based on provider cost.

Comment: A few commenters recommended that, at a minimum, CMS should require all States to complete the more extensive access analysis under § 447.203(c)(2) shortly after publication of the final rule to establish a baseline assessment of access to care for Medicaid beneficiaries. Such analysis should include FFS as well as managed care, enabling comparison of payment and access within and across delivery systems. These commenters urged that this baseline analysis should serve as a comparison point for future access monitoring. Other commenters suggested that the requirement for the analysis in § 447.203(c) should be decoupled from a State's intention to reduce or restructure rates, suggesting instead that all States should be required to conduct this analysis annually, every 2 years, or at least every 3 years across all rates for all Medicaid FFS and managed care programs for which a Medicare comparison is possible.

Response: We appreciate the suggestion of the commenters. The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and

restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements. CMS is discontinuing the previous AMRP process in this final rule, and did not propose and is not finalizing a substantially similar process, as we believe doing so would impose a great deal of burden on States and CMS without commensurate programmatic value, as discussed in the proposed rule and in this final rule (88 FR 27965). We note that the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input provide impacted parties opportunities to raise access concerns or issues to the State at any point through State-provided input processes.

Comment: One commenter requested that CMS clarify the criteria in both tiers which CMS will use to determine the appropriate level of access on which to provide analyses and documentation of adequate access, claiming there are no details available on the criteria. The commenter requested that CMS define a measurable methodology with which to determine and demonstrate adequacy of access to care in relation to the criteria of the analysis required in the applicable provisions of § 447.203(c).

Response: We are finalizing § 447.203(c)(1) and (2) as proposed, and are providing a template which will assist States with the data demonstrations which will be used to comply with the provisions of the final rule. We produced a template that was submitted to OMB for public review under control number 0938–1134 (CMS–10391) and will be submitted for approval with this final rule and a final template will be available shortly thereafter. Between the regulation text, the preamble of this final rule, and the components of the analysis template, we believe that the criteria we will use to evaluate SPA proposals are clear. We are electing not to otherwise define adequate levels of access to care under § 447.203(c) because section 1902(a)(30)(A) of the Act establishes that a measure for access is that payment rates are ''sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,'' which level of access (based on whatever metric might be selected) will vary based on geographic area and the level of access available to the general population for a given service. Although CMS reserves the right to request additional information, we have developed the template to ensure that a State has a mechanism through which all of the data elements in § 447.203(c) can be gathered and presented in a straightforward format. Completing the applicable fields of the template will ensure that the State provides all required data elements of under § 447.203(c), and we will review the materials provided by the State to determine that the State has demonstrated current and anticipated levels of access under the SPA in a manner demonstrates compliance with section 1902(a)(30)(A) of the Act. CMS will review each proposal and the State-provided supporting information to ensure compliance with section 1902(a)(30)(A) of the Act and all other applicable Federal requirements before approving any SPA.

Comment: One commenter urged CMS to require States to identify the unique number of Medicaid-paid claims for beneficiaries (in addition to the full number of services required in the regulations as proposed) and the unique number of beneficiaries who received services. The commenter also stated that measuring providers' capacity to provide Medicaid services, by including an estimated number of beneficiaries who could have received the respective services, would allow States to fully assess the gaps in service and number of providers required to meet the need, noting that this assessment would be needed to assess proposed rate reductions or restructuring under proposed § 447.203(c).

Response: We are finalizing § 447.203(c)(2)(v) as proposed. The measures mentioned by the commenter are often associated with health care system capacity by looking at enrolled providers with open panels, which is very useful in addressing individual beneficiary requests for services, or finding care for individuals within a geographic area, which are the type of request we would expect to be made through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input, and States should be using any information they can to address beneficiary needs in this way. We encourage any interested parties to engage with their State partners to ensure that real-time access to care concerns are able to be addressed by the State as applicable. Further, the provisions of § 447.203(c)(2) are designed to present an overall picture of access to care for each affected benefit category in the State's program. States are welcome to use any additional measures the State believes would be helpful to assess access to care within each affected benefit category, above and beyond the requirements of this final rule.

Comment: One commenter, citing the 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2), supported the use of statistical methods that provide an accurate picture of utilization trends, but recommended that CMS use its discretion in analyzing the information States provide to meet the required data elements. The commenter stated use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization.

Response: The requirements in § 447.203(c)(2)(iii), (iv), and (v) to use 3-year periods are being finalized as proposed. The purpose of the 3-year analysis is to help identify and appropriately account for statistical anomalies that might appear in the data demonstration. Further, we wanted to provide a clear expectation for what States would be required to provide and thereby remove ambiguity, which we believe existed in the previous AMRP process from the 2015 final rule with comment period. In the 2015 final rule with comment period, the previous AMRP data elements were limited to those specified in § 447.203(b)(1)(i) through 447.203(b)(1)(v), which stated that the AMRP and monitoring analysis will consider: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including

other public and private payers, by provider type and site of service. Within the final rule with comment period, there was discussion regarding the types of data States might use to provide the required information, but much of the final rule with comment period left the specifics of the particular data elements up to the States. In this rulemaking, we proposed and are finalizing considerably more detail in § 447.203(c)(2) than was present in the previous AMRP requirements in the former 447.203(b)(1).

We are also finalizing the 3-year time frame for data analysis in this final rule in § 447.203(c)(2) because we determined that a 3-year look back on provider enrollment, beneficiary enrollment, and beneficiary utilization provides sufficient data to show trends in the data while also helping to identify data anomalies. Where the commenter stated that the use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization, we disagree. The commenter's statement implies that a determination would still need to be made that utilization was stable, therefore by requiring 3 years' worth of data, CMS and the State will be able to document that utilization was stable during the prior 3 years.

Comment: One commenter opposed the requirement to provide an additional summary of the proposed payment change, as described in § 447.203(c)(2)(i), to both § 447.203(c)(1) and (2) equally. The commenter was concerned about the administrative burden these requirements place on States, which could delay SPA submission and in turn affect access to services. The commenter also specifically pointed out that SPAs for services without comparable Medicare rates would, by default, need to complete the additional analysis under § 447.203(c)(2), adding administrative burden. The commenter further recommended CMS implement a form similar to the Standard Funding Questions submitted for Medicaid payment SPAs, in which the State would be able to answer a specific set of questions that would capture the analysis that is being sought. Another commenter noted that the § 447.203(c)(2) data submission requirements may impact significant portions of Medicaid services, such as LTSS, and creates administrative burdens, disincentivizing States from modernizing rate methodologies for these services. This commenter recommended that for services without comparable Medicare rates, the initial analysis be sufficient if all other criteria of the initial review (that is, § 447.203(c)(1)(ii) and (iii)) are satisfied.

Response: States are responsible to ensure that their proposed reduction or restructuring SPA submission includes all of the information required under § 447.203(c)(1) prior to submission. If the proposed reduction or restructuring SPA does not meet all of the paragraph (c)(1) requirements, then the State would need to provide the additional analysis required under § 447.203(c)(2).

We understand that there is burden associated with these new requirements. However, as discussed in the proposed rule in section III.C.11.d, this new process will be less burdensome on States than the previous AMRP process. We also do not believe a State could adequately demonstrate access by answering a standard set of questions as suggested by the commenter, as we would be concerned that static questions may not be well suited to solicit the full scope of data elements that could be necessary to evaluate a particular proposal and therefore prefer to keep data submission requirements open-ended so that States are able to provide the most complete and appropriate information possible to stablish that their proposal satisfies section 1902(a)(30)(A) of the Act as implemented in this final rule. We anticipate providing a considerable amount of technical assistance and templates to assist States with the preparation and submission of data and analysis required under § 447.203(c)(1) and (2).

The rule does not limit a State's ability to reduce or restructure rates where the State believes it appropriate to do so, for example, based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. This includes efforts to modernize rates, as noted by the commenter, including by implementing or adjusting. VBP arrangements. While we appreciate that the analysis creates a burden for States, we note that we are replacing a process that was more burdensome. For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates. As the § 447.203(c)(2) elements are based upon and similar to the elements included in the former § 447.203(b)(1) of the 2015 final rule with comment period, we do not believe the new requirements are more burdensome than the 2015 final rule with comment period which created the previous AMRP process. Therefore, we do not believe this final rule disincentivizes States from modernizing payment rates or methodologies as compared to the previous requirements under the 2015 final rule with comment period. For some services, particularly for those for which the State can demonstrate that the § 447.203(c)(1) requirements are met, the final rule considerably reduces burden on States.

Comment: A few commenters urged caution not to impose overly rigid restrictions on States' and CMS' ability to adjust provider payment rates, noting that State Medicaid programs are constrained by the same factors that constrain all State spending, including general economic conditions, State balanced budget requirements, and State general fund revenue. One commenter noted that requiring a significant analysis for proposed reductions in Medicaid FFS payment rates will create administrative burden for States that have been mandated by their legislatures to reduce certain rates or Medicaid spending in general. The commenter noted that in such circumstances, States have a limited number of ''levers'' at their disposal—(1) they can reduce the number of individuals enrolled in Medicaid, (2) they can impose reductions on the covered services that Medicaid beneficiaries receive, or (3) they can adjust provider payment rates. If CMS makes it impossible (or inordinately difficult) to restructure provider payment rates, then States may be forced to make other undesirable reductions to coverage and/or eligibility in order to cope with difficult economic conditions.

Response: We understand the concerns of the commenters. States are required to operate their Medicaid programs within their budgetary constraints, and we agree with the commenter that, of the options available for States facing budgetary issues, none of the available approaches typically is ideal. However, we also note that States are also obligated to comply with section 1902(a)(30)(A) of the Act, which requires States to ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' The requirement specifically references payment rates for ''care and services available under the plan'' such that the services that are covered under the State plan as both mandatory and optional

benefits, must be supported by adequate payment rates for those services. We anticipate providing a considerable amount of technical assistance to ease the administrative burden on States that both need to reduce rates and need to satisfy the requirements of § 447.203(c) to ensure that the statutory access standard is met. We are also finalizing the template we proposed to accompany these requirements and assist States with supplying the necessary data to fulfil these requirements.

Comment: One commenter recommended that CMS build into the review and approval of all SPAs, waiver amendments, and waiver renewals a process for the review of payment rates. The commenter further suggested that CMS require adequate payment rates prior to approving these amendments and renewals. The commenter indicated that this would allow CMS to review rates more often and prevent years or decades passing without rates being reviewed or adjusted.

Response: CMS reviews all SPAs affecting Medicaid payment for compliance with section 1902(a)(30)(A) of the Act. Outside of the SPA process, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to address access issues that may arise even when the State has not submitted a payment SPA. Further, to the extent that a State submits a SPA that updates coverage of a Medicaid service but does not amend Medicaid payment rates or the rate methodology in the Attachment 4.19A (for Medicaid inpatient services such as inpatient hospital services), 4.19B (for Medicaid non-institutional services such as physician services), or 4.19D (for Medicaid nursing facility services) State plan pages, CMS will not necessarily disapprove that SPA on the basis of insufficient Medicaid payment rates as the payment rates were not submitted along with the corresponding coverage and benefit changes for our consideration. States certainly can submit payment rate information to CMS of the State's own volition or upon request during review of a coverage SPA; however, CMS provides States in this situation (where the SPA would amend State plan coverage, but not payment, pages) with an option to instead defer review of the payment rate compliance issue through a mechanism called a ''companion letter,'' as noted in the 2010 SMDL #10–0020.[375] As noted above, even in the absence of a SPA, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to for CMS to take compliance action where it is aware of an access problem due to insufficient rates.

With the policies finalized throughout this final rule, we hope and anticipate that both States and the public will more closely examine existing rates. Our policies around payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures will enhance opportunities to determine where an existing rate may not be supporting adequate access to care and identify for States where a need for increased payments and/or updated payment methodologies should be addressed. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries, providers, and other interested parties opportunities to engage with States on existing payment rates and their impact on beneficiaries' access to care.

d. Compliance With Requirements for State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(3))

Comment: A few commenters applauded CMS for including a clear enforcement mechanism for these provisions at § 447.203(c)(3). One of the commenters specifically offered that this provision helpfully codifies CMS's longstanding authority to enforce access standards under section 1902(a)(30)(A) of the Act by denying SPAs or taking compliance action to protect access for Medicaid enrollees.

Response: We appreciate the support of the commenters.

Comment: One commenter opposed the provision at § 447.203(c)(3) that SPAs may be subject to disapproval. The commenter did not believe that approval of a SPA should be contingent on the submission of a satisfactory access analysis required under paragraphs (c)(1) and (c)(2) of this section of the final rule.

Response: The final rule requires States to submit information with their payment rate reduction or restructuring SPAs in circumstances where those types of rate changes may result in diminished access to care. We are requiring this information in order to determine compliance with section 1902(a)(30)(A) of the Act, which requires that a State plan for medical assistance ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' In the event that a State does not provide the information required under this final rule, we would be unable to determine that the State's proposal is consistent with the statute, and therefore, we would be unable to approve the SPA.

e. Public Input Process (§ 447.203(c)(4))

Comment: Several commenters supported the proposal at § 447.203(c)(4) regarding ongoing mechanisms for beneficiary and provider input on access. One commenter specifically appreciated CMS' recognition of the importance of ongoing feedback from providers and beneficiaries to the State regarding access to care and for the State to track and take account of those interactions in a meaningful way. Another commenter supported this requirement, noting that HCBS recipients enrolled in managed care are currently provided with a grievance system and indicating that FFS recipients must be afforded this same right.

Response: We appreciate the support of the commenters. We believe that the provision in § 447.203(c)(4) of this final rule provides beneficiaries with opportunities to raise their concerns through hotlines, surveys, ombudsman, grievance, and appeals processes that the State makes available, or other equivalent mechanisms offered by the State.

Comment: One commenter recommended that CMS update the public notice requirements in § 447.205 to require notice 30 days before the effective date in order to increase the transparency of the proposed SPA process and ensure that States provide interested parties with meaningful notice and opportunity to provide feedback.

Response: Changes to the public notice requirements in § 447.205 are outside the scope of this rulemaking.

Comment: One commenter recommended that CMS change ''should'' to ''must'' at § 447.203(c)(4)(ii). They pointed out that § 447.203(c)(4)(i) and (iii) under ''Mechanisms for ongoing beneficiary and provider input,'' both use ''must,'' while item (ii) notes States ''should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and

[375] SMDL #10–020, ''Revised State Plan Amendment Review Process.'' Published October 1, 2010. *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SMD10020.pdf.*

response.'' The commenter stated this provision is important and that if it is not mandated on States, some States may ignore it.

Response: This provision is being finalized as proposed because this section is carried over from prior regulatory language at § 447.203(b)(7) and was proposed to be recodified without change. We acknowledge that responses to public input can take time and resources to manage, and point out that this final rule provision is carrying forward the same regulatory language from the 2015 final rule with comment period. In our experience, States do respond timely and appropriately, and therefore did not think it necessary to propose a change to this provision. We note that § 447.203(c)(4)(iii) requires States to maintain a record of data on public input and how the State responded to this input, and the record of input and responses ''will be made available to CMS upon request.''

Comment: One commenter supported requiring States to maintain a record of data on public input and how the State responded to this input, which will be made available to CMS upon request.

Response: We thank the commenter for their support and are finalizing the recodification of § 447.203(b)(7) at § 447.203(c)(4) as proposed.

Comment: One commenter stated that States should establish mechanisms for ongoing monitoring, evaluation, and feedback from beneficiaries, direct care workers, and underserved communities, and that States should create opportunities for meaningful engagement through advisory boards, focus groups, public comment periods, and partnerships with advocacy organizations. The commenter suggested that such an approach ensures that the perspectives and needs of these interested parties are considered in policy development and implementation.

Response: We are finalizing the provisions of § 447.203(c)(4) as proposed, as we believe that the mechanisms for ongoing beneficiary and provider input in paragraph (c)(4) provide opportunities for meaningful engagement by requiring States to develop some of the mechanisms suggested by the commenter. However, in addition to the mechanisms required under § 447.203(c)(4) for ongoing beneficiary and provider input, States are welcome to develop additional processes to facilitate beneficiary and provider feedback, as well as feedback from other interested parties.

Comment: One commenter stated that the mechanisms for ongoing beneficiary and provider input provision in § 447.203(c)(4) lack enforcement to get States to respond in a meaningful way to concerns about access, noting that the question of whether there is a ''deficiency'' will be left to the States themselves to determine. The commenter suggested that there needs to be some way for interested parties to elevate concerns to CMS in a formal fashion when this process does not work at the State level.

Response: The steps States must take to respond to concerns about access raised through input pursuant to § 447.203(c)(4) are detailed in § 447.203(c)(5), which we are finalizing as proposed as a recodification from § 447.203(b)(8). Section 447.203(c)(5) requires States to develop and submit a corrective action plan to CMS within 90 days of discovery of an access deficiency. The submitted action plan must aim to remediate the access deficiency within 12 months. This requirement ensures that the access deficiency is addressed in a timely manner while allowing the State time to address underlying causes of the access issue, be it payment rates, provider participation, etc. These remediation efforts can include but are not limited to: increasing payment rates; improving outreach to providers; reducing barriers to provider enrollment; providing additional transportation to services; or improving care coordination.

Because each State designs and administers its own Medicaid program within the Federal framework, we believe it is most appropriate for beneficiaries and interested parties to raise access concerns with the State directly, rather than to CMS. To the extent that a beneficiary or interested parties' access concerns are not addressed by the State adequately, we continue to urge interested parties to elevate concerns to the State through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider feedback. We further note that we are finalizing as proposed compliance actions for access deficiencies that have not been remedied under § 447.203(c)(6), as recodified from § 447.204(d).

Comment: One commenter noted that some of the proposed policies, such as strengthening the role of Medicaid beneficiaries in the policymaking process, have been pioneered at the State level.

Response: We appreciate the perspective of the commenter and agree that many of these activities have been pioneered at the State level. We often look to actions undertaken by our State partners to identify areas of policy that may be appropriate to enact at the Federal level.

f. Addressing Access Questions and Remediation of Inadequate Access to Care (§ 447.203(c)(5))

Comment: A couple commenters strongly supported the retention of § 447.203(b)(8) language concerning a State's response to problems with access to Medicaid services, which now appears in § 447.203(c)(5). However, one commenter also expressed concerns about whether that requirement has historically served to require States to make meaningful efforts to correct access issues, considering that the commenter stated there are serious problems with access to Medicaid services in many States today, which the commenter asserted CMS has also acknowledged. The commenter suggested this may be a problem of the resources that CMS devotes to enforcement and insisted that CMS needs to commit to stricter and more effective enforcement of this language.

Response: We appreciate the support of the commenters and the sentiment expressed in the comment. CMS is committed to an agency-wide strategy for oversight and enforcement of Federal requirements concerning access to care. Although the language pointed out by the commenter is unchanged from how it previously appeared in § 447.203(b)(8), we are confident the changes to § 447.203(c)(1)(iii), § 447.203(c)(2)(vi), and § 447.203(c)(4) in this final rule will enhance oversight of access and work to enhance the importance of input from beneficiaries, providers, and other interested parties.

Comment: One commenter noted that concerns around timely access may be identified by enrollees, patient advocacy organizations, or providers long before they become apparent to Medicaid managed care plans or State officials, particularly if those access challenges are specific to a disease group such as complex and rare cancers. The commenter urged CMS to clarify that, if such groups present plausible access concerns to State officials, that can be sufficient to make the State aware of the access issue, such that the State must submit a proposed remedy plan to CMS within 90 days of receiving a report of such concern.

Response: We encourage beneficiaries, patient advocacy organizations, and providers to work closely with States in order to raise issues such as inability to connect patients to care, or inability to find an appointment within the patient's geographic area, through the mechanisms for ongoing beneficiary and provider input the State established under § 447.203(c)(4). Section

447.203(c)(5), which was formerly § 447.203(b)(8), then requires States to submit a corrective action plan to remedy the access deficiency within 90 days from when it is identified to the State. We agree with the commenters that beneficiaries, patient advocacy organizations, and providers raising plausible access concerns to State officials would be considered as identifying an access deficiency when raised to the State through appropriate State channels.

g. Compliance Actions for Access Deficiencies (§ 447.203(c)(6))

Comment: One commenter supported the proposal to clarify that CMS may use the procedures set forth in § 430.35 when necessary to ensure compliance with access requirements.

Response: We appreciate the support of the commenter. We are finalizing as proposed to recodify § 447.204(d) at § 447.203(c)(6).

After consideration of public comments, we are finalizing the provisions of § 447.203(c) as proposed aside from minor typographical corrections.

4. Medicaid Provider Participation and Public Process To Inform Access to Care (§ 447.204)

In § 447.204, we proposed conforming changes to reflect proposed changes in § 447.203, if finalized. These conforming edits are limited to § 447.204(a)(1) and (b) and are necessary for consistency with the newly proposed changes in § 447.203(b). The remaining paragraphs of § 447.204 would be unchanged.

Specifically, we proposed to update the language of § 447.204(a)(1), which previously referenced § 447.203, to reference § 447.203(c). Because we proposed wholesale revisions to § 447.203(b) and the addition of § 447.203(c), the proposed data and analysis referenced in the previous citation to § 447.203 would be located more precisely in § 447.203(c). Previous § 447.204(b)(1) referred to the State's most recent AMRP performed under previous § 447.203(b)(6) for the services at issue in the State's payment rate reduction or payment restructuring SPA; we proposed to remove this requirement to align with our proposal to rescind the previous AMRP requirements in § 447.203(b). Previous § 447.204(b)(2) and (3) required the State to submit with such a payment SPA an analysis of the effect of the change in the payment rates on access and a specific analysis of the information and concerns expressed in input from affected interested parties; we noted our belief that the previous requirements are addressed in proposed § 447.203(c)(1) and (2), as applicable. We explained our belief that the continued inclusion of these paragraphs (b)(2) and (3) would be unnecessary or redundant in light of the proposals in § 447.203(c)(1) and (2), if finalized. The objective processes proposed under § 447.203(c)(1) and (2), which would require States to submit quantitative and qualitative information with a proposed payment rate reduction or payment restructuring SPA, would be sufficient for us to obtain the information necessary to assess the State's proposal with the same or similar information as previously required under § 447.204(b)(2) and (3).

With the removal of § 447.204(b)(1) through (b)(3), we proposed to revise § 447.204(b) to read, ''[t]he State must submit to us with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.''

Finally, as noted in the previous section, we proposed to remove and relocate § 447.204(d), as we believed the nature of that provision is better suited to codification in § 447.203(c)(6).

We solicited comments on the proposed amendments to § 447.204. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the conforming edits to § 447.204. Another commenter specifically supported the proposal to make technical changes to § 447.204(a) to cross-reference the analysis that CMS proposes to require under § 447.203(c).

Response: We appreciate the support of the commenters.

Comment: One commenter recommended that CMS amend § 447.204(a)(2) to specifically include reference to the interested parties advisory group described in § 447.203(b)(6).

Response: We appreciate the recommendation of the commenter. We are confident that the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) of the final rule will provide interested parties opportunity for meaningful input on State rate actions.

After consideration of public comments, we are finalizing the provisions of § 447.204 as proposed.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the rule, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule (88 FR 28037 through 28066) we solicited public comment on each of these issues for the following sections of the proposed rule (CMS–2442–P, RIN 0938–AU68) that contained collection of information requirements. Comments were received with respect to ICR #4 (Incident Management System). A summary of the comment and our response is set out below.

A. Wage Estimates

States and the Private Sector: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2022 [376] National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2022/may/oes_nat.htm*). In this regard, Table 2 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs [377] (calculated at 100 percent of salary), and our adjusted hourly wage.

[376] In this final rule, we used the most recently available data, May 2022, from the BLS. This is an update from the proposed rule, (88 FR 27960), which used data from the BLS' May 2021 National Occupational Employment and Wage Estimates for salary estimates.

[377] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

TABLE 2: National Occupational Employment and Wage Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Services Manager	11-3012	55.59	55.59	111.18
Business Operations Specialist	13-1000	40.04	40.04	80.08
Business Operations Specialist, All Other	13-1199	39.75	39.75	79.50
Chief Executive	11-1011	118.48	118.48	236.96
Compensation, Benefits, and Job Analyst	13-1141	36.50	36.50	73.00
Computer and Information Analyst	15-1210	53.15	53.15	106.30
Computer Programmer	15-1251	49.42	49.42	98.84
Data Entry Keyers	43-9021	18.26	18.26	36.52
General and Operations Manager	11-1021	59.07	59.07	118.14
Human Resources Manager	11-3121	70.07	70.07	140.14
Management Analyst	13-1111	50.32	50.32	100.64
Social and Community Service Managers	11-9151	38.13	38.13	76.26
Social Science Research Assistants	19-4061	27.77	27.77	55.54
Statistician	15-2041	50.73	50.73	101.46
Survey Researcher	19-3022	31.94	31.94	63.88
Training and Development Specialist	13-1151	33.59	33.59	67.18

For States and the private sector, the employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Beneficiaries: We believe that the costs for beneficiaries undertaking administrative and other tasks on their own time is a post-tax hourly wage rate of $20.71/hr.

We adopt an hourly value of time based on after-tax wages to quantify the opportunity cost of changes in time use for unpaid activities. This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' [*] We start with a measurement of the usual weekly earnings of wage and salary workers of $998. [**] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in a post-tax hourly wage rate of $20.71. We adopt this as our estimate of the hourly value of time for changes in time use for unpaid activities.[378] [379] Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Adjustment to State Cost Estimates

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. For medical assistance services, the Federal government provides funding based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capital incomes. For Medicaid, all States receive a 50 percent Federal matching rate for most administration expenditures. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. As such, and taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimate State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be smaller.

C. Information Collection Requirements (ICRs)

1. ICRs Regarding Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The following changes will be submitted to OMB for approval under

[378] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[379] U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/LEU0252881500A.* Annual Estimate, 2021.

control number 0938–TBD (CMS–10845).

Currently, most States have an established Medical Care Advisory Committee (MCAC), which we are renaming the Medicaid Advisory Committee (MAC), whereby each State has the discretion on how to operate its MCAC. A small number of States also use consumer advisory subcommittees as part of their current MCACs, similar to the Beneficiary Advisory Council (BAC) in § 431.12. We reviewed data from 10 States to determine the current status of MCACs and to determine the burden needed to comply with the § 431.12 requirements across 50 States and the District of Columbia.

Under the provision, States will be required to:

- Select members to the MAC and BAC on a rotating and continuous basis.
- Develop and publish a process for MAC and BAC member recruitment and selection of MAC and BAC leadership.
- Develop and publish:

++ Bylaws for governance of the MAC.

++ A current list of MAC and BAC membership.[380]

++ Past meeting minutes, including a summary from the most recent BAC Meeting.

- Develop, publish, and implement a regular meeting schedule for the MAC and BAC.

Additionally, the State must provide and post to its website an annual report written by the MAC to the State describing its activities, topics discussed, recommendations. The report must also include actions taken by the State based on the MAC recommendations.

The requirements will require varying levels of effort by States. For example, a handful of States already have a BAC. However, we believe that most States will be required to create new structures and processes. The majority of States reviewed are already meeting some of the new requirements for MACs, such as publication of meeting schedules, publication of membership lists, and publication of bylaws. However, all MAC bylaws will need to be updated to meet the new requirements. Our review showed that most States are not currently publishing their recruitment and appointment processes for MAC members, and those that did will need to update these processes to meet the new requirements. About half of the States reviewed published meeting minutes with responses and State actions, as required under the new requirements. However, only one State reviewed published an annual report, so this will likely be a new requirement for almost all State MACs. States will not need to modify or build reporting systems to create and post these annual reports. Due to the wide range in the use and maturity of current MCACs across the States, we are providing a range of estimates to address these variations.

We recognize that some States, which do not currently operate a MCAC, will have a higher burden to implement the requirements of § 431.12 to shift to the MAC and BAC structure. However, our research showed that the majority of States do have processes and procedures for their current MCACs, which will require updating, but at a much lower burden. Therefore, we believe it is appropriate to offer average low and high burden estimates.

For a low estimate, we estimate it will take a team of business operations specialists 120 hours at $79.50/hr to develop and publish the processes and report. In aggregate, we estimate an annual burden of 6,120 hours (120 hr/response × 51 responses) at a cost of $486,540 (6,120 hr × $79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $243,270 ($486,540 × 0.50). We also estimate that it will take 40 hours at $140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur every 2 years. In aggregate, we estimate a biennial burden of 2,040 hours (40 hr/response × 51 responses) at a cost of $285,885 (2,040 hr × $140.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $142,942 ($285,885 × 0.50). Additionally, we estimate it will take 10 hours at $118.14/hr for an operations manager to review the updates and prepare the required reports for annual publication. In aggregate, we estimate an annual burden of 510 hours (10 hr/response × 51 responses) at a cost of $60,251 (510 hr × $118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $30,125 ($60,251 × 0.50).

We derived the high estimate by doubling the hours from the low estimate. We used this approach because all States already have a MCAC requirement which means the type of work being discussed is already underway in most States and that there is reference point for the type of work described. For example, we estimate it will take a team of business operations specialists 240 hours at $79.50/hr to develop and publish the processes and annual report. In aggregate, we estimate an annual burden of 12,240 hours (240 hr/response × 51 responses) at a cost of $973,080 (12,240 hr × $79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $486,540 ($973,080 × 0.50). We also estimate that it will take 80 hours at $140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur every 2 years. In aggregate, we estimate a biennial burden of 4,080 hours (80 hr/response × 51 responses) at a cost of $571,771 (4,080 hr × $140.14). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $285,885 ($571,771 × 0.50). Additionally, we estimate it will take 20 hours at $118.14/hr for an operations manager to review the updates and prepare the required annual report for publication. In aggregate, we estimate an annual burden of 1,020 hours (20 hr/response × 51 responses) at a cost of $120,503 (1,020 hr × $118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $60,251 ($120,503 × 0.50).

We have summarized the total burden in Table 3. To be conservative and not underestimate our burden analysis, we are using the high end of our estimates to score the PRA-related impact of the finalized requirements.

[380] BAC members may choose to not have their names listed on the publicly posted membership list.

TABLE 3: Summary of High Burden Estimates for Medical Care Advisory Committee Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 431.12 (develop/ publish report)	51	51	Annual	240	12,240	79.50	973,080	486,540
§ 431.12 (review/approve bylaws)	51	51	Biennial	80	4,080	140.14	571,771	285,885
§ 431.12 (review updates/prepare reports)	51	51	Annual	20	1,020	118.14	120,503	60,251
Total	51	153	varies	Varies	17,340	varies	1,665,354	832,676

While a few commenters made general or high-level comments regarding concerns about burden (which are addressed in section II.A of this final rule) we did not receive specific comments on this ICR. The general comments we received were about the overall burden related to the MAC and BAC provisions and not about the burden estimated in the ICR Table 3 nor the information outlined in this section. In this rule we are finalizing the MAC and BAC reporting requirements and burden estimates as proposed.

2. ICRs Regarding Person-Centered Service Plans (§ 441.301(c)(3); Applied to Other HCBS Authorities at §§ 441.450(c), 441.540(c), and 441.725(c), and 438.72(b) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as ''person-centered service plans'' or ''service plans''). Existing Federal regulations at § 441.301(c)(1) through (3) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [381] (hereinafter the ''2014 guidance'') that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures.

In this rule, we are finalizing a new requirement at § 441.301(c)(3)(i) to specify that States demonstrate that the person-centered service plan **for every individual** is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. At § 441.301(c)(3)(ii)(A) we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at new § 441.301(c)(3)(ii)(B), that States demonstrate that they reviewed for every individual the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

In addition, we also proposed (and are finalizing) several changes to current regulations for person-centered planning at § 441.301(c)(1) to reposition, clarify, and remove extraneous language from § 441.301(c)(1).

We are finalizing the person-centered planning requirements at § 441.301(c)(1) and (3) without substantive changes. Below are our burden estimates for these requirements.

[381] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

a. One Time Person-Centered Service Plan Requirements: State (§ 441.301(c)(3))

As discussed above, at new § 441.301(c)(3)(ii)(A), we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at § 441.301(c)(3)(ii)(B), a requirement that States demonstrate for every individual that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. The burden associated with the person-centered service plan reporting requirements at § 441.301(c)(3)(ii)(A) and (B) affects the 48 States (including the District of Columbia) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[382] We anticipate that States will need to update State policy, as well as oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with these requirements.

However, because we are codifying a minimum performance level associated with existing regulations but not otherwise changing the regulatory requirements under § 441.301(c)(3)(ii)(A) and (B), we do not estimate any additional burden related to those requirements. We also hold that there is no additional burden associated with repositioning, clarifying, and removing extraneous language from the regulatory text at § 441.301(c)(1). In this regard we are only estimating burden for updating State policy and oversight and monitoring processes related to the codification of the finalized 90 percent minimum performance level requirement.

We estimate it will take 8 hours at $111.18/hr for an administrative services manager to update State policy and oversight and monitoring processes, 2 hours at $118.14/hr for a general and operations manager to review and approve the updates to State policy and oversight and monitoring processes, and 1 hour at $236.96/hr for a chief executive to review and approve the updates to State policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 528 hours (48 States × [8 hr + 2 hr + 1 hr]) at a cost of $65,409 (48 States × [(8 hr × $111.18/hr) + (2 hr × $118.14/hr) + (1 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is $32,704 ($65,409 × 0.50).

TABLE 4: Summary of One-Time Burden Estimates for States for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Update State policy and oversight and monitoring processes	48	48	Once	8	384	111.18	42,693	21,347
Review and approval of State policy update at the management level	48	48	Once	2	96	118.14	11,341	5,671
Review and approval of State policy update at the chief executive level	48	48	Once	1	48	236.96	11,374	5,687
Total	48	48	Once	Varies	528	Varies	65,409	32,704

b. One Time Person-Centered Service Plan Requirements: Managed Care Plans (§ 441.301(c)(3))

As discussed above, we are requiring managed care delivery systems to also comply with the requirements finalized at § 441.301(c)(3) to demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days and to demonstrate that they reviewed the person centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. As with the burden estimate for States, we do not estimate an ongoing burden related to the codification of a minimum performance level associated with the requirements at § 441.301(c)(3).

For managed care plans, we estimate it would take 5 hours at $111.18/hr for an administrative services manager to update organizational policy and oversight and monitoring processes related to the codification of a new minimum performance level and 1 hour at $236.96/hr for a chief executive to review and approve the updates to organizational policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 966 hours (161 managed care plans × [5 hr + 1 hr]) at a cost of $127,650 (161 managed care plans × [(5 hr × $111.18/hr) + (1 hr × $236.96/hr)]).

[382] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

TABLE 5: Summary of One-Time Burden Estimates for Managed Care Plans for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Update organizational policy and oversight and monitoring processes	161	161	Once	5	805	111.18	89,500	n/a
Review and approval of policy and oversight and monitoring processes	161	161	Once	1	161	236.96	38,151	n/a
Total	161	161	Once	Varies	966	Varies	127,650	n/a

3. ICRs Regarding Grievance System (§ 441.301(c)(7); Applied to Other HCBS Authorities at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our reporting tools and survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.301(c)(7), we are finalizing requirements that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system to file a complaint or expression or dissatisfaction related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6).

We are finalizing at § 441.301(c)(7)(vii) a list of recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we are finalizing that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(*1*) through (*7*), we are finalizing that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we are finalizing that grievance records be accurately maintained and in a manner that would be available upon our request.

We are finalizing the application of these requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively. However, to avoid duplication with the grievance requirements for managed care plans at part 438, subpart F, we did not propose to apply these requirements to managed care delivery systems.

We are finalizing the grievance process requirements we proposed at § 441.301(c)(7) with one substantive change. As discussed in section II.B.2. of this final rule, we are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) that States must have a 14-day expedited resolution process in addition to a standard 90-day resolution process for grievances. We do not anticipate that this change affects the burden estimates, as it does not change the recordkeeping requirements finalized at § 441.301(c)(7)(vii). In general, even with this change, the States will still have to perform all activities described below in order to establish and maintain the standard grievance process outlined in § 441.301(c)(7). Additionally, as we encourage States to develop their own expedited grievance process, we are calculating the burden estimate with the assumption that all States will choose to create their own version of an expedited resolution process within the grievance process required at § 441.301(c)(7).

We are finalizing the other grievance process proposals without substantive changes. Burden estimates for our finalized grievance process requirements are below.

a. States

The burden associated with the grievance system requirements finalized at § 441.301(c)(7) affect the 48 States (including the District of Columbia) that deliver at least some HCBS under sections 1915(c), (i), (j), or (k) authorities through FFS delivery systems.[383] [384]

[383] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[384] While some States deliver the vast majority of HCBS through managed care delivery systems, States would be subject to these requirements if they deliver any HCBS under section 1915(c), (i), (j), or (k) authorities through a fee-for service delivery system. Based on data showing that the percent of LTSS expenditures delivered through managed LTSS delivery systems varied between 3 percent and 93 percent in 2019 across all States with managed LTSS, we assume that all States deliver at least some HCBS through fee-for-service delivery systems (*https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf*). We anticipate that the burden associated with implementing these requirements will be lower for States that deliver the vast majority of HCBS through managed care delivery systems.

While some States may have existing grievance systems in place for their FFS delivery systems, we were unable to determine the number of States with existing grievance systems or whether those grievance systems would meet the finalized requirements at § 441.301(c)(7). As a result, we do not take this information into account in our burden estimate calculated below. We estimate a one-time and ongoing burden to implement these requirements at the State level.

Specifically, States will have to: (1) develop and implement policies and procedures; (2) establish processes and data collection tools for accepting, tracking, and resolving, within required timeframes, beneficiary grievances, including processes and tools for: providing beneficiaries with reasonable assistance with filing a grievance, for accepting grievances orally and in writing, for reviewing grievance resolutions with which beneficiaries are dissatisfied, and for providing beneficiaries with a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance; (3) inform beneficiaries, providers, and subcontractors about the grievance system; and (4) develop beneficiary notices; and (5) collect and maintain information on each grievance, including the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed.

i. One-Time Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the one-time requirements, we estimate it will take: 240 hours at $111.18/hr for an administrative services manager to draft policy and procedure content, prepare notices and informational materials, draft rules for publication, and conduct public hearings; 100 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection and tracking; 120 hours at $67.18/hr for a training and development specialist to develop and conduct training for staff; 40 hours at $118.14/hr for a general and operations manager to review and approve policies, procedures, rules for publication, notices, and training materials; and 20 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate a one-time burden of 24,960 hours (520 hr × 48 States) at a cost of $2,596,493 (48 States × [(240 hr × $111.18/hr) + (100 hr × $98.84/hr) + (120 hr × $67.18/hr) + (40 hr × $118.14/hr) + (20 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $1,298,246 ($2,596,493 × 0.50).

TABLE 6: Summary of One-Time Burden Estimates for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy and procedures, rules for publication; prepare beneficiary notices, informational materials; conduct public hearings	48	48	Once	240	11,520	111.18	1,280,794	640,397
Build, design, operationalize internal systems for data collection and tracking	48	48	Once	100	4,800	98.84	474,432	237,216
Develop and conduct training for staff	48	48	Once	120	5,760	67.18	386,957	193,478
Review and approve policies, procedures, rules for publication, notices, and training materials at the management level	48	48	Once	40	1,920	118.14	226,829	113,415
Review and approve all operations in collection of information requirement at the chief executive level	48	48	Once	20	960	236.96	227,482	113,741
TOTAL	48	48	Once	Varies	24,960	Varies	2,596,493	1,298,246

ii. Ongoing Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the on-going requirements, we estimate that approximately 2 percent of 1,460,363 Medicaid beneficiaries who receive HCBS under section 1915(c), (i), (j), or (k) authorities through FFS delivery systems annually [385] will file a grievance or appeal (29,207 grievances = 1,460,363 × 0.02).[386] We estimate it will take: 0.333 hours or 20 minutes at $79.50/hr for a business operations specialist to collect the required information for each grievance from the beneficiary (29,207 total grievances), 0.166 hours or 10 minutes at $36.52/hr for a data entry worker to record the required information on each grievance (29,207 total grievances), 20 hours at $98.84/hr for a computer programmer to maintain the system for storing information on grievances (48 States), 12 hours at $118.14/hr for a general and operations manager to monitor and oversee the collection and maintenance of the required information (48 States), and 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (48 States). In aggregate, we estimate an on-going burden of 16,206 hours at a cost of $1,135,949 ([(29,207 grievances × 0.333 hr × $79.50/hr) + (29,207 grievances × 0.166 hr × $36.52/hr) + (48 States × 20 hr × $98.84/hr) + (48 States × 12 hr × $118.14/hr) + (48 States × 2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is $567,975 ($1,135,949 × 0.50) per year.

TABLE 7: Summary of Ongoing Burden for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect required grievance data and information	48	29,207	On occasion	0.333	9,726	79.50	773,217	386,609
Enter required grievance data and information into data collection and tracking system	48	29,207	On occasion	0.166	4,848	36.52	177,049	88,525
Perform maintenance on system for storing data and information on grievances	48	48	Annually	20	960	98.84	94,886	47,443
Monitor and oversee the collection and maintenance of the required information at the management level	48	48	Annually	12	576	118.14	68,049	34,025
Review and approve all operations associated with collection of information requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
TOTAL	48	29,255 (29,207 + 48)	Varies	Varies	16,206	Varies	1,135,949	567,975

[385] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[386] We based this percent on an estimate of the percent of Medicaid beneficiaries that file appeals and grievances in Medicaid managed care in Supporting Statement A for the information collection requirements for the Medicaid Managed Care file rule (CMS–2408–F, RIN 0938–AT40). See *https://omb.report/icr/202205-0938-015/doc/121334100* for more information.

4. ICRs Regarding Incident Management System (§ 441.302(a)(6); Applied to Other HCBS Authorities at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.302(a)(6), we are finalizing a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. At § 441.302(a)(6)(i)(A), we are finalizing that States must establish a minimum standard definition of a critical incident. At § 441.302(a)(6)(i)(B) we are finalizing a requirement that States must have electronic incident management systems that, at a minimum, enable electronic collection, tracking (including tracking of the status and resolution of investigations), and trending of data on critical incidents.

We are finalizing the requirements we proposed at § 441.302(a)(6)(i) without substantive changes, but we are finalizing a change to the applicability date for the electronic management system requirement. We had proposed that States would need to comply with the requirements at § 441.302(a)(6) in 3 years. We are finalizing the 3-year applicability date for the requirements at § 441.302(a)(6) with the exception of the electronic incident management system finalized at § 441.302(a)(6)(i)(B), which has a finalized applicability date of 5 years. We do not anticipate that this change will affect the activities described in these burden estimates; the primary effect of this change is to grant States two additional years in which to develop electronic incident management systems, for which they will perform the same activities.

At § 441.302(a)(6)(i)(C), we finalized that States require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan or are a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(D), we finalized that States must use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(E) we finalized a new requirement that the State must ensure medical records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b) to ensure that records with protected health information used during critical incident review are obtained and used with beneficiaries' consent. We are finalizing at § 441.302(a)(6)(i)(F) a requirement that States share information on the status and resolution of investigations if the State refers critical incidents to other entities for investigation. We are finalizing at § 441.302(a)(6)(i)(G) a requirement that States separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. We are finalizing at § 441.302(a)(6)(i)(H) a requirement that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems.

At § 441.302(a)(6)(iii), we are the application of these requirements to services delivered under FFS or managed care delivery systems. We also finalized the application of the requirements finalized at § 441.302(a)(6) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively.

With the exception of the change to the effective date for electronic incident management systems noted above, we are finalizing the requirements described herein without substantive modification. Burden estimates for these requirements are discussed below.

We received one comment on the proposed burden estimate for the incident management provision. This comment, and our response, is summarized below.

Comment: One commenter noted that when their State investigated developing a single electronic incident management system in 2014, the State estimated the cost of consolidating multiple State systems into a single system would be $100 million and believed that it would be even more expensive to create such a system now.

Response: We thank the commenter for their feedback. Without more detailed information, provided, we decline to update our burden estimate for the incident management ICR based on this comment. We believe most States that require upgrades to their system could do so within the costs that we estimated; we will provide technical assistance on an as-need basis for States to identify efficient ways to upgrade their systems.

We also note that according to the finalized requirements in § 441.302(a)(6), States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We are recommending, but not requiring, that States develop a single electronic critical incident system for all of their HCBS programs under sections 1915(c), (i), (j), and (k) authorities, as we believe that a single system will best enable States to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. We recognize that States may have to make certain decisions about the development of their electronic incident management system according to current system constraints.

a. States

The burden associated with the incident management system requirements proposed at § 441.302(a)(6) will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), (i), (j), or (k) authorities.[387] We estimate a one-time and on-going burden to implement these requirements at the State level. The burden for the reporting requirements at § 441.311(b)(1) is included in the ICR #8, which is the ICRs Regarding Compliance Reporting (§ 441.311(b)).

All of the States impacted by § 441.302(a)(6)(i)(B), requiring that States use an information system, as

[387] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

defined in 45 CFR 164.304 and compliant with 45 CFR part 164, have existing incident management systems in place. However, we assume that all States will need to make at least some changes to their existing systems to fully comply with the proposed requirements. Specifically, States will have to update State policies and procedures; implement new or update existing electronic incident management systems; publish revised provider requirements through State notice and publication processes; update provider manuals and other policy guidance; amend managed care contracts; collect required information from providers; use other required data sources to identify unreported incidents; and share information with other entities in the State responsible for investigating critical incidents.

i. One Time Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the one-time requirements related to § 441.302(a)(6), we estimate it will take: 120 hours at $111.18/hr for an administrative services manager to draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 20 hours at $100.64/hr for a management analyst to update provider manuals; 80 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $79.50/hr for a business operations specialist to establish processes for information sharing with other entities; 80 hours at $106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; 24 hours at $118.14/hr for a general and operations manager to review and approve managed care contract modifications, policy and rules for publication, and training materials; and 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a one-time burden of 19,872 hours (414 hr × 48 States) at a cost of $1,958,292 (48 States × [(120 hr × $111.18/hr) + (20 hr × $100.64/hr) + (80 hr × $67.18/hr) + (80 hr × $79.50/hr) + (80 hr × $106.30/hr) + (24 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $979,146 ($1,958,292 × 0.50).

In addition, we estimate that States, based on the results of the incident management system assessment discussed earlier in section II.B.3. of this preamble, that 82 percent of States, or 39 States (48 States × 0.82), will need to update existing electronic incident management systems, while the remaining 9 States would need to implement new electronic incident management systems, to meet the proposed requirement at § 441.302(a)(6)(i)(B). We estimate based on information reported by some States in spending plans for section 9817 of the American Rescue Plan Act of 2021 that the cost per State to update existing electronic systems is $2 million while the cost per State to implement new electronic systems is $5 million.[388] In aggregate, we estimate a one-time technology burden of $123,000,000 [($2,000,000 × 39 States) + ($5,000,000 × 9 States)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $61,500,000 ($123,000,000 × 0.50).

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[388] Enhanced Federal Financial Participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP rate is also available for operations of such systems, in accordance with applicable Federal requirements. However, the receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. As a result, we do not assume for the purpose of this burden estimate that States will qualify for the enhanced Federal match. This estimate overestimates State burden to the extent that States qualify for the enhanced Federal match.

TABLE 8: Summary of One-Time Burden for States for the Incident Management System Requirements (§ 441.302(a)(6))

Requirement	No. Respond-ents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans	48	48	Once	120	5,760	111.18	640,397	320,198
Update provider manuals	48	48	Once	20	960	100.64	96,614	48,307
Develop and conduct training for providers	48	48	Once	80	3,840	67.18	257,971	128,986
Establish processes for information sharing with other entities	48	48	Once	80	3,840	79.50	305,280	152,640
Build, design, and implement reports for using claims and other data to identify unreported incidents	48	48	Once	80	3,840	106.30	408,192	204,096
Review and approve managed care contract modifications, policy and rules for publication, and training materials at the management level	48	48	Once	24	1,152	118.14	136,097	68,049
Review and approve all operations associated with this requirement at the executive level	48	48	Once	10	480	236.96	113,741	56,871
Subtotal Labor-Related Burden	*48*	*48*	*Once*	*Varies*	*19,872*	*Varies*	*1,958,292*	*979,146*
Update existing electronic incident management systems	48	39	Once	n/a	n/a	$2,000,000/ system (contractor)	78,000,000	39,000,000
Implement new electronic systems	48	9	Once	n/a	n/a	$5,000,000/ system (contractor)	45,000,000	22,500,000
Subtotal Non-Labor Burden	*48*	*48*	*Once*	*n/a*	*n/a*	*Varies*	*123,000,000*	*61,500,000*
TOTAL	48	96	Once	varies	19,872	Varies	124,958,292	62,479,146

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ii. Ongoing Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the ongoing requirements § 441.302(a)(6), we estimate that there are 0.5 critical incidents annually [389] for each of the 1,889,640 Medicaid beneficiaries who receive HCBS under sections 1915(c), (i), (j), or (k) authorities annually, or 944,820 (1,889,640 × 0.5) critical incidents annually.[390] We further estimate that, based on data on unreported incidents, these requirements will result in the identification of 30 percent more critical incidents annually, or 283,446 (944,820 × 0.3) critical incidents; [391] that 76 percent, or 215,419 (283,446 × 0.76) will be reported for individuals enrolled in FFS delivery systems; [392] and that 10 percent of those for individuals enrolled in FFS delivery systems (21,542 = 215,419 × 0.1) will be made through provider reports and 90 percent (193,877 = 215,419 × 0.9) through claims identification and other sources.[393] We estimate 0.166 hr or 10 minutes at $36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. In aggregate, we estimate an ongoing burden each year of 3,576 hours (21,542 incidents × 0.166 hr) at a cost of $130,594 (3,576 hr × $36.52/hr) to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. While States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the managed care plans would be responsible for reporting the identified critical incidents to the State.[394] We further assume that the information reported by managed care plans to the State and identified by the State through claims and other data sources would be in an electronic form. For the 68,027 more critical incidents for individuals enrolled in managed care (283,446 more critical incidents identified × 24 percent for individuals enrolled in managed care), and the 193,877 more critical incidents identified through claims and other data sources for individuals enrolled in FFS (283,446 more critical incidents identified × 76 percent for individuals enrolled in FFS × 90 percent identified through claims and other sources), we estimate 2 minutes (0.0333 hr) at $36.52/hr for a data entry worker to record the information on each of these 261,904 critical incidents (68,027 + 193,877). In aggregate, for § 441.302(a)(6), we estimate an ongoing annual burden of 8,721 hours (261,904 incidents × 0.0333 hr) at a cost of $318,491 (8,721 hr × $36.52/hr) on these critical incidents.

In total, for § 441.302(a)(6), we estimate an ongoing burden each year of 12,297 hours (3,576 hr + 8,721 hr) at a cost of $449,085 ($130,594 + $318,491) to record the information on all critical further estimate it would take 12 hours at $79.50/hr for a business operations specialist to maintain processes for information sharing with other entities; 20 hours at $106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents; 24 hours at $118.14/hr for a general and operations manager to monitor the operations associated with this requirement; and 4 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement in each State. In aggregate, we estimate an ongoing burden of 15,177 hours ([60 hr × 48 States] + 12,297 hr) at a cost of $778,520 ($449,085 + [48 States × ((12 hr × $79.50/hr) + (20 hr × $106.30/hr) + (24 hr × $118.14/hr) + 4 hr × $236.96/hr)]). In addition, we estimate an on-going annual technology-related cost of $500,000 per State for States to maintain their electronic incident management systems. In aggregate, we estimate an ongoing burden of $24,000,000 ($500,000 × 48 States) for States to maintain their electronic incident management systems. In total, we estimate an ongoing annual burden of 15,177 hours at a cost $24,778,520 ($778,520 + $24,000,000). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $12,389,260 ($24,778,520 × 0.50).

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[389] Data on the number of critical incidents is limited. We base our estimate on available public information, such as *https://oig.hhs.gov/oas/reports/region7/71806081.pdf* and *https://dhs.sd.gov/servicetotheblind/docs/2015%20CIR%20Annual%20Trend%20Analysis.pdf.*

[390] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[391] Data on the number of unreported critical incidents is limited. We base our estimate on available public information, such as *https://pennlive.com/news/2020/01/possible-abuse-of-group-home-residents-wasnt-adequately-tracked-in-pa-federal-audit.html* and *https://www.kare11.com/article/news/local/federal-audit-finds-maine-dhhs-failed-to-investigate-multiple-deaths-critical-incidents/97-463258015.*

[392] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[393] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of more critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

[394] Addressing Critical Incidents in the MLTSS Environment: Research Brief, ASPE, *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

TABLE 9: Summary of Ongoing Burden for States for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems	48	21,542	Annually	0.166	3,576	36.52	130,596	65,298
Record the information on critical incidents for individuals enrolled in managed care and critical incidents identified through claims and other data sources for individuals enrolled in FFS	48	261,904	Annually	0.033	8,721	36.52	318,491	159,245
Maintain processes for information sharing with other entities	48	48	Annually	12	576	79.50	45,792	22,896
Update and maintain reports for using claims and other data to identify unreported incidents	48	48	Annually	20	960	106.30	102,048	51,024
Monitor operations associated with this requirement at the management level	48	48	Annually	24	1,152	118.14	136,097	68,048
Review and approve all operations associated with this collection of information requirement at the executive level	48	48	Annually	4	192	236.96	45,496	22,748
Subtotal: Labor Related Burden	*48*	*283,494 (21,542 + 261,904 + 48)*	*Annually*	*Varies*	*15,177*	*Varies*	*778,520*	*389,260*
Maintain electronic incident management systems (specifically, § 441.302(a)(6)(i)(B))	48	48	Annually	n/a	n/a	500,000/ system (contractor)	24,000,000	12,000,000
Total Technology Cost	*48*	*48*	*Annually*	*n/a*	*n/a*	*500,000 system (contractor)*	*24,000,000*	*12,000,000*
TOTAL	48	283,542 (283,494 + 48)	Annually	Varies	15,177	Varies	24,778,520	12,389,260

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b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect service providers that provide HCBS under sections 1915(c), (i), (j), and (k) authorities, as well as managed care plans that States contract with to provide managed long-term services and supports.

The following discussion estimates an ongoing burden for service providers to implement these requirements and both a one-time and ongoing burden for managed care plans.

i. On-Going Incident Management System Requirements: Service Provider

To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i), (j), and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally × 48 States subject to the proposed requirement/51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention [395] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers × 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes.

As discussed earlier, we estimate that providers will report 10 percent, or 28,345, of the more critical incidents (283,446 more critical incidents × 0.10) identified annually as a result of these requirements. Based on these figures, we estimate that, on average, each provider will report 1.8 (28,345 incidents/15,742 providers) more critical incidents annually. We further estimate that, on average, it would take a provider 1 hour at $118.14/hr for a general and operations manager to collect the required information and report the information to the State or to the managed care plan as appropriate for each incident.[396] In aggregate, for § 441.302(a)(6), we estimate an ongoing burden of 28,345 hours (28,345 incidents × 1 hr) at a cost of $3,348,678 (28,345 hr × $118.14/hr).

TABLE 10: Summary of Ongoing Burden for Service Providers for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect the required information and report the information to the State or to the managed care plan (§ 441.302(a)(6)(i)(C))	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a
Total	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a

ii. One Time Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

As required under § 441.302(a)(6), while States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States will delegate provider reporting of critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the plans will be responsible for reporting the identified critical incidents to the State.[397] We further assume that the information reported by managed care plans to the State would be in an electronic form.

We estimated that there are 161 managed long-term services and supports plans providing services across 25 States.[398] With regard to the one-time requirements at § 441.302(a)(6), we estimate it would take: 20 hours at $111.18/hr for an administrative

[395] *https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.*

[396] The actual amount of time for each incident will vary depending on the nature of the critical incident and the specific reporting requirements of each State and managed care plan. This estimate assumes that some critical incidents will take substantially less time to report, while others could take substantially less time.

[397] Addressing Critical Incidents in the MLTSS Environment: Research Brief, available at *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

[398] ''A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020,'' *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/.*

services manager to draft policy for contracted providers; 20 hours at $100.64/hr for a management analyst to update provider manuals; 40 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; and 6 hours at $236.96/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 26,726 hours (161 managed care plans × 166 hr) at a cost of $2,712,747 (161 managed care plans × [(20 hr × $111.18/hr) + (20 hr × $100.64/hr) + (40 hr × $67.18/hr) + (80 hr × $106.30/hr) + (6 hr × $236.96/hr)]).

TABLE 11: Summary of One-Time Burden for Managed Care Plans for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy for contracted providers	161	161	Once	20	3,220	111.18	358,000	n/a
Update provider manuals	161	161	Once	20	3,220	100.64	324,061	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Build, design, and implement reports for using claims and other data to identify unreported incidents	161	161	Once	80	12,880	106.30	1,369,144	n/a
Review and approve all operations associated with this requirement	161	161	Once	6	966	236.96	228,903	n/a
Total	161	161	Once	Varies	26,726	Varies	2,712,747	n/a

iii. Ongoing Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

The ongoing burden to managed care plans consists of the collection and maintenance of information on critical incidents. As noted earlier, we estimate that these requirements will result in the identification of 283,446 more critical incidents annually than are currently identified by States. We further estimate that 24 percent, or 68,027 (283,446 × 0.24), will be reported for individuals enrolled in managed care delivery systems [399] and that 10 percent, or 6,803 (68,027 × 0.10), will be made through provider reports and 90 percent, or 61,224 (68,027 × 0.90), through claims identification and other sources.[400] We estimate that it will take 0.166 hr at $36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(*2*)). In aggregate, we estimate an ongoing burden of 1,129 hours (6,803 critical incidents made through provider reports × 0.166 hr) at a cost of $41,231 (1,129 hr × $36.52/hr). We also estimate that it will take: 20 hours at $106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents (§ 441.302(a)(6)(i)(B)(*3*)); 6 hours at $118.14/hr for a general and operations manager to monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)); and 1 hour at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (§ 441.302(a)(6)(i)(G)). In aggregate, we estimate an ongoing burden of 5,476 hours (1,129 hr + [161 managed care plans × 27 hr]) at a cost of $535,791 ($41,231 + (161 managed care plans × [(20 hr × $106.30/hr) + (6 hr × $118.14/hr) + (1 hr × $236.96/hr)]).

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[399] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[400] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of additional critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

TABLE 12: Summary of Ongoing Burden for Managed Care Plans for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Record the information on each reported critical incident reported by providers (§441.302(a)(6)(i)(B)(2))	161	6,803	Annually	0.166	1,129	36.52	41,231	n/a
Update and maintain reports for using claims and other data to identify unreported incidents (§441.302(a)(6)(i)(B)(3))	161	161	Annually	20	3,220	106.30	342,286	n/a
Monitor the operations associated with this requirement and report the information to the State (§441.302(a)(6)(i)(E))	161	161	Annually	6	966	118.14	114,123	n/a
Review and approve all operations associated with this requirement (§441.302(a)(6)(i)(G))	161	161	Annually	1	161	236.96	38,151	n/a
Total	161	6,964 (6,803 + 161)	Annually	Varies	5,476	Varies	535,791	n/a

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5. ICRs Regarding Payment Adequacy Reporting (§ 441.311(e); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We finalized at § 441.311(e)(2) a new requirement that States report to us annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that are spent on compensation for direct care workers.

Section 441.311(e)(1)(i), as finalized, defines compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778); benefits (such as health and dental benefits, paid leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act. Section 441.311(e)(1)(ii), as finalized, defines direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating), or provide support with instrumental activities of daily living (such as cooking, grocery shopping, managing finances). Specifically, direct care workers include nurses (registered

nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living. Direct care workers include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. (Refer to section II.B.5. of this final rule for complete discussion of these definitions.)

We are also finalizing § 441.311(e) to include a definition of excluded costs at § 441.311ek)(1)(iii). Excluded costs are costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to: costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); travel reimbursements (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and personal protective equipment for direct care workers. This policy was not included in the NPRM calculations. While we do not believe the policy of allowing providers to deduct excluded costs will affect the activities described in this cost estimate, we acknowledge that they may require additional time for some of the activities (such as drafting policy manuals or training providers on the policy.) These costs have been added to the revised burden estimate.

As discussed in section II.B.7. of this rule, we had initially proposed at § 441.311(e) that States would be required to report on the percent of Medicaid compensation spent on compensation for direct care workers providing homemaker, home health aide, and personal care services as defined at § 440.180(b)(2) through (4), and that the State must report this data for each service, with self-directed services reported separately. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)). We are also finalizing a new requirement that in addition to reporting by service, with separate reporting for self-directed services, States must also report facility-based services separately. Below, we include in our revised calculations the increased anticipated burden associated with the addition of reporting on habilitation services and separate reporting for facility-based services in § 441.311(e). We anticipate an increased burden on States and managed care plans to address data collection on the additional services. While we are increasing our estimate of the number of impacted providers, we do not believe this will change providers' activities associated with this requirement.

To ensure that States are prepared to comply with the reporting requirement at § 441.311(e)(2), we are finalizing a requirement at § 441.311(e)(3) to require that one year prior to the first payment adequacy report, States must provide a status update on their readiness to report the data required in § 441.311(e)(2). This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2) and provide targeted technical assistance to States as needed. Our burden estimate below has been revised to include the activities associated with the State's one-time submission of this report. We do not anticipate an additional burden on managed care plans or providers associated with this requirement.

We also finalized at § 441.311(e)(4) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.311(e). Based on internal figures, we believe that about 100 HCBS provide As discussed in section II.B.7. of this final rule, we are applying the finalized requirements at § 441.311(e) to services delivered in both FFS and managed care delivery systems. We are applying the requirements to services that are delivered in 1915(c), (i) and (k) programs. We note also that the reporting requirement will go into effect 4 years after this rule is finalized.

We are finalizing the requirements at §§ 441.311(e) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the payment adequacy reporting requirement at § 441.311(e) and the HCBS payment adequacy minimum performance requirements at § 441.302(k) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.302(k) under a separate ICR (ICR 11) in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with HCBS payment adequacy performance requirements at § 441.302(k). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for certain HCBS is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in this ICR for § 441.311(e). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates. Burden estimates associated specifically with the minimum performance requirements in § 441.302(k) are presented in ICR 11 of this Collection of Information (section IV. of this final rule.)

a. State Burden

The burden associated with the requirements at § 441.311(e) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[401] [402] We estimate both a one-time and ongoing burden to implement these requirements at the State level.

Under § 441.311(e), we expect that States will have to: (1) draft new policy (one-time); (2) update provider manuals and other policy guidance to include reporting requirements (including information regarding excluded costs) for each of the services subject to the requirement (one-time); (3) inform providers of services through State notification processes, both initially and annually of reporting requirements (one-time and ongoing); (4) assess State systems and submit a one-time report to us on the State's readiness to comply with the ongoing reporting requirement at 441.311(e)(2) (one-time); (5) collect the information from providers for each service required (ongoing); (6) aggregate the data broken down by each service, as well as self-directed services

[401] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[402] For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

(ongoing); (7) derive an overall percentage for each service including self-directed services (ongoing); and (8) report to us on an annual basis (ongoing).

i. One Time Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the one-time requirements, we estimate it will take: 40 hours at $111.18/hr for an administrative services manager to: draft policy content, and draft provider agreements and contract modifications for managed care plans; 20 hours at $100.64/hr for a management analyst to update provider manuals for each of the affected services; 32 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice; 50 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 20 hours at $118.14/hr for a general and operations manager to: review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS; and 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 7,776 hours (172 hr × 48 States) at a cost of $850,285 (48 States × [(40 hr × $111.18/hr) + (20 hr × $100.64/hr) + (32 hr × $98.84/hr) + (50 hr × $67.18/hr) + (20 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $425,143 ($850,285 × 0.50).

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TABLE 13: Summary of One-Time Burden for States for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content, and draft provider agreements and contract modifications for managed care plans	48	48	Once	40	1,920	111.18	213,466	106,733
Update provider manuals for each of the affected service	48	48	Once	20	960	100.64	96,614	48,307
Build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice	48	48	Once	32	1,536	98.84	151,818	75,909
Develop and conduct training for providers on the reporting elements and reporting process	48	48	Once	50	2,400	67.18	161,232	80,616
Review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,74	56,780
Total	48	48	Once	Varies	7,776	varies	850,285	425,173

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the ongoing requirements, we estimate it will take 8 hours at $98.84/hr for a computer programmer to: (1) collect the information from all providers for each service required; (2) aggregate and stratify by each service as well as self-directed services; (3) derive an overall percentage for each service including self-directed and facility-based services; and (4) develop the reports for CMS on an annual basis. We also estimate it will take: 10 hours at $67.18 for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 5 hours at $118.14/hr by a general and operations manager to

review, verify, and approve reporting required at § 441.311(e)(2) to CMS; and 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 1,200 hours (25 hr × 48 States) at a cost of $121,302 (48 States × [(8 hr × $98.84/hr) + (10 hr × $67.18) + (5 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $60,651 ($121,302 × 0.50) per year.

TABLE 14: Summary of Ongoing Burden for States for Payment Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	8	384	98.84	37,954	18,977
Develop and conduct annual training for providers on the reporting elements and reporting process	48	48	Annually	10	480	67.18	32,246	16,123
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	5	240	118.14	28,354	14,177
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	48	Annually	Varies	1,200	Varies	121,302	60,651

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b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect both service providers that provide the services listed at § 440.180(b)(2) through (4) and (6) across HCBS programs as well as managed care plans that contract with the States to provide managed long-term services and supports. We estimate both a one-time and ongoing burden to implement the reporting requirements § 441.311(e) for both service providers and managed care plans.

As noted in the proposed rule at 88 FR 28049, we had estimated an impact on 11,155 HCBS providers that provided homemaker, home health aide, or personal care services. We are adjusting this burden estimate to account for the inclusion of providers that also provide habilitation services in the finalized requirements in § 441.311(e). To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i) and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally × 48 States subject to the requirement/51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention[403] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider

[403] *https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.*

definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers × 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes. We also note that it is possible that some of the providers included in this count do not provide the services impacted by § 441.311(e) (homemaker, home health aide, personal care, or habilitation services.) However, as we believe a significant number of the providers included in this count do provide at least one of these services. We note that from this number (15,742) we are subtracting 100 providers to represent the providers we believe will be eligible for the exemption at § 441.311(e)(4) for HIS and Tribal providers subject to 25 U.S.C. 1641. This brings the estimated number of providers impacted by the reporting requirement at § 441.311(e) to 15,642.

i. One Time HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the one-time requirements, we estimate it would take: 35 hours at $73.00/hr for a compensation, benefits and job analysis specialist to calculate compensation, as defined by § 441.(311)(e)(1)(i) for each direct care worker defined at § 441.311(e)(1)(ii); 40 hours at $98.84/hr for a computer programmer to build, design and operationalize an internal system to calculate each direct care worker's compensation as a percentage of total revenues received, aggregate the sum of direct care worker compensation as an overall percentage, and separate self-directed services to report to the State; and 8 hours at $118.14/hr for a general and operations manager to review and approve reporting to the State.

In aggregate, we estimate a one-time burden of 1,298,286 hours (15,642 providers × 83 hr) at a cost of $116,591,088 (15,642 providers × [(35 hr × $73.00/hr) + (40 hr × $98.84/hr) + (8 hr × $118.14/hr)]).

TABLE 15: Summary of One-Time Burden for Service Providers for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Calculate compensation for each direct care worker	15,642	15,642	Once	35	547,470	73.00	39,965,310	n/a
Build, design and operationalize an internal system for reporting to the State	15,642	15,642	Once	40	625,680	98.84	61,842,211	n/a
Review and approve reporting to the State	15,642	15,642	Once	8	125,136	118.14	14,783,567	n/a
Total	15,642	15,642	Once	Varies	1,298,286	varies	116,591,088	n/a

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Service Providers

With regard to the on-going requirements, we estimate it will take 8 hours at $73.00/hr for a compensation, benefits, and job analysis specialist to account for new hires and/or contracted employees; 8 hours at $98.84/hr for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 5 hours at $118.14/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate an on-going burden of 328,482 hours (15,742 providers × 21 hr) at a cost of $30,743,100 (15,642 providers × [(8 hr × $73.00/hr) + (8 hr × $98.84/hr) + (5 hr × $118.14/hr)]).

TABLE 16: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Account for new hires and/or contracted employees	15,642	15,642	Once	8	125,136	73.00	9,134,928	n/a
Calculate compensation, aggregate data, and report to the State	15,642	15,642	Once	8	125,136	98.84	12,368,442	n/a
Review and approve reporting to the State	15,642	15,642	Once	5	78,210	118.14	9,239,729	n/a
Total	15,642	15,642	Once	Varies	328,482	varies	30,743,100	n/a

iii. On-Time Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

As noted earlier, the burden associated with this final rule will affect managed care plans that contract with the States to provide managed long-term services and supports. We estimate that there are 161 managed long-term services and supports plans providing services across 25 States.[404] We estimate both a one-time and ongoing burden for managed care plans to implement these requirements. Specifically, managed care plans would have to: (1) draft new policy (one-time); (2) update provider manuals for each of the services subject to the requirement (one-time); (3) inform providers of requirements (one-time and ongoing); (4) collect the information from providers for each service required (ongoing); (5) aggregate the data as required by the States (ongoing); and (6) report to the State on an annual basis (ongoing).

With regard to the one-time requirements, we estimate it would take 50 hours at $111.18/hr for an administrative services manager to draft policy for contracted providers; 32 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting; 40 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; and 4 hours at $236.96/hr for a chief executive to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 20,286 hours (161 MCPs × 126 hr) at a cost of $1,989,464 (161 MCPs × [(50 hr × $111.18/hr) + (32 hr × $98.84/hr) + (40 hr × $67.18/hr) + (4 hr × $236.96/hr)]).

[404] *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/*; Profiles & Program Features | Medicaid.

TABLE 17: Summary of One-time Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy for contracted providers	161	161	Once	50	8,050	111.18	894,999	n/a
Build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting	161	161	Once	32	5.152	98.84	509,224	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Review and approve reporting to the State	161	161	Once	4	644	236.96	152,602	n/a
Total	161	161	Once	Varies	20,286	varies	1,989,464	n/a

iv. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

With regard to the ongoing requirements, we estimate it will take: 8 hours at $98.84/hr for a computer programmer to: (1) collect the information from all providers for each service required, (2) aggregate and stratify data as required, and (3) develop report to the State on an annual basis; and 2 hours at $236.96/hr for a chief executive to review and approve the reporting to the State. In aggregate, we estimate an ongoing burden of 1,610 hours (161 MCPs × 10 hr) at a cost of $203,607 (161 MCPs × [(8 hr × $98.84/hr) + (2 hr × $236.96/hr)]).

TABLE 18: Summary of Ongoing Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect information from providers; aggregate and stratify data as required; and develop report annually	161	161	Annually	8	1,288	98.84	127,306	n/a
Review and approve the report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	1,610	varies	203,607	n/a

6. ICRs Regarding Supporting Documentation for HCBS Access (§§ 441.303(f)(6) and 441.311(d)(1); Applied to Managed Care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c) of the Act authorizes States to set enrollment limits or caps

on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. States vary in the way they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Some States permit individuals to join a waiting list as an expression of interest in receiving waiver services, while other States require individuals to first be determined eligible for waiver services to join the waiting list. States have not been required to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI [405] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists.

In this final rule, we are finalizing an amendment to § 441.303(f)(6) by adding language to the end of the regulatory text to specify that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1). Per the finalized requirements at § 441.311(d)(1), for States that limit or cap enrollment in a section 1915(c) waiver and maintain a waiting list, States will be required to provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program. The description must include, but not be limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically rescreens individuals on the waiver list for eligibility, and the frequency of rescreening, if applicable. In addition, States will be required to report on the number of people on the waiting list if applicable, as well as the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable.

We are finalizing these proposals without substantive modifications. Burden estimates for this requirement are presented below.

a. One Time Waiting List Reporting Requirements: States (§ 441.311(d)(1))

The one-time State burden associated with the waiting list reporting requirements in § 441.311(d)(1) will affect the 39 State Medicaid programs with waiting lists for section 1915(c) waivers.[406] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the number of people on existing waiting lists and how long they wait; and write or update their existing waiting list policies and the information collected. In some States, HCBS waivers are administered by more than one operating agency, in these cases each will have to report this data up to the Medicaid agency for submission to us.

With regard to the one-time requirements, we estimate it will take: 16 hours at $111.18/hr for an administrative services manager to write or update State policy, direct information collection, compile information, and produce a report; 20 hours at $98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 1,599 hours (39 States × 41 hr) at a cost of $178,777 (39 States × [(16 hr × $111.18/hr) + (20 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $89,388 ($178,777 × 0.50).

Assuming no changes to the State waiting list policies, each year States will only need to update the report to reflect the number of people on the list of individuals who are waiting to enroll in the waiver program and average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list.

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[405] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[406] *https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/.*

TABLE 19: Summary of One-Time Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Write or update State policy, direct information collection, compile information, and produce a report	39	39	Once	16	624	111.18	69,376	34,688
Query internal systems for reporting requirements	39	39	Once	20	780	98.84	77,095	38,548
Review and approve report at management level	39	39	Once	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Once	2	78	236.96	18,483	9,242
Total	39	39	Once	Varies	1,599	Varies	178,777	89,388

b. Ongoing Waiting List Reporting Requirements: States (§ 441.311(d)(1))

With regard to the on-going burden for the section 1915(c) waiver waiting list reporting requirements at § 441.311(d)(1), we estimate it will take: 4 hours at $111.18/hr for an administrative services managers across relevant operating agencies to direct information collection, compile information, and produce a report; 6 hours at $98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 585 hours (39 States × 15 hr) at a cost of $72,778 (39 States × [(4 hr × $111.18/hr) + (6 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $36,389 ($72,778 × 0.50) per year.

TABLE 20: Summary of Ongoing Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	39	39	Annually	4	156	111.18	17,344	8,672
Query internal systems for reporting requirements	39	39	Annually	6	234	98.84	23,129	11,564
Review and approve report at the management level	39	39	Annually	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Annually	2	78	236.96	18,483	9,241
Total	39	39	Annually	Varies	585	Varies	72,778	36,389

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7. ICRs Regarding Additional HCBS Access Reporting (§ 441.311(d)(2)(i); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed additional HCBS access reporting at § 441.311(d)(2)(i). We proposed at § 441.311(d)(2)(i) to require States to report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, listed in § 440.180(b)(2) through (4), are initially approved to when services began for individuals newly approved to begin receiving services within the past 12 months. We also proposed at § 441.311(d)(2)(ii) to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. States are allowed to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months.

We are finalizing the requirements at § 441.311(d)(2) with a modification to add reporting on habilitation services as defined at § 440.180(b)(6), in addition to the other services. We have adjusted our burden estimates below to reflect additional reporting on habilitation services.

The burden associated with the additional HCBS access reporting requirements at § 441.311(d)(2) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915I, (i), (j), or (k) authorities.[407] Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the average amount of time from which homemaker services, home health aide services, personal care, and habilitation services, as listed

[407] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

in § 440.180(b)(2) through (4) and (6), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months, and the percent of authorized hours for these services that are provided within the past 12 months. We expect many States will need to analyze report this metric for a statistically valid random sample of beneficiaries. They will then need to produce a report for us within such information. For States with managed long-term services and supports, they will need to direct managed care plans to report this information up to them.

We estimate one-time and ongoing burden to implement the requirements at § 441.311(d)(2) at the State level.

One-Time HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the one-time burden related to the HCBS access reporting requirements, we estimate it will take: 30 hours at $111.18/hr for an administrative services manager across relevant operating agencies to direct information collection, compile information, and produce a report; 80 hours at $98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 50 hours at $101.46/hr for a statistician to conduct data sampling; 4 hours at $118.14/hr for a general and operations manager to review and approve report; and 3 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a one-time burden of 8,016 hours (48 States × 167 hr) at a cost of $839,954 (48 States × [(20 hr × $111.18/hr) + (60 hr × $98.84/hr) + (40 hr × $101.46/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $419,977 ($839,954 × 0.50) per year.

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TABLE 21: Summary of One-Time Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	48	48	Once	30	1,440	111.18	160,099	80,050
Analyze service authorization and claims data	48	48	Once	80	3,840	98.84	379,546	189,773
Conduct data sampling	48	48	Once	50	2,400	101.46	243,504	121,752
Review and approve report at the management level	48	48	Once	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Once	3	144	236.96	34,122	17,061
Total	48	48	Once	Varies	8,016	Varies	839,954	419,977

b. Ongoing HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the on-going burden related to the HCBS access reporting requirements for States, we estimate it will take: 15 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report; 30 hours at $98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 15 hours at $101.46/hr for a statistician to conduct data sampling; 4 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 3,168 hours (48 States × 67 hr) at a cost of $340,861 (48 States × [(15 hr × $111.18/hr) + (30 hr × $98.84/hr) + (15 hr × $101.46/hr) + (4 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $170,431 ($340,861 × 0.50) per year.

TABLE 22: Summary of Ongoing Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	48	48	Annually	15	720	111.18	80,050	40,025
Analyze service authorization and claims data	48	48	Annually	30	1,440	98.84	142,330	71,165
Conduct data sampling	48	48	Annually	15	720	101.46	73,051	36,526
Review and approve report at the management level	48	48	Annually	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annual	Varies	3,168	Varies	340,861	170,431

c. One-Time HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the one-time HCBS access reporting requirements at § 441.311(d)(2) for managed care plans, we estimate it will take: 15 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 45 hours at $98.84/hr for a computer programmer to analyze service authorization and claims data; 15 hours at $101.46/hr for a statistician to conduct data sampling; and 2 hours at $236.96/hr for a chief executive review and approval. In aggregate, we estimate a one-time burden of 12,397 hours (161 MCPs × 77 hr) at a cost of $1,305,923 (161 MCPs × [(15 hr × $111.18/hr) + (45 hr × $98.84/hr) + (15 hr × $101.46/hr) + (2 hr × $236.96/hr)]).

TABLE 23: Summary of One-Time Burden for Managed Care Plans for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report to the State	161	161	Once	15	1,610	111.18	179,000	n/a
Analyze service authorization and claims data	161	161	Once	45	5,635	98.84	556,963	n/a
Conduct data sampling	161	161	Once	15	1,610	101.46	163,351	n/a
Review and approve report	161	161	Once	2	322	236.96	76,301	n/a
Total	161	161	Once	Varies	12,397	Varies	1,305,923	n/a

d. Ongoing HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the ongoing requirements associated with the annual collection, aggregation, and reporting of the HCBS access measures at § 441.311(d)(2), we estimate it will require: 5 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 25 hours at $98.84/hr for a computer programmer to analyze service authorization and claims data; 10 hours at $101.46/hr for a statistician to conduct data sampling; and 2 hours at $236.96/hr for a chief executive to review and approve. In aggregate, we estimate a burden of 6,762 hours (161 MCPs × 42 hr) at a cost of $726,983 (161 MCPs × [(5 hr × $111.18/hr) + (25 hr × $98.84/hr) + (10 hr × $101.46/hr) + (2 hr × $236.96/hr)]).

TABLE 24: Summary of Ongoing Burden for Managed Care Plans for Additional HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report to the State	161	161	Annually	5	805	111.18	89,500	n/a
Analyze service authorization and claims data	161	161	Annually	25	4,025	98.84	397,831	n/a
Conduct data sampling	161	161	Annually	10	1,610	101.46	163,351	n/a
Review and approve report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	6,762	Varies	726,983	n/a

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8. ICRs Regarding Compliance Reporting (§ 441.311(b); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

a. Ongoing Incident Management System Assessment Requirements: States (§ 441.311(b)(1)

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10692 (OMB control number 0938–1362).

As discussed in II.B.3 of this final rule, we are finalizing at § 441.302(a)(6), a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. We are finalizing at § 441.311(b)(1)(i) a requirement that States must report, every 24 months, on the results of an incident management system assessment to demonstrate that they meet the requirements in § 441.302(a)(6). We are also finalizing at § 441.311(b)(1)(ii) a flexibility in which we may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

The reporting requirements finalized at § 411.311(b)(1) are intended to standardize our expectations and States' reporting requirements to ensure that States operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. The requirements were informed by the responses to the HCBS Incident Management Survey (CMS–10692; OMB 0938–1362) recently released to States.

We estimate that the reporting requirement at § 441.311(b)(1) would apply to the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. Some States employ the same incident management system across their waivers, while others employ an incident management system specific to each waiver and will require multiple assessments to meet the requirements at § 441.311(b)(1). Based on the responses to the previously referenced survey, we estimate that on average States will conduct assessments on two incident management systems, totaling approximately 96 unique required assessments (48 State Medicaid programs × 2 incident management system assessments per State). Because the requirements under § 441.311(b)(1) are required every 24 months, we estimate 48 assessments on an annual basis (96 unique assessments every 2 years). With regard to the ongoing requirements, we estimate that it will take 1.5 hours at $76.26/hr for a social/community service manager to gather information and complete the required assessment; and 0.5 hours at $118.14/hr for a general and operations manager to review and approve the assessment. In aggregate, we estimate an ongoing annual burden of 96 hours (48 States × 2 hr) at a cost of $8,326 (48 States × [(1.5 hr × $76.26/hr) + (0.5 hr × $118.14/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State

share of this cost would be $4,163 ($8,326 × 0.50) per year.

TABLE 25: Summary of the Ongoing Burden for States for the Incident Management System Assessment Requirements at § 441.311(b)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Gather information and complete the required assessment	48	48	Annually	1.5	72	76.26	5,491	2,745
Review and approve the assessment	48	48	Annually	0.5	24	118.14	2,835	1,418
Total	48	48	Annually	Varies	96	varies	8,326	4,163

b. Reporting on Critical Incidents (§ 441.311(b)(2)), Person-Centered Planning (§ 441.311(b)(3)), and Type, Amount, and Cost of Services (§ 441.311(b)(4))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS 0938–0272 (CMS–372(S)).

This final rule codifies existing compliance reporting requirements on critical incidents, person-centered planning, and type, amount, and cost of services. At § 441.311(b)(2), we are finalizing a reporting requirement which requires States to report annually on the minimum performance standards for critical incidents that are finalized at § 441.302(a)(6). At § 441.311(b)(3), we are finalizing a reporting requirement to require States to report annually on the minimum performance standards for person-centered planning that are finalized at § 441.301(c)(3). Similar reporting requirements were previously described in 2014 guidance.[408] We are also finalizing a redesignation of the existing requirement at § 441.302(h)(1) to report on type, amount, and cost of services as § 441.311(b)(4), to make the requirement part of the new consolidated compliance reporting section finalized at § 441.311.

This final rule removes our currently approved burden and replaces it with the burden associated with the amendments to § 441.311(b)(2) through (4). In aggregate, the change will remove 11,132 hours (253 waivers × 44 hr) and $891,451 (11,132 hr × $80.08/hr for a business operations specialist). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost reduction would be minus $445,725 (−$891,451 × 0.50).

[408] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

TABLE 26: Summary of the Removal of Approved Ongoing Burden for Form 372(S) as a Result of the Requirements at § 441.311(b)(2) through (b)(4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Remove currently approved burden under control number 0938–0272 (CMS–372(S))	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)
Total	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)

We expect, as a result of the changes discussed in this section, to revise the Form CMS–372(S) and the form's instructions based on the reporting requirements. The consolidated reporting requirements at § 441.311(b)(2) through (4) also assume that 48 States (including Washington DC) are required to submit the Form CMS–372(S) Report on an annual basis. However, a separate form will no longer be required for each of the 253 approved waivers currently in operation. We estimate a burden of 50 hours at $80.08/hr for a business operations specialist to draft each Form CMS–372(S) Report submission. The per response increase reflects the increase to the minimum State quality performance level for person-centered planning (finalized at § 441.301(c)(3)(ii)) and critical incident reporting (finalized at § 441.302(a)(6)(ii)) from the 86 percent threshold established by the 2014 guidance to 90 percent in this final rule. This slight increase to the minimum performance level will help ensure that States are sufficiently meeting all section 1915(c) waiver requirements but may also increase the evidence that some States may need to submit to document that appropriate remediation is being undertaken to resolve any compliance deficiencies. As a result, we estimate a total of 50 hours for each Form CMS–372(S) Report submission, comprised of 30 hours of recordkeeping, collection and maintenance of data, and 20 hours of record assembly, programming, and completing the Form CMS–372(S) Report in the required format. We also estimate 3 hours at $118.14/hr for a general and operations manager to review and approve the report to CMS; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement.

TABLE 27: Summary of the New Burden for Form 372(S) Annual Report on HCBS Waivers, Inclusive of Updates to § 441.311(b)(2) through (4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft Form CMS 372(S) Report submission	48	48	Annually	50	2,400	80.08	192,192	96,096
Review and approve the report at the management level	48	48	Annually	3	144	118.14	17,012	8,506
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annually	Varies	2,640	varies	231,952	115,976

The net change resulting from reporting requirements on critical incidents, person-centered service planning, and type, amount, and cost of services, finalized in § 441.311(b)(2) through (4) is a burden decrease of 8,492 hours (2,640 hr—11,132 hr) and $329,749 (State share) ($115,976—$445,725).

9. ICRs Regarding Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

At § 441.311(c), we finalized a requirement that States report every other year on the HCBS Quality Measure Set, which is described in section II.B.8. of this final rule. The reporting requirement will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), 1915(i), 1915(j), and 1915(k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. Unlike other reporting requirements finalized at § 441.311, the effective date of § 441.311(c) will be 4 years, rather than 3 years, after the effective date of the final rule.

As finalized at § 441.311(c), the data collection includes reporting every other year on all measures in the HCBS Quality Measure Set that are identified by the Secretary.[409] For certain measures which are based on data already collected by us, the State can elect to have the Secretary report on their behalf.

As finalized at§ 441.312(c)(1)(iii), States are required to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.

We are finalizing the requirements at § 441.312 without substantive modification. Our burden estimates are described below.

i. One Time HCBS Quality Measure Set Requirements: States (§ 441.311(c))

This one-time burden analysis assumes that States must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community-Based (HCBS CAHPS®) Survey, National Core Indicators®-Intellectual and Developmental Disabilities (NCI®-IDD), National Core Indicators-Aging and Disability (NCI–AD)™, or Personal Outcome Measures (POM)® to fully meet the HCBS Quality Measures Set mandatory requirements.

[409] Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

Currently most States use at least one of these surveys; however, States may need to use multiple ''experience of care'' surveys, depending on the populations served by the States' HCBS program and the particular survey instruments that States select to use, to ensure that all major population groups are assessed using the measures in the HCBS Quality Measure Set.

The estimate of one-time burden related to the effort associated with the requirements is for the first year of reporting. It assumes that the Secretary will initially require 25 of the 97 measures currently included in the HCBS Quality Measure Set. The estimate disregards costs associated with the voluntary reporting of measures in the HCBS Quality Measure Set that are not yet mandatory, and voluntary stratification of measures ahead of the phase-in schedule, discussed later in this section.

Additionally, we are finalizing a requirement at § 441.312(f) that the Secretary will require stratification by demographic characteristics of 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations. The burden associated with stratifying data is considered in the ongoing cost estimate only. We anticipate that certain costs will decline after the first year of reporting, but that some of the reduction will be supplanted with costs associated with stratifying data.

With regard to the one-time requirements at § 441.311(c) for reporting on the initial mandatory elements of the HCBS Quality Measure Set, we estimate that will take: 540 hours at $111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report; 40 hours at $101.46/hr for a statistician to determine survey sampling methodology; 500 hours at $63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 200 hours at $36.52/hr for a data entry worker to input the data; 60 hours at $98.84/hr for a computer programmer to synthesize the data; and 5 hours at $236.96/hr for a chief executive to verify, certify, and approve the report. In aggregate, we estimate a one-time burden of 64,560 hours (48 States × 1,345 hr) at a cost of $5,301,830 (48 States × [(540 hr × $111.18/hr) + (40 hr × $101.46/hr) + (500 hr × $63.88/hr) + (200 hr × $36.52/hr) + (60 hr × $98.84/hr) + (5 hr × $236.96/hr)]) Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $2,650,915 ($5,301,830 × 0.50).

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TABLE 28: Summary of the One-Time Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report	48	48	Once	540	25,920	111.18	2,881,786	1,440,893
Determine survey sampling methodology	48	48	Once	40	1,920	101.46	194,803	97,402
Receive training in survey administration and administer an in-person survey	48	48	Once	500	24,000	63.88	1,533,120	766,560
Input data	48	48	Once	200	9,600	36.52	350,592	175,296
Synthesize data	48	48	Once	60	2,880	98.84	284,659	142,330
Verify, certify, and approve the report	48	48	Once	5	240	236.96	56,870	28,435
Total	48	48	Once	Varies	64,560	varies	5,301,830	2,650,915

ii. Ongoing HCBS Quality Measure Set Requirements: States (§ 441.311(c))

With regard to the ongoing burden of fulfilling requirements at § 441.311(c), every other year, for reporting on mandatory elements of the HCBS Quality Measure Set, including data stratification by demographic characteristics, we estimate it will take: 520 hours at $111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report; 80 hours at $101.46/hr for a statistician to determine survey sampling methodology; 1,250 hours at $63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 500 hours at $36.52/hr for a data entry worker to input the data; 100 hours at $98.84/hr for a computer programmer to synthesize the data; and 5 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to us. In aggregate, we estimate an ongoing burden of 117,840 hours (48 States × 2,455 hr) at a cost of $8,405,242 (48 States × [(520 hr × $111.18/hr) + (80 hr × $101.46/hr) + (1,250 hr × $63.88/hr) + (500 hr × $36.52/hr) + (100 hr × $98.84/hr) + (5 hr × $236.96/hr)]). Given that reporting is every other year, the annual burden will be 58,920 hours (117,840 hr/2 years) and $4,202,621 ($8,405,242/2 years). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $2,101,310 ($4,202,621 × 0.50).

TABLE 29: Summary of the Ongoing Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage ($/hr)	Total Cost ($)*	State Share ($)*
Conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report	48	12 per year) (24 biennially)	Biennial	520	12,480	111.18	1,387,526	1,387,526
Determine survey sampling methodology	48	12 per year) (24 biennially)	Biennial	80	1,920	101.46	194,803	194,803
Receive training in survey administration and administer an in-person survey	48	12 per year) (24 biennially)	Biennial	1,250	30,000	63.88	1,916,400	958,200
Input data	48	12 per year) (24 biennially)	Biennial	500	12,000	36.52	438,240	219,120
Synthesize data	48	12 per year) (24 biennially)	Biennial	100	2,400	98.84	237,216	118,608
Verify, certify, and approve the report	48	12 per year) (24 biennially)	Biennial	5	120	236.96	28,435	14,218
Total	48	12 per year) (24 biennially)	Biennial	Varies	58,920	Varies	4,202,620	2,101,310

*Annualized over 2 years.

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b. HCBS Quality Measure Set Requirements: Beneficiary Experience Survey (§ 441.311(c))

State adoption of existing beneficiary experience surveys, contained in the HCBS Quality Measure Set, to fulfill the mandatory reporting requirements includes a burden on beneficiaries. As finalized in § 441.312, a State must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community Based (HCBS CAHPS®) Survey, National Core Indicators® Intellectual and Developmental Disabilities (NCI® IDD), National Core Indicators Aging and Disability (NCI AD)™, or Personal Outcome Measures (POM)®.

With regard to beneficiary burden, we estimate it will take 45 minutes (0.75 hr) at $20.71/hr for a Medicaid beneficiary to complete a survey every other year that will be used to derive one or more of the measures in the HCBS Quality Measure Set. At 1,000 beneficiaries/State and 48 States, we estimate an aggregate burden of 36,000 hours (1,000 beneficiary responses/State × 48 States × 0.75 hr/survey) at a cost of $745,560 (36,000 hr × $20.71/hr). Given that survey is every other year, the annual burden will be 18,000 hours (36,000 hr/2 years) and $372,780 ($745,560/2 years).

TABLE 30: Summary of Ongoing Beneficiary Experience Survey Burden for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage ($/hr)	Total Cost ($)*	State Share ($)
Complete beneficiary experience survey	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a
Total	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a

*Annualized over 2 years.

10. ICRs Regarding Website Transparency (§ 441.313; Applied to Other HCBS Authorities at §§ 441.486, 441.595, and 441.750, and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We are finalizing a new section, at § 441.313, titled, ''website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS under section 1915(c) of the Act.'' Specifically, at § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the data and information that States are required to report under the newly finalized reporting section at § 441.311. At § 441.313(a)(1), we proposed to require that the data and information that States are required to report under § 441.311 be provided on one website, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. At § 441.313(a)(2), we proposed to require that the web page include clear and easy to understand labels on documents and links.

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. At § 441.313(c), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. At § 441.313(a)(4), we proposed to require that States explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. Further, we proposed to apply the proposed requirements at § 441.313 to sections 1915(j), (k), and (i) State plan services by finalizing §§ 441.486, 441.595, and 441.750, respectively.

We are finalizing the requirements without substantive changes. Our burden estimates are described below. The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We are requiring at § 441.313(c) to apply the website transparency requirements to services delivered under FFS or managed care delivery systems, and we are providing States with the option to meet the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. However, we are not requiring managed care plans to report the data and information required under § 441.311 on their website. As such, we estimate that there is no additional burden for managed care plans associated with the requirements to link to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services for § 441.313. Further, the burden associated with the requirements for managed care plans to report the data and information required under § 441.311 is estimated in the ICRs Regarding Compliance Reporting (§ 441.311(b)).

If a State opts to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services, the State will incur a burden. However, such burden will be less than the burden associated with posting the information required under § 441.311 on their own website. We are unable to estimate the number of States that may opt to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. As a result, we do not take into account the option in our burden estimate and conservatively assume that all States subject to the requirements at § 441.313 by posting the information required under § 441.311 on their own website.

We estimate both a one-time and ongoing burden to implement these requirements at the State level.

a. One Time Website Transparency Requirements: States (§ 441.313)

The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. In developing our burden estimate, we assumed that States will provide the data and information that States are required to report under newly proposed § 441.311 through an existing website, rather than develop a new website to meet this requirement.

With regard to the one-time burden, based on the website transparency requirements, we estimate it will take: 24 hours at $111.18/hr for an administrative services manager to determine the content of the website; 80 hours at $98.84/hr for a computer programmer or contractor to develop the website; 3 hours at $118.14/hr for a general and operations manager to review and approve the website; and 2 hours at $236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 5,232 hours (48 States × 109 hr) at a cost of $547,385 (48 States × [(24 hr × $111.18/hr) + (80 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $273,693 ($547,385 × 0.50) per year.

TABLE 31: Summary of the One-Time Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)/year
Determine content of website	48	48	Once	24	1,152	111.18	128,080	64,040
Develop website	48	48	Once	80	3,840	98.84	379,546	189,773
Review and approve the website at the management level	48	48	Once	3	144	118.14	17,012	8,506
Review and approve the website at the executive level	48	48	Once	2	96	236.96	22,748	11,374
Total	48	48	Once	Varies	5,232	Varies	547,385	273,693

b. Ongoing Website Transparency Requirements: States (§ 441.313)

With regard to the State on-going burden related to the website transparency requirement, per quarter we estimate it will take: 8 hours at $111.18/hr for an administrative services manager to provide updated data and information for posting and to verify the accuracy of the website; 20 hours at $98.84/hr for a computer programmer or contractor to update the website; 3 hours at $118.14/hr for a general and operations manager to review and approve the website; and 2 hours at $236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 6,336 hours (33 hr × 48 States × 4 quarters) at a cost of $709,359 (48 States × 4 quarters × [(8 hr × $111.18/hr) + (20 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $354,680 ($709,359 × 0.50) per year.

TABLE 32: Summary of the Ongoing Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Provide updated data and information for posting and verify the accuracy of the website	48	192	Quarterly	8	1,536	111.18	170,772	85,386
Update website	48	192	Quarterly	20	3,840	98.84	379,546	189,773
Review and approve website at the management level	48	192	Quarterly	3	576	118.14	68,049	34,024
Review and approve website at the executive level	48	192	Quarterly	2	384	236.96	90,993	45,496
Total	48	192	Quarterly	Varies	6,336	Varies	709,359	354,680

11. ICRs Regarding HCBS Payment Adequacy (§ 441.302(k); Applied to Other HCBS Authorities at §§ 441.464(f), 441.570(f), 441.745(a)(1)(vi), and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed, and are finalizing, a new policy at § 441.302(k)(3)(i), which requires that 80 percent of Medicaid payments for the following services for homemaker services, home health aide services, and personal care services (as set forth in § 440.180(b)(2) through (4)) be spent on compensation for direct care workers. We proposed, and are finalizing, definitions for compensation and direct care workers at §§ 441.302(k)(1) and (2), respectively, which are discussed in greater detail in section II.B.5. of this final rule. As finalized, States must comply with the requirements in § 441.302(k) 6 years after this rule is finalized.

As discussed in greater detail in section II.B.5. of this final rule, we are finalizing this policy with additional modifications which have an impact on our burden estimates. We are finalizing a policy at § 441.302(k)(3)(ii) that allows States to apply a different minimum performance threshold for small providers. We are finalizing a requirement at § 441.302(k)(4)(i) that allows States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to identify small providers that the State would require to meet this alternative minimum performance requirement. We are finalizing a requirement at § 441.302(k)(4)(ii) that the State must set the percentage for a small provider to meet the minimum performance level based on reasonable, objective criteria that it develops through a transparent process that includes public notice and opportunities for comment from interested parties. The costs associated with establishing the small provider threshold (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not estimate an impact on managed care plans associated with the small provider threshold. We estimate a small impact on providers associated with this requirement; while we believe providers' activities would remain the same whether they were complying with the 80 percent threshold or a State-set small provider threshold, we also assume an additional activity associated with demonstrating eligibility for the State-set small provider threshold. We note that while we have not specified a process by which a State would have providers determine eligibility for a small provider threshold, we are calculating a burden based on the assumption that States would have such a process.

We are also finalizing at § 441.302(k)(5) a flexibility to allow States to offer certain providers temporary hardship exemptions. As finalized, this requirement would allow States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to exempt from the minimum performance requirement at paragraphs (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with either the 80 percent threshold requirement or the State's small provider threshold. The costs associated with establishing the hardship exemption (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not anticipate a specific impact on managed care plans as a result of this requirement. We do not estimate an impact on managed care plans associated with the hardship exemption. We estimate a small impact on providers associated with this requirement, as we assume an additional activity associated with demonstrating eligibility for the State-set hardship exemption. We note that while we have not specified a process by which a State would have providers determine eligibility for a hardship exemption, we are calculating a burden based on the assumption that States would have such a process.

We are finalizing at § 441.302(k)(6) reporting requirements for small provider minimum performance levels and hardship exemptions. Under this requirement, States that establish a small provider minimum performance level must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section; the State's small provider minimum performance level; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time. States that provide a hardship exemption must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's hardship criteria; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption; and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We also finalized a flexibility at § 441.302(k)(6)(iii) that CMS may waive the reporting requirements if the State demonstrates it has applied the small provider minimum performance level or the hardship exemption to less than 10 percent of the State's providers.

We have added the burden associated with the reporting requirement finalized at § 441.302(k)(6) to the burden estimate. We do not expect that all States will need to submit such a report (because some States will expect most, if not all, of their providers to comply with the minimum performance threshold); we also expect that over time, fewer States will need to submit such a report (again, as more States begin to require that more than 90 percent of their providers comply with the minimum performance threshold.) However, to avoid underestimating burden, we have calculated the burden of this requirement based on the assumption that all 48 States will submit such a report annually. We do not anticipate an impact on managed care plans or providers associated with this additional requirement.

We also finalized at § 441.302(k)(7) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.302(k). Based on internal data, we believe that about 100 providers would be eligible for this exclusion as § 441.302(k)(7) requires no additional action on the part of the State or providers impacted by this exemption) we did not calculate a change in the burden activities as a result of this exemption.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We are finalizing the requirements at §§ 441.302(k) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the HCBS payment adequacy provision at § 441.302(k) and the payment adequacy reporting requirement at § 441.311(e) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.311(e) under a separate ICR in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with the 80 percent threshold at § 441.302(k)(3)(i) or the small provider threshold at § 441.302(k)(3)(ii). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for homemaker, home health aide, or personal care services is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in the ICR for § 441.311(e) (ICR 5 of this section IV. of the final rule). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates.

The burden estimates below include costs associated specifically with § 441.302(k), namely: development and application of the small provider threshold under § 441.302(k)(3)(ii) and (4), development and application of the hardship exemption under § 441.302(k)(5), and the reporting on the small provider threshold and hardship exemption under § 441.302(k)(6).

a. States

The burden associated with the requirements at § 441.302(k) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[410] [411] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, under §§ 441.302(k) States will have to: (1) draft new policy regarding the application of the 80 percent minimum performance level at

[410] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[411] For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

§ 441.302(k)(3), the small provider performance level and criteria described in § 441.302(k)(4), and the hardship exemptions described in § 441.302(k)(5) (one-time); (2) publish the proposed requirements for the small provider performance level described in § 441.302(k)(4) and threshold and the hardship exemption described in § 441.302(k)(5) through State notice and publication processes (one-time); (3) update provider manuals and other policy guidance regarding the performance levels described in § 441.302(k)(3) and (4) and the hardship exemption described in § 441.302(k)(5) for each of the services subject to the requirement (one-time); (4) inform providers of the process for demonstrating eligibility for the small provider performance level described at § 441.302(k)(4) or the hardship exemption described at § 441.302(k)(5) through State notification processes, both initially and annually (one-time and ongoing); (5) review providers' eligibility for the small provider performance level described at § 441.302(k)(4) or hardship exemption described in § 441.302(k)(5) (ongoing); and (6) provide the report on the small provider performance level and the hardship exemption required at § 441.302(k)(6) to us on an annual basis (ongoing).

i. One Time HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

With regard to the one-time requirements, we estimate it will take 100 hours at $111.18/hr for an administrative services manager to: draft policy content; prepare notices and draft rules for publication, conduct public hearings on the small provider performance level and hardship exemptions in accordance with § 441.302(k)(4) and (5), respectively. We estimate it will take 50 hours at $100.64/hr for a management analyst to: update provider manuals for each of the affected services (explaining the policies for § 441.302(k) generally, and the policies and criteria related to the small provider performance level and hardship exemption described at § 441.302(k)(4) and (5), respectively; and draft provider agreement and managed care contract amendments regarding the requirements at § 441.302(k)(3), (4) and (5). We estimate it will take 8 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for identifying providers falling under § 441.302(k)(4) or (5). We estimate it will take 40 hours at $67.18/hr for a training and development specialist to: develop and conduct training for providers specific to the requirements associated with § 441.302(k)(3), (4), and (5). We estimate it will take 20 hours at $118.14/hr for a general and operations manager to: review and approve provider agreement amendment sand managed care contract modifications; and to review and approve policy guidance for publication. We estimate it will take 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 10,944 hours (228 hr × 48 States) at a cost of $1,169,295 (48 States × [(100 hr × $111.18/hr) + (50 hr × $100.64/hr) + (8 hr × $98.84/hr) + (40 hr × $67.18/hr) + (20 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $584,648 ($1,169,295 × 0.50).

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TABLE 33: Summary of One-Time Burden for States for the HCBS Payment Adequacy Requirements at § 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content; prepare notices and draft rules for publication, conduct public hearings for § 441.302(k)(4) and (5)	48	48	Once	100	4,800	111.18	533,664	266,832
Update provider manuals for each of the affected services (explaining the policies related to § 441.302(k) (4) and (5); and draft provider agreement and managed care contract amendments	48	48	Once	50	2,400	100.64	241,536	120,768
Build, design, and operationalize internal systems for marking providers identified as under § 441.302(k)(4) or (5)	48	48	Once	8	384	98.84	37,955	18,977
Develop and conduct training for providers for the requirements associated with § 441.302(k)	48	48	Once	40	1,920	67.18	128,986	64,493
Review, approve managed care contract modifications, provider agreement updates, policy and rules for publication, and training materials	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,740	56,780
Total	48	48	Once	Varies	10,944	varies	1,169,295	584,648

ii. Ongoing HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

We also expect that States will have to review, on an ongoing basis, providers' requests to be considered under the small provider performance level at § 441.302(k)(4) or the hardship exemption at § 441.302(k)(5). As noted in the Collection of Information in the proposed rule at 88 FR 28049, we estimate that 11,555 HCBS providers provide homemaker, home health aide, or personal care services and thus are subject to the requirements at § 441.302(k). We estimate that around 15 percent of these providers will request consideration under either the

small provider performance level or hardship exemption; 10 percent is selected as we expect States will set criteria to apply to 10 percent or less of providers. Thus, we expect that States (collectively) will need to review 1,155 requests for flexibilities under § 441.302(k)(4) or (5) on an ongoing, annual basis; we expect that it will take 0.5 hours at $100.64/hr for a management analyst to review each request.

With regard to additional ongoing requirements, we estimate it will take 2 hours at $98.84/hr for a computer programmer to update providers' status in any system that tracks providers subject to the small provider performance level and hardship exemptions under § 441.302(k)(4) or (5), respectively, and calculate the percent of providers subject to 441.302(k)(4) or (5). We also estimate it will take 2 hours at $118.14/hr by a general and operations manager to generate the report required at § 441.302(k)(6) for submission to CMS. We estimate it will take 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 866 hours [(0.5 hr × 1,155 providers) + (6 hr × 48 States)] at a cost of $101,698 [1,155 providers × (0.5 hr × $100.65) + (48 States × [(2 hr × $98.84/hr) + (2 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $50,849 ($101,698 × 0.50) per year.

TABLE 34: Summary of Ongoing Burden for States for the HCBS Payment Adequacy Requirements at §§ 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Review providers' requests for classification under § 441.302(k)(4) or (5)	1,155	1,155	Annually	0.5	576	100.64	58,120	29,060
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	2	96	98.84	9,489	4,744
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	2	96	118.14	11,341	5,671
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	1,203 (1,155 + 48)	Annually	Varies	866	Varies	101,698	50,849

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b. Service Providers

The burden associated with § 441.302(k) being finalized in this final rule will affect service providers that provide the services listed at § 440.180(b)(2) through (4) and (6). We estimate an ongoing burden on providers to request, on an ongoing basis, either qualification as a small provider under the small provider criteria (in accordance with § 441.302(k)(4)) or eligibility for the hardship exemption (in accordance with § 441.302(k)(5)). (We do also expect there to be a burden on providers to implement the separate payment adequacy reporting requirement at § 441.311(e); these costs are addressed in a separate ICR.)

As noted above, we expect that annually, we estimate that 1,155 providers will request consideration for eligibility for the small provider performance level or the hardship exemption under § 441.302(k)(4) or (5), respectively.

With regard to the ongoing requirement, we estimate it would take: 1 hour at $118.14/hr for a general and operations manager to file the request for the State. In aggregate, we estimate an ongoing burden of 1,155 hours (1,155 providers × 1 hr) at a cost of $136,452 (1,155 providers × (1 hr × $118.14/hr).

TABLE 35: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 442.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Request qualification under § 441.302(k)(4) or (5)	1,155	1,155	Once	1	1,155	118.14	136,452	n/a
Total	1,155	1,155	Once	1	1.155	118.14	136,452	n/a

12. ICRs Regarding Payment Rate Transparency (§ 447.203)

The following changes will be submitted to OMB for approval under control number 0938–1134 (CMS–10391).

This final rule will update documentation requirements in § 447.203. To develop the burden estimates associated with these changes, we account for the removal of existing information collection requirements in current § 447.203(b), and the introduction of new requirements at 447.203(b) and (c). As described later in this section, we estimate the impact of the revisions to § 447.203 will result in a net burden reduction. We do not anticipate any additional information collection burden from the conforming edits finalized in § 447.204, as the conforming edits merely alter the items submitted as part of an existing submission requirement, and the burden of producing those items is reflected in the estimates related to § 447.203, including instances where we move language from § 447.204 to § 447.203.

a. Removal of Access Monitoring Review Plan: States (§ 447.203(b)(1) Through (8))

The burden reduction associated with the removal of § 447.203(b)(1) through (8) consists of the removal of time and effort necessary to develop and publish AMRPs, perform ongoing monitoring, and corrective action plans.

Former § 447.203(b)(1) and (2) described the minimum factors that States must consider when developing an AMRP. Specifically, the AMRP must include: input from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data, and a description of the specific measures the State will use to analyze access to care. Section 447.203(b)(3) required that States include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, provider payments rates in Medicaid managed care or Medicare rates) and private health coverage rates within geographic areas of the State. Section 447.203(b)(4) described the minimum content that must be included in the monitoring plan. States were required to describe: measures the State uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the State Medicaid agency's recommendations on the sufficiency of access to care based on the review. Section 447.203(b)(5) described the timeframe for States to develop the AMRP and complete the data review for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the State has submitted a SPA to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the State or CMS based on complaints or as selected by the State. While the initial AMRPs have been completed, the plan had to be updated at least every 3 years, but no later than October 1 of the update year. Section 447.203(b)(6)(i) required that any time a State submits a SPA to reduce provider payment rates or restructure provider payments in a way that could diminish access, the State must submit an AMRP associated with the services affected by the payment rate reduction or payment restructuring that has been completed within the prior 12 months.

Former § 447.203(b)(6)(ii) required that States have procedures within the AMRP to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures were required to be in place for a period of at least 3 years following the effective date of the SPA. However, States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. Therefore, removal of § 447.203(b)(6)(ii) results in a burden reduction.

Finally, we note that this section references the rescission of the AMRP process contained in § 447.203(b)(1) through (b)(8). However, the requirements of former paragraph (b)(7) are reflected in new paragraph (b)(4), and the requirements of former paragraph (b)(8) are reflected in new paragraph (c)(5). As such, there is not a change in impact related to the rescission of these specific aspects of the AMRP process and are not reflected in this section.

In our currently approved information collection request, we estimated that the requirements to develop and make the AMRPs publicly available for the specific categories of Medicaid services will affect each of the 50 State Medicaid programs and the District of Columbia

(51 total respondents). We will use that estimate here as well, although we note that the requirements may not be limited to solely those States, as some territories may not be exempt under waivers; however, because these figures fluctuate, we are maintaining the estimate for consistency. As such, for consistency, we will maintain the estimate of 51 respondents subject to this final rule. We further note that the one-time cost estimates have already been met for AMRPs, and the ongoing monitoring requirements are every 3 years. As such, the estimates in this section for burden reduction are for 17 respondents, which is one-third of the 51 affected respondents, to provide an annual estimate of the reduced burden.

We estimated that every 3 years, it would take: 80 hours at $55.54/hr for a social science research analyst to gather data, 80 hours at $106.30/hr for a computer and information analyst to analyze the data, 100 hours at $100.64/hr for a management analyst to develop the content of the AMRP, 40 hours at $80.08/hr for a business operations specialist to publish the AMRP, and 10 hours at $118.14/hr for a general and operations manager to review and approve the AMRP. In aggregate, and as shown in Table 36, we estimate the reduced annual burden of the rescission of the ongoing AMRP requirements would be minus 5,270 hours (17 States × 310 hr) and minus $465,729 (17 States × [(80 hr × $55.54/hr) + (80 hr × $106.30/hr) + (100 hr × $100.64/hr) + (40 hr × $80.08/hr) + (10 hr × $118.14/hr)]). Taking into account the 50 percent Federal contribution for administrative expenditures, the rescission represents a saving to States of minus $232,865 ($465,729 × 0.50).

The currently approved ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it takes each of the State Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. In our currently approved information collection request, we estimated that in each SPA submission cycle, 22 States will submit SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010. Using our currently approved burden estimates we estimate a reduction of: 40 hours at $100.64/hr for a management analyst to develop the monitoring procedures, 24 hours at $100.64/hr for a management analyst to periodically review the monitoring results, and 3 hours at $118.14/hr for a general and operations manager to review and approve the monitoring procedures. In aggregate, we estimate burden reduction of minus 1,474 hours (22 responses × 67 hr) and minus $149,498 (22 States × [(40 hr × $100.64/hr) + (24 hr × $100.64/hr) + (3 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost reduction is adjusted to minus $74,749 ($149,498 × 0.50).

TABLE 36: Summary of Annual Burden Reduction Associated with Removal of Access Monitoring Review Plan Requirements (§ 447.203(b)(1) through (8))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Rescission of §447.203(b)(1) through (b)(6)(i)	17	17	Triennial (figures are annualized)	(310)	(5,270)	Varies	(465,729)	(232,865)
Rescission of § 447.203(b)(6)(ii)	22	22	Varies (figures are annualized)	(67)	(1,474)	Varies	(149,498)	(74,749)
TOTAL	39	39	Varies	Varies	(6,744)	Varies	(615,227)	(307,614)

b. Payment Rate Transparency (§ 447.203(b)(1) Through (5))

We proposed to replace the AMRP requirements with new payment rate transparency and analysis requirements at § 447.203(b)(1) through (5), which we are finalizing as proposed apart from minor technical adjustments. The burden associated with these requirements consists of the time and effort to develop and publish a Medicaid FFS provider payment rate information and analysis.

Section 447.203(b)(1) specifies that all FFS Medicaid payments must be published on a publicly accessible website that is maintained by the State. Section 447.203(b)(2) specifies the service types that are subject to the proposed payment analysis, which include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and certain HCBS. Section 447.203(b)(3) describes the required components of the payment analysis to include, for services in § 447.203(b)(2)(i) through (iii), a percentage comparison of Medicaid payment rates to the most recently published Medicare payment rates effective for the time period for each of the service categories specified in paragraph (b)(2). We also specify that the payment analysis must include percentage comparisons made on the basis of Medicaid base payments. For HCBS described in § 447.203(b)(2)(iv), we require a State-based comparison of average hourly payment rates. Section 447.203(b)(4) details the payment analysis timeframe, with the first payment analysis required to be published by the State agency by July 1, 2026, which is a change from our proposed date of January 1, 2026, and updated every 2 years by July 1. Section 447.203(b)(5) describes our mechanism

for ensuring compliance and that we may take compliance action against a State that fails to meet the requirements of the payment rate transparency, comparative payment rate analysis, and payment rate disclosure provisions in preceding paragraphs in § 447.203(b), including a deferral or disallowance of certain of the State's administrative expenditures following the procedures described at part 430, subpart C.

We estimate that the requirements to complete and make publicly available all FFS Medicaid payments and the comparative payment rate analysis and payment rate disclosures under § 447.203(b)(1) through (5) for the specific categories of Medicaid services will affect 51 total respondents, based on the estimate in the prior section regarding the variation in States and territories subject to these requirements. We require applicable States and territories to publish all FFS Medicaid payments initially by July 1, 2026, while future updates to the payment rate transparency information would depend on when a State submits a SPA updating provider payments and we have approved that SPA. As such, we assume 51 one-time respondents for the initial rates publication. Because the comparative payment rate analysis and payment rate disclosure requirement is biennial, we assume 26 annual respondents in any given year, and we will assume this figure would account for the updates made following a rate reduction SPA or rate restructuring SPA approval. The comparative payment rate analysis will be similar to the prior requirement at § 447.203(b)(3) that required AMRPs to include a comparative payment rate analysis against public or private payers. The inclusion of levels of provider payment available from other payers is also one of five required components of the AMRP as specified by current § 447.203(b)(1). To estimate the burden associated with our comparative payment rate analysis and payment rate disclosure provisions, we assume this work will require approximately 25 percent of the ongoing labor hour burden that we previously estimated to be required by the entire AMRP, to account for the service categories subject to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(2) as decreased from the full body of AMRP service requirements. We invited comment on these estimated proportions. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)) in the payment rate disclosure. Below, we include in our burden calculations the minimal increased anticipated burden associated with the addition of reporting on habilitation services.

With regard to the developing and publishing the payment rate transparency data under § 447.203(b)(1), we estimate a low one-time and ongoing burden due to the data being available, and the main work required to meet the proposed requirement would be formatting and web publication. As such, we estimate it will initially take: 5 hours at $55.54/hr for a research assistant to gather the data, 5 hours at $80.08/hr for a business operations specialist to publish, and 1 hour at $118.14/hr for a general and operations manager to review and approve the rate transparency data. In aggregate, we estimate a one-time burden of 561 hours (51 responses × 11 hr) at a cost of $40,608 (51 responses × [(5 hr × $55.54/hr) + (5 hr × $80.08/hr) + (1 hr × $118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $20,304 ($40,608 × 0.50).

For the ongoing cost to update assumed to take place every 2 years (although we proposed that updates would only be required as necessary to keep the data current, with any update made no later than 1 month following the date of CMS approval of the SPA or similar amendment providing for the change), we estimate an annualized impact on 26 respondents (51 respondents every 2 years) of: 2 hours at $55.54/hr for a research assistant to update the data, 1 hour at $80.08/hr for a business operations specialist to publish the updates, and 1 hour at $118.14/hr for a general and operations manager to review and approve the rate transparency update. In aggregate, we estimate an annualized burden of 104 hours (26 responses × 4 hr) at a cost of $8,042 (26 responses × [(2 hr × $55.54/hr) + (1 hr × $80.08/hr) + (1 hr × $118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $4,021 ($8,042 × 0.50).

With regard to developing and publishing the comparative payment rate analysis and payment rate disclosure at § 447.203(b)(2), we estimate it will take: 22 hours at $55.54/hr for a research assistant to gather the data, 22 hours at $106.30/hr for an information analyst to analyze the data, 25 hours at $100.64/hr for a management analyst to design the comparative payment rate analysis, 11 hours at $80.08/hr for a business operations specialist to publish the comparative payment rate analysis and payment rate disclosure, and 3 hours at $118.14/hr for a general and operations manager to review and approve the comparative payment rate analysis and payment rate disclosure. In aggregate, we estimate an annualized burden, based on 51 respondents every 2 years, of 2,054 (26 responses × 79 hr) at a cost of $190,107 (26 States × [(22 hr × $55.54/hr) + (22 hr × $106.30/hr) + (25 hr × $100.64/hr) + (11 hr × $80.08/hr) + (3 hr × $118.14/hr)]). We then adjust the total cost to $95,053 ($190,107 × 0.50) to account for the 50 percent Federal administrative match. We have summarized the total burdens in Table 37.

TABLE 37: Summary of Burden Associated with Payment Rate Transparency Requirements (§ 447.203(b)(1) through (5))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(b)(1) Rate Transparency	51	51	One-time	11	561	Varies	40,608	20,304
§ 447.203(b)(1) Rate Transparency	26	26	Biannual (figures are annualized)	4	104	Varies	8,042	4,021
§ 447.203(b)(2) and (3) Rate Analysis	26	26	Biannual (figures are annualized)	79	2,054	Varies	190,107	95,053
TOTAL	51	103	Varies	Varies	2,719	Varies	238,757	119,378

c. Medicaid Payment Rate Interested Parties' Advisory Group (§ 447.203(b)(6))

The burden associated with the recordkeeping requirements at § 447.203(b)(6), specifically the online publication associated with the reporting and recommendations of the interested parties advisory group, will consist of the time and effort for all 50 States and the District of Columbia to:

- Appoint members to the interested parties' advisory group.
- Provide the group members with materials necessary to:

++ Review current and proposed rates.

++ Hold meetings.

++ Provide a written recommendation to the State.

- Publish the group's recommendations to a website maintained by the single State agency.

The requirements will require varying levels of efforts for States depending on the existence of groups that may fulfil the requirements of this group. However, because it is unknown how many States will be able to leverage existing practices, and to what extent, this estimate does not account for those differences. We are finalizing the requirements at § 447.203(b)(6) with a modification to add habilitation services as defined at § 440.180(b)(6), in addition to the previously identified services, to the group's purview. However, this addition is not expected to create any additional burden. We estimate that it will take 40 hours at $140.14/hr for a human resources manager to recruit interested parties and provide the necessary materials for the group to meet. In aggregate, we estimate a one-time burden of 2,040 hours (51 responses × 40 hr) at a cost of $285,886 (2,040 hr × $140.14/hr). Taking into account the 50 percent administrative match, the total one-time State cost is estimated to be $142,943 ($285,886 × 0.50).

We believe the ongoing work to maintain the needs of this group will take a human resources manager 5 hours at $140.14/hr annually. Additionally, we estimate it will take 4 hours for the biennial requirement, or 2 hours annually at $118.14/hr for an operations manager to review and prepare the recommendation for publication. In aggregate, we estimate an ongoing annualized burden of 182 hours (26 responses × 7 hr) at a cost of $24,361 (26 Respondents × [(5 hr × $140.14/hr) + (2 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $12,181 ($24,361 × 0.50). We have summarized the total burden in Table 38.

TABLE 38: Summary of Burden for Medicaid Payment Rate Interested Parties' Advisory Group

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(b)(6) (Establish advisory group)	51	51	One-time	40	2,040	140.14	285,886	142,943
§ 447.203(b)(6) (Support and publish recommendation)	51	26	Biennial (figures are annualized)	7	182	Varies	24,361	12,181
TOTAL	51	77	Varies	Varies	2,222	Varies	310,247	155,124

d. State Analysis Procedures for Payment Rate Reductions or Payment Restructuring (§ 447.203(c))

The State analysis procedures for payment rate reductions and payment restructurings at § 447.203(c)(1) through (3) within this final rule effectively will replace payment rate reduction or payment restructuring procedures in current § 447.203(b)(6). As noted, the burden reduction associated with the removal of § 447.203(b)(6)(i) has already been accounted for in the recurring burden reduction estimate shown in Table 36 for the removal of the AMRP requirements, and the burden reduction associated with the removal of monitoring requirements at current § 447.203(b)(6)(ii) has been accounted for in Table 36 as well. Our replacement procedures at § 447.203(c)(1) through (3) will introduce new requirements as follows.

i. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Section 447.203(c)(1) will require that for States proposing to reduce or restructure provider payment rates, the State must document that their program and proposal meet all of the following requirements: (1) Medicaid rates in the aggregate for the service category following the proposed reduction(s) or restructurings are at or above 80 percent of most recent Medicare prices or rates for the same or a comparable set of services; (2) Proposed reductions or restructurings result in no more than a 4 percent reduction of overall spending for each service category affected by a proposed reduction or restructuring in a single State fiscal year; and (3) Public process yields no significant access concerns or the State can reasonably respond to concerns.

Section 447.203(c)(1) will apply to all States that submit a SPA that proposes to reduce or restructure provider payment rates. We limited our estimates for new information collection burden to the requirements at § 447.203(c)(1)(i) through (ii). Our estimates assume States will build off the comparative analysis required by § 447.203(b)(2) through (4) to complete the requirements by § 447.203(c)(1)(i), which will limit the additional information collection burden. We also assume no additional information collection burden posed by the public review process required by § 447.203(c)(1)(iii), as this burden is encapsulated by current public process requirements at § 447.204.

The requirements of § 447.203(c) apply to all 50 States and the District of Columbia, as well as US territories. We will again use the estimate of 51 utilized in preceding sections, although we note some territories may be subject to these requirements if not exempt under waivers, and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this rule. While we cannot predict how many States will submit a rate reduction SPA or rate restructuring SPA in a given year, the figures from 2019 provide the best recent estimate, as the years during the COVID pandemic do not reflect typical behavior. In 2019, we approved rate reduction and rate restructuring SPAs from 17 unique State respondents. Therefore, to estimate the annualized number of respondents subject to this information collection burden, we will utilize a count of 17 respondents.

With regard to the burden associated with completing the required State analysis for rate reductions or restructurings at § 447.203(c)(1), we estimate that it will take: 20 hours at $100.64/hr for a management analyst to structure the rate reduction or restructuring analysis, 25 hours at $106.30/hr for an information analyst to complete the rate reduction or restructuring analysis, and 3 hours at $118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 816 hours (17 States × 48 hr) at a cost of $85,420 (17 States × [(20 hr × $100.64/hr) + (25 hr × $106.30/hr) + (3 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative reimbursement, this adjusts to a total State cost of $42,710 ($85,420 × 0.50).

TABLE 39: Burden Associated with Tier 1 State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c)(1))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(c)(1)	17	17	Annual	48	816	Varies	85,420	42,710
TOTAL	17	17	Annual	48	816	Varies	85,420	42,710

We solicited public comment on these estimates as well as relevant State data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

ii. Additional State Rate Analysis (§ 447.203(c)(2))

Section 447.203(c)(2) describes requirements for payment proposals that do not meet the requirements in paragraph (c)(1), requiring the State to provide the nature of the change and policy purpose, the rates compared to Medicare and/or other payers pre- and post-reduction or restructuring, counts/trends of actively participating providers by geographic areas, counts of FFS Medicaid beneficiaries residing in geographic areas/characteristics of the beneficiary population, service utilization trends, access to care complaints from beneficiaries, providers, and other interested parties, and the State's response to access to care complaints.

The information collection requirements at § 447.203(c)(2) applies to those States that submit rate reduction or restructuring SPAs that do not meet one or more of the criteria proposed by § 447.203(c)(1). Using 2019 rate reduction and restructuring SPA figures, we estimate that 17 States will submit rate reduction or restructuring SPAs per year. Then, a 2019 Urban Institute analysis [412] indicates that 22 States (or 43 percent) have rates that meet the 80 percent fee ratio threshold proposed in § 447.203(c)(1)(i) across all services. Although our proposal did not

[412] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019.'', *Health Affairs,* Volume 40, Number 2, February 2021, p. 343–348, *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00611,* accessed August 31, 2022.

include all services, using this all services amount is our best method to estimate how many States may fall below on any given service without knowing which. Because we cannot predict the amount a State may propose to reduce, once or cumulatively for the SFY, and because failure of any one criterion in § 447.203(c)(1) will require additional analysis under § 447.203(c)(2), we will use that percentage to assess how many States will need to perform additional analysis. Using this percentage, we estimate that 7 (43 percent × 17) of the estimated 17 unique State respondents may submit rate reduction or restructuring SPAs meet the criteria for the streamlined analysis process under proposed § 447.203(c)(1). Therefore, we assume that 10 out of 17 unique annual State respondents who submit rate reduction or restructuring SPAs will also need to perform the additional analysis § 447.203(c)(2).

The required components of the review and analysis in § 447.203(c)(2) are similar to the AMRP requirements found at current § 447.203(b)(1). However, due to the availability of a template for States to facilitate completion of the required analysis, as well as the lack of a requirement to publish the analysis, we anticipate a moderately reduced burden associated with § 447.203(c)(2) when compared to the burden estimated for the AMRPs.

With regard to our requirements, we estimate that it would take: 64 hours at $55.54/hr for a social science research assistant to gather data, 64 hours at $106.30/hr for a computer and information analyst to analyze data, 80 hours at $100.64/hr for a management analyst to structure the analyses and organize output, and 8 hours at $118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 2,160 hours (10 States × 216 hr) at a cost of $193,541 (10 States × [(64 hr × $55.54/hr) + (64 hr × $106.30/hr) + (80 hr × $100.64/hr) + (8 hr × $118.14/hr)]). The total cost is adjusted down to $96,771 ($193,541 × 0.50) for States after accounting for the 50 percent Federal administrative match. We solicited public comment on these estimates as well as relevant State data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

We do not assume any additional information collection imposed by the compliance procedures at § 447.203(c)(3).

Table 40 shows our estimated combined annualized burden for § 447.203(c), which includes 17 States for § 447.203(c)(1) and 10 States for § 447.203(c)(2). In total, we estimate an annualized burden of 2,976 (816 hours + 2,160 hours) hours at a cost of $278,961 ($85,420 + $193,541). This cost to States is then adjusted to $139,481 after the 50 percent Federal administrative reimbursement is applied.

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TABLE 40: Summary of Burden Associated with State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(c)(1) (initial State analysis)	17	17	Annual	48	816	Varies	85,420	42,710
§ 447.203(c)(2) (additional State analysis)	10	10	Annual	216	2,160	Varies	193,541	96,771
TOTAL	17	27	Annual	264	2,976	Varies	278,961	139,481

D. Burden Summary

TABLE 41: Summary of Annual Burden Estimates

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§431.12 (Table 3) (MACs & BACs)	0938-TBD (CMS-10845)	51 States	153	Varies	17,340	Varies	1,665,354	832,676	n/a
§441.301(c)(3) – One-time burden to States (Table 4) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	48 States	48	Varies	528	Varies	65,409	32,704	n/a
§441.301(c)(3) – One-time burden to Managed Care Plans (Table 5) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	966	Varies	127,650	n/a	n/a
§441.301(c)(7) – One-time burden to States (Table 6) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	48	Varies	24,960	Varies	2,596,493	1,298,246	n/a
§441.301(c)(7) – Ongoing burden to States (Table 7) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	29,255	Varies	16,206	Varies	1,135,949	567,975	n/a
§441.302(a)(6) – One-time burden to States (Table 8) (Incident Management System)	0938-TBD (CMS-10854)	48 States	96	Varies	19,872	Varies	124,958,292	62,479,146	n/a
§441.302(a)(6) – Ongoing burden to States (Table 9) (Incident Management System)	0938-TBD (CMS-10854)	48 States	283,542	Varies	15,177	Varies	24,778,520	12,389,260	n/a
§441.302(a)(6) – Ongoing burden to Service Providers (Table 10) (Incident Management System)	0938-TBD (CMS-10854)	15,742 Providers	28,345	1	28,345	118.14	3,348,678	n/a	n/a
§441.302(a)(6) – One-time burden to Managed Care Plans (Table 11) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	26,726	Varies	2,712,747	n/a	n/a
§441.302(a)(6) – Ongoing burden to Managed Care Plans (Table 12) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	6,964	Varies	5,476	Varies	535,791	n/a	n/a
§441.311(b)(1) Ongoing burden to States (Table 25) (Incident Management System Assessment)	0938-1362 (CMS-10692)	48 States	48	Varies	96	Varies	8,326	4,163	n/a
§ 441.311(e) – One-time burden to States (Table 13) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	7,776	Varies	850,285	425,173	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§ 441.311(e) – Ongoing burden to States (Table 14) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	1,200	Varies	121,302	60,651	n/a
§ 441.311(e) – One-time burden to service providers (Table 15) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	1,298,286	Varies	116,591,088	n/a	n/a
§ 441.311(e) – Ongoing burden to service providers (Table 16) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	328,482	Varies	30,743,100	n/a	n/a
§ 441.311(e) – One-time burden to managed care plans (Table 17) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	20,286	Varies	1,989,464	n/a	n/a
§ 441.311(e) – Ongoing burden to managed care plans (Table 18) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	1,610	Varies	203,607	n/a	n/a
§ 441.302(k) One-time burden to States (Table 33) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	48 States	48	Varies	10,944	Varies	1,169,295	584,648	n/a
§ 441.302(k) Ongoing burden to States (Table 34) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	Varies	1,203	Varies	866	Varies	101,698	50,849	n/a
§441.303(f)(6), § 441.311(d)(1) – One-Time burden to States (Table 19) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	1,599	Varies	178,777	89,388	n/a
§441.303(f)(6), § 441.311(d)(1) – Ongoing burden to States (Table 20) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	585	Varies	72,778	36,389	n/a
§441.311(d)(2)(i) One-Time burden to States (Table 21) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	8,016	Varies	839,954	419,977	n/a
§441.311(d)(2)(i) Ongoing burden to States (Table 22) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	3,168	Varies	340,861	170,431	n/a
§441.311(d)(2)(i) One-Time burden to managed care plans (Table 23) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	12,397	Varies	1,305,923	n/a	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§441.311(d)(2)(i) Ongoing burden to managed care plans (Table 24) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	6,762	Varies	726,983	n/a	n/a
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 26)	0938–0272 (CMS–372(S))	48 States	253	(44)	(11,132)	75.32	(891,451)	(445,725)	n/a
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)-(4) (Table 27)	0938-TBD (CMS-10854)	48 States	48	Varies	2,640	Varies	231,952	115,976	n/a
§441.311(c) One-time burden to States (Table 28) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48 States	48	Varies	64,560	Varies	5,301,830	2,650,915	n/a
§441.311(c) Ongoing burden to States (Table 29) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	24 States	24	Varies	58,920	Varies	4,202,621	2,101,310	n/a
§441.311(c) Ongoing burden to beneficiaries (Table 30) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48,000 Beneficiaries	24,000	0.75	18,000	20.71	n/a	n/a	372,780
§441.313 One-time burden to States (Table 31) (Website Transparency)	0938-TBD (CMS-10854)	48 States	48	Varies	5,232	Varies	547,385	273,693	n/a
§441.313 Ongoing burden to States (Table 32) (Website Transparency)	0938-TBD (CMS-10854)	48 States	192	Varies	6,336	Varies	709,359	354,680	n/a
Removal of § 447.203(b)(1)-(6)(i)) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	17	(310)	(5,270)	*varies*	(465,729)	(232,865)	n/a
Removal of § 447.203(b)(6)(ii) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	22	(67)	(1,474)	*varies*	(149,498)	(74,749)	n/a
§ 447.203(b)(1) (Table 37) (Rate transparency)	0938–1134 (CMS–10391)	51 States and Territories	26	4	104	*varies*	8,042	4,021	n/a
§ 447.203(b)(2) (Table 37) (Rate analysis)	0938–1134 (CMS–10391)	51 States and Territories	26	83	2,158	*varies*	190,107	95,053	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§ 447.203(b)(6) (Table 38) (advisory group)	0938–1134 (CMS–10391)	51 States and Territories	26	7	182	*varies*	24,361	12,181	n/a
§ 447.203(c)(1) (Table 39) (initial State analysis)	0938–1134 (CMS–10391)	51 States and Territories	17	48	816	*varies*	85,420	42,710	n/a
§ 447.203(c)(2) (Table 39) (additional State analysis)	0938–1134 (CMS–10391)	51 States and Territories	12	216	2,160	*varies*	193,541	96,771	n/a
TOTAL		Varies	407,029	Varies	2,200,901	Varies	327,156,264	84,435,647	372,380

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IV. Regulatory Impact Analysis

A. Statement of Need

1. Medicaid Advisory Committee

The changes to § 431.12 are intended to provide beneficiaries a greater voice in State Medicaid programs. In making policy and program decisions, it is vital for States to include the perspective and experience of those served by the Medicaid program. States are currently required to operate a MCAC, made up of health professionals, consumers, and State representatives to ''advise the Medicaid agency about health and medical care services.'' This rule establishes new requirements for a MAC in place of the MCAC, with additional membership requirements to include a broader group of interested parties, to advise the State Medicaid agency on matters related to the effective administration of the Medicaid program. We seek to expand the viewpoints represented on the MAC, to provider States with richer feedback on Medicaid program and policy issues. States are already required to set up and use MCACs. The changes will result in the State also setting up a smaller group, the BAC, which will likely have a cost implication. The additional cost will depend on whether or not States already have a beneficiary committee—we know that many States already do. This smaller group which feeds into the larger MAC will benefit the Medicaid program by creating a forum for beneficiaries to weigh in on key topics and share their unique views as Medicaid program participants. The new provisions of § 431.12 also enhance transparency and accountability through public reporting requirements related to the operation and activities of the MAC and BAC, and guidelines for operation of both bodies.

2. Home and Community-Based Services (HCBS)

The proposed changes at part 441, subpart G, seek to amend and add new Federal requirements, which are intended to improve access to care, quality of care, and health outcomes, and strengthen necessary safeguards that are in place to ensure health and welfare, and promote health equity for people receiving Medicaid-covered HCBS. The provisions in this final rule are intended to achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs in accordance with section 2402(a) of the Affordable Care Act, and is made applicable to part 441, subparts J, K, and M, as well as part 438 to achieve these goals.

Specifically, the proposed rule seeks to: strengthen person-centered services planning and incident management systems in HCBS; require minimum percentages of Medicaid payments for certain HCBS to be spent on compensation for the direct care workforce; require States to establish grievance systems in FFS HCBS programs; report on waiver waiting lists in section 1915(c) waiver programs, service delivery timeframes for certain HCBS, and a standardized set of HCBS quality measures; and promote public transparency related to the administration of Medicaid-covered HCBS through public reporting on measures related to incident management systems, critical incidents, person-centered planning, quality, access, and payment adequacy.

In 2014, we released guidance [413] for section 1915(c) waiver programs, which described a process in which States were to report on State-developed performance measures to demonstrate that they meet the six assurances that are required for section 1915(c) waiver programs. Those six assurances include the following:

1. *Level of Care:* The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facilities for Individuals with Intellectual Disabilities.

2. *Service Plan:* The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants.

3. *Qualified Providers:* The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.

4. *Health and Welfare:* The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.

[413] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

5. *Financial Accountability:* The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program.

6. *Administrative Authority:* The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.

Despite these assurances, there is evidence that State HCBS systems still need to be strengthened and that there are gaps in existing reporting requirements. We believe that this final rule is necessary to address these concerns and strengthen HCBS systems. The requirements in this final rule are intended to supersede and fully replace reporting and performance expectations described in the 2014 guidance for section 1915(c) waiver programs. They are also intended to promote consistency and alignment across HCBS programs, as well as delivery systems, by applying the requirements (where applicable) to sections 1915(i), (j), and (k) authorities State plan benefits and to both FFS and managed care delivery systems.

3. Fee-for-Service (FFS)

Provisions under § 447.203 from this final rule will impact States' required documentation of compliance with section 1902(a)(30)(A) of the Act to ''assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' We have received comments from State agencies that the existing AMRP requirement first established by the 2015 final rule with comment period imposes excessive administrative burden for its corresponding value in demonstrating compliance with section 1902(a)(30)(A) of the Act.

This final rule will replace the existing AMRP requirement with a more limited payment rate transparency requirement under proposed § 447.203(b), while requiring a more detailed access impact analysis (as described at proposed § 447.203(c)(2)) when a State proposes provider rate reductions or restructurings that exceed certain thresholds for a streamlined analysis process under proposed § 447.203(c)(1). By limiting the data collection and publication requirements imposed on all States, while targeting certain provider rate reductions or restructuring proposals for a more detailed analysis, this final rule will provide administrative burden relief to States while maintaining a transparent and data-driven process to assure State compliance with section 1902(a)(30)(A) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for rules that meet section 3(f)(1) of the Executive Order. This final rule does meet that criterion as the aggregate amount of benefits and costs may meet the $200 million threshold in at least 1 year.

Based on our estimates using a ''no action'' baseline in accordance with OMB Circular A–4, (available at *https://www.whitehouse.gov/wpcontent/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is significant or otherwise meets section 3(f)(1). Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

As mentioned in the prior section, and in accordance with OMB Circular A–4, the following estimates were determined using a ''no action'' baseline. That is, our analytical baseline for impact is a direct comparison between the provisions and not proposing them at all.

1. Benefits

a. Medicaid Advisory Committees (MAC)

We believe the changes to § 431.12 will benefit State Medicaid programs and those they serve by ensuring that beneficiaries have a significant role in advising States on the experience of receiving health care and services through Medicaid. These benefits cannot be quantified. However, the BAC and a more diverse and transparent MAC will provide opportunities for richer interested parties feedback and expertise to positively impact State decision making on Medicaid program and policy chances. For example, beneficiary feedback on accessing health care services and the quality of those services can inform decisions on provider networks and networks adequacy requirements. Issues that States need to address, like cultural competency of providers, language accessibility, health equity, and disparities and biases in the Medicaid program, can be revealed through beneficiary experiences. The MAC falls into the Public Administration 921 Executive, Legislative, and Other General Government Support.

b. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

The changes benefit Medicaid beneficiaries and States by requiring States to demonstrate through reporting requirements that they provide safeguards to assure eligibility for Medicaid-covered care and services is determined and provided in a manner that is in the Medicaid beneficiaries'

best interest, although these potential benefits cannot be monetarily quantified at this time. The changes will provide further safeguards that ensure health and welfare by strengthening the person-centered service plan requirements, establishing grievance systems, amending requirements for incident management systems, and establishing new reporting requirements for States, and contracted managed care plans identified by the North American Industry Classification System (NAICS) industry code (Direct Health and Medical Insurance Carriers (524114).

These changes will benefit individuals on HCBS waiver wait lists, and individuals who receive homemaker, home health aide, personal care, and habilitation services under the finalized regulations found at §§ 441.301(c), 441.302(a)(6), 441.302(h), 441.303(f), 441.311, 441.725, and amended regulations in §§ 441.464, 441.474, 441.540, 441.555, 441.570, 441.580, and 441.745. These benefits cannot be monetarily quantified at this time.

c. Home and Community-Based Services (HCBS) Payment Adequacy and Payment Adequacy Reporting

This final rule adds a new reporting requirement at § 441.311(e) (and amends §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) to require States to demonstrate through reporting what percent of payments to providers of certain HCBS (homemaker, home health aide, personal care, and habilitation services) are spent on compensation to direct care workers. The goal of this requirement is to promote transparency and to assure that payments are consistent with efficiency, economy, and quality of care, in accordance with section 1902(a)(30)(A) of the Act. This final rule seeks to address access to care that is being affected by direct care workforce shortages. States will be required to report annually and will be required to separately report on payments for services that are self-directed and services that include facility costs. benefit from reporting in the aggregate for each service subject to the requirement across HCBS programs and delivery systems, which minimizes administrative burden while providing us better oversight of compensation of the direct care workforce. These potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

Additionally, through this final rule, we are finalizing § 441.302(k), which establishes certain minimum thresholds for the percent of Medicaid payments for certain HCBS must be spent on compensation for direct care workers. We believe this requirement will help to ensure that payments to workers are sufficient to provide access to care that is at least comparable to that of the general population in the same geographic location, in accordance with section 1902(a)(30)(A) of the Act. We are also finalizing a number of flexibilities to allow States to address needs of specific providers, such as providers that are small or rural, or are experiencing particular hardship that would temporarily prevent the provider for adhering to the minimum payment level. Through this requirement, we can better ensure payment adequacy to a provider population experiencing worker shortages that impact beneficiary access. While we believe this requirement will promote increases in direct care worker compensation in some regions, these potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

d. Home and Community-Based Services (HCBS) Quality Measure Set Reporting

As described in section II.B.8. of this final rule, on July 21, 2022, we issued State Medicaid Director Letter (SMDL) #22–003 [414] to release the first official version of the HCBS Quality Measure Set. This final rule provides definitions and sets forth requirements at § 441.312 that expand on the HCBS Quality Measure Set described in the SMDL. By expanding and codifying aspects of the SMDL, we can better drive improvement in quality of care and health outcomes for beneficiaries receiving HCBS. States will also benefit from the clarity afforded by this final rule, and from the assurance that other States they may be looking to for comparison are adhering to the same requirements. The clarity and assurance, at this time, cannot be measured.

e. Fee-for-Service (FFS) Payment Transparency

The changes to § 447.203 will update requirements placed on States to document access to care and service payment rates. The updates create a systematic framework through which we can assess compliance with section 1902(a)(30)(A) of the Act, while reducing existing burden on States and maximizing the value of their efforts, as described in section III.C.11.a. of this rule.

The payment rate transparency provisions at § 447.203(b) create a process that will facilitate transparent oversight by us and other interested parties. By requiring States to calculate Medicaid payment rates as a percent of corresponding Medicare payment rates, this provision offers a uniform benchmark through which CMS and interested parties can assess payment rate sufficiency. When compared to the existing AMRP requirement, the rate analysis proposed by § 447.203(b) should improve the utility of the reporting, while reducing the associated administrative burden, as reflected in the Burden Estimate Summary Table 38. Updates at § 447.203(c) specify required documentation and analysis when States propose to reduce or restructure provider payment rates. By establishing thresholds at § 447.203(c)(1), this final rule will generally limit the more extensive access review prescribed by § 447.203(c)(2) to those SPAs that we believe more likely to cause access concerns. In doing so, these proposed updates reduce the State administrative burden imposed by existing documentation requirements for proposed rate reductions or restructurings, without impeding our ability to ensure proposed rate reduction and restructuring SPAs comply with section 1902(a)(30)(A) of the Act. These burden reductions are reflected in the Collection of Information section of this rule.

When considering the benefits of these regulatory updates, we considered the possibility that the improved transparency required by § 447.203(b) could create upward pressure on provider payment rates, and that the tiered nature of documentation requirements set by § 447.203(c) could create an incentive for States to moderate proposed payment reductions or restructurings that were near the proposed thresholds that would trigger additional analysis and documentation requirements. If either of these rate impacts were to occur, existing literature implies there could be follow-on benefits to Medicaid beneficiaries, including but not limited to increased physician acceptance rates,[415] increased appointment availability,[416] and even improved self-reported health.[417] However, nothing in this final rule will require States to directly adjust payment

[414] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

[415] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[416] Candon, M., et al. *JAMA Internal Medicine,* January 2018, p. 145–146.

[417] Alexander, D., and Molly Schnell. ''The Impacts of Physician Payments on Patient Access, Use, and Health'', National Bureau of Economic Research, Working Paper 26095, July 2019 (revised August 2020), p. 1–74. *https://www.nber.org/papers/w26095.* Accessed June 16, 2022.

rates, and we recognize that multiple factors influence State rate-setting proposals, including State budgetary pressures, legislative priorities, and other forces. These competing influences create substantial uncertainty about the specific impact of the provisions at § 447.203 on provider payment rate-setting and beneficiary access. Rather, the specific intent and anticipated outcome of these provisions is the creation of a more uniform, transparent, and less burdensome process through which States can conduct required payment rate and access analyses and we can perform our oversight role related to provider payment rate sufficiency.

2. Costs

a. Medicaid Advisory Committee (MAC)

In addition to the costs reflected in section III.C.1 of this final rule, States will incur additional ongoing costs (estimated below in Table 42) in appointing and recruiting members to the MAC and BAC and, also developing and publishing bylaws, membership lists, and meeting minutes for the MAC and BAC. All of these costs can be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support) since States are the only entity accounted for in the MAC and BAC. How often these costs occur will also vary in how often the State chooses to make changes such as add or replace members of the MAC and BAC or change its bylaws. Additionally, there will be new, ongoing costs, estimated below, for States related to meeting logistics and administration for the BAC. All of these new costs can also be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support). To derive average costs, as in the previous section of this final rule, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2022/may/oes_nat.htm*). Costs include our estimated cost of fringe benefits and other indirect costs, calculated at 100 percent of salary, in our adjusted hourly wage.

Since most States are already holding MAC meetings under current regulatory requirements, any new costs related to MAC requirements would likely be minimal. In terms of the MAC and BAC meeting costs, we estimate a total cost for 5 years of $3.414 million or $682,821 annually for States. We estimate it will take a business operations specialist 10 hours to plan and execute each BAC meeting, at a total cost of $162,180 ($79.50/hour × 10 hours × 4 meetings/year) × 51 States and the District of Columbia). To satisfy the requirements of § 431.12(h)(3)(i), a public relations specialist will spend an estimated 80 hours/year supporting Medicaid beneficiary MAC and BAC members at a total cost of $308,122 ($75.50/hour × 80 hours) × 51 States and the District of Columbia). A chief executive in State government, as required by § 431.12(h)(3)(iii) will spend a total of 8 hours a year attending BAC meetings, which we estimate will be 2 hours in duration, 4 times a year at a total cost of $ 49,319 ($120.88/hour × 2 hours/meeting × 4 meetings) × 51 States and the District of Columbia). Each meeting of the BAC will cost States an estimated $200 in meeting costs and telecommunication, at an annual total cost of $40,800 ($200 × 4 meetings) × 51 States and the District of Columbia). The meeting costs are estimated by adding the average cost for telecommunications (approximately $130[418] per meeting) to the average cost of meeting supplies (approximately $70 per meeting for photocopies, name tags, etc.). While we cannot estimate precisely the costs for meeting materials and additional items to support meetings, we are including a nominal estimate of $70 per meeting to acknowledge these costs.

There will also be a per meeting cost to States for financial support for beneficiary members participating in MAC and BAC meetings, as described in § 431.12(h)(3)(ii). We estimate a cost of $75/beneficiary/meeting in the form of transportation vouchers, childcare reimbursement, meals, and/or other financial compensation. Assuming 4 meetings per year (with BAC and MAC meetings co-located and occurring on the same day) and an average of 8 beneficiary members on the BAC and MAC, the cost of financial support for beneficiary members across States is estimated to cost approximately $122,400 annually (($75/beneficiary × 8 beneficiaries × 4 meetings/year) × 51 States and the District of Columbia). This cost will vary depending on the decisions States make around financial support, the number of beneficiary members of the BAC and MAC, and the number of meetings per year. We solicited comment on the costs associated with planning, execution, and participation in the MAC and BAC meetings.

We did not receive public comments specifically on these estimates, and therefore, we are finalizing as proposed.

[418] Sources: *https://www.usnews.com/360-reviews/business/best-conference-calling-services; https://money.com/best-conference-calling-services/.*

TABLE 42: Projected Ten Year Costs for Proposed Updates

Provision	Year										Total CY 2024-2033 ($ in millions)
	Year One ($ in millions)	Year Two ($ in millions)	Year Three ($ in millions)	Year Four ($ in millions)	Year Five ($ in millions)	Year Six ($ in millions)	Year Seven ($ in millions)	Year Eight ($ in millions)	Year Nine ($ in millions)	Year Ten ($ in millions)	
§ 431.12 MAC & BAC logistic and admin support	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	5.6
§ 431.12 Financial support to MAC/BAC beneficiary members (cost will range per State)	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	1.22
Total	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	6.82
Costs will vary depending by State, on how many in person meetings are held, and how many Medicaid beneficiaries are selected for the MAC and BAC											

b. Home and Community-Based Services (HCBS)

Costs displayed in Table 43 are inclusive of both one-time and ongoing costs. One-time costs are split evenly over the years leading up to the provision's applicability date. For example, if a finalized provision is applicable 3 years after the final rule's publication, the one-time costs would be split evenly across each of the years leading to that applicability date. Please note the following applicability dates (beginning after the effective date of this final rule): 2 years for the grievance process requirements finalized at § 441.302(c)(7); 3 years for the person-centered planning, incident management, changes to Form 372(S), access reporting, and website transparency requirements finalized at §§ 441.301(c)(3), 441.302(a)(6), 441.311(b), 441.311(d) and 441.313, respectively; 4 years for the reporting requirements for the HCBS Quality Measure Set and for payment adequacy reporting finalized at § 441.311(c) and (e), respectively; 5 years for the electronic incident management system requirement at § 441.302(a)(6); and 6 years for the HCBS payment adequacy requirements finalized at § 441.302(k). The estimates below do not account for higher costs associated with medical care, as the costs are related exclusively to reporting costs. Costs to States, the Federal government, and managed care plans do not account for enrollment fluctuations, as they assume a stable number of States operating HCBS programs and managed care plans delivering services through these programs. Similarly, costs to providers and beneficiaries do not account for enrollment fluctuations. In the COI section, costs are based on a projected range of HCBS providers and beneficiaries. Given this uncertainty, here, we based cost estimates on the mid-point of the respective ranges and kept those assumptions consistent over the course of the 5-year projection. Per OMB guidelines, the projected estimates for future years do not include ordinary inflation. (that is, they are reported in constant-year dollars).

Table 44 summarizes the estimated ongoing costs for States, managed care plans (Direct Health and Medical Insurance Carriers (NAICS 524114)), and providers (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610)) from the Collection of Information section (section III. of this final rule) of the HCBS provisions of the final rule projected over 10 years. This comprises the entirety of anticipated quantifiable costs associated with changes to part 441, subpart G. It is also possible that increasing the threshold from 86 percent to 90 percent for compliance reporting at § 441.311(b)(2) through (3) may lead to additional costs to remediate issues pertaining to critical incidents or person-centered planning. However, the various avenues through which States could address these concerns creates substantial uncertainty as to what those costs may be. While we acknowledge the potential for increased costs in a limited number of States that may fall within the gap between the existing and the compliance thresholds, we do not quantify them here.

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TABLE 43: Projected 10-Year Costs for Updates to 441 Subparts G, J, K, and M

Provision Costs (in millions)	**Year 1**	**Year 2**	**Year 3**	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
§ 441.301(c)(3) (Person-Centered Service Plans)	0.06	0.06	0.06	-	-	-	-	-	-	-	0.19
§ 441.301(c)(7) (Grievance Systems)	1.30	1.30	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	11.68
§ 441.302(a)(6) (Incident Management System)	1.56	1.56	1.56	28.66	28.66	28.66	28.66	28.66	28.66	28.66	205.31
§ 441.302(a)(6) (Incident Management System – Electronic Incident Management System)	24.60	24.60	24.60	24.60	24.60	0	0	0	0	0	123.00
§ 441.311(b)(1)(Incident Management System Assessment)	-	-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.06
§ 441.311(e) (Payment Adequacy Reporting)	29.86	29.86	29.86	29.86	31.07	31.07	31.07	31.07	31.07	31.07	305.84
§ 441.302(k) (HCBS Payment Adequacy)	0.19	0.19	0.19	0.19	0.19	0.19	0.24	0.24	0.24	0.24	2.12
§441.303(f)(6), § 441.311(d)(1) (Supporting Documentation for HCBS Access)	0.06	0.06	0.06	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.69
§441.311(d)(2)(i) (Additional HCBS Access Reporting)	0.71	0.71	0.71	1.07	1.07	1.07	1.07	1.07	1.07	1.07	9.62
Removal of Current Form 372(S) Ongoing Reporting Information Collection	-	-	-	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(6.24)
Form 372(S) Reporting Requirement to include § 441.311(b)(2)-(4)	-	-	-	0.23	0.23	0.23	0.23	0.23	0.23	0.23	1.62
§441.311(c) (HCBS Quality Measure Set)	1.33	1.33	1.33	1.33	4.58	4.58	4.58	4.58	4.58	4.58	32.75
§441.313 (Website Transparency)	0.18	0.18	0.18	0.71	0.71	0.71	0.71	0.71	0.71	0.71	5.51
Total*	59.85	59.85	59.69	87.00	91.44	66.84	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

The costs displayed in Table 44 are inclusive of costs anticipated to be incurred by State Medicaid agencies, the Federal government, providers, managed care plans, and beneficiaries.

Table 44 distributes those costs across these respective entities.

TABLE 44: Projected Distribution of Costs for Updates to 42 CFR 441 Subpart G, J, K, and M

Costs (in millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
State Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Federal Government Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Managed Care Plan Costs	1.88	1.88	1.88	1.76	1.47	1.47	1.47	1.47	1.47	1.47	16.20
HCBS Provider Costs	29.15	29.15	29.15	32.50	34.09	34.09	34.23	34.23	34.23	34.23	325.03
Beneficiary costs	0	0	0	0	0.37	0.37	0.37	0.37	0.37	0.37	2.24
Total*	59.86	59.86	59.70	91.44	66.84	66.88	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

c. Fee-for-Service (FFS) Payment Rate Transparency

The costs associated with the payment rate transparency proposals are wholly associated with information collection requirements, and as such those impacts are reflected in the COI section of this rule. For ease of reference, and for projection purposes, we are including those costs here in Table 45.

TABLE 45: Projected 5-Year State Costs for Updates to 42 CFR 447.203

Provision	Calendar year (CY)					Total CY 2024-2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
Removal of current § 447.203 (AMRPs)	-0.615	-0.615	-0.615	-0.615	-0.615	-3.075
§ 447.203(b)	0.516	0.254	0.254	0.254	0.254	1.532
§ 447.203(c)(SPAs)	0.279	0.279	0.279	0.279	0.279	1.395
Total	**0.18**	**-0.082**	**-0.082**	**-0.082**	**-0.082**	**-0.148**

TABLE 46: NAICS Classification of Services and Their Distribution of Costs

Services	NAICS	Percentage of Costs
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent

TABLE 47: One Time and Annual Costs Detailed

	Cost to States ($)	Cost to Beneficiaries ($)	Cost to Providers ($)	Cost to Managed Care Plans ($)	Costs to Federal Government ($)	One Time Burden Overall Total ($)	Annual Burden Overall Total ($)
Regulatory Review	19,587.06	39,174.12	-	61,833.66	-	120,594.84	0
§ 431.12 Medical Care Advisory Committee Requirements	790,795	-	-		790,795	-	1,581,590
§ 441.301(c)(3) (Person-Centered Service Plans) (One-time Costs) (Tables 4, 5)	32,704	-	-	127,650	32,704	193,059	-
§ 441.301(c)(7) (Grievance Systems) (One-time Costs) (Table 6)	1,298,246	-	-	-	1,298,246	2,596,493	-
§441.301(c)(7) (Grievance Systems) (Ongoing Costs) (Table 7)	567,975	-	-	-	567,975	-	1,135,949
§ 441.302(a)(6) (Incident Management System) (One-time Costs) (Tables 8, 11)	62,479,146	-	-	2,712,747	62,479,146	127,671,039	-
§ 441.302(a)(6) (Incident Management System) (Ongoing Costs) (Tables 9, 10, 12)	12,389,260	-	3,348,678	535,791	12,389,260	-	28,662,989
§ 441.311(b)(1) (Incident Management System Assessment) (Ongoing Costs) (Table 25)	4,163	-	-	-	4,163	-	
§ 441.311(e) (Payment Adequacy Reporting) (One-time Costs) (Tables 13, 15, 17)	425,173	-	116,591,088	1,989,464	425,173	119,430,837	-
§ 441.311(e) (Payment Adequacy	60,651	-	30,743,100	203,607	60,652	-	31,068,009

Reporting) (Ongoing) (Tables 15, 16, 18)							
§ 441.302(k) (HCBS Payment Adequacy) (One-time Costs) (Table 33)	584,648	-	-	-	584,648	1,169,295	-
§ 441.302(k) (HCBS Payment Adequacy) (Ongoing Costs) (Tables 34, 36)	50,849	-	136,452	-	50,849	-	238,150
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (One-time Costs) (Table 19)	89,388	-	-	-	89,388	178,777	-
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (Ongoing Costs) (Table 20)	36,389	-	-	-	36,389	-	72,778
§ 441.311(d)(2)(i) (HCBS Access Reporting) (One-time Costs) (Tables 21, 23)	419,977	-	-	1,305,923	419,977	2,140,427	-
§ 441.311(d)(2)(i) (HCBS Access Reporting) (Ongoing Costs) (Tables 22, 24)	170,431	-	-	726,983	170,431	-	1,067,845
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Ongoing Costs) (Table 26)	(445,725)	-	-	-	(445,725)	-	(891,450)

Form 372(S) Reporting Requirement to include § 441.311(b)(2) through (4) (Ongoing Costs) (Table 27)	115,976	-	-	-	115,976	-	231,952
§ 441.311(c) (HCBS Quality Measure Set) (One-time Costs) (Table 28)	2,650,915	-	-	-	2,650,915	5,302,480	-
§ 441.311(c) (HCBS Quality Measure Set) (Ongoing Costs) (Tables 29, 30)	2,101,310	372,780	-	-	2,101,310	-	4,575,400
§ 441.313 (Website Transparency) (One-time Costs) (Table 31)	273,693	-	-	-	273,693	547,385	-
§ 441.313 (Website Transparency) (Ongoing Costs) (Table 32)	354,680	-	-	-	354,680	-	709,359
Removal of § 447.203(b)(1) through (6) (Removal of AMRP) (Table 36)	(307,614)	-	-	-	307,614)	(615,228)	-
§ 447.203(b)(1) (Rate transparency) (Table 36)	23,453	-	-	-	23,453	39,195	7,712
§ 447.203(b)(2) (Rate analysis) (Table 37)	87,103	-	-	-	87,103	-	174,206
§ 447.203(b)(6) (advisory group) (Table 38)	145,386	-	-	-	145,386	267,934	22,837
§ 447.203(c)(1) (initial State analysis) (Table 40)	40,678	-	-	-	40,678	-	81,356
§ 447.203(c)(2) (additional State analysis) (Table 40)	92,716	-	-	-	92,716	-	185,432

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3. Transfers

Transfers are payments between persons or groups that do not directly affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Because this rule proposes changes to requirements to State agencies without changes to payments from Federal to State governments, the transfer impact is null, and cost impacts are reflected in the other sections of this rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. There is uncertainty involved with accurately quantifying the number of entities that will review the rule. However, for the purposes of this final rule we assume that on average, each of the 51 affected State Medicaid agencies will have one contractor per State review this final rule. This average assumes that some State Medicaid agencies may use the same contractor, others may use multiple contractors to address the various provisions within this final rule, and some State Medicaid agencies may perform the review in-house. We also assume that each affected managed care plan (estimated in the COI section to be 161 managed care plans) will review the final rule. Lastly, we assume that an average of two advocacy or interest group representatives from each State will review this final rule. In total, we are estimating that 314 entities (51 State Contractors + 161 Managed Care Plans + 102 Advocacy and Interest Groups) will review this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We did not receive public comment on this issue.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We solicited comments on this assumption.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

Using the wage information from the Bureau of Labor Statistics, *https://www.bls.gov/oes/current/oes_nat.htm,* we are considering medical and health service managers (Code 11–9111), as including the 51 State Contractors, 161 Managed Care Plans and 102 Advocacy and Interest Groups identified in this final rule, and we estimate that the cost of reviewing this rule is $123.06 per hour, including fringe benefits and other indirect costs. Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 6.67 hours for each individual to review half of this final rule ([200,000 words × 0.5]/250 words per minute/60 minutes per hour). For each entity that reviews the rule, the estimated cost is $820.40 (6.67 hours × $123.06). Therefore, we estimate that the total one-time cost of reviewing this regulation is $257,605.60 ($820.40 per individual review × 314 reviewers).

D. Alternatives Considered

1. Medicaid Advisory Committee (MAC)

In determining the best way to promote beneficiary and interested parties' voices in State Medicaid program decision making and administration, we considered several ways of revising the MCAC structure and administration. We considered setting minimum benchmarks for each category of all types of MAC members, but we viewed it as too restrictive. We ultimately concluded that only setting minimum benchmarks (at least 25 percent) for beneficiary representation on the MAC and requiring representation from the other MAC categories would give States maximum flexibility in determining the exact composition of their MAC. However, we understand that some States may want us to set specific thresholds for each MAC category rather than determine those categories on their own.

We also considered having not having a separate BAC, but we ultimately determined that requiring States to establish a separate BAC assures that there is a dedicated forum for States to receive beneficiary input outside of the MAC. In the MAC setting, a beneficiary might not feel as comfortable speaking up among other Medicaid program interested parties. The BAC also provides an opportunity for beneficiaries to focus on the issues that are most important to them, and bring those issues to the MAC.

Finally, we also considered setting specific topics for the MAC to provide feedback. However, due to the range of issues specific to each State's Medicaid program, we determined it was most conducive to allow States work with their MAC to identify which topics and priority issues would benefit from interested parties' input.

2. Home and Community-Based Services (HCBS)

a. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

We considered whether to codify the existing 86 percent performance level that was outlined in the 2014 guidance for both person-centered service plans and incident management systems. We did not choose this alternative due to feedback from States and other interested parties of the importance of these requirements, as well as concerns that an 86 percent performance level may not be sufficient to demonstrate that a State has met the requirements.

We considered whether to apply these requirements to section 1905(a) ''medical assistance'' State Plan personal care, home health, and case management services. We decided against this alternative based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for HCBS delivered under sections 1915(c), (i), (j), and (k) of the Act and because of differences between the requirements of those authorities and section 1905(a) State Plan benefits.

Finally, we considered allowing a good cause exception to the minimum performance level reporting requirements to both the person-centered service plan and the incident management system. We decided against this alternative because the 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Furthermore, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

b. HCBS Payment Adequacy and Payment Adequacy Reporting

We considered several alternatives to this final rule. We considered whether the requirements at § 441.302(k) relating to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with mental illness. As discussed in section II.B.5, we decided against these alternatives because the services (homemaker, home health aide, and personal care) are those for which the vast majority of payment should be comprised of compensation for direct care workers and for which there will be low facility or other indirect costs. We

also did not include other services for which the percentage might be variable due to the diversity of services included or for which worker compensation will be reasonably expected to comprise only a small percentage of the payment.

As an alternative to the payment adequacy reporting requirement finalized at § 441.311(e), we considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to collect data from States regarding the percent of Medicaid payments is spent on compensation to direct care workers. We determined, upon reviewing public comment, that collecting the data is necessary to promote transparency and inform future policymaking. We considered whether to require reporting at the delivery system, HCBS waiver program, or population level but decided against additional levels of reporting because it will increase reporting burden for States without providing additional information necessary for demonstrating that Medicaid payments are being allocated efficiently in accordance with section 1902(a)(30)(A) of the Act.

We considered whether to apply both § 441.302(k) and the reporting requirements finalized at § 441.311 to section 1905(a) ''medical assistance'' State Plan personal care and home health services, but decided not to, largely due to concerns that the statutory and regulatory requirements for section 1905(a) services are different from the statutory and regulatory requirements for section 1915 services; these differences will require additional consideration and rulemaking should the requirements be applied to section 1905(a) services. States also provided feedback that, for the purposes of § 441.311, they do not have the same data collection and reporting capabilities for these services as they do for sections 1915(c), (i), (j), and (k) HCBS.

c. Supporting Documentation Requirements

No alternatives were considered.

d. HCBS Quality Measure Set Reporting

We considered giving States the flexibility to choose which measures they will stratify and by what factors but decided against this alternative as discussed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule (see 87 FR 51313). We believe that consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[419] Consistency could not be achieved if each State made its own decisions about which data, it would stratify and by what factors.

3. Payment Rate Transparency

In developing this final rule, we considered multiple alternatives. We considered not proposing this rule and maintaining the status quo under current regulations at § 447.203 and 204. However, as noted throughout the Background and Provisions sections of this rule, since the 2011 proposed rule, we have received concerns from interested parties, including State agencies, about the administrative burden of completing AMRPs and questioning whether they are the most efficient way to determine access to care. These comments expressed particular concern about the AMRPs' value when they are required to accompany a proposed nominal rate reduction or restructuring, or where proposed rate changes are made via application of a previously approved rate methodology. At the same time, and as we have discussed, in *Armstrong* v. *Exceptional Child Care, Inc.,* 575 U.S. 320 (2015), the Supreme Court held that Medicaid providers and beneficiaries do not have private right of action against States to challenge State-determined Medicaid payment rates in Federal courts. This decision made our administrative review of SPAs proposing to reduce or restructure payment rates all the more important. For both of these reasons, this rule includes requirements that will create an alternative process that both reduces the administrative burden on States and standardizes and strengthens our review of payment rate reductions or payment restructurings to ensure compliance with section 1902(a)(30)(A) of the Act.

We considered, but did not propose, adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. Although such processes could further our goals of ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act, we concluded similar effects can be achieved through methods that did not require the significant amount of Federal effort that will be necessary to develop either or both of these processes. Additionally, a complaint-driven process will not necessarily ensure a balanced review of State-proposed payment rate or payment structure changes, and it is possible that a large volume of complaints could be submitted with the intended or unintended effect of hampering State Medicaid program operations. Therefore, the impact of adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns may be negligible given existing processes. Instead, we believe that relying on existing processes that States are already engaged in, such as the ongoing provider and beneficiary feedback channels under paragraph (b)(7) in § 447.203 and the public process requirement for States submitting a SPA that are required to reduce or restructure Medicaid service payments in § 447.204, will be more effective than creating a new process. While we are relying on existing public feedback channels and processes that States are already engaged in, we solicited public comment regarding our alternative consideration to adopting a complaint driven process or developing a Federal review process for assessing access to care concerns.

We also considered numerous variations of the individual provisions of the final rule. We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type, calculate an average Medicaid payment rate of all providers for each E/M CPT code subject to the comparative payment rate analysis. We also considered, but did not propose, different points of comparison other than Medicare under the comparative payment rate analysis proposed under § 447.203(b)(2) or using a peer payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate under the comparative payment rate analysis proposed under § 447.203(b)(2) and (3). We considered, but did not propose, varying timeframes for the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered not

[419] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

proposing the payment rate transparency aspect of this rule proposed under § 447.203(b)(1), leaving the comparative payment rate analysis to replace the AMRP process as proposed under § 447.203(b)(2). With regard to the proposal in § 447.203(c), we considered, but did not propose, establishing alternative circumstances from those described in the 2017 SMDL for identifying nominal payment rate adjustments, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring, using measures that are different from the proposed measures that would be reflected in the forthcoming template, allowing States to use their own unstructured data for States that fail to meet all three criteria in § 447.203(c)(1), and CMS producing and publishing the comparative payment rate analysis proposed in § 447.203(b).

We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). Maintaining the benefits in previous § 447.203(b)(5)(ii)(A) through (H) might have simplified the transition from the AMRP process to the payment rate transparency and comparative payment rate analysis requirements. However, our experience implementing the 2015 final rule with comment period, as well as interested parties' and States' feedback about the AMRP process, encouraged us to review and reconsider the current list of benefits subject to the AMRP process under current regulations § 447.203(b)(5)(ii)(A) through (H) to determine where we could decrease the level of effort required from States while still allowing ourselves an opportunity to review for access concerns. During our review of the current list of benefits under § 447.203(b)(5)(ii)(A) through (H), we considered, but did not propose, requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis. However, when considering the existing burden of the AMRP process under current § 447.203)(b), we believed that expanding the list of benefits to include under proposed § 447.203(b) and (c) would not support our goal to develop a new access strategy that aims to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i). Additionally, we solicited public comment regarding our alternative consideration to propose maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or propose requiring all mandatory Medicaid benefit categories.

We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis. Rather than proposing States distinguish their Medicaid payment rates by each provider type in the comparative payment rate analysis, we considered proposing States calculate an average Medicaid payment rate of all providers for each E/M CPT code. This consideration would have simplified the comparative payment rate analysis because States would include a single, average Medicaid payment rate amount and only need to separately analyze their Medicaid payment rates for services delivered to pediatric and adult populations, if they varied. However, calculating an average for the Medicaid payment rate has limitations, including sensitivity to extreme values and inconsistent characterizations of the payment rate between Medicaid and Medicare. In this rule, we propose to characterize the Medicare payment rate as the non-facility payment rate listed on the Medicare PFS for the E/M CPT/HCPCS codes subject to the comparative payment rate analysis. If we were to propose the Medicaid payment rate be calculated as an average Medicaid payment rate of all provider types for the same E/M CPT/HCPCS code, then States' calculated average Medicaid payment rate could include a wide variety of provider types, from a single payment rate for physicians to an average of three payment rates for physicians, physician assistants, and nurse practitioners. This wide variation in how the Medicaid payment rate is calculated among States would provide a less meaningful comparative payment rate analysis to Medicare. The extremes and outliers that would be diluted by using an average are not necessarily the same for both Medicaid and Medicare, so even if both sides of the comparison used an average, we would not be able to look more closely at specific large differences between the respective rates. As previously noted in section II. of this final rule, we solicited public comment on the proposed characterization of the Medicaid payment rate, which accounts for variation in payment rates for pediatric and adult populations and distinguishes payment rates by provider type, in the comparative payment rate analysis. Additionally, we solicited public comment regarding our alternative consideration to propose requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis.

We considered, but did not propose, requiring States to use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer, such as pediatric dental services or HCBS. The impact of requiring a different point of comparison, other than Medicare, would have carried forward the current regulation requiring States to ''include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, provider payment rates in Medicaid managed care) and private health insurer payment rates within geographic areas of the State'' in their AMRPs. As previously discussed in this rule, FFS States expressed concerns following the 2015 final rule with comment period that private payer payment rates were proprietary information and not available to them, therefore, the challenges to comply with current regulations would be carried forward into the proposed rule. Therefore, we also considered, but did not propose, using various payment rate benchmarking approaches for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. As previously noted in section II. of this final rule, we considered benchmarks based on national Medicaid payment averages for certain services included within the LTSS benefit category, benchmarks that use average daily rates for certain HCBS that can be compared to other State Medicaid programs, and benchmarks that use payment data specific to the State's Medicaid program for similarly situated services so that the service payments may be benchmarked to national average. Notwithstanding the

previously described limitations of the alternative considered for situations where differences between Medicaid and Medicare coverage and payment exists, we solicited public comment regarding our alternative consideration to propose States use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer or States use a payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. Specifically, we solicited public comment on the feasibility and burden on States to implement these alternatives considered for the proposed comparative payment rate analysis. For any comparison to other State Medicaid programs or to a national benchmark, we also solicited public comment on the appropriate role for such a comparison in the context of the statutory requirement to consider beneficiary access relative to the general population in the geographic area.

We considered, but did not propose, various timeframes for the comparative payment rate analysis, including annual (every year), triennial (every 3 years), or quinquennial (every 5 years) updates after the initial effective date of January 1, 2026. As noted in section II. of this final rule, we did not propose an annual timeframe as we believed that an annual update requirement was too frequent due to many States' biennial legislative sessions that provide the Medicaid agency with authority it make Medicaid payment rate changes as well as create more or maintain a similar level of administrative burden of the AMRPs. While some States do have annual legislative sessions and may have annual Medicaid payment rate changes, we believed that proposing annual updates solely for the purpose of capturing payment rate changes in States that with annual legislative sessions would be overly burdensome and duplicative for States with biennial legislative sessions who do not have new, updated Medicaid payment rates to update in their comparative payment rate analysis. Therefore, for numerous States with biennial legislative sessions, the resulting analysis would likely not vary significantly from year to year. Additionally, the comparative payment rate analysis proposes to use the most recently published Medicare payment rates and we are cognizant that Medicare payment rate updates often occur on a quarterly basis. While Medicare often increases rates by the market basket inflation amount, as well as through rulemaking, it does not always result in payment increases for providers.[420] [421] We also considered, but did not propose, maintaining the triennial (every 3 years) timeframe currently in regulation, because we thought it necessary to make significant changes to the non-SPA-related reported in § 447.203(b) that would represent a significant departure from the initial AMRP process in the 2015 final rule with comment in the current § 447.203(b)(1) and this new proposed approach did not lend itself to the triennial timeframe of the current AMRP process. Lastly, we considered, but did not propose, the comparative payment rate analysis be published on a quinquennial basis (every 5 years), because this timeframe was too infrequent for the comparative payment rate analysis to provide meaningful, actionable information. As previously noted in section II. of this rule, we are solicited public comment on the proposed timeframe for the initial publication and biennial update requirements of the comparative payment rate analysis as proposed in § 447.203(b)(4). Additionally, we solicited public comment regarding our alternative consideration to propose an annual, triennial, or quinquennial timeframe for the updating the comparative payment rate analysis after the initial effective date.

We considered, but did not propose, requiring the comparative payment rate analysis be submitted directly to us, as this would not achieve the public transparency goal of the proposed rule. As proposed in § 447.203(b)(3), we are requiring States develop and publish their Medicaid comparative payment rate analysis on the State's website in an accessible and easily understandable format. This proposal is methodologically similar to the current regulation, which requires AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance. As previously noted in section II. of this rule, we solicited public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services and comparative payment rate analysis and payment rate disclosure information on the State's website under the proposed § 447.203(b)(1) and (3), respectively. Additionally, we solicited public comment regarding our alternative consideration to propose requiring the comparative payment rate analysis be submitted directly to us and not publicly published.

We considered, but did not propose, that we produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates. Shifting responsibility for this analysis would remove some burden from States and allow us to do a full cross-comparison of State Medicaid payment rates to Medicare payment rates, while ensuring a consistent rate analysis across States. However, this approach would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it, and introduce uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Although our proposed approach still relies on State-supplied data, they are able to perform the comparisons on their own regardless of the readiness and compliance of any other State. Furthermore, we would need to validate its results with States and work through any discrepancies. Ultimately, we determined the increased lag time and uncertainty in results would diminish the utility of the rate analyses proposed in § 447.203(b), if performed by us instead of the States, to support our oversight of State compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on our proposal to require States to develop and publish a comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(2) and (3). Additionally, we solicited public comment regarding our alternative consideration to propose that we produce and publish the comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(2) and (3) for all States.

We considered, but did not propose, establishing alternative circumstances

[420] Although ''market basket'' technically describes the mix of goods and services used in providing health care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the various CMS input price indexes. A CMS market basket is described as a fixed-weight, Laspeyres-type index because it measures the change in price, over time, of the same mix of goods and services purchased in the base period. FAQ—Medicare Market Basket Definitions and General Information, updated May 2022. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf* Accessed January 4, 2023.

[421] Medicare Unit Cost Increases Reported as of April 2022. *https://www.cms.gov/files/document/ffs-trends-2021-2023-april-2022.pdf.* Accessed January 4, 2023.

from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring. We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This final rule will not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. We considered, but did not propose, setting a different percentage for the criteria that State Medicaid rates for each benefit category affected by the reductions or restructurings must, in the aggregate, be at or above 80 percent of the most recent comparable Medicare payment rates after the proposed reduction or restructuring as a threshold. We considered setting the threshold at 100 percent of Medicare to remain consistent with the 2017 SMDL. However, after conducting a literature review, we determined that 80 percent of the most recently published Medicare payment rates is currently the most reliable benchmark of whether a rate reduction or restructuring is likely to diminish access to care. We also considered, but did not propose, setting a different percentage for the criteria that proposed reductions or restructurings result in no more than 4 percent reduction of overall FFS Medicaid expenditures for a benefit category. We considered a variety of percentages, but determined that codifying the 4 percent threshold from the 2017 SMDL and proposed in the 2018 proposed rule [422] was the best option based on our experience implementing this established policy after the publication of the 2017 SMDL. Additionally, we received a significant number of comments in the 2018 proposed rule from State Medicaid agencies that signaled strong support for this percentage threshold as a meaningful threshold for future rate changes.[423] [424] [425] Lastly, we considered, but did not propose, defining what is meant by ''significant'' access concerns received through the public process described in § 447.204 when a State proposes a rate reduction or restructuring. As proposed, we expect State Medicaid agencies to make reasonable determinations about which access concerns are significant when raised through the public process, and as part of our SPA review, may request additional information from the State to better understand any access concerns that have been raised through public processes and whether they are significant. Based on our experience implementing the policies outlined in the 2017 SMDL and a literature review of relevant research about payment rate sufficiency, we proposed criteria for States proposing rate reductions or restructurings that would reduce the SPA submission requirements when those criteria are met. Additionally, each of these thresholds is one of a three-part test where States must meet all three, or else it will trigger a requirement for additional State analysis of the rate reduction or restructuring. As previously noted in section II. of this rule, we solicited public comment on the streamlined criteria proposed in § 447.203(c)(1). Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring regardless of the remaining criteria. This requirement would minimize administrative burden on States by not requiring States submit all items in § 447.203(c)(2) and establish a baseline for comparison if future rate reductions or restructurings are proposed that may lower the State's payment rates below 80 percent of the most recent Medicare payment rates. However, we determined that, while we believe 80 percent to be an effective threshold point, we did not want that to serve as the only trigger for additional analysis. As proposed, only States that do not meet all of the proposed requirements in § 447.203(c)(1) will have to submit the required data outlined in § 447.203(c)(2). As previously noted in section II. of this rule, we solicited public comment on our proposal to require all three criteria described in § 447.203(c)(1)(i) through (iii) for assessing the effect of a proposed payment rate reduction or payment restructuring on access to care. Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1), thereby eliminating the need for us to develop a template for States proposing rate reductions or restructurings. While this would reduce administrative burden on us and provide States with flexibility in determining relevant data for complying with statutory and regulatory requirements, we received feedback after the 2015 final rule with comment period that States found developing an AMRP from scratch with minimal Federal guidelines a challenging task and other interested parties noted that States had too much discretion in documenting sufficient access to care. Therefore, we proposed developing a template to support State analyses of rate reduction or restructuring SPAs that fail to meet the criteria in § 447.203(c)(1). As noted elsewhere in the preamble, we are releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), alongside this final rule. We also anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act. Additionally, we solicited public comment regarding our alternative consideration to propose allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1).

After careful consideration, we ultimately determined that the requirements in proposed § 447.203(b) and (c) would strike a more optimal balance between alleviating State and Federal administrative burden, while ensuring a transparent, data-driven, and consistent approach to States' implementation and our oversight of

[422] 83 FR 12696 at 12705.

[423] Connecticut Department of Social Services, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.*

[424] California Department of Health Care Services, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0090/attachment_1.pdf.*

[425] Florida Agency for Health Care Administration, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0083/attachment_1.pdf.*

State compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about the requirement to breakdown bundled payment rates into constituent services and rates, we added regulatory language to provide States with flexibility in complying with the payment rate transparency publication requirements when individual rates for constituent services within a State's bundle payment rate do not exist. Specifically, we added the following language: ''unless this information is not reasonably available'' to the requirement that ''in the case of a bundled or similar payment methodology'' States must ''identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' We also clarified in this final rule through a previous comment response that facility payment rates (for example, provider-specific rates and per diem rates) are not considered to be bundled payment rates and are not subject to the payment rate transparency provisions. We believe this additional regulatory language and clarification will reduce administrative burden on States by narrowing the scope of bundled payment rates subject to the payment rate transparency requirements. While we still believe this requirement is necessary to ensure maximum transparency of payment rates in the case of bundled fee schedule payment rates, it is also necessary to account for circumstances where a State does not have information available to comply with this regulatory requirement.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about requiring States with prospective effective dates to publish rates that are not yet in effect, we added regulatory language to address this circumstance. Specifically, the regulation now states that the agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than either 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or 1 month following the effective date of the approved amendment, whichever date occurs latest. If we finalized the regulatory language as proposed, then States would be required to update their payment rate transparency publications with payment rates that are not yet in effect, and this would not align with our transparency efforts to ensure a States' payment rate transparency publication is as current as possible, and accurate once published.

We considered finalizing the payment rate transparency provisions under § 447.203(b)(1) with a requirement to organize the payment rate transparency publication by CPT/HCPCS code, similar to the comparative payment rate analysis, but in response to commenter concerns about administrative burden on States to comply with the provisions as proposed, we did not require the payment rate transparency publication to be organized in this manner. While we still require both the payment rate transparency publication and comparative payment rate analysis to be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service, requiring the publication to be organized by CPT/HCPCS code would create substantial burden for States that do not current organize their payment rates in this manner as all fee schedule payment rates are subject to this provision. By not requiring the payment rate transparency publication to be organized a particular way, we are providing States with the flexibility to use existing fee schedule publications for compliance with the regulations finalized in this rule.

We considered, but did not finalize, an increase to the 80 percent of Medicare threshold in § 447.203(c)(1)(i) to 100 percent of Medicare as suggested by some of the commenters. Taking such an action would have increased the threshold for States to qualify for the streamlined review process and increased administrative burden on the States. We ultimately decided not to pursue this alternative because this threshold was not intended to provide absolute assurance that a provider would participate in the Medicaid program. Instead, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act and allow CMS to focus its review efforts on proposals at the highest risk of access concerns. We also note that the 80 percent threshold was just one of three criteria that must be met for a streamlined review. Our stated intention in this rule was that we were intending this to provide States with relief from the more burdensome AMRP process defined in the 2015 final rule with comment period, and establishing a higher threshold would not fit within that stated purpose.

We received public comments on several of these alternatives, but many of those comments blended with discussion of the relevant provisions, so in general our responses to those comments are contained in section II.C. However, we did receive some comments on alternatives not already addressed in this final rule.

Comment: One commenter responded to our decision not to propose adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. That commenter stated that CMS' reliance on existing State processes, such as the ongoing provider and beneficiary feedback channels and the public process requirement for States submitting a SPA that proposed to reduce or restructure Medicaid services would be acceptable if the existing processes are responsive and delivered timely action when concerns are raised.

Response: We agree with the commenter regarding existing processes being responsive and timely. As described in the proposed rule, these processes must meet requirements under newly finalized § 447.203(c)(4) (which includes existing requirements from the 2015 final rule with comment period that was relocated from § 447.203(b)(7)), as well as § 447.204 (which includes existing requirements from the 2015 final rule with comment period with confirming changes to align with this final rule). These existing regulatory requirements require States have ongoing mechanisms for beneficiary and provider input on access to care in which they promptly respond to public input and maintain a record the public input, as well as how the State responded. While this is a general requirement for ensuring States have a method for collecting access to care issues from the public, these requirements also specifically apply to States proposing a rate reduction or restructuring.

Comment: One commenter agreed with CMS' decision to exclude outpatient drugs from the proposed comparative payment rate analysis under § 447.203(b)(2) noting that, in addition to the reasons CMS outlined in the proposed rule, the cost of outpatient drugs can change weekly and there are anticipated cost differences compared to other payers, such as Medicare or States. The commenter recommended that, if CMS decides to subject outpatient drugs to the comparative payment rate

analysis, then CMS should develop a unique methodology for States to follow in making the comparison to another payer.

Response: We appreciate the commenter's support for our decision, as well as their recommendation for how we could subject outpatient drugs to the comparative payment rate analysis if we did end up deciding to include them. We are not changing the services subject to the analysis in this final rule, although we note we have updated ''outpatient behavioral health services'' to ''outpatient mental health and substance use disorder services.''

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 48 showing the classification of the impact associated with the provisions of this final rule. Note, Table 47 shown previously in this final rule provides a summary of the one-time and annual costs estimates.

TABLE 48: Accounting Table

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Regulatory Review Costs				
Annualized Monetized ($million/year)	.112	2023	7%	2024 - 2028
	.117	2023	3%	2024 - 2028
Costs to States				
Annualized Monetized ($million/year)	72.12	2023	7%	2024 - 2028
	75.22	2023	3%	2024 - 2028
Costs to Beneficiaries				
Annualized Monetized ($million/year)	0.47	2023	7%	2024 - 2028
	0.49	2023	3%	2024 - 2028
Costs to Providers				
Annualized Monetized ($million/year)	102.05	2023	7%	2024 - 2028
	106.44	2023	3%	2024 - 2028
Costs to Managed Care Plans				
Annualized Monetized ($million/year)	6.84	2023	7%	2024 - 2028
	7.13	2023	3%	2024 - 2028

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that *almost all* of Home Health Care Services, Services for the Elderly and Persons with Disabilities, and Direct Health and Medical Insurance Carriers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $9.0 million to $47 million in any 1 year).

For purposes of the RFA, approximately 95 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of $47 million or less in any 1 year.

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards* HCBS Provider Costs and Managed care Plan fall in the North American Industrial Classification System 621610 Home Health Care Services, 624120 Services for the Elderly and Persons with Disabilities, and 524114 Direct Health and Medical Insurance Carriers.

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TABLE 49: HCBS Providers Costs and Managed Care Plan Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/ Small Entity Threshold	Total Small Businesses
621610	Home Health Care Services	$19 Million	22,840
624120	Services for the Elderly and Persons with Disabilities	$15 Million	26,051
524114	Direct Health and Medical Insurance Carriers	$47 Million	455

Source: 2017 Statistics of U.S. Businesses

TABLE 50: NAICS 62160 Home Health Care Servies ($19 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**22,840**	**100%**	**$ 5,320,704.31**
<$100K	5,861	26%	$ 35,948.98
$100K -$499K	5,687	25%	$ 256,725.47
$500 - $999K	3,342	15%	$ 414,742.71
$1M - $2.49M	4,434	19%	$ 1,201,189.90
$2.5M - $4.9M	1,951	9%	$ 1,135,879.03
$5M - $7.5M	672	3%	$ 667,476.88
$7.6M - $9.9M	356	2%	$ 496,663.20
$10M - $14.9M	346	2%	$ 642,844.22
$15M - $19.9M	191	1%	$ 469,233.92
LARGE FIRMS			
Receipts > $20M	961	N/A	$ 6,451,412.39 (for firms > $100M

Source: 2017 Statistics of U.S. Businesses

TABLE 51: NAICS 624120 Services for the Elderly and Persons with Disabilities ($15 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**26,051**	**100%**	**$ 3,117,267.70**
<$100K	8,293	32%	$ 31,953.45
$100K -$499K	6,864	26%	$ 215,283.61
$500 - $999K	3,449	13%	$ 298,760.76
$1M - $2.49M	4,093	16%	$ 764,108.16
$2.5M - $4.9M	1,827	7%	$ 705,634.63
$5M - $7.5M	695	3%	$ 404,539.85
$7.6M - $9.9M	401	2%	$ 295,453.88
$10M - $14.9M	429	2%	$ 401,533.34
LARGE FIRMS			
Receipts > $15M	1,211	N/A	$57,136,066.67 (for firms > $100M

Source: 2017 Statistics of U.S. Businesses

TABLE F52: NAICS 524114 Direct Health and Medical Insurance Carriers ($47 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**455**	**100%**	**$25,087,240.51**
<$100K	79	17%	$ 52,101.27
$100K -$499K	170	37%	$ 542,278.48
$500 - $999K	42	9%	$ 388,329.11
$1M - $2.49M	48	11%	$ 946,037.97
$2.5M - $4.9M	31	7%	$ 1,371,468.35
$5M - $7.5M	12	3%	$ 939,797.47
$7.6M - $9.9M	10	2%	$ 1,126,303.80
$10M - $14.9M	14	3%	$ 2,033,645.57
$15M - $19.9M	13	3%	$ 2,802,481.01
$20M- $24.9M	5	1%	$ 1,389,189.87
$25M- $29.9M	4	1%	$ 1,523,012.66
$30M - $34.9M	9	2%	$ 3,417,797.47
$35M- $39.9M	6	1%	$ 2,599,443.04
$40M- $49.9M	12	3%	$ 5,955,354.43
LARGE FIRMS			
Receipts > 50M	290	N/A	$ 3,244,413,424.12 (for firms > $100M

Tables 50, 51, and 52 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. All the industries combined, according to the 2017 Economic Census, earned approximately $46,771,961,000.00. Hence, all the costs combined, amounts to about 1 percent.

TABLE 53: NAICS Classification of Services, the Distribution of Costs, Annualized Cost per Industry, Average Annual Revenue for Small Firms, and Revenue Test

Services	NAICS	Percentage of Costs	Annualized Cost* per Industry	Avg. Annual Revenue for Small Firms	Revenue Test
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent	$370,989,000	**$5,320,704.31**	**1.4%**
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent	$248,562,630.00	**$3,117,267.70**	**1.3%**
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent	$137,265,930.00	**$25,087,240.51**	**18%**

*Annualized Cost per Industry was determined from the Accounting Table 7.

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Therefore, as its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent.

According to Table 12, for Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120), we do not believe that the 3 to 5 percent threshold will be reached by the requirements in this final rule. However, Home Health Care Services (621610) has a substantial effect on its small businesses.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities in

the Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120) industries. However, the Secretary cannot certify that this final rule will not have a significant economic impact on the Home Health Care Services (621610) industry.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on the operations of small rural hospitals since small hospitals are not affected by the proposed rule. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This final rule will impose a mandate that will result in the expenditure by the private sector, of more than $177 million in at least 1 year.

Several of the provisions in this final rule address gaps in existing regulations. In these cases, the costs for States to implement the changes to existing processes will likely be minimal. For the remaining areas of the rule, we have sought to minimize burden whenever possible, while still achieving the goals of this rulemaking, as reflected in the burden analyses and estimates described in sections III. and IV. of this final rule. We further note that, as reflected in those sections, States would be able to claim administrative match for the work required to implement the proposals.

We have described the projected paperwork costs to providers, as well as to States, the Federal Government, and managed care plans (as applicable) in the Collection of Information section (section III. of this final rule.) We note that the requirements finalized at § 441.302(k) regarding the HCBS payment adequacy requirements represent the biggest impact on small entities. We have not calculated an additional financial impact on providers beyond what is reflected in the Collection of Information (in section III.) and the Regulatory Impact Analysis (section (this section, section IV. of the final rule.) The requirements finalized at § 441.302(k) may require that a number of HCBS providers ensure that they allocate more of their Medicaid payments to direct care workers than they had prior to the implementation of § 441.302(k); this does not reflect a change in the Medicaid payments. The underlying assumption of this requirement is that providers are capable of allocating 80 percent their Medicaid payments to direct care workers by ensuring that payments are allocated efficiently and that overhead is kept to a minimum. Additionally, as discussed in II.B.5. of this final rule, we have provided States with several flexibilities for certain providers that would be unable to operate successfully under this requirement. While we received anecdotal data from public commenters regarding current Medicaid rates, workforce shortages, and survey responses from providers regarding their reaction to the proposal in the proposed rule, we did not receive data (nor do we have other sources of data) on which to estimate additional costs associated with § 441.302(k) aside from what is presented in the Collection of Information and Regulatory Impact Analysis sections above.

H. Federalism

E.O. 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct costs on State or local governments, preempt State law, or otherwise have Federalism implications. As mentioned in the previous section of this rule, the costs to States by our estimate do not rise to the level of specified thresholds for significant burden to States. In addition, many proposals amend existing requirements or further requirements that already exist in statute, and as such would not create any new conflict with State law.

I. Conclusion

The policies in this final rule, will enable us to implement enhanced access to health care services for Medicaid beneficiaries across FFS, managed care, and HCBS delivery systems.

The analysis in section IV. of this final rule, together with the rest of this preamble, provides a regulatory impact analysis. In accordance with the provisions of E.O. 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 11, 2024.

List of Subjects

42 CFR Part 431

Administrative practice and procedure, Consumer protection, Grant programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirement.

42 CFR Part 438

Administrative practice and procedure, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 441

Administrative practice and procedure, Consumer protection, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 431.12 is revised to read as follows:

§ 431.12 Medicaid Advisory Committee and Beneficiary Advisory Council.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee

(MAC) with a dedicated Beneficiary Advisory Council (BAC) comprised of current and former Medicaid beneficiaries, their family members, and caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.

(b) *State plan requirement.* The State plan must provide for a MAC and a BAC that will advise the director of the single State Agency for the Medicaid program on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(c) *Selection of members.* The Director of the single State Agency for the Medicaid program must select members for the MAC and BAC for a term of length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis. The State must create a process for recruitment and selection of members and publish this information on the State's website as specified in paragraph (f).

(d) *MAC membership and composition.* The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:

(1) For the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

(2) The remaining committee members must include representation of at least one from each of the following categories:

(A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.

(B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.

(C) As applicable, participating Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2, or a health plan association representing more than one such plans; and

(D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio, non-voting members.

(e) *Beneficiary Advisory Council.* The State must form and support a BAC, which can be an existing beneficiary group, that is comprised of: individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAC.

(2) The BAC must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAC member preparation for each MAC meeting.

(f) *MAC and BAC administration.* The State agency must create standardized processes and practices for the administration of the MAC and the BAC that are available for public review on the State website. The State agency must—

(1) Develop and publish, by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members. States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.

(2) Develop and publish by posting publicly on its website a process for MAC and BAC member recruitment and selection along with a process for selection of MAC and BAC leadership;

(3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC and BAC; the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.

(4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. BAC meetings are not required to be open to the public, unless the State's BAC members decide otherwise. The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.

(5) Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, at a minimum, telephone dial-in option at the MAC and BAC meetings for its members. If the MAC or BAC meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;

(6) Ensure that the meeting times and locations for MAC and BAC meetings are selected to maximize member attendance and may vary by meeting; and

(7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.

(g) *MAC and BAC participation and scope.* The MAC and BAC participants must have the opportunity to advise the director of the single State Agency for the Medicaid program on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAC must determine, in collaboration with the State, which topics to provide advice on related to—

(1) Additions and changes to services;

(2) Coordination of care;

(3) Quality of services;

(4) Eligibility, enrollment, and renewal processes;

(5) Beneficiary and provider communications by State Medicaid agency and Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2;

(6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program;

(7) Access to services; and

(8) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.

(h) *State agency staff assistance, participation, and financial help.* The single State Agency for the Medicaid program must provide staff to support planning and execution of the MAC and the BAC to include—

(1) Recruitment of MAC and BAC members;

(2) Planning and execution of all MAC and BAC meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must produce and post on its website an annual report as specified in paragraph (i) of this section; and

(3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include—

(i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement;

(ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and

(iii) Attendance by at least one staff member from the single State Agency for the Medicaid program's executive staff at all MAC and BAC meetings.

(i) *Annual report.* The MAC, with support from the State, must submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then—

(1) Provide MAC members with final review of the report;

(2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and

(3) Post the report to the State's website. States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

(j) *Federal financial participation.* FFP is available at 50 percent of expenditures for the MAC and BAC activities.

(k) *Applicability dates.* Except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) of this section are applicable July 9, 2025.

■ 3. Section 431.408 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 431.408 State public notice process.

(a) * * *

(3) * * *

(i) The Medicaid Advisory Committee and Beneficiary Advisory Council that operate in accordance with § 431.12 of this subpart; or

* * * * *

PART 438—MANAGED CARE

■ 4. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) [Reserved]

(b) *Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.* The State must comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 6. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 7. Section 441.301 is amended by revising paragraphs (c)(1) introductory text and (c)(3), and adding paragraph (c)(7) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(c) * * *

(1) *Person-centered planning process.* The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term ''individual'' is used throughout § 441.301(c)(1) through (3), it includes the individual's authorized representative if applicable. In addition, the person-centered planning process:

* * * * *

(3) *Review of the person-centered service plan*—(i) *Requirement.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(3), that it ensures the following minimum performance levels are met:

(A) Complete a reassessment of functional need at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days; and

(B) Review, and revise as appropriate, the person-centered service plan, based upon the reassessment of functional need, at least every 12 months, for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days.

(iii) *Applicability date.* States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

* * * * *

(7) *Grievance system*—(i) *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.

(ii) *Definitions.* As used in this section:

Grievance means an expression of dissatisfaction or complaint related to

the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section, regardless of whether remedial action is requested.

Grievance system means the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

(iii) *General requirements.* (A) The beneficiary or a beneficiary's authorized representative, if applicable, may file a grievance. All references to beneficiary include the role of the beneficiary's representative, if applicable.

(*1*) Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative.

(*2*) A provider cannot file a grievance that would violate the State's conflict of interest guidelines, as required in § 441.540(a)(5).

(B) The State must:

(*1*) Base its grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this paragraph (c)(7);

(*2*) Provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and providing meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability;

(*3*) Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf;

(*4*) Accept grievances and requests for extension of timeframes from the beneficiary;

(*5*) Provide to the beneficiary the notices and information required under this subsection, including information on their rights under the grievance system and on how to file grievances, and ensure that such information is accessible for individuals with disabilities and individuals with Limited English Proficiency in accordance with § 435.905(b);

(*6*) Review any grievance resolution with which the beneficiary is dissatisfied; and

(*7*) Provide information about the grievance system to all providers and subcontractors approved to deliver services.

(C) The process for handling grievances must:

(*1*) Allow the beneficiary to file a grievance with the State either orally or in writing;

(*2*) Acknowledge receipt of each grievance;

(*3*) Ensure that the individuals who make decisions on grievances are individuals:

(*i*) Who were neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual;

(*ii*) Who are individuals who have the appropriate clinical and non-clinical expertise, as determined by the State; and

(*iii*) Who consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State;

(*4*) Provide the beneficiary a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance. The State must inform the beneficiary of the limited time available for this sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section;

(*5*) Provide the beneficiary their case file, including medical records in compliance with the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E), other documents and records, and any new or additional evidence considered, relied upon, or generated by the State related to the grievance. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section; and

(*6*) Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

(iv) *Filing timeframes.* A beneficiary may file a grievance at any time.

(v) *Resolution and notification*—(A) *Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(B) *Resolution timeframes.* For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

(C) *Extension of timeframes.* The States may extend the timeframe from that in paragraph (c)(7)(v)(B) of this section by up to 14 calendar days if –

(*1*) The beneficiary requests the extension; or

(*2*) The State documents that there is need for additional information and how the delay is in the beneficiary's interest.

(D) *Requirements following extension.* If the State extends the timeframe not at the request of the beneficiary, it must complete all of the following:

(*1*) Make reasonable efforts to give the beneficiary prompt oral notice of the delay;

(*2*) Within 2 calendar days of determining a need for a delay, but no later than the timeframes in paragraph (c)(7)(v)(B) of this section, give the beneficiary written notice of the reason for the decision to extend the timeframe; and

(*3*) Resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires.

(vi) *Format of notice.* The State must establish a method to notify a beneficiary of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 435.905(b) of this chapter.

(vii) *Recordkeeping.* (A) The State must maintain records of grievances and must review the information as part of its ongoing monitoring procedures.

(B) The record of each grievance must contain, at a minimum, all of the following information:

(*1*) A general description of the reason for the grievance;

(*2*) The date received;

(*3*) The date of each review or, if applicable, review meeting;

(*4*) Resolution of the grievance, as applicable;

(*5*) Date of resolution, if applicable; and

(*6*) Name of the beneficiary for whom the grievance was filed.

(C) The record must be accurately maintained in a manner available upon request to CMS.

(viii) *Applicability date.* States must comply with the requirement at paragraph (c)(7) of this section beginning 2 years after July 9, 2024.

■ 8. Section 441.302 is amended by—
■ a. Adding paragraph (a)(6);
■ b. Revising paragraph (h); and
■ c. Adding paragraph (k).

The additions and revision read as follows:

§ 441.302 State assurances.

* * * * *

(a) * * *

(6) Assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents.

(i) *Requirements.* The State must:

(A) Define critical incident to include, at a minimum—

(*1*) Verbal, physical, sexual, psychological, or emotional abuse;

(*2*) Neglect;

(*3*) Exploitation including financial exploitation;

(*4*) Misuse or unauthorized use of restrictive interventions or seclusion;

(*5*) A medication error resulting in a telephone call to, or a consultation with, a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or

(*6*) An unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect;

(B) Use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, that, at a minimum, enables—

(*1*) Electronic critical incident data collection;

(*2*) Tracking (including of the status and resolution of investigations); and

(*3*) Trending;

(C) Require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(D) Use claims data, Medicaid fraud control unit data, and data from other State agencies, such as Adult Protective Services or Child Protective Services, to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occur as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(E) Ensure that there is information sharing on the status and resolution of investigations, such as through the use of information sharing agreements, between the State and the entity or entities responsible in the State for investigating critical incidents as defined in paragraph (a)(6)(i)(A) of this section if the State refers critical incidents to other entities for investigation;

(F) Separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes; and

(G) Demonstrate that it meets the requirements in paragraph (a)(6) of this section through the reporting requirement at § 441.311(b)(1).

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(2), that it meets the following minimum performance levels:

(A) Initiate an investigation, within State-specified timeframes, for no less than 90 percent of critical incidents;

(B) Complete an investigation and determine the resolution of the investigation, within State-specified timeframes, for no less than 90 percent of critical incidents; and

(C) Ensure that corrective action has been completed within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

(iii) *Applicability date.* States must comply with the requirements in paragraph (a)(6) of this section beginning 3 years after July 9, 2024; except for the requirement at paragraph (a)(6)(i)(B) of this section, with which the State must comply beginning 5 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years after July 9, 2024, except for the requirement at paragraph (a)(6)(i)(B) of this section, with which the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after 5 years after July 9, 2024.

* * * * *

(h) *Reporting.* Assurance that the agency will provide CMS with information on the waiver's impact, including the data and information as required in § 441.311.

* * * * *

(k) *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

(1) *Definitions.* As used in this paragraph—

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

(2) *Requirement.* (i) Except as provided in paragraph (k)(2)(ii) of this section, the State must demonstrate annually, through the reporting requirements at paragraph (k)(6) of this section and § 441.311(e), that it meets the minimum performance levels in paragraph (k)(3) of this section for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), that are delivered by direct care workers and authorized under section 1915(c) of the Act.

(ii) *Treatment of certain payment data under self-directed services delivery models.* If the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3) of this section.

(3) *Minimum performance at the provider level.* Except as provided in paragraphs (k)(5) and (7) of this section, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) to a provider for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the provider's total compensation to direct care workers:

(i) Except as provided in paragraph (k)(3)(ii) of this section, the State must ensure that each provider spends 80 percent of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(ii) At the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(4) *Small provider minimum performance level*—(i) *Small provider criteria.* The State may develop reasonable, objective criteria through a transparent process to identify small providers that the State would require to meet the minimum performance requirement at paragraph (k)(3)(ii) of this section. The transparent process for developing criteria to identify providers that qualify for the minimum performance requirement in paragraph (k)(3)(ii) of this section must include public notice and opportunities for comment from interested parties.

(ii) *Small provider minimum performance level.* The State must set the percentage for a small provider to meet the minimum performance level at paragraph (k)(3)(ii) of this section based on reasonable, objective criteria it develops through a transparent process that includes public notice and opportunities for comment from interested parties.

(5) *Hardship exemption.* The State may develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at paragraph (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with paragraph (k)(3) of this section. The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, then the State does not include that provider in its calculation of the State's compliance with the minimum performance level at paragraph (k)(3) of this section.

(6) Reporting on small provider minimum performance level and hardship exemption.

(i) States that establish a small provider minimum performance level under paragraph (k)(4) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section;

(B) The State's small provider minimum performance level developed in accordance with paragraph (k)(4)(ii) of this section;

(C) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level at paragraph (k)(4) of this section; and

(D) A plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time.

(ii) States that provide a hardship exemption in accordance with paragraph (k)(5) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's hardship criteria developed in accordance with paragraph (k)(5) of this section;

(B) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption as provided in paragraph (k)(5) of this section; and

(C) A plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

(iii) CMS may waive the reporting requirements in paragraphs (k)(6)(i)(D) or (k)(6)(ii)(C) of this section, as applicable, if the State demonstrates it has applied the small provider minimum performance level at paragraph (k)(4)(ii) of this section or the hardship exemption at paragraph (k)(5) of this section to less than 10 percent of the State's providers.

(7) *Exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641.* The Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at paragraph (k) of this section.

(8) *Applicability date.* States must comply with the requirements set forth in paragraph (k) of this section beginning 6 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4) in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 6 years after July 9, 2024.

■ 9. Section 441.303 is amended by revising paragraph (f)(6) to read as follows:

§ 441.303 Supporting documentation required.

* * * * *

(f) * * *

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver

participants in a waiver amendment. If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

* * * * *

■ 10. Section 441.311 is added to subpart G to read as follows:

§ 441.311 Reporting requirements.

(a) *Basis and scope.* Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interests of Medicaid beneficiaries. This section describes the reporting requirements for States for section 1915(c) waiver programs, under the authority at section 1902(a)(6) and (a)(19) of the Act.

(b) *Compliance reporting*—(1) *Incident management system.* As described in § 441.302(a)(6)—

(i) The State must report, every 24 months, in the form and manner, and at a time, specified by CMS, on the results of an incident management system assessment to demonstrate that it meets the requirements in § 441.302(a)(6).

(ii) CMS may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

(2) *Critical incidents.* The State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS:

(i) Number and percent of critical incidents for which an investigation was initiated within State-specified timeframes;

(ii) Number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes;

(iii) Number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes.

(3) *Person-centered planning.* To demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS—

(i) Percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(4) Annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.

(c) *Reporting on the Home and Community-Based Services Quality Measure Set,* as described in § 441.312.

(1) *General rules.* The State—

(i) Must report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the measure set described in § 441.312(d), on all measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) of this subpart.

(ii) May report on all other measures in the Home and Community-Based Services Quality Measure Set that are not described in § 441.312(d)(1)(ii) and (iii) of this subpart.

(iii) Must establish, subject to CMS review and approval, State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(iv) May establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are not identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(2) Measures identified per § 441.312(d)(1)(iii) of this subpart will be reported by the Secretary on behalf of the State.

(3) In reporting on Home and Community-Based Services Quality Measure Set measures, the State may, but is not required to:

(i) Report on the measures identified by the Secretary pursuant to § 441.312(c) of this subpart for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

(ii) Report on the populations identified by the Secretary pursuant to § 441.312(c) of this subpart for whom reporting will be, but is not yet required.

(d) *Access reporting.* The State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS:

(1) *Waiver waiting lists.* (i) A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, as described in § 441.303(f)(6), and maintains a list of individuals who are waiting to enroll in the waiver program. This description must include, but is not limited to:

(A) Information on whether the State screens individuals on the list for eligibility for the waiver program;

(B) Whether the State periodically re-screens individuals on the list for eligibility; and

(C) The frequency of re-screening, if applicable.

(ii) Number of people on the list of individuals who are waiting to enroll in the waiver program, if applicable.

(iii) Average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list of individuals waiting to enroll in the waiver program, if applicable.

(2) *Access to homemaker, home health aide, personal care, and habilitation services.* (i) Average amount of time from when homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), are initially approved to when services began, for individuals newly receiving services within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of authorized hours for homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that

are provided within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(e) *Payment adequacy*—(1) *Definitions.* As used in this paragraph (e)-

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that are spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Cost of personal protective equipment for direct care workers.

(2) *Payment adequacy reporting.* (i) Except as provided in paragraphs (e)(2)(ii) and (e)(4) of this section, the State must report to CMS annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

(ii) If *the* State provides that homemaker, home *health* aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

(3) *Payment adequacy reporting readiness.* One year prior to the applicability date for paragraph (e)(2)(i) of this section, the State must report on its readiness to comply with the reporting requirement in (e)(2)(i) of this section.

(4) *Exclusion of data from the Indian Health Service and Tribal health programs that are subject to 25 U.S.C. 1641.* States must exclude the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2) of this section.

(f) *Applicability dates.* (1) The State must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after July 9, 2024; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

(2) The State must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after July 9, 2024; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after July 9, 2024.

■ 11. Section 441.312 is added to subpart G to read as follows:

§ 441.312 Home and community-based services quality measure set.

(a) *Basis and scope.* Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. This section describes the Home and Community-Based Services Quality Measure Set, which States are required to use in section 1915(c) waiver programs to promote public transparency related to the administration of Medicaid-covered HCBS, under the authority at sections 1102(a) and 1902(a)(6) of the Act.

(b) *Definitions.* As used in this subpart—

(1) *Attribution rules* means the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Home and Community-Based Services Quality Measure Set.

(2) *Home and Community-Based Services Quality Measure Set* means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section.

(c) *Responsibilities of the Secretary.* The Secretary shall—

(1) Identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section.

(2) Make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.

(3) Consult at least every other year with States and other interested parties identified in paragraph (g) of this section to—

(i) Establish priorities for the development and advancement of the Home and Community-Based Services Quality Measure Set;

(ii) Identify newly developed or other measures which should be added including to address any gaps in the measures included in the Home and Community-Based Services Quality Measure Set;

(iii) Identify measures which should be removed as they no longer strengthen the Home and Community-Based Services Quality Measure Set; and

(iv) Ensure that all measures included in the Home and Community-Based Quality Measure Set reflect an evidenced-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate.

(4) In consultation with States, develop and update, no more frequently than every other year, the Home and Community-Based Services Quality Measure Set Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

(d) *Process for developing and updating the HCBS Quality Measure Set.* The process for developing and updating the Home and Community-Based Services Quality Measure Set Quality Measure Set will address all of the following:

(1) Identification of all measures in the Home and Community-Based Services Quality Measure Set, including:

(i) Measures newly added and measures removed from the prior version of the Home and Community-Based Services Quality Measure Set;

(ii) The specific measures for which reporting is mandatory;

(iii) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(iv) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.

(2) Technical information to States on how to collect and calculate the data on the Home and Community-Based Services Quality Measure Set.

(3) Standardized format and reporting schedule for reporting measure data required under this section.

(4) Procedures that State agencies must follow in reporting measure data required under this section.

(5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (e) of this section, which may include, but is not limited to beneficiaries—

(i) Receiving services through specified delivery systems, such as those enrolled in a MCO, PIHP, or PAHP as defined in § 438.2 or receiving services on a fee-for-service basis;

(ii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums or cost sharing;

(iii) Who are older adults;

(iv) Who have physical disabilities;

(v) Who have intellectual and development disabilities;

(vi) Who have serious mental illness; and

(vii) Who have other health conditions.

(6) Technical information on attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (d)(5) of this section, during the reporting period.

(7) The subset of measures among the measures in the Home and Community-Based Services Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with paragraphs (b)(2) and (g) of this section.

(8) Describe how to establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set.

(e) *Phasing in of certain reporting.* As part of the process that allows for developing and updating the Home and Community-Based Services Quality Measure Set described in paragraph (d) of this section, the Secretary may provide that mandatory State reporting for certain measures and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting.

(f) *Selection of measures for stratification.* In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (d)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after July 9, 2024, 50 percent of such measures by 6 years after July 9, 2024, and 100 percent of measures by 8 years after July 9, 2024.

(g) *Consultation with interested parties.* For purposes of paragraph (c)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) State Medicaid Agencies and agencies that administer Medicaid-covered home and community-based services.

(2) Health care and home and community-based services professionals, including members of the allied health professions who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs.

(3) Health care and home and community-based services professionals (including members of the allied health professions), providers, and direct care workers who provide services to older adults, children and adults with disabilities, and individuals with complex medical and behavioral health care needs who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor outcomes.

(4) Providers of home and community-based services.

(5) Direct care workers and national organizations representing direct care workers.

(6) Consumers and national organizations representing older adults, children and adults with disabilities, and individuals with complex medical needs.

(7) National organizations and individuals with expertise in home and community-based services quality measurement.

(8) Voluntary consensus standards setting organizations and other

organizations involved in the advancement of evidence-based measures of health care.

(9) Measure development experts.

(10) Such other interested parties as the Secretary may determine appropriate.

■ 12. Section 441.313 is added to subpart G to read as follows:

§ 441.313 Website transparency.

(a) The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311. The State must:

(1) Include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2 of this chapter;

(2) Include clear and easy to understand labels on documents and links;

(3) Verify no less than quarterly, the accurate function of the website and the timeliness of the information and links; and

(4) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(b) CMS must report on its website the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311 that the State reports to CMS.

(c) The State must comply with these requirements beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

■ 13. Section 441.450 is amended in paragraph (c) by revising the definition of ''Service plan'' to read as follows:

§ 441.450 Basis, scope, and definitions.

* * * * *

(c) * * *

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to live in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan supports the participant's engagement in community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends, and professionals, as desired or required by the participant, will be involved in the service-planning process. Service plans must meet the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

■ 14. Section 441.464 is amended by—

■ a. Adding paragraph (d)(5);

■ b. Redesignating paragraphs (e) and (f) as paragraphs (g) and (h); and

■ c. Adding new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 441.464 State assurances.

* * * * *

(d) * * *

(5) Implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(e) *Incident management system.* The State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents and adheres to requirements of § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(f) *Payment rates. Payment rates* are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

■ 15. Section 441.474 is amended by adding paragraph (c) to read as follows:

§ 441.474 Quality assurance and improvement plan.

* * * * *

(c) The quality assurance and improvement plan must comply with all components of §§ 441.302(k)(6), 441.311 and 441.312 and related reporting requirements relevant to the State's self-directed PAS program, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

■ 16. Section 441.486 is added to subpart J to read as follows:

§ 441.486 Website transparency.

For States subject to the requirements of subpart J, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

■ 17. Section 441.540 is amended by revising paragraph (c) to read as follows:

§ 441.540 Person-centered service plan.

* * * * *

(c) *Reviewing the person-centered service plan.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 18. Section 441.555 is amended by adding paragraph (e) to read as follows:

§ 441.555 Support system.

* * * * *

(e) Implement and maintain a grievance process, in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 19. Section 441.570 is amended by adding paragraphs (e) and (f) to read as follows:

§ 441.570 State assurances.

* * * * *

(e) An incident management system in accordance with § 441.302(a)(6) is implemented, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

(f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 20. Section 441.580 is amended by redesignating paragraph (i) as (j), and adding a new paragraph (i) to read as follows:

§ 441.580 Data collection.

* * * * *

(i) Data and information as required in §§ 441.302(k)(6) and 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

* * * * *

■ 21. Section 441.585 is amended by adding paragraph (d) to read as follows:

§ 441.585 Quality assurance system.

* * * * *

(d) The State must implement the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 22. Section 441.595 is added to subpart K to read as follows-

§ 441.595 Website transparency.

For States subject to the requirements of subpart K, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 23. Section 441.725 is amended by revising paragraph (c) to read as follows:

§ 441.725 Person-centered service plan.

* * * * *

(c) Reviewing the person-centered service plan. The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

■ 24. Section 441.745 is amended by–

■ a. Revising paragraph (a)(1)(iii) and adding (a)(1)(iv) through (vii);

■ b. Revising paragraph (b)(1)(i); and

■ c. Adding paragraph (b)(1)(v).

The revision and additions read as follows:

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

* * * * *

(a) * * *

(1) * * *

(iii) *Grievances.* A State must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(iv) *Appeals.* A State must provide individuals with advance notice of and the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E, of this chapter.

(v) A State must implement an incident management system in accordance with § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vi) A State must assure payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vii) A State must assure the submission of data and information as required in § 441.302(k)(6) and § 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

(b) * * *

(1) * * *

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement, including recognizing and reporting critical incidents, as defined in § 441.302(a)(6)(i)(A), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

(v) Implementation of the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

■ 25. Section 441.750 is added to subpart M to read as follows—

§ 441.750 Website transparency.

For States subject to the requirements of subpart M, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

PART 447—PAYMENT FOR SERVICES

■ 26. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1396r–8, and Pub. L. 111–148.

■ 27. Section 447.203 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b)(1) *Payment rate transparency.* The State agency is required to publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.

(i) For purposes of this paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.

(ii) The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.

(iii) Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service.

(iv) In the case of a bundled payment methodology, the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.

(v) If the rates vary, the State must separately identify the Medicaid fee-for-service payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(vi) The initial publication of the Medicaid fee-for-service payment rates shall occur no later than July 1, 2026 and include approved Medicaid fee-for-service payment rates in effect as of July 1, 2026. The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment. In the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State will ensure that its payment rate transparency

publication is updated no later than 1 month after the effective date of the most recent update to the payment rate.

(2) *Comparative payment rate analysis and payment rate disclosure.* The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(i) Primary care services.

(ii) Obstetrical and gynecological services.

(iii) Outpatient mental health and substance use disorder services.

(iv) Personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6), provided by individual providers and provider agencies.

(3) *Comparative payment rate analysis and payment rate disclosure requirements.* The State agency must develop and publish, consistent with the publication requirements described in paragraphs (b)(1) through (b)(1)(ii) of this section, a comparative payment rate analysis and a payment rate disclosure.

(i) For the categories of services described in paragraph (b)(2)(i) through (iii) of this section, the comparative payment rate analysis must compare the State agency's Medicaid fee-for-service fee schedule payment rates to the most recently published Medicare payment rates effective for the same time period for the evaluation and management (E/M) codes applicable to the category of service. The State must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS, and the analysis must meet the following requirements:

(A) The State must organize the analysis by category of service as described in paragraphs (b)(2)(i) through (iii) of this section.

(B) The analysis must clearly identify the base Medicaid fee-for-service fee schedule payment rates for each E/M CPT/HCPCS code identified by CMS under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(C) The analysis must clearly identify the Medicare non-facility payment rates as established in the annual Medicare Physician Fee Schedule final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid fee-for-service fee schedule payment rates, that correspond to the base Medicaid fee-for-service fee schedule payment rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type.

(D) The analysis must specify the base Medicaid fee-for-service fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section as a percentage of the Medicare non-facility payment rate as established in the annual Medicare Physician Fee Schedule final rule identified under paragraph (b)(3)(i)(C) of this section for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(E) The analysis must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(ii) For each category of services specified in paragraph (b)(2)(iv) of this section, the State agency is required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid fee-for-service fee schedule payment rates, separately identified for payments made to individual providers and provider agencies, if the rates vary. The payment rate disclosure must meet the following requirements:

(A) The State must organize the payment rate disclosure by category of service as specified in paragraph (b)(2)(iv) of this section.

(B) The disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(C) The disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly Medicaid fee-for-service fee schedule payment rates are published pursuant to paragraph (b)(3)(ii)(B) of this section.

(4) *Comparative payment rate analysis and payment rate disclosure timeframe.* The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025 as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure must be published consistent with the publication requirements described in paragraphs (b)(1)introductory text, (b)(1)(i) and (b)(1)(ii) of this section.

(5) *Compliance with payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.* If a State fails to comply with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of this section, including requirements for the time and manner of publication, future grant awards may be reduced under the procedures set forth at 42 CFR part 430, subparts C and D by the amount of FFP CMS estimates is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of this section for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. Unless otherwise prohibited by law, deferred FFP for those expenditures will be released after the State has fully complied with all applicable requirements.

(6) *Interested parties advisory group for rates paid for certain services.* (i) The State agency must establish an advisory

group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, 1915(c) waiver, and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4), and (6).

(ii) The interested parties advisory group must include, at a minimum, direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State.

(iii) The interested parties advisory group will advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6), to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and habilitation services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

(iv) The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency will ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy reporting information as described in § 441.311(e), and applicable access to care metrics as described in § 441.311(d)(2) for HCBS in order to produce these recommendations. The process by which the State selects interested party advisory group members and convenes its meetings must be made publicly available.

(v) The Medicaid agency must publish the recommendations produced under paragraph (b)(6)(iv) of the interested parties advisory group consistent with the publication requirements described in paragraph (b)(1) through (b)(1)(ii) of this section, within 1 month of when the group provides the recommendation to the agency.

(c)(1) *Initial State analysis for rate reduction or restructuring.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the criteria in paragraphs (c)(1)(i) through (iii) of this section are met, the State agency must provide written assurance and relevant supporting documentation that the following conditions are met as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act, as part of the State plan amendment submission in a format prescribed by CMS as a condition of approval:

(i) Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

(ii) The proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(iii) The public processes described in paragraph (c)(4) of this section and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

(2) *Additional State rate analysis.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) of this section are not met, the State must also provide the following to CMS as part of the State plan amendment submission as a condition of approval, in addition to the information required under paragraph (c)(1) of this section, in a format prescribed by CMS:

(i) A summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(ii) Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services.

(iii) Information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State must provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of actively participating providers in each geographic area over this period. The State may provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(iv) Information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish). The State must document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area

over this period. The State must provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State must provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(v) Information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State must provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(vi) A summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2).

(3) *Compliance with requirements for State analysis for rate reduction or restructuring.* A State that submits a State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access that fails to provide the information and analysis to support approval as specified in paragraphs (c)(1) and (2) of this section, as applicable, may be subject to State plan amendment disapproval under § 430.15(c) of this chapter. Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed State plan amendment, including any raised by CMS in its review of the proposal and any raised through the public process as specified in paragraph (c)(4) of this section or under § 447.204(a)(2), may be subject to State plan amendment disapproval. If State monitoring of beneficiary access after the payment rate reduction or restructuring takes effect shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, CMS may take a compliance action using the procedures described in § 430.35 of this chapter.

(4) *Mechanisms for ongoing beneficiary and provider input.* (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the State responded to this input. This record will be made available to CMS upon request.

(5) *Addressing access questions and remediation of inadequate access to care.* When access deficiencies are identified, the State must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The State's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, providing additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

(6) *Compliance actions for access deficiencies.* To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.

■ 28. Section 447.204 is amended by—

■ a. Revising paragraphs (a)(1) and (b); and

■ b. Removing paragraph (d).

The revisions read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) * * *

(1) The data collected, and the State analysis performed, under § 447.203(c).

* * * * *

(b) The State must submit to CMS with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–08363 Filed 4–22–24; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 442, and 483

Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438, 442, and 483

[CMS–3442–F]

RIN 0938–AV25

Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule establishes minimum staffing standards for long-term care facilities, as part of the Biden-Harris Administration's nursing home reform initiative to ensure safe and quality care in long-term care facilities. In addition, this rule requires States to report the percent of Medicaid payments for certain Medicaid-covered institutional services that are spent on compensation for direct care workers and support staff.

DATES:

Effective date: These regulations are effective on June 21, 2024.

Implementation date: Except as set forth in this section, these regulations must be implemented upon the effective date.

- The regulations at § 483.71 must be implemented by August 8, 2024, for all facilities.
- The regulations at § 483.35(b)(1) and (c)(1) must be implemented by May 11, 2026, for non-rural facilities and May 10, 2027, for rural facilities as defined by the Office of Management and Budget.
- The regulations at § 483.35(b)(1)(i) and (ii) must be implemented by May 10, 2027, for non-rural facilities and May 10, 2029, for rural facilities as defined by the Office of Management and Budget.
- The regulations at §§ 438.72(a) and 442.43 must be implemented by all States and territories with Medicaid-certified nursing facilities and intermediate care facilities for individuals with intellectual disabilities beginning May 10, 2028.

FOR FURTHER INFORMATION CONTACT: The Clinical Standard Group's Long Term Care Team at *HealthandSafetyInquiries@cms.hhs.gov* for information related to the minimum staffing standards.

Anne Blackfield, (410) 786–8518, for information related to Medicaid institutional payment transparency reporting.

SUPPLEMENTARY INFORMATION: To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

I. Executive Summary

A. Purpose

This final rule establishes minimum staffing standards to address ongoing safety and quality concerns for the 1.2 million [1] residents receiving services in Medicare and Medicaid certified Long-Term Care (LTC) facilities each day. As we have heard from residents, staff, and advocates across the country in response to the proposed rule, ensuring adequate staffing levels is essential to the safety and quality of long-term care facilities. On February 28, 2022, President Biden announced that CMS would establish minimum staffing standards that nursing homes must meet, based in part on evidence from a new research study that would focus on the level and type of staffing needed to ensure safe and quality care.[2] This announcement was part of an overall reform plan to improve the quality and safety of nursing homes. In addition, on April 18, 2023, President Biden issued Executive Order 14095, ''Increasing Access to High-Quality Care and Supporting Caregivers,'' [3] which directs the Secretary of HHS to consider actions to reduce nursing staff turnover, which is associated with negative impacts on safety and quality of care.[4] [5] On September 6, 2023, we published the ''Medicare and Medicaid programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting'' [6] proposed rule (referred to as the ''proposed rule'').

The safety and quality concerns identified by the President stem, at least in part, from chronic understaffing in LTC facilities, and are particularly associated with insufficient numbers of registered nurses (RNs) and nurse aides (NAs), as evidenced from, among other things, a review of data collected since 2016 and lessons learned during the COVID–19 Public Health Emergency (PHE). Numerous studies, including a new research study commissioned by CMS as well as existing literature, have shown that staffing levels are closely correlated with the quality of care that LTC facility residents receive as well as with improved health outcomes. Higher staffing levels also provide staff in LTC facilities the support they need to safely care for residents. Minimum staffing standards can thus help prevent staff burnout, thereby reducing staff turnover, which can lead to more consistent care and improved safety and quality for residents and staff. This final rule also promotes public transparency related to the percent of Medicaid payments for certain institutional services that are spent on compensation to direct care workers and support staff.

B. Summary of Provisions

We are updating the Federal ''Requirements for Medicare and Medicaid Long Term Care Facilities'' minimum staffing standards (''LTC requirements''). We will survey facilities for compliance with the updated LTC requirements in the rule and enforce them as part of CMS's existing survey, certification, and enforcement process for LTC facilities. In addition, consistent with the President's reform plan, we will display our determinations of

[1] *https://data.cms.gov/provider-data/dataset/4pq5-n9py.*

[2] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

[3] E.O. 14095, 88 FR 24669 (Apr. 21, 2023).

[4] Zheng, Q, Williams, CS, Shulman, ET, White, AJ. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. *J Am Geriatr Soc.* 2022; 70(9): 2508–2516. doi:10.1111/jgs.17843.

[5] Castle, Nicholas G, and John Engberg. ''Staff turnover and quality of care in nursing homes.'' *Medical care* vol. 43,6 (2005): 616–26. doi:10.1097/01.mlr.0000163661.67170.b9.

[6] 88 FR 61352 through 61429.

facility compliance with the minimum staffing standards on Care Compare [7] and require facilities to post a public notice within the facility if they are out of compliance with the standards so it is easily visible for staff and residents.

We are establishing Federal minimum nurse staffing standards for a number of reasons, including the growing body of evidence demonstrating the importance of staffing to resident health and safety, continued insufficient staffing, non-compliance by a subset of facilities, the need to create a consistent floor to reduce variability in the minimum floor for nurse-to-resident ratios across States, the need to support nursing home staff, and, most importantly, to reduce the risk of residents receiving unsafe and low-quality care.

The regulatory updates are based on evidence we collected using a multifaceted approach, informed by multiple sources of information, including the 2022 Nursing Home Staffing Study; more than 3,000 public comment submissions from the Fiscal Year 2023 Skilled Nursing Facility Prospective Payment System proposed rule (FY2023 SNF PPS) request for information (RFI); academic and other literature; Payroll Based Journal (PBJ) System data; detailed listening sessions with residents and their families, workers, health care providers, and advocacy groups; and analyzing the 46,520 comments received on the proposed rule.

Specifically, in the final rule, we are revising § 483.35(b) to require an RN to be on site 24 hours per day and 7 days per week (24/7 RN) to provide skilled nursing care to all residents in accordance with resident care plans, with an exemption from 8 hours per day of the onsite RN requirement under certain circumstances. Requirements for this exemption are consistent with the requirements for other waivers and exemptions set forth in the LTC requirements. We are also adopting total nurse staffing and individual minimum nurse staffing standards, based on case-mix adjusted data for RNs and NAs, to supplement the existing ''Nursing Services'' requirements at 42 CFR 483.35(a)(1)(i) and (ii). We are specifying that facilities must provide, at a minimum, 3.48 total nurse staffing hours per resident day (HPRD) of nursing care, with 0.55 RN HPRD and 2.45 NA HPRD. We are defining ''hours per resident day'' as staffing hours per resident per day which is the total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS. We note that while the 3.48 total nurse staffing, 0.55 RN, and 2.45 NA HPRD standards were developed using case-mix adjusted data sources, the standards themselves will be implemented and enforced independent of a facility's case-mix. In other words, facilities must meet the minimum 3.48 total nurse staffing, 0.55 RN, and 2.45 NA HPRD standards regardless of the individual facility's resident case-mix, as they are the minimum standard of staffing. If the acuity needs of residents in a facility require a higher level of care, as the acuity needs in many facilities will, a higher total, RN, and NA staffing level will likely be required. As further described below, the minimum staffing standard is supported by literature evidence, analysis of staffing data and health outcomes, discussions with residents, staff, and industry [8] and other factors.

Each of the minimum staffing requirements independently supports resident health and safety and is evaluated separately. Therefore, compliance with the 24/7 RN requirement does not simultaneously constitute compliance with the minimum 3.48 HPRD total nurse staffing standard, the 0.55 RN HPRD, or the 2.45 NA HPRD requirements or vice versa. Similarly, but separately, a minimum number of total nurse staffing including RN and NA hours per resident per day improves overall quality of care. Both independently and collaboratively, these requirements and the totality of the LTC requirements for participation, will support compliance with statutory mandates to provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care.

The resulting, evidence-based final rule appropriately prioritizes quality and safety of care gains from establishing minimum standards for nurse staffing, including RNs and NAs, with a particular emphasis on the direct care delivered at the bedside, and effective implementation of these new requirements. These new required minimum staffing requirements will increase staffing in more than 79 percent of nursing facilities nationwide,[9] and the specific RN and NA HPRD requirements exceed the existing minimum staffing requirements in nearly all States.[10] We remain committed to continued examination of staffing thresholds, including careful work to review quality and safety data resulting from initial implementation of the final rule and robust public engagement. Should subsequent data indicate that additional increases to staffing minimums are warranted and feasible, we anticipate that we will revisit the minimum staffing standards to shift them toward the higher ranges supported by the evidence, with continued consideration of all relevant factors.

We are also revising the existing Facility Assessment requirements at § 483.70(e). We are redesignating the provisions at § 483.70(e) to a standalone section at § 483.71. We are further modifying the requirements to ensure that facilities have an efficient process for consistently assessing and documenting the necessary resources and staff that the facility requires to provide ongoing care for its population that is based on the specific needs of its residents.

As we indicated in the proposed rule, we are finalizing a staggered implementation of these requirements over a period of up to 5 years for rural facilities and 3 years for non-rural facilities to allow all facilities the time needed to prepare and comply with the new requirements.

Exemption from the minimum standards of 0.55 HPRD for RNs, 2.45 HPRD for NAs and 3.48 HPRD for total nurse staffing, and the 8-hours per day of the 24/7 RN onsite requirement would be available only in limited circumstances. In order to qualify for an exemption, a facility must meet the following criteria: (1) the workforce is unavailable as measured by having a nursing workforce per labor category that is a minimum of 20 percent below the national average for the applicable nurse staffing type, as calculated by CMS, by using the Bureau of Labor Statistics and Census Bureau data; [11] (2) the facility is making a good faith effort to hire and retain staff; (3) the facility provides documentation of its financial commitment to staffing; (4) the facility posts a notice of its exemption status in a prominent and publicly viewable location in each resident facility; and (5) the facility provides individual notice of its exemption status and the degree to

[7] *https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome.*

[8] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Report prepared for the Centers for Medicare & Medicaid Services. *https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.*

[9] PBJ data from the October 2021 *Nursing Home Care Compare* data set.

[10] Based on information in the staffing study report appendix E2 all States with the exception of 2 have a total staffing HPRD greater than 3.48 or for RN greater than .55HPRD (source: PBJ data Average 2022 Q1 nursing staffing levels by State).

[11] For example, *Hospital Review* at *https://www.beckershospitalreview.com/workforce/nurses-per-capita-ranked-by-state.html.*

which it is not in compliance with the HPRD requirements to each current and prospective resident and sends a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman. If the exemption is granted, CMS will post on Care Compare a notice of its exemption status and the degree to which it is not in compliance with the requirements.

A facility will be excluded from being eligible to receive an exemption if it: (1) has failed to submit PBJ data in accordance with re-designated § 483.70(p); (2) is a Special Focus Facility (SFF); (3) has been cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm, as determined by CMS; or (4) has been cited at the ''immediate jeopardy'' level of severity with respect to insufficient staffing within the 12 months preceding the survey during which the facility's non-compliance is identified. We note that the existing statutory waiver for all RN hours over 40 hours per week will still be available as required by sections 1819(b)(4)(C)(ii) and 1919(b)(4)(C)(ii) of the Act, as this rule does not purport to eliminate or modify the existing statutory waiver.

As with other LTC requirements for participation, enforcement actions, also called remedies, may be taken against facilities that are not in substantial compliance with these Federal participation requirements under 42 CFR part 488, subpart F. The remedies that may be imposed include, but are not limited to, the termination of the provider agreement, denial of payment for new admissions, and/or civil money penalties.

We also proposed, and are finalizing, new regulations at 42 CFR 442.43 (with a cross-reference at 42 CFR 438.72) to require that State Medicaid agencies report on the percent of payments for Medicaid-covered services in nursing facilities and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID) that are spent on compensation for direct care workers and support staff. This requirement is designed to inform efforts to address the link between sufficient payments being received by the institutional direct care and support staff workforce and access to and, ultimately, the quality of services received by Medicaid beneficiaries. In addition, the requirements being finalized in this final rule are consistent with efforts to address the sufficiency of payments for home and community-based services (HCBS) to direct care workers and access to and the quality of services received by beneficiaries of HCBS finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. As finalized, States will have to comply with these requirements beginning 4 years from the effective date of this final rule.

C. Summary of Cost and Benefits

Table 1: Cost and Benefits

Provision Description	Total Transfers/Costs
Comprehensive Staffing Requirement for LTC Facilities	Without accounting for any exemptions, we estimate that the overall economic impact for the proposed minimum staffing requirements for LTC facilities (that is, collection of information costs and compliance with the 24/7 RN, facility assessment, and minimum 3.48 total nurse staffing, 0.55 RN, and 2.45 NA HPRD requirements), which includes staggered implementation of the requirements, would result in an estimated cost of approximately $53 million in year 1; $1.43 billion in year 2; $4.4 billion in year 3; with costs increasing to $5.8 billion by year 10. We estimate the total cost over 10 years will be $43 billion, which was derived from *FY 2021 Worksheet S-3, Part V* of the Medicare Cost Report. LTC facilities are responsible for these costs. Quantified benefits include but are not limited to, increased community discharges, reduced hospitalizations, and emergency department visits, with a minimum estimated savings of gross costs of $318 million per year for Medicare starting in year 3. Various categories of other important but hard to quantify benefits include reduced staff burnout and turnover, increased safety and quality of care for LTC residents as well. Lack of quantification is also noteworthy as regards key categories of costs.
Medicaid Institutional Payment Transparency Reporting	The overall total economic impact for the reporting requirements is a one-time cost of $37.6 million and ongoing annual costs of $18.3 million per year. We estimate a 10-year cost of $147.9 million. The burden will be shared among States, the Federal Government, and Medicaid-certified nursing facilities and ICFs/IID as follows: • States: $540,000 one-time costs, $200,000 ongoing annual costs • Federal Government: $540,000 one-time costs, $200,000 ongoing annual costs • Nursing facilities and ICFs/IID: $36.6 million one-time costs, $17.9 million annual ongoing costs.

II. Minimum Staffing Standards for Long-Term Care Facilities

A. Background

1. Statutory Authority and Regulatory Requirements for Direct Care Nurse Staffing in Long-Term-Care (LTC) Facilities

Sections 1819 and 1919 of the Social Security Act (the Act) set out regulatory requirements for Medicare and Medicaid long-term care facilities, respectively. Specific statutory language at sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act permits the Secretary of the Department of Health and Human Services (the Secretary) to establish any additional requirements relating to the health, safety, and well-being [12] of residents in skilled nursing facilities (SNF) and nursing facilities (NF), as the Secretary finds necessary. This provision and other statutory authorities set out in section 1819 and 1919 of the Act provide CMS with the authority to issue a regulation revising the existing requirements and to mandate a staffing minimum for nursing care.

Under sections 1866 and 1902 of the Act, providers of services in Long Term Care (LTC) facilities seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the State Medicaid agency, respectively. In order to be certified to participate in Medicare and Medicaid programs, prospective and existing providers of services must meet and continue to meet all applicable Federal participation requirements. These Federal participation requirements are the basis for survey activities in LTC facilities for ensuring that residents' minimum health and safety requirements are met and maintained, as well as for facilities to receive payment and remain in the Medicare or Medicaid program or both. LTC facilities include SNFs for Medicare and NFs for Medicaid. The Federal participation requirements for SNFs, NFs, or dually certified (SNF/NF) facilities, are codified in the implementing regulations at 42 CFR part 483, subpart B.

In addition to those provisions, sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act require that a SNF or NF must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the safety and quality of life of each resident. Section 1819(b)(4)(C)(i) of the Act requires that a SNF must provide 24-hour licensed nursing services, sufficient to meet the nursing needs of its residents, and must use the services of a registered professional nurse at least 8 consecutive hours a day. These provisions are largely paralleled at section 1919(b)(4)(C)(i) of the Act for NFs. Sections 1819(f)(1) and 1919(f)(1) of the Act require that the Secretary assure that requirements that govern the provision of care in skilled nursing facilities under this title, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.

In addition, sections 1819(b)(2) and 1919(b)(2) of the Act require that a SNF or NF provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. The plan of care must describe the medical, nursing, and psychosocial needs of the resident and how the needs will be met. The plan of care is developed with the resident or resident's family or legal representative, and by a team which includes the resident's attending physician and an RN with responsibility for the resident. The plan of care should be periodically reviewed and revised by the team after required assessments. Sections 1819(b)(3) and 1919(b)(3) of the Act require that a SNF or NF conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. Assessments are required to be conducted or coordinated by a registered nurse at specified frequencies.[13]

The participation requirements for LTC facilities (Federal requirements) are set forth at §§ 483.1 through 483.95. In general, the health and safety standards for LTC facilities address facility administration, resident rights, care planning, quality assessment, performance improvement, services provided, emergency preparedness, as well as staffing requirements. Federal requirements state that LTC facilities must use the services of a registered nurse (RN) for at least 8 consecutive hours a day, 7 days a week (§ 483.35(b)(1)), and must provide the services of ''sufficient numbers'' of licensed nurses and other nursing personnel, which includes but is not limited to nurse aides (NAs), 24 hours a day to provide nursing care to all residents in accordance with the resident care plans (§ 483.35(a)(1)). The LTC facility must also designate an RN to serve as the director of nursing (DON) on a full-time basis (§ 483.35(b)(2)).

While these Federal requirements do specify a specific number of hours that these licensed nurses and other nursing personnel must be available, there is no requirement that those hours be specifically dedicated to direct resident care. With respect to staffing requirements specific to individual residents, such as RN staffing levels per resident, Federal regulations currently require that facilities provide staff sufficient to ''assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident''.

2. The Need for a Minimum Nurse Staffing Requirement in LTC Facilities

On October 4, 2016, we issued a final rule titled ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (81 FR 68688). This final rule significantly revised the list of requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. As part of this 2016 final rule, we revised the LTC requirements to include competency requirements for determining the sufficiency of nursing staff, based on a facility assessment requirement that LTC facilities must conduct to determine what resources are needed to competently care for their residents during both day-to-day operations and emergencies. Prior to issuing this final rule, in August 2015 we mandated the requirement for LTC facilities to submit direct care staffing information based on payroll data to CMS as part of the ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection final rule'' (80 FR 46390).[14] In the 2015 Reform of Requirements for Long-Term Care Facilities proposed rule, we included a robust discussion regarding the long-standing interest in increasing the required hours of nurse staffing per day and the various literature surrounding the issue of minimum nurse staffing standards in LTC facilities (see 80 FR 42199). Since

[12] Section 1819(d)(4)(B) of the Act contains the word ''well-being'', which does not appear in section 1919(d)(4)(B). We do not interpret the presence of this word as requiring separate regulatory treatment of Medicare and Medicaid long term care facilities.

[13] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-483#483.70.*

[14] Medicare Program; SNF PPS FY 2016 Final Rule. *https://www.federalregister.gov/documents/2015/08/04/2015-18950/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities.*

issuing the 2016 final rule and establishing a competency-based approach to staffing in the list of LTC requirements, we have collected several years of mandated PBJ System data, which was unavailable at the time, and new evidence from the literature.

Additionally, as a part of the FY 2023 Skilled Nursing Facility Prospective Payment System Proposed Rule Request for Information (FY 2023 SNF PPS RFI) commenters provided examples of ongoing quality and safety concerns within LTC facilities.[15] These included, but were not limited to, residents going entire shifts without receiving toileting or multiple days without bathing assistance, increases in falls, residents not receiving basic feeding or changing services, and even abuse in cases where no one was watching. The 2022 Nursing Home Staffing Study [16] corroborated these comments and identified that basic care tasks, such as bathing, toileting, and mobility assistance, are often delayed when LTC facilities are understaffed, which is not sufficient to meet the nursing needs of residents. Interviews with various nurse staff highlighted ongoing concerns that care is often rushed, including for high-acuity residents, which can often lead to errors or safety issues. We refer readers to the proposed rule for a detailed discussion of the concerns highlighted in interviews as part of the 2022 Staffing Study (88 FR 61359).[17]

The academic literature also suggests the importance of adequate staffing in LTC facilities. In a 2021 study, where interview data were examined, and multivariate analyses of resident outcomes were conducted, the authors concluded that higher total nurse staffing had a significant correlation with a decreased number of pressure ulcers, an increase in influenza vaccination, an increase in pneumonia vaccination, and a decreased number of outpatient emergency department visits.[18] Some studies have demonstrated that increased staffing levels were specifically beneficial to vulnerable subpopulations in nursing homes, such as residents with dementia or Alzheimer's disease. One cross sectional study of long-stay residents with Alzheimer's disease and related dementias found that residents in nursing homes that had higher licensed nurse staffing levels had better end-of-life care and were less likely to experience potentially avoidable hospitalizations.[19]

The COVID–19 Public Health Emergency (PHE) further highlighted and exacerbated long-standing concerns about inadequate staffing in LTC facilities. The COVID–19 PHE also yielded evidence that appropriate staffing made a difference as a part of the overall response in LTC facilities. One study looking at 4,254 LTC facilities across eight States found that there were fewer COVID–19 cases in LTC facilities with four or more stars for nurse staffing in the Five Star Quality Rating System than in counterpart facilities with a rating of one to three stars for staffing.[20] These findings suggest that LTC facilities with low nurse staffing levels may have been more susceptible to the spread of the COVID–19 infection. Findings from a 2020 study involving all 215 nursing homes in Connecticut revealed that a 20-minute increase in RN time spent providing direct care to residents was associated with 22 percent fewer confirmed cases of COVID–19 and 26 percent fewer COVID–19 related deaths.[21] These findings suggest that there is a positive relationship between the hours of direct care that RNs provide and infection transmission in LTC facilities.

Workforce challenges have also contributed to understaffing, nurse burnout, and position turnover.[22] While workforce challenges have existed for years and have many contributing factors, interested parties have reported that the COVID–19 PHE exacerbated the problem as many long-term care facilities experienced high worker turnover. Although the COVID–19 PHE has officially ended, the long-term care nursing workforce has been slower to recover than the nursing workforce in other healthcare settings for a variety of reasons including the difficulty of the work and comparatively lower pay, although it has steadily increased over the past year and a half.[23] [24] There is also evidence that facilities have additional funding that they could be devoting to staffing. For example, one paper found that nursing homes in Illinois were much more profitable than claimed but that 63 percent of those profits were hidden and directed to related parties of the owner. If those hidden profits were instead put toward staffing, the study found, RN staffing could be substantially increased and the share of facilities in compliance with the registered nurse requirements of the proposed rule would rise by twenty percentage points from 55.2 percent to 75.6 percent and compliance with the nurse aide HRPD requirement would rise from 15.3 percent to 36.1 percent in Illinois.[25]

The studies discussed in this section, corroborated by public comment submissions, input provided through listening sessions, and the 2022 Nursing Home Staffing Study, demonstrate the consequences of understaffing on resident health and safety. Yet, ongoing insufficient staffing as well as the widespread variability in existing minimum staffing standards across the United States (for example, 38 States and the District of Columbia have minimum nursing staffing standards; however, there are significant variations in their requirements) highlight the need for national minimum staffing standards for direct care in LTC facilities.

[15] Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Request for Information on Revising the Requirements for Long-Term Care Facilities To Establish Mandatory Minimum Staffing Levels. 87 FR 22720, April 15, 2022 (*https://www.federalregister.gov/documents/2022/04/15/2022-07906/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities*).

[16] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Report prepared for the Centers for Medicare & Medicaid Services. *https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.*

[17] *https://www.federalregister.gov/documents/2023/09/06/2023-18781/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid.*

[18] Wagner, L.M., Katz, P., Karuza, J., Kwong, C., Sharp, L., & Spetz, J. (2021). Medical staffing organization and quality of care outcomes in post-acute care settings. Gerontologist, 61(4),605–614. 10.1016/j.outlook.2020.06.008. Epub 2020 Oct 4. PMID: 33023759; PMCID: PMC7532952.

[19] Jessica Orth, Yue Li, Adam Simning, Sheryl Zimmerman, Helena Temkin-Greener, End-of-Life Care among Nursing Home Residents with Dementia Varies by Nursing Home and Market Characteristics Journal of the American Medical Directors Association, Volume 22, Issue 2, 2021, Pages 320–328.e4,ISSN 1525–8610, *https://doi.org/10.1016/j.jamda.2020.06.021.*

[20] Figueroa JF, Wadhera RK, Papanicolas I, et al. Association of Nursing Home Ratings on Health Inspections, Quality of Care, and Nurse Staffing With COVID–19 Cases. JAMA. 2020;324(11):1103–1105. doi:10.1001/jama.2020.14709.

[21] *https://agsjournals.onlinelibrary.wiley.com/doi/epdf/10.1111/jgs.16689.*

[22] Kelly LA, Gee PM, Butler RJ. Impact of nurse burnout on organizational and position turnover. Nurs Outlook. 2021 Jan-Feb;69(1):96–102. doi:

[23] Refer, for example, to a report from the Kaiser Family Foundation indicating that as of March 20, 2022, 28 percent of nursing facilities reported a staffing shortage, as reported in Ochieng, N., Chidambaram, P., Musumeci, M. Nursing Facility Staffing Shortages During the COVID–19 Pandemic. Apr 04, 2022. Kaiser Family Foundation. Accessed at *https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staffing-shortages-during-the-covid-19-pandemic.*

[24] *https://data.bls.gov/timeseries/CES6562300001?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.*

[25] Ashvin Gandhi and Andrew Olenski, Tunneling and Hidden Profits in Health Care, NBER Working Paper (March 2024), Tunneling and Hidden Profits in Health Care (nber.org).

Chronic understaffing nonetheless continues in LTC facilities, and evidence demonstrates the benefits of increased nurse staffing in these facilities. For example, a report by the HHS Office of the Inspector General (OIG) highlighted that in 2018, roughly 7 percent of nursing homes failed to provide 8 hours per day of RN staffing on at least 30 total days during the year.[26] The literature also suggests that staffing levels within facilities across the United States vary considerably, with less-staffed facilities more likely to be for-profit, larger, rural, and have a higher share of Medicaid residents. In particular, there has been evidence of new for-profit owners reducing levels of registered nurse staffing in order to reduce costs.[27]

Finally, multiple studies have shown that nursing home quality is generally lower in LTC facilities that serve high proportions of minority residents.[28] [29] [30] Facilities that have a higher proportion of minority residents tend to have limited clinical and financial resources, low nurse staffing levels, and a high number of care deficiency citations.[31] [32] Furthermore, disparities in safety and quality of care exist between LTC facilities with a high number of Medicaid residents and LTC facilities that have a high number of Medicare residents, with facilities with a high number of Medicaid residents tending to have worse outcomes.[33] These disparities can contribute to differences in quality across facilities' sites.[34] As such, we believe that national minimum staffing standards in LTC facilities and the adoption of a 24/7 RN and enhanced facility assessment requirements, will help to advance equitable, safe, and quality care sufficient to meet the nursing needs for all residents and greater consistency across facilities.

[26] Office of Inspector General (OIG), Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased, OEI–04–18–00450, August 2020. *https://oig.hhs.gov/oei/reports/oei-04-18-00450.asp.*

[27] *https://www.nber.org/system/files/working_papers/w28474/w28474.pdf.*

[28] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3805666/.*

[29] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4108174/.*

[30] *https://onlinelibrary.wiley.com/doi/epdf/10.1111/1475-6773.12079.*

[31] *https://www.jamda.com/article/S1525-8610(21)00243-7/fulltext.*

[32] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0094.*

[33] Mor, Vincent et al. ''Driven to tiers: socioeconomic and racial disparities in the quality of nursing home care.'' The Milbank quarterly vol. 82,2 (2004): 227–56. doi:10.1111/j.0887–378X.2004.00309.x.

[34] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0094.*

3. CMS Actions and Key Considerations To Inform Mandatory Minimum Staffing Standards

In February 2022, President Biden announced a comprehensive set of reforms aimed at improving the safety and quality of care within the Nation's nursing homes. One key initiative within the Biden-Harris Administration's strategy was to establish a minimum nursing home staffing requirement for LTC facilities participating in Medicare and Medicaid.[35] To help inform our efforts in establishing consistent and broadly applicable national minimum staffing standards, we launched a multi-faceted approach aimed at determining the minimum level and type of staffing needed to enable safe and quality care in LTC facilities. This effort included issuing the FY 2023 SNF PPS RFI,[36] hosting listening sessions with various interested parties, and conducting a 2022 Nursing Home Staffing Study, which builds on existing evidence and several research studies using multiple data sources. In addition to launching our multi-faceted approach, we considered how any potential minimum staffing standards would affect other CMS programs and/or initiatives as well as the enforceability of such standards.

We published the FY 2023 SNF PPS RFI in April 2022, soliciting public comments on minimum staffing standards. In response to the FY 2023 SNF PPS RFI, we received over 3,000 comments from a variety of parties interested in addressing LTC facilities' issues including advocacy groups, long-term care ombudsmen, providers and provider industry associations, labor unions and organizations, nursing home residents, staff and administrators, industry experts, researchers, family members, and caregivers of residents in LTC facilities.

In the proposed rule we discussed the 2022 nursing home staffing study[37] that CMS commissioned (see 88 FR 61359–61364). In brief, the key takeaways were:

- There is no clear, consistent, and universal methodology for setting specific minimum staffing standards, as evidenced by the varying current standards across the 38 States and the District of Columbia that have adopted their own staffing standards.
- The relationship between staffing and quality of care and safety, varies by staff type and level as follows:

++ Total Nurse Staffing hours per resident day of 3.30 or more have a strong association with safety and quality care.

++ RN hours per resident day of 0.45 or more have a strong association with safety and quality care.

++ NA hours per resident day of 2.45 or more also have a strong association with safety and quality care.

++ LPN/LVN hours per resident day, at any level, do not appear to have any consistent association with safety and quality of care.

However, we recognize that LPN/LVN professionals undoubtedly provide important services to LTC facility residents despite the findings that LPN/LVN staffing levels do not appear to have a consistent association with safety and quality of care, unlike RN and NA staffing levels.

- Increasing nursing staffing levels are associated with benefits including enhanced safety and quality, as well as costs, namely financial costs to LTC facilities.

In addition to commissioning the 2022 Nursing Home Staffing Study and issuing the FY 2023 SNF PPS RFI, CMS also held two listening sessions on June 27, 2022, and August 29, 2022, to provide information on the study and solicit additional input on the study design and approach for establishing minimum staffing standards. We described the general content of these listening sessions in the 2023 proposed rule (see 88 FR 61352).

4. Ongoing CMS Initiatives and Programs Impacting LTC Facilities

In establishing the proposed and final minimum staffing standards, we also considered ongoing CMS policies, programs, and operations, including the SNF Prospective Payment System (SNF PPS), the SNF Value-based Purchasing Program (SNF VBP), oversight and enforcement, and CMS policies intended to enhance access to Medicaid home and community-based services and promote community-based placements.

[35] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

[36] Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2023; Request for Information on Revising the Requirements for Long-Term Care Facilities To Establish Mandatory Minimum Staffing Levels. *https://www.federalregister.gov/documents/2022/04/15/2022-07906/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities.*

[37] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Report prepared for the Centers for Medicare & Medicaid Services. *https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.*

a. Medicare Skilled Nursing Facility Prospective Payment System

The Medicare SNF PPS is a comprehensive per diem rate under Medicare for all costs for providing covered Part A SNF services (that is, routine, ancillary, and capital-related costs) that is statutorily required to be updated annually. The FY 2025 SNF PPS proposed rule published on April 3, 2024, and proposed to update the Medicare payment policies and rates for SNFs for FY 2025. For the proposed FY 2025 update, CMS estimated that the aggregate impact of the payment policies in the proposed rule would result in a net increase of 4.1 percent, or approximately $1.3 billion, in Medicare Part A payments to SNFs in FY 2025, if finalized. We note that section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. These updates take into account a number of factors, including but not limited to, wages, salaries, and other labor-related prices. Specifics regarding the process to update SNF PPS payment rates are discussed in the rule.[38]

b. Skilled Nursing Facility (SNF) Value-Based Payment (VBP) Program Staffing Measure

In the FY 2023 SNF PPS final rule, we adopted a new Total Nurse Staffing quality measure under the SNF VBP Program, which is used to provide an incentive to LTC facilities to improve quality of care provided to residents.[39] Performance on the Total Nurse Staffing measure in FY 2024 will be used to make payment adjustments in FY 2026. This is a structural measure that uses auditable electronic data reported to CMS' PBJ system to calculate HPRD for total nurse staffing. Our minimum staffing standards are not duplicative of this existing measure; rather, they are complementary by establishing a consistent and broadly applicable national floor (baseline) at which residents are at a significantly lower risk of receiving unsafe and low-quality care. At the same time, the Total Nurse Staffing quality measure will drive continued improvement in staffing across LTC facilities.

c. Nursing Home Survey and Enforcement

The LTC minimum staffing standards in this regulation are part of the Federal participation requirements for LTC facilities which are the basis for survey activities and for the minimum health and safety requirements that must be met and maintained to receive payment and remain as a Medicare or Medicaid provider. As such compliance with these requirements will be assessed through CMS' existing survey, certification, and enforcement processes under 42 CFR part 488.[40] Section 1864(a) of the Act authorizes the Secretary to enter into agreements with the State survey agencies to determine whether SNFs meet the Federal participation requirements for Medicare. Section 1902(a)(33)(b) of the Act provides for the State survey agencies to perform the same survey tasks for NFs in Medicaid. The results of these surveys are used by CMS and the State Medicaid Agency, respectively, as a basis for a decision to enter into, deny, or terminate a provider agreement with the facility. They are also used to determine whether one or more enforcement remedies should be imposed against LTC facilities that are not in substantial compliance with these Federal participation requirements. Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR 488.404, 488.406, and 488.408, provide that CMS or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the CMS or the State finds that a facility is out of substantial compliance with the Federal participation requirements. Specifically, enforcement remedies that may be imposed include the following:

- Termination of the provider agreement;
- Temporary management;
- Denial of payment for all Medicare and/or Medicaid individuals by CMS to a facility, for Medicare, or to a State, for Medicaid;
- Denial of payment for all new Medicare and/or Medicaid admissions;
- Civil money penalties;
- State monitoring;
- Transfer of residents;
- Transfer of residents with closure of facility;
- Directed plan of correction;
- Directed in-service training; and
- Alternative or additional State remedies approved by CMS.

In general, to select the appropriate enforcement remedy(ies), the seriousness, that is, scope and severity levels, of the deficiencies is assessed. The severity level reflects the impact of the deficiency on resident health and safety and the scope level reflects how many residents were affected by the deficiency. The survey agency determines the scope and severity levels for each deficiency cited at a survey.

As part of these survey and enforcement activities, we currently publish data for all Medicare and Medicaid LTC facilities on the CMS public-facing Care Compare website, including the number of certified beds and a facility's overall Five Star quality rating, including three individual star ratings in the categories of inspections, staffing, and quality measurement.[41] In addition, individual performance quality measures are included on Care Compare. With respect to nursing home staffing, this includes the following staffing data: total number of nurse staff HPRD, RN HPRD, LPN/LVN HPRD, and NA HPRD, as well as some additional staffing measures, including weekend hours. These published data are collected through a variety of mechanisms, including during CMS surveys (health inspection data), reporting through the PBJ System, and resident assessment data reported by LTC facilities to us.

Over the last several years, CMS has taken a number of actions to strengthen our oversight and enforcement of compliance. For example, in 2022, CMS began integrating PBJ data into the survey process to help target surveyors' investigations of a facility's compliance; in 2023, CMS announced it would undertake new analyses of State inspection findings to ensure cited deficiencies receive the appropriate consequence, particularly involving resident harm.[42] Additionally, we began posting levels of weekend staffing and rates of staff turnover, and using these metrics in the Five Star Quality Rating System to help provide more useful information to consumers. Furthermore, CMS revised the policies in the Special Focus Facility (SFF) program to ensure these facilities make sustainable improvements to protect residents' health and safety.[43] In January 2023, CMS began conducting audits of

[38] Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2025. *https://www.cms.gov/newsroom/fact-sheets/fy-25-skilled-nursing-facility-prospective-payment-system-proposed-rule-cms-1802-p.*

[39] *https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2023-skilled-nursing-facility-prospective-payment-system-final-rule-cms-1765-f.*

[40] *https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertification enforcement/nursing-home-enforcement.*

[41] Centers for Medicare & Medicaid Services *Medicare.gov.* Find and Compare Nursing Homes Providers near you *https://www.medicare.gov/care-compare/?providerType=NursingHome&redirect=true.*

[42] *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/.*

[43] *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-strengthens-oversight-nations-poorest-performing-nursing-homes.*

facilities' medical records to identify if residents were inappropriately given a diagnosis of schizophrenia, and administered antipsychotics drugs, which are very dangerous for residents. Lastly, in November 2023, CMS released a final rule that implemented portions of section 6101 of the Affordable Care Act, requiring the disclosure of certain ownership, managerial, and other information regarding LTC facilities.[44]

As noted previously in this section, we have been moving towards more data-driven enforcement, including use of the PBJ System data to guide monitoring, surveys and enforcement of existing staffing requirements. Additionally, starting in late 2023, CMS expanded audits of these data. We continue to recognize, however, the value of assessing the sufficiency of a facility's staffing based on observations of resident care conducted during the onsite survey. For example, while compliance with numeric minimum staffing standards could be assessed using PBJ System data, it is possible that due to a facility's layout, management, and staff assignments, a facility could meet the numeric staffing standards but not provide the sufficient level of staffing needed to protect residents' health and safety. Resident health status and acuity (for example, proportion of residents with cognitive decline or use of ventilators) are also factors in determining adequate staffing. Therefore, when assessing the sufficiency of a facility's staffing it is important to note that any numeric minimum staffing requirement is not a target and facilities must assess the needs of their resident population and make comprehensive staffing decisions based on those needs. Often, that will require higher staffing than the minimum requirements. The additional requirements in this rule to bolster facility assessments are intended to address this need and guard against any attempts by LTC facilities to treat the minimum staffing standards included here as a ceiling, rather than a floor (baseline).

In summary, the benefits and success of minimum staffing standards are heavily dependent on our utilization of the survey and enforcement process. Therefore, in establishing numerical minimum staffing standards our goal is to ensure that they are both implementable and enforceable, as determined through both the PBJ System as well as on-site surveys.

d. Medicaid Home and Community-Based Services

We remain committed to a holistic approach to meeting the long-term care needs of Americans and their families. This requires a focus on access to high-quality care in the community while also ensuring the health and safety of those who receive care in LTC facilities. In the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register** and Medicaid and CHIP Managed Care Access, Finance, and Quality final rule published elsewhere in this **Federal Register**, we finalized several policies that will work alongside those included in this rule. These finalized proposals require that at least 80 percent of Medicaid payments for personal care, homemaker and home health aide services be spent on compensation for the direct care workforce (as opposed to administrative overhead or profit); establish standardized reporting requirements related to health and safety, beneficiary service plans and assessments, access, and quality of care; and promote transparency through public reporting on quality, performance, compliance as well as certain Medicaid HCBS providers' payment rates for direct care workers. Additionally, we remain committed to facilitating transfers from LTC facilities to the community through the continued implementation of the ''Money Follows the Person'' program.[45]

Notably, similar to the findings in the 2022 Nursing Home Staffing Study, we believe that the minimum staffing standards finalized in this rule will improve quality of care which includes facilitating the transition of care to community-based care services and potential Medicare savings.

B. Provisions of the Proposed Regulations and Analysis and Response to Public Comments

In response to the proposed rule, we received 46,520 total comments. Commenters included long term care consumers, advocacy groups for long-term care consumers, organizations representing providers of long-term care and senior service, long-term care ombudsmen, State survey agencies, various health care associations, legal organizations, labor unions, residents, families, and many individual health care professionals (such as nursing organizations) and administrative staff. Our goal is to protect resident health and safety and ensure that facilities are considering the unique characteristics of their resident population in developing staffing plans, while balancing operational requirements and supporting access to care. Moreover, the comprehensive staffing standards will provide staff with the support they need to safely care for residents. Most commenters supported the proposed rule's goals to ensure safe and quality care in LTC facilities.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and an explanation for changes in the policies that we are finalizing.

1. General Comments

Comment: Many commenters shared their personal stories of care provided and received in nursing homes. While a majority of these commenters shared observations of the compassion shown by well-meaning staff, they also shared observations of missed care and avoidable harm that occurred due to insufficient staffing. A resident stated:

- ''I was in a nursing home for rehab on discharge from hospital the day after I broke my shoulder in a fall down a staircase. When a fire alarm sounded I was on the toilet. I heard the automatic fire doors close. I stayed as calm as I could, reminding myself someone would come to get me off the toilet and out to safety. Half an hour later activity resumed nearby and a CNA did help me off the toilet. She said 'Oh I wasn't worried about you, I knew you'd get yourself out through the window if you needed to.' ''

Many family members and friends shared personal stories, urging CMS to adopt minimum staffing standards to prevent future incidences like the ones that their loved ones experienced. Families and friends wrote:

- ''She was a successful Real-estate broker her whole adult life, who suffered a tragic fall that left her with multiple breaks in her leg and landed her in a nursing home for rehab. What she lost in the nursing home was far greater than the break, she lost her dignity and self-worth as she was forced to lay in her own urine on a regular basis and on several occasion her own feces. The staff were caring and capable but there was never enough of them.''
- ''The major concern was the stage 4 bed sores that Jerry developed after 6 weeks at BNR while Jerry was under their care. Jerry was continually left sitting in his own feces as he was both urinary and bowel incontinent. He was unable to get help or attention on numerous occasions by pressing the call button, to the point of purchasing a bull

[44] *https://www.cms.gov/newsroom/fact-sheets/disclosures-ownership-and-additional-disclosable-parties-information-skilled-nursing-facilities-and-0.*

[45] Money Follows the Person | Medicaid, *https://www.medicaid.gov/medicaid/long-term-services-supports/money-follows-person/index.html.*

horn with a siren to summon help, of course this didn't improve matters. Several times his roommate would be unconscious and hanging out of his bed a hairs breadth away from falling with no belts or restraints, which I personally witnessed and alerted an aide who replied 'he likes it that way' ''.

• ''I had a loved one recently fall in a Memory Care Facility. She was on the floor for quite some time before she was discovered. She had a broken hip and no ability to become ambulatory. All she had done was attempt to go to the bathroom in the middle of the night. My recommendation is that a patient should not be left to get themself to the bathroom alone in the night. Why can't they have enough staff on hand that they can provide someone to help each patient to the bathroom and safely return to bed?''

• ''This past year my partner spent several months in a nursing home/rehab facility and I personally saw how shorthanded they were. The lack of adequate staff, number of part-time and substitute staffing, poor pay, was obvious. The nights were the worse time. A patient could ring for help and wait and wait an hour for a response. They could ask for a glass of water and wait hours for it to come. They could lay in their own waste or urine-soaked bedding for way too long, day or night. Those who needed help being fed would often just have the food delivered and if a family member wasn't there to help them eat they would go hungry.''

• ''They were supposed to check in on him every hour and to help him turn from side to side at least every two hours. Later, when he got better, they were supposed to check on him every four hours, but they didn't. They were supposed to change his clothing and bedsheets regularly. They did none of that often enough, so he developed bedsores/open wounds as big as your hand on his backside because of a lack of care. How would you like your dad to go through that experience in the last 24 months of his life, after all he'd been through in 90 years?''

• ''In June 2021 while the day shift nurse was making morning rounds she found my family member aspirating on vomit, having seizures, with a 106 degree temperature which turned in to a case of sepsis. The nurse said she had no idea how long my family member was lying there in that condition as there was only 1 nurse and 1 aide for over 100 residents on the overnight shift. Since that incident my family member has lost the ability to speak and/or respond to questions and or commands. As a result I have personally spent 10 to 12 hours a day, every day, with my family member at the LTC to ensure they are getting the care they need.''

• ''My loved one was basically starved to death—all dementia patients in that specific ward were, due to not enough staff helping them eat. Two people were on staff to help 20 patients, so only the three catatonic people got help. Other patients would be distracted, which is natural, at meals, but then weren't encouraged to eat, due to lack of sufficient staff. The patients would therefore lose weight weekly and be dizzy, malnourished weak, leading to frequent falls and more and more bedridden patients. These patients would then get pneumonia and die. There were never enough staff to clean up spills and urine fast enough- I visited frequently and witnessed fall after fall constantly around me due to this problem. There were never enough staff to do ANYthing.''

Likewise, many nursing home staff wrote of their own experiences and observations while trying to safely deliver care to residents. Staff wrote:

• ''Personal observations from my nursing home consulting work as a Registered Dietitian: Nurses so short staffed they declare a 'med holiday' and throw away all the meds for one shift because they don't have time to pass them out. Nursing so understaffed that bedtime snacks, though made and delivered to the nursing station, are not passed out. Resulting in one insulin dependent diabetic resident's blood sugar zeroing out in the wee hours of the night. Patient died.''

• ''Recently a resident got skin ulcers after no one was able to see him for the entire 8-hour shift, and who knows how long before that? When you have 14 or 18 or 20 residents to care for, there's simply not enough time for everyone. Feeding them all takes so much time, several hours combined right there. Thats how other basic needs fall by the wayside. When you're doing the job of two CNAs, it really means that half of your residents are going to have to go without.''

• ''Last week, after two aides did not show up for their shift, it led to several residents missing their breakfast. Thats just one example unfortunately, residents regularly miss meals or have to eat them late. The problem is that whenever staff is needed for one urgent task, were usually in the middle of another urgent task that cannot be interrupted.''

• ''Residents in our facility are recovering from surgery or things like strokes and they need a lot of help. With how many residents I am caring for, I don't have time to give them the best care. I feel like I'm always rushing to the next person, and they get upset, and this is not good for their recovery. If they have to go to the bathroom and can't wait, they try to go by themselves and they end up falling.''

Response: We thank commenters for sharing their personal stories. The compelling narratives shared by commenters demonstrate the dangers of inadequate staffing in nursing homes, not as an impersonal set of numbers and percentages, but as the lived experiences of the more than 1 million people receiving nursing home services each year. As evidenced by the thousands of personal stories told in the comments, there is a persistent, pervasive problem in the safety of nursing home care across the country that must be addressed. This final rule includes policies that will advance resident safety, and we are committed to using all available CMS authorities to continue protecting residents now and in the future.

Comment: Comments on the proposed rule varied in level of support and opposition. Many commenters expressed overall support for the proposed revisions to the regulations and concern about the health and safety of nursing home residents. Numerous commenters encouraged CMS to further strengthen the requirements and not finalize the version of the rule as proposed. A large number of commenters applauded CMS for taking a first step toward improvements for staff and residents in LTC facilities and noted additional opportunities to address workforce challenges. Many NAs and family representatives described the negative impact of low staffing levels on meeting residents' needs, writing of situations that ranged from residents that needed assistance with meals not getting that assistance and losing weight, to accounts of residents that had to stay in bed all weekend because the facility was short staffed. Many comments centered on unnecessary falls that occur because no one is around to assist residents to and from the bathroom. For example, one commenter who described themselves as a family member of many residents shared a personal description of their experience with a nursing facility, noting that their loved ones often share that ''they have been waiting for hours just to go to the bathroom.'' Commenters noted that most LTC direct staff are doing the best they can and that increasing staff will decrease burnout, make their jobs safer, and lessen the potential for resident's safety events such as falls and pressure ulcers. For example, one NA with over 22 years of

experience highlighted that while they love their jobs, it has been one the hardest they ever held and having ''Federal guidelines in place could help the elderly and their families feel more confident in the facilities.'' This commenter also indicated that having Federal guidelines in place will provide individuals ''more of an incentive to work in a long-term care facility.''

In contrast, other commenters expressed a desire to rescind the proposed rule, citing overall concerns about the financial burden and workforce shortages, training challenges, administrative burden, and limited housing options in sparsely populated areas for new staff.

Response: The large volume of comments that we received demonstrates the interest in resident health and safety issues. Numerous comments from residents, families, staff, and ombudsmen make it clear that there is a widespread lack of sufficient care by nursing staff in our nation's LTC facilities. These comments provide further evidence of and support for our view that we will significantly improve resident safety through the establishment of minimum staffing requirements. The changes that we discuss in this final rule are intended to promote resident health, safety, and access to care.

We acknowledge the workforce challenges in LTC facilities. According to the Bureau of Labor Statistics (BLS), in March 2020, there were 3,372,000 staff working in nursing homes and other LTC facilities and an average of 1,319,318 residents per day in nursing homes. Total staffing dropped to a low of 2,961,200 for staff working in nursing homes and other LTC facilities in January 2022, a decrease of approximately 410,000 staff from March 2020. The daily census of residents averaged 1,152,842 per day in nursing homes in January 2022. Workforce challenges may have contributed to the drop in staff, but it appears to have been caused by multiple factors, such as the drop in the number of nursing home residents. The number of staff is improving, as of November 2023 there are 3,216,700 staff working in nursing homes and other LTC facilities, still 155,300 less than March 2020. Facilities averaged 1,201,585 residents per day in November 2023. Please note, this data is for all employees in these facilities, not just healthcare staff.[46] As stated in the proposed rule, it is the policy of the Biden-Harris Administration to ensure that the LTC workforce is supported, valued, and well-paid.[47]

We note the efforts that many commenters described regarding their recruitment, hiring and training of employees along with retention efforts for existing employees. We support the concept of implementing workforce development programs, as they benefit not only the employees but ultimately the residents. CMS is launching a comprehensive workforce development initiative [48] and is also exploring the potential to provide technical assistance to LTC facilities through the existing Quality Improvement Organizations. While the requirements of this rule are intended to improve resident safety and care, they may also improve the working environment in LTC facilities. Establishing staffing minimums will assure that NAs, for example, have enough nursing staff present in the facility for a safe 2-person resident transfer using a mechanical lift, reducing resident and staff injuries, as well as staff burnout. The new requirement that facilities must involve their direct care workers and their representatives in the facility assessment allows the staff to provide meaningful input regarding the facility's operations, which has the potential to lead to a better working environment that complements retention and hiring efforts. In addition, having a 24/7 RN presence can improve resident safety [49] with the added benefit of providing more professional support to all facility workers.

Comment: Some commenters stated that the pool of former nursing home workers who left the sector is more than sufficient to cover the demand for new workers, while numerous commenters voiced questions about the availability of workforce and whether this is the right time to implement staffing minimums. A few commenters denied the existence of a staffing shortage. One commenter stated it was a pay shortage and that challenges with a lack of qualified staff would be readily resolved by higher pay and better working conditions. Some commenters explained that the LTC workforce has not recovered from the impact of the COVID PHE. Some commenters noted that LTC facilities were already having issues hiring sufficient staff due to the lack of qualified, available staff in their area. For example, one commenter pointed out that in the State of Missouri, less than 4 percent of RNs were looking for work and that more than a quarter of RNs were 54 or older, suggesting that not only were there few RNs looking for work but also a significant number would likely be retiring in the next several years.[50] The commenter noted that compliance with these minimum staffing requirements would require hundreds of new RNs. Some commenters asked where these additional RNs would come from to staff LTC facilities. Some commenters shared concern about shortages of RNs overall and specifically the scarcity of RNs who chose to work in LTC facilities. They stated this needs to be recognized as an impediment to some facilities being able to meet staffing minimums. A commenter expressed concerns that due to the minimum staffing requirements, providers will likely encounter heightened levels of competition in each labor market for RNs and NAs. Moreover, the commenter stated that it would be even more challenging to recruit and retain staff for ''smaller LTC facilities and those located in rural areas than larger, better-funded facilities in nearby urban areas''. Some recommended that this minimum staffing standards regulation be suspended until there were enough RNs to staff LTC facilities to comply with the 24/7 RN and 0.55 RN HPRD requirements. Other commenters stated that their facilities have been trying to hire nursing staff without success and that they rely on staffing agencies, a process which offers its own set of unique challenges for facilities.

Response: We acknowledge that there are workforce challenges in various areas of the country. CMS is committing over $75 million to launch an initiative to help increase the long-term care workforce.[51] We expect that these funds

[46] Bureau of Labor Statistics. *https://data.bls.gov/timeseries/CES6562300001?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.* Accessed 02/28/24.

[47] *Executive Order on Increasing Access to High Quality Care and Supporting Caregivers.* White House. Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/18/executive-order-on-increasing-access-to-high-quality-care-and-supporting-caregivers/.* Published on April 18, 2023. Accessed on March 19, 2023.

[48] FACT SHEET: Biden-Harris Administration Takes Steps to Crack Down on Nursing Homes that Endanger Resident Safety | The White House: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/.*

[49] National Academies of Sciences, Engineering, and Medicine. 2022. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/26526.*

[50] Missouri State Board of Nursing. (2022). 2022 Missouri Nursing Workforce Report. Jefferson City, MO: Missouri State Board of Nursing. *https://pr.mo.gov/boards/nursing/2022%20Missouri%20Nursing%20Workforce%20Report.pdf.*

[51] FACT SHEET: Biden-Harris Administration Takes Steps to Crack Down on Nursing Homes that Endanger Resident Safety | The White House:

Continued

will be allocated for such purposes as for tuition reimbursement, we are also exploring the potential to provide additional technical assistance to LTC facilities through the Quality Improvement Organizations. The Department of Labor and other parts of the Biden-Harris Administration are also investing in building a strong nursing workforce and expanding the pipeline of new staff. In response to comments, and in addition to the $75 million workforce development investment and potential technical assistance, we have made some changes to the proposed minimum staffing standards requirements to provide additional flexibility and time for facilities to implement these changes while maintaining safety and quality. The final requirements have staggered implementation dates over a period of up to five years. A total nurse staffing standard has been added and there are exemptions from the minimum staffing standards. We will continue to examine resident safety issues and potential changes going forward. The minimum staffing standards will provide staff in LTC facilities the support they need to safely care for residents, and help prevent staff burnout, thereby reducing staff turnover, which can lead to improved safety.

Comment: Numerous commenters voiced support for the proposed regulations but asked for funding, indicating that the financial implication of hiring staff to meet the standards was a roadblock. Commenters stated that the implementation of the minimum nursing staffing requirement will bring increased costs, and in the absence of reimbursement for these costs, the LTC facilities will have to absorb those increased costs, causing financial strain. One commenter recommended increasing payment rates using wage pass through rules. Some commenters stated that nursing homes cannot compete with hospitals for RN salaries. Other commenters expressed concern that unintended consequences of hiring more staff would result in higher fees for residents and their families. In contrast, other commenters suggested that nursing homes have the financial means to provide quality staffing, without additional funding. Some of these commenters highlighted the profits earned by nursing homes, which make them a desirable investment opportunity, as well as diversion of funds to related-party expenses or excess administrative costs.[52]

Response: While funding, salaries paid by other healthcare providers, and fees that residents are charged are outside the scope of this rulemaking, we crafted the rule with careful consideration that the majority of LTC facilities will need to recruit, hire, and train new staff. In the proposed rule we noted that non-profit nursing homes were three times more likely to already be in compliance with the proposed minimum staffing requirements suggesting a relationship between profit model and staffing.[53] Through phased-in implementation facilities may not have to hire all the necessary nursing staff at one time. There are also waivers and hardship exemptions available to LTC facilities on a case-by-case basis. Please see sections II B.4, ''Registered Nurse 24 hours per day 7 days per week,'' and II B.5, ''Hardship Exemption from Minimum Hours per Resident Day and RN onsite 24 hours per day 7 days per week,'' of this rule for more details. In addition, please see section VI, ''Regulatory Impact Analysis,'' for estimates of expenditures related to this final rule.

Comment: A commenter noted that LTC facilities must meet State and Federal requirements for health and safety. Some commenters were concerned about the burden of meeting both their State requirements and Federal requirements. A commenter expressed concern about conflicts between State and Federal staffing requirements. The commenter suggested rewards for facilities located in States that have higher staffing standards and reimbursement cuts for facilities located in States that have reduced or eliminated staffing standards compared to Federal minimum staffing standards.

Response: Complying with State and Federal requirements is not new to LTC facilities. Generally, healthcare facilities in the United States function under State and Federal regulations. With regard to the updates to the requirements for Medicare and Medicaid participation for LTC facilities, the provisions in this final rule are not intended to and would not preempt the applicability of any State or local law providing a higher standard. In States where there is a higher HPRD requirement for RNs or NAs, or an RN coverage requirement in excess of at least one RN on site 24-hours per day, 7 days a week, or a total nurse staffing minimum above 3.48 HPRD that is required by this final rule, or any other specific requirement such as for LPNs/LVNs, the facility would be expected by its State or local government to meet the higher standard. To the extent Federal standards exceed State and local law minimum staffing standards, no Federal pre-emption is implicated because facilities complying with Federal law would also be in compliance with State or local law. Facilities in states that have eliminated their staffing standards are required to comply with Federal law. We are not aware of any State or local law providing for a maximum staffing level. This final rule, however, is intended to and would preempt the applicability of any State or local law providing for a maximum staffing level, to the extent that such a State or local maximum staffing level would prohibit a Medicare, Medicaid, or dually certified LTC facility from meeting the minimum HPRD requirements and RN coverage levels finalized in this rule or from meeting higher staffing levels required based on the facility assessment provisions finalized in this rule. Financial adjustments related to State staffing requirements are outside the scope of this rule.

Comment: Numerous commenters described various issues involving nursing education and the volume of new nurse graduates. Some commenters suggested investing in nursing school infrastructure. Another commenter recommended a policy that includes educational opportunities for individuals to enter nursing and other health care fields, increasing the number of nursing educators, and subsidies for NA training programs. One commenter asked that CMS offer student loan forgiveness, or no-interest student loans for those entering the nursing profession. Some commenters stated that the proposed $75 million workforce campaign that will be coordinated by CMS and was announced in tandem with the proposed rule, is not sufficient to train the additional nursing staff that are needed. Other commenters asked that CMS work to ensure funding for training and recruiting qualified staff that includes home health and hospice providers. Another commenter asked CMS to work on recruitment and retention of LTC facility nursing staff. Other commenters expressed concern that the $75 million workforce campaign funds should not be used to train surveyors who will eventually

https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/.

[52] Comments of the Long Term Care Community Coalition at 10–11.

[53] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Report prepared for the Centers for Medicare & Medicaid Services. *https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.*

assess enforcement actions against nursing homes.

Response: We agree that educating and training new nursing staff is important for the nursing home workforce. On September 1, 2023, the White House published a fact sheet detailing various initiatives that promote safety in LTC facilities.[54] One of the initiatives is focused on growing the nursing workforce. CMS is launching a new nursing home staffing campaign to help workers pursue careers in nursing homes. This campaign will support the recruitment, training, and retention of nursing home workers, including the CMS investment of over $75 million in financial incentives for nurses to work in nursing homes, through the Civil Money Penalty (CMP) Reinvestment Program. Other parts of the Federal Government are also investing in the nursing workforce. The Substance Abuse and Mental Health Services Administration (SAMHSA) provides training and technical assistance to nursing facility staff serving individuals with serious mental illness and/or substance use disorders through its Center of Excellence for Building Capacity in Nursing Facilities to Care for Residents with Behavioral Health Conditions. The Department of Labor also provided $80 million in grants last year as part of its Nursing Expansion Grant program to increase clinical and vocational nursing instructors and educators in the U.S., and train healthcare professionals, including direct care workers. The Health Resources and Services Administration (HRSA) has also administered other programs to increase the number of nurse preceptors, an example of a HRSA program that supports the training of clinical nurse preceptors is the Nurse Education, Practice, Quality and Retention-Clinical Faculty and Preceptor Academies (NEPQR–CFPA) Program.[55] Another nurse education program administered by HRSA is the FY 2023 Nurse Education, Practice, Quality and Retention (NEPQR)-Pathway to Registered Nurse Program (PRNP) Awards, this program creates a pathway for LPNs and LVNs to become RNs.[56]

While the comments received on the specific details of the CMS nursing home staffing campaign are outside the scope of this rule, we acknowledge that workforce development is a shared responsibility, and encourage LTC facilities to partner with education and training sources to meet their staffing needs. We are also exploring the potential to provide additional technical assistance to LTC facilities through the Quality Improvement Organizations. We appreciate the information regarding nursing education, the number of new graduates and the suggestion to invest in nursing school infrastructure; however, these issues are not within the scope of CMS authority and this final rule. Likewise, the request for training and recruiting home health and hospice providers is also outside the scope of this rule. The request for student loan considerations is also outside the scope of this rule.

Comment: Several commenters suggested that CMS should work to promote an immigration policy that supports nursing staff to enter the United States and the nursing home workforce. Another commenter suggested building a domestic and international pipeline for potential nursing home workers to be recruited and trained.

Response: We appreciate these comments regarding the relationship between staffing and immigration policy. However, immigration policy is not within the scope of CMS authority.

Comment: One commenter stated that CMS should revisit the standards, at minimum, within one to two years of full implementation to determine if the agency's approach is yielding its intended outcomes and assess their impact on quality, safety, and access, followed by periodic reevaluations and redeterminations.

Response: We agree that it is important to review the impact that this final rule has on the delivery of care and services in LTC facilities. We also intend to monitor emerging research in this area to further inform our policy decisions. CMS continually reviews existing regulations to assess their appropriateness, effectiveness, and continued necessity. We intend to monitor LTC facility services, as well as the safety and quality of resident care, through the survey process, quality measure performance, and PBJ data to assess the impact of these new requirements and determine what, if any, future actions should be taken to assure that all residents receive safe care at all times and that their needs are met. We realize that standards of care are constantly evolving and staffing standards may need to be raised to meet the health and safety needs of facilities over time. The requirements in this rule are minimum baseline standards for safety and quality without accounting for resident acuity. We will continue to engage stakeholders as the requirements are implemented.

Comment: Many commenters expressed concern about potential systemwide impacts of the proposed changes, ranging from the potential for reductions in LTC facility admissions and census, facility closures, and the impact of those closures on residents and their families. Commenters gave scenarios of residents or individuals that may need admission to a LTC facility and not be able to find the care they need if fewer beds were available. Commenters suggested that residents in LTC facilities might face forced discharge or transfer if sufficient RNs and other staff were not available at the facility, resulting in inappropriate discharges to home or other inappropriate settings for residents. Some commenters expressed concern about readmission protections for residents when facilities say they can't readmit due to low staffing.

In addition, commenters stated that various issues may occur in other provider settings as the current state of nurse staffing at LTC facilities evolves. Some commenters noted that fewer LTC facility beds could result in hospitals having a harder time discharging patients in need of LTC. The commenters stated that without the ability to transfer patients in need of LTC to an appropriate facility, people in need of admission to a hospital might have to wait longer for an available bed. This could also result in a backup in the emergency department resulting in longer waits for care. A commenter stated that patients discharged from hospitals to LTC facilities have more acute clinical needs than patients discharged to home.

Response: While increased staffing needs in one provider setting can impact other provider settings, LTC facilities must be able to demonstrate that the care and services they provide meet the resident's needs. LTC facilities are responsible for compliance with requirements for participation, including but not limited to § 483.24, which requires that each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the

[54] FACT SHEET: Biden-Harris Administration Takes Steps to Crack Down on Nursing Homes that Endanger Resident Safety | The White House: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/*.

[55] Nurse Education, Practice, Quality and Retention-Clinical Faculty and Preceptor Academies (NEPQR–CFPA) Program | HRSA.

[56] FY 2023 Nurse Education, Practice, Quality and Retention (NEPQR)-Pathway to Registered Nurse Program (PRNP) Awards | Bureau of Health Workforce (*hrsa.gov*).

resident's comprehensive assessment and plan of care. This rule provides flexibilities through phased implementation timeframes and hardship exemptions, which can provide temporary relief to facilities that are having workforce issues. We have built in these flexibilities for facilities while still prioritizing resident safety and quality of care. The minimum staffing standards support existing regulations and help to ensure the staff needed to meet the care needs and improve the LTC facilities' ability to care for patients discharged from the hospital and prevent hospital readmissions. Although the practices of other healthcare settings are not within the scope of this rule, we intend to monitor its impact for unintended system-wide changes that may hinder or harm patient and resident care. We encourage LTC facilities to work with local hospitals to ensure safe care patient transitions. The requirements for participation at § 483.15(e)(1) are in place to ensure that facilities develop and implement policies that help facilitate the return of residents to the facility after a hospitalization. Facilities must have a sufficient number of qualified staff to meet each resident's needs, to protect resident health and safety while supporting access to care. We will use available data for monitoring residents' health, and safety and any unintended consequences during the multi-year implementation of this final rule.

Comment: Commenters expressed concerns that the proposed rule would draw funding and staff away from home and community-based services (HCBS) to facility-based settings. Moreover, this would lead to an increased unmet need for HCBS, poorer health outcomes for individuals, and reduced access to training and support for caregivers. Furthermore, the commenter thought that it would lead to reduced access to culturally and linguistically appropriate HCBS which will negatively impact communities of color.

Response: The HCBS workforce comprises a diverse array of worker categories including workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. While these workers do include nurses (RNs and licensed practical nurses) and NAs, the HCBS workforce comprises many other workers (both with and without professional degrees) that are not included in the minimum staffing requirement. Although there may be some overlap in demand for staff in LTC facilities and HCBS programs, we do not have reason to believe the overlap will be significant. We appreciate the comments, and CMS will continue to monitor these trends. Over time, additional, useful information will be supplied through finalized policies in the Medicaid access rule and this rulemaking concerning Medicaid funds dedicated to the direct care workforce in HCBS, LTC, and other institutional settings.

Comment: Some commenters included requests for staffing minimums for other categories of nursing home employees, including full time social workers and infection prevention control specialists. Other commenters suggested that CMS conduct research to determine why nurses are leaving the nursing workforce, noting that, since the COVID–19 PHE, many staff are going back to school for degrees not related to nursing.

Response: We agree that other LTC facility staff provide important services for resident well-being. However, suggestions related to establishing minimum standards for other types of employees are outside the scope of this final rule. We also agree that it is critical to understand the drivers of changes in the national nursing workforce and encourage interested parties to conduct research into these issues that can inform future policy decisions.

Comment: A commenter urged CMS to conduct research and rulemaking to enhance social work in nursing homes.

Response: We support the use of social work services in LTC facilities and encourage interested parties to conduct research into the care and services provided by social workers and the impacts to residents' highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care. However, suggestions related to establishing minimum standards for other types of employees are outside the scope of this rule.

Comment: A commenter asked CMS to support and protect union rights through implementation of a labor relations quality measure.

Response: The protection of union rights through the development of quality measures or any other means is outside the scope of this rule. This rule, however, is intended to support all workers in nursing facilities by ensuring there is sufficient staff to care for residents safely and thus reducing the burden on existing workers.

Comment: A commenter expressed concern that the proposed rule would undermine payments for LTC pharmacy services. For example, a facility census may decline resulting in a decrease in the use of pharmacy services causing various economic challenges for LTC pharmacies.

Response: We disagree with the commenter's assumption that implementation of this rule will result in an overall decline in resident census that undermines reimbursement and affects LTC pharmacy services. This final rule includes multiple flexibilities for eligible facilities located in areas affected by pronounced workforce shortages and provides staggered implementation periods to allow time for additional workforce development to comply with the requirements of this rule.

Comment: A commenter made suggestions to add additional items related to revenue and costs to the Federal cost reports that LTC facilities must complete and recommended that CMS publicly release that additional data after it is collected.

Response: Federal cost reporting changes are not within the scope of this final rule. We note that information collections require statutory authority. We will take the request under advisement.

Comment: Several commenters asked if every nursing home survey would assess compliance with the staffing requirements and staffing adequacy, while other commenters asked if we would bolster the survey process, to accommodate enforcement of the staffing standard. Commenters voiced concern about the additional time that would be required by surveyors to determine compliance with the minimum staffing requirements, and other commenters questioned whether States would get more funds for training and technical support to conduct surveys. Some commenters suggest increasing the State survey budget and the survey workforce so that enforcement of staffing requirements will be timely and successful.

Response: We appreciate the comments received on the survey process. We envision using a combination of PBJ data and onsite surveys to assess compliance with various aspects of these requirements.

We will publish more details on how compliance will be assessed after the publication of this final rule in advance of each implementation date for the different components of the rule. We intend to use the traditional process of

communication of information to providers and surveyors via CMS's Quality, Safety and Oversight Group (QSO) memoranda and publication of information in the CMS State Operations Manual (internet Only Publication, 100–07). The links to these resources are listed below.

- Policy & Memos to States and CMS Locations | CMS: *https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states-and-cms-locations.*
- Quality Safety & Oversight-Guidance to Laws & Regulations | CMS: *https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulations.*

We are also committed to robustly funding the survey, certification, and enforcement programs to the extent possible. The President's FY 2025 Budget calls for an increase in funding for these important programs and for the survey and certification funding to be shifted to mandatory spending starting in the FY 2026 budget to better align the continued need for surveys with the type of funding.

Comment: Several commenters asked for an evidence-based template and updated surveyor guidance for monitoring and enforcing staffing levels. In addition, commenters questioned whether surveyors will be taught principles of evidence-based staffing research so that their determinations of compliance with staffing minimums are neither subjective nor the opinion of the surveyor.

Response: We thank the commenters for their feedback. We will publish more details on how compliance will be assessed after the publication of this final rule in advance of each implementation date for the different components of the rule. We envision using a combination of PBJ data and onsite surveys to assess compliance with various aspects of the requirements. We note that since the requirements specify specific staffing minimum thresholds, the determination of compliance with these thresholds will be objective, and not subjective. However, our decisions to grant exceptions are based on criteria that will require the agency to use its best judgment (for instance, in determining whether a facility has made a good-faith effort to hire additional staff).

Comment: Many commenters expressed concerns related to the importance of identifying noncompliance and taking appropriate enforcement actions so that residents' health and safety are protected. Commenters asked about the timeframe between the determination that a provider is found out of substantial compliance with the new staffing standards and any resultant enforcement actions, citing concerns about potential significant time lags. Many commenters suggested CMS consider survey results and PBJ data for compliance determinations and enforcement actions. Other commenters noted that PBJ data is available on a quarterly basis and could be used for more frequent compliance reviews. A commenter asked if day to day fluctuations in staffing will result in citations. Some commenters suggested rulemaking to adopt specific enforcement rules for the HPRD numerical minimums. Some commenters stated that when enforcement actions are taken, they are too severe. Several commenters urged CMS to establish detailed guidelines on when a surveyor should assess appropriate penalties at the harm or immediate jeopardy level whenever there is serious harm, injury, impairment or death of a resident. Others recognized that enforcement is critical to ensure successful implementation of the minimum staffing standards and that nursing homes should know that they face consequences for substantial non-compliance.

Response: We appreciate and will consider the comments as we move forward and recognize that rigorous data-driven enforcement will be critical to the successful implementation of this rule. We will publish more details on how compliance will be assessed and how enforcement remedies will be imposed after the publication of this final rule in advance of each implementation date for the different components of the rule. We envision using a combination of PBJ data and onsite surveys to assess compliance with various aspects of the requirements. Additionally, if finalized, the proposal for revisions to CMPs in the forthcoming FY 25 SNF payment rule will give CMS more flexibility to assess fines associated with the severity of the citation.

Comment: The PBJ allows staffing data to be collected from LTC facilities on a regular basis. Several commenters suggested that CMS improve PBJ implementation so that it allows facilities to report all hours worked by staff including nurses and nurse aides and offers facilities a reasonable opportunity to appeal/correct PBJ data. A commenter suggested that CMS should send letters to facilities that submit PBJ data showing staffing levels that do not comply with requirements and ask for an explanation. Many commenters recommended monitoring PBJ staffing data and wanted automatic citations issued for failure to comply with the standards. One commenter suggested that Federal surveyors use the PBJ data as the basis for citations for deficiencies and to conduct more frequent reviews of facility compliance with HPRD minimums than what is currently required.

Response: Per Federal law, staffing data submitted by a facility to the PBJ system must be auditable back to payrolls and other verifiable information. Therefore, CMS does not agree that all hours worked by staff (such as hours that cannot be verified) should be reported and credited, but auditable back to verifiable information should be reported and credited to the HPRD calculations (unless they meet the reporting requirements). Furthermore, facilities have up to 45 days after the end of each quarter to review and make any corrections needed to the data prior to submission. Therefore, facilities already have the opportunity to correct their PBJ data. We note that providers will retain their ability to exercise existing regulatory provisions to dispute or appeal citations for noncompliance, such as informal dispute resolution. Additionally, CMS does inform providers of their staffing levels prior to public posting. However, we disagree that CMS should give facilities an opportunity for an explanation, as compliance with the requirements is based on whether the facility meets the specific required staffing thresholds, regardless of justification. A facility that in good faith believes that it cannot consistently meet the HPRD standards may request an exemption, pursuant to § 483.35(g) as set out in this final rule. For comments related to automatic citations, we appreciate the suggestion and note that surveys of compliance and enforcement actions are conducted pursuant to 42 CFR part 488, subparts E and F, respectively. We will publish more details on how compliance will be assessed after the publication of the final rule in advance of each implementation date for the different components of the rule.

Comment: Several commenters requested that CMS publicly identify nursing homes that fail to adjust staffing levels for resident acuity. Other commenters suggest that CMS should include easy to understand information about whether a nursing home meets the minimum staffing standards on Care Compare.

Response: As part of CMS' survey and enforcement activities, we currently publish data for all LTC facilities on the

Care Compare website. We appreciate the suggestions and are committed to providing consumers, families, and caregivers with useful information to help support their healthcare decisions. Care Compare will be updated to show whether a facility has an exemption and will note the extent to which a facility falls short of the minimum staffing standards.

Comment: A commenter suggested that PBJ and Minimum Data Set (MDS) be improved to ensure compliance with minimum staffing standards.

Response: We appreciate this suggestion, and welcome suggestions for improvement. However, the commenter did not provide details on how PBJ and the MDS could be improved.

Comment: A commenter requested that CMS issue guidance prior to the final rule on additional staffing standards based on resident acuity and activities of daily living (ADL) needs.

Response: We appreciate the suggestion. CMS will issue subregulatory guidance to surveyors for specific requirements after the publication of this final rule in advance of each implementation date for the different components of the rule. However, we note the existing regulations require facilities to consider residents' conditions and acuity when developing their facility assessment to determine the personnel needed to meet residents' needs. Subregulatory guidance for this requirement can be found in the State Operations Manual, appendix PP, sec. 483.70(e) (*https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf*).

Comment: Some commenters suggested that CMS consider ways to enhance compliance among LTC facilities with automated data collection techniques or other forms of information technology.

Response: We appreciate the suggestion. CMS remains open to exploring ways that technology can be leveraged to streamline data collection and improve compliance and enforcement.

Comment: One commenter expressed concern that PBJ reporting guidelines are technical and the data submitted do not always reflect the actual staffing levels. The concern centered around rural providers with small census using one nurse per shift, the nurse stays onsite for the entire shift, including the lunch break. However, the PBJ reporting guidelines always exclude a 30-minute rest period, regardless of whether the nurse took a 30-minute uninterrupted break.

Response: We appreciate the concern raised by the commenter. It is very important that PBJ data is auditable. Facilities need to deduct a 30-minute meal-break from each eight-hour shift. As the staffing data must be auditable back to payrolls, there is no way to audit and verify the portion of their meal break that was spent working versus eating. Also, some facilities pay for meal breaks, and some do not. Allowing some facilities to report hours for paid meal breaks would result in reporting higher levels of staffing based on whether or not a facility pays for meal breaks, instead of actual differences in the amount of direct resident care their staff provide. Therefore, to measure all facilities equally, we require all facilities to deduct 30 minutes per shift. Information on this and other policies related to PBJ can be found on the CMS website for Staffing Data Submission Payroll-Based Journal: *https://www.cms.gov/medicare/quality/nursing-home-improvement/staffing-data-submission.*

Comment: One commenter suggested better coordination between State surveyors and the CMS designated Quality Innovation Network Quality Improvement Organizations (QIN–QIOs).

Response: We thank the commenter for their feedback. CMS is committed to ensuring coordination between State surveyors and QIN–QIOs as they conduct their individual and unique responsibilities.

Comment: We received many recommendations for alternative policies or strategies for supplementing or enhancing the LTC facility workforce. Commenters suggested various ways of substituting staff when determining compliance with HPRD minimums set out in this rule: one commenter suggested allowing LPNs to substitute for NAs, another suggested facilities will substitute NAs for LPNs, yet another commenter related that LPNs and RNs can substitute for NAs in addition to their own job requirements. A commenter proposed the creation of a transportation aide role so that residents could move around the facility, and this would in turn improve quality of life. One commenter stated that expansion of training for paid feeding assistants would be beneficial to the residents. The same commenter suggested flexibility within the regulations to allow technology to supplement the workforce such as robots, that can deliver food to residents at their tables.

Response: We thank commenters for these recommendations. Under the current regulations, facilities can already use many of these suggestions, such as using feeding assistants, transportation aides, and technology to supplement the nursing workforce in LTC facilities, paying nurse aides while they are in training, and using LPNs/LVNs to deliver some NA care. Facilities may continue to implement these strategies as needed to ensure that all residents receive high-quality care in accordance with their plan of care and consistent with the requirements for participation.

Comment: A small number of commenters addressed the relationship between the proposed requirements and CMS' statutory authority. A commenter noted that CMS is taking these minimum staffing requirement actions based on the statutory authority to provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care. This commenter urged CMS to establish higher minimum staffing levels in a way that fulfills this statutory mandate. One commenter suggested that CMS did not have authority to establish RN staffing standards for 24 hours per day, 7 days per week, and suggested that CMS should augment the current 8 hours per day, 7 days a week RN services requirement with a higher minimum RN HPRD to achieve our policy goal. Finally, one commenter contended that CMS lacks the authority to finalize the minimum staffing standards, suggesting that CMS cannot require HPRD standards or increase the current 8 consecutive hours of registered nurse hours a day 7 days a week minimum standard to 24 hours a day standard.

Response: We appreciate the comments received on whether or not CMS has the authority to enact these regulations. As discussed in section II.A.1. of this final rule, various provisions in sections 1819 and 1919 of the Act provide CMS with the statutory authority for the requirements of this rule. The Secretary has concluded that these HPRD levels and RN onsite 24/7 requirements are necessary for resident health, safety, and well-being, under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act, which instruct the Secretary to issue such regulations relating to the health, safety, and well-being of residents as the Secretary may find necessary. We agree with the commenter that section 1819(b)(2) and 1919(b)(2) of the Act, which require facilities to provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, also

supports CMS authority to establish these requirements. Also, sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act require that a SNF or NF must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the safety and quality of life of each resident. While sections 1819(b)(4)(C) and 1919(b)(4)(C) of the Act state that a facility must provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents, and must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week, CMS is using separate authority as described above to establish these new requirements rather than the authorities found at sections 1819(b)(4)(C) and 1919(b)(4)(C) of the Act. Our goal is to protect resident health and safety, and the persistent and pervasive safety issues described in the proposed rule and in this final rule make it clear that it is necessary to establish new minimum requirements to fulfill the Secretary's responsibility to establish other requirements related to resident health and safety.

2. Definitions (§ 483.5)

We proposed to revise § 483.5 to include the definition of ''hours per resident day'' (HPRD), that is, staffing hours per resident per day is the total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS.[57] We also proposed to add the definition of ''representative of direct care employees'' who is an employee of the facility or a third party authorized by direct care employees at the facility to provide expertise and input on behalf of the employees for the purposes of informing a facility assessment. We received no comments on how we define hours per resident per day (HPRD). We received no comments on how we define representative of direct care employees. As such, we are finalizing the definition of ''hours per resident day'' (HPRD) and ''representative of direct care employees'' as proposed.

Final Rule Action: We are finalizing the definition of ''hours per resident day'' as the total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS. We are finalizing the definition of ''representative of direct care employees'' as an employee of the facility or a third party authorized by direct care employees at the facility to provide expertise and input on behalf of the employees for the purposes of informing a facility assessment.

3. Minimum Staffing Standards (§ 483.35(a))

In the proposed rule, we discussed revisions to the Nursing Services regulations at § 483.35(a)(1)(i) and (ii) to require facilities to meet minimum staffing standards—0.55 HPRD of RNs and 2.45 HPRD of NAs (see 88 FR 61366 through 61370, 61428). Specifically, at § 483.35(a)(1)(i) we proposed individual nurse staffing type standards for RNs and NAs. We proposed to require facilities to meet minimum staffing standards—0.55 HPRD of RNs and 2.45 HPRD of NAs—as well as to maintain sufficient additional personnel, including but not limited to LPN/LVNs, and other clinical and non-clinical staff, to ensure safe and quality care, based on the proposed facility assessment requirements at new § 483.71. We also solicited comments on establishing an alternative total nurse staffing standard, such as 3.48 HPRD, in place of a requirement only for RNs and NAs, or in addition to a requirement for RNs and NAs that could also encompass other nursing staff types. We considered an alternative standard of 3.48 HPRD for total nurse staffing—inclusive of the 0.55 HPRD of RNs and 2.45 HPRD of NAs minimum standards—based on the literature evidence (see 88 FR 61259 through 61366 for more details). CMS solicited comments on a minimum total nurse staffing standard of 3.48 HPRD, the necessity of a total staffing standard, and whether a total staffing standard should be adopted in place of a requirement only for RNs and NAs, or in addition to a requirement for RNs and NAs. We also emphasized that comments on the recommended policy or an alternative, must support and promote acceptable quality and safety in LTC facilities, which is the intended goal. We also requested that commenters submit evidence and data to support their recommendations to the extent possible.

Comment: We received many comments on the numerical HPRD minimum staffing standards. Commenters offered numerous reasons for supporting CMS efforts to establish minimum staffing standards, including increased accountability for facilities regarding the treatment of staff and residents, and the care provided. Commenters that supported establishing numerical HPRD standards also noted that such requirements would assure that safety is not compromised for both staff and residents. Commenters also stated that the proposed staffing requirements should be considered as the start of improvements to be built upon over time, rather than as the singular end goal for addressing LTC facility safety and quality challenges. Others commended the Administration for proposing minimum nurse staffing standards, stating that ''the NPRM [notice of proposed rulemaking] represents a paradigm shift in nursing home oversight to promote quality of care''. Another commenter stated, ''we strongly encourage CMS to adopt the proposed standards. These standards will set a floor (baseline) that prevents overall resident harm and jeopardy and ensure all residents, regardless of race or geography, and allows for nursing home to staff above those standards based on resident acuity.'' Another commenter noted that CMS must clarify that, ''the minimum staffing levels are considered to be only for residents with the lowest acuity needs.''

Response: We thank commenters for their support in improving resident care and safety. We agree that establishing minimum staffing requirements will promote quality in LTC facilities and ensure safety is not compromised for both staff and all residents. Facilities must meet, at a minimum, the 3.48 total nurse staffing, .55 RN, and 2.45 NA HPRD (as finalized in this rule and discussed in detail later in this section) regardless of the individual facility's resident case-mix, as these requirements establish the minimum floor (baseline) for staffing requirements. We expect that many facilities will need to staff above the minimum standards to meet the acuity needs of their residents depending on case-mix and as mandated by the facility assessment required at § 483.71.

Comment: We received several comments on establishing individual minimum standards for RNs and NAs. Some commenters supported establishing individual standards, noting that setting individual minimum staffing standards will ''avoid aggregating HPRD across job classifications.'' For example, commenters noted that mandating a specific number of minimum hours for care provided by NAs would increase facility accountability and reduce discretion regarding the type of staff facilities may use to comply with the requirement. In addition, one commenter noted the specific individual standards for RNs and NAs would improve some residents' health and quality of life.

Commenters also questioned our use of the acronyms ''NA'' (nurse aide) versus ''CNA'' (certified nurse aide) and requested clarification regarding the

[57] *https://data.cms.gov/provider-data/dataset/4pq5-n9py.*

type of staff that would count towards the minimum requirement. Some commenters supported having a minimum staffing standard for NAs. However other commenters suggested that CMS require the use of CNAs since this is a Federal requirement and strongly opposed the use of ''uncertified and untrained staff''. For example, one commenter noted that nursing assistants are required to meet certification standards within a specified period and indicated that nursing homes are not allowed to rely on NAs to provide basic care unless they meet the training requirements as required.

Response: We appreciate the commenters' support for the minimum HPRD staffing standard. Current regulations at § 483.35(a)(1)(i) and (ii) require facilities to have sufficient numbers of licensed nurses and other nursing personnel, including but not limited to NAs, available 24 hours a day to provide nursing care to all residents in accordance with the resident care plans.[58] Nurse aides include certified nurse aides (CNAs), aides in training and medication aides/technicians, which all require training. Specifically, at § 483.5 existing regulations define ''nurse aide'' as any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in 42 CFR 488.301. As such, we disagree with having a staffing standard for CNAs only. In addition, in some facilities there is an overlap in responsibilities between CNAs, medication aides/technicians, and aides in training. We agree with commenters that having a separate, specific minimum staffing level requirement for RNs and NAs is important to improving resident health and safety and are finalizing this proposed requirement at § 483.35.

Comment: Many commenters who supported establishing numerical staffing standards recommended ways to strengthen the proposed minimum HPRD staffing requirements. The commenters stated that the proposed 0.55 RN and 2.45 NA HPRD requirements were ''not sufficient to protect the health and safety of residents'' and ''risk normalizing staffing levels associated with poor quality of care. . . .'' Commenters also noted that facilities in both urban and rural areas already meet far higher nurse staffing standards than what CMS proposed and as such CMS should consider strengthening the proposed minimum nurse staffing standard. Commenters offered varying modifications to strengthen the proposed minimum nurse staffing standard, which included establishing a range of minimum staffing standards based on resident acuity and need for assistance with activities of daily living (ADLs) or establishing a higher HPRD as the minimum standard. For example, one commenter suggested that CMS revise the proposal to require facilities to meet a minimum 0.75 HPRD for RNs and 2.8 HPRD for NAs, noting that many nursing homes currently staff at an average of 3.63 HPRD which is above the proposed minimum standard. While some commenters supported establishing specific minimum requirements for RNs and NAs, several commenters strongly supported the creation of a minimum total direct care nurse staffing standard that would include minimum HPRD requirements for RNs and nurse aides and incorporate LPNs/LVNs either as part of a minimum licensed nursing standard that includes a minimum RN HPRD or as a separate minimum LPN/LVN HPRD standard. For example, one commentator indicated that ''a minimum standard for LPNs would reinforce a minimum standard of 1.4 HPRD for licensed nurses''. Others suggested ''LPNs need to count toward either RN or CNA mandated ratios. One commentator noted that ''LPNs should also be counted in the 0.55 RN HPRD requirement.'' Commenters who supported the inclusion of LPNs emphasized the unique role that LPNs play in providing quality care and the importance of capturing their contributions in a minimum nurse staffing standard. Commenters indicated that LPNs provide essential skilled care and critical services that are not within a CNA's scope of practice. Furthermore, some commenters shared concerns about the unintended consequences that establishing a minimum nurse staffing standard that lacks LPNs may have on staff retention and career advancement. These commenters suggested that our proposal, and the lack of incorporating LPNs into the requirement, marginalized the contributions of LPNs in the LTC facility workforce. However, commentators were not consistent in their suggestions for HPRD ratios of LPN/LVNs.'' Lastly, many commenters strongly supported a minimum threshold of 3.48 HPRD for total nurse staffing and suggested finalizing an even higher numerical standard than the 3.48 total HPRD, ranging up to 4.2 HPRD.

Response: We appreciate the thoughtful and nuanced comments received on the proposed minimum HPRD staffing standard and the suggestions for revision to further strengthen the requirement. Ensuring that nursing home residents receive safe, reliable, and quality care is a critical function of the Medicare and Medicaid programs and a top priority for CMS. As such, requiring Federal minimum nurse staffing standards will create a consistent minimum floor specific to nurse staffing levels and reduce the variability in nurse staffing across States. In addition, while establishing minimum nurse staffing standards will create broadly applicable standards at which all residents across all facilities will be at significantly lower risk of receiving unsafe and low-quality care. We emphasized in the proposed rule and reiterate here that facilities are also required to staff above the minimum standard, as appropriate, to address the specific needs of their resident population (88 FR 61369). We expect that most facilities will do so in line with strengthened facility assessment requirements at § 483.71 (88 FR 61368). As stated in the proposed rule, we will also revisit the Federal minimum staffing standard over time, as the rule is implemented, to determine whether upward revisions in staffing levels are needed.

We appreciate the comments received requesting that we incorporate a total nursing standard that includes a minimum HPRD specifically for LPN/LVNs. In the proposed rule, we indicated minimum individual standards for RNs and NAs based on evidence demonstrating that RNs and NAs have a consistently greater demonstrable effect on quality. While we believe LPNs, in addition to all staff, are vitally important to resident care, we detailed in the proposed rule the research evidence that suggest that a greater RN presence has been associated with higher quality of care and fewer deficiencies. We also noted literature in support of having adequate staffing levels, specifically NAs, to prevent a high rate of unusual patient safety events such as resident falls.

We recognize the importance of the role of LPN/LVNs staffing in LTC facilities and acknowledge their increasing responsibilities for providing resident care. However, we found

[58] 42 CFR 483.35, *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

insufficient research evidence that supports a particular minimum standard for LPN/LVNs nor did we receive supporting evidence for particular minimum standards for LPN/LVNs from commenters. We also noted that facilities must maintain sufficient additional personnel, including but not limited to LPN/LVNs, and other clinical and non-clinical staff, to ensure safe and quality care based on the proposed facility assessment requirements at § 483.71 (88 FR 61368). Additionally, hours worked by LPN/LVNs may be counted toward the 3.48 total nurse staffing HPRD requirement being finalized as part of this rule.

We agree that a higher HPRD of nursing staff such as 0.75 HPRD of RNs, 2.8 HPRD of NAs, and 4.1 HPRD of total nurse staffing could produce increased improvements in safety and quality of resident care and that the alternative approach to establish a minimum total nursing standard is one effective way to create improvements while also providing flexibility. We also recognize that there is evidence that suggests that a lower HPRD of nursing staff—0.45 HPRD of RNs, 2.15 HPRD of NAs, and 3.30 HPRD of total nurse staffing could lead to a 3.3 percent of care delayed, whereas having no minimum staffing requirements could result in a higher *i.e.* a. 5.6 percent of care delayed. However, we maintain that establishing individual minimum staffing standards for RNs and NAs specifically is the best approach to increasing quality and safety given the evidence suggesting that RNs and higher numbers of NAs significantly improve quality.

We also recognize that establishing a total nurse staffing standard could produce increased improvements in safety and quality of resident care. We agree with commenters' assertions that the proposed staffing standards could be strengthened, and we believe that the addition of a total nurse staffing standard will promote resident safety and high-quality care. We have chosen 3.48 HPRD as the minimum total staffing standard, which is inclusive of individual staff-specific standards, in light of comments on the proposed rule indicating the value of this addition and evidence from the 2022 Nursing Home Staffing Study, in addition to other factors discussed in the proposed rule. Finally, we share the concern raised by commenters about the potential for unintended consequences resulting from the absence of an LPN/LVN standard, noting facilities may be incentivized to terminate LPN/LVNs and replace them with either nurse aides, RNs or a lower paid unlicensed staff. A total nurse staffing standard guards against these unintended consequences. Therefore, we are finalizing a minimum standard for total nurse staffing and requiring minimum individual standards for RNs and NAs. Specifically, we are finalizing a requirement for facilities to provide the minimum 3.48 HPRD of total nurse staffing, which must include at least 0.55 HPRD of RNs and 2.45 HPRD of NAs. We note that facilities may use any combination of nurse staffing (RN, LPN/LVN, or NA) to account for the additional 0.48 HPRD to comply with the total nurse staffing standard. We remain committed to continued examination of staffing thresholds, including careful work to review quality and safety data resulting from initial implementation of finalized policies and robust public engagement. Should subsequent data indicate that additional revisions to the staffing minimums are warranted, we will revisit the minimum staffing standards with continued consideration of all relevant factors.

Comment: Many commenters did not support the proposed rule and establishing minimum staffing standards, whether at the individual or total nurse staffing levels. Commenters cited several concerns, including workforce shortages, costs of implementing the proposed changes, Medicaid underfunding, the diversity of nursing homes and their resident needs, and potential unintended consequences. For example, one commenter stated that ''the proposed rule fails to consider in a serious way where nursing homes will find the estimated 12,639 additional registered nurses (RNs) and 76,376 additional nurse aides (NAs) needed to comply with its requirements.'' Other commenters suggested that compliance with the HPRD minimums will be difficult or impossible to achieve with staffing shortages and major challenges with workforce training and development. Many commenters focused on the challenges faced by rural facilities, noting that they may face greater challenges recruiting staff.

Several commenters shared concerns regarding the costs and burden imposed by the proposed rule and opposed a minimum staffing standard without dedicated funding to support its implementation. These commenters suggested that the cost of compliance would create unsustainable financial burdens for facilities and negatively impact residents by forcing facilities to limit admissions or close. For example, we received many comments from certain categories of facilities that expressed concerns about the potential impact of the minimum HPRD requirements on the operations of their individual facilities and unique resident populations, such as tribally-owned facilities. However, several commenters also asserted that existing facility resources may be allocated to support staffing improvements and a minimum staffing standard, but indicated that facilities may be allocating such resources elsewhere. Moreover, commenters opposed to establishing a minimum staffing standard described the proposal as a ''one-size-fits-all'' numeric standard and strongly encouraged CMS not to proceed with finalizing the proposed rule, especially as the LTC workforce continues to rebound from the COVID–19 PHE. These commenters preferred that staffing standards be regulated at the State level and shared concerns about conflict between our proposal and States that already have staffing standards. Some commenters also suggested that there are currently facilities that demonstrate a high quality of care delivery, despite not currently meeting the proposed staffing levels. They also noted that there are facilities with some of the poorest quality outcomes based on CMS data who currently meet the proposed staffing levels.

Response: We appreciate the concerns raised by commenters regarding the challenges that a minimum staffing requirement will impose on LTC facilities. We also acknowledge the impact of the COVID–19 PHE on the health care industry, as discussed in the proposed rule, and recognize the challenges that nursing homes are facing as they relate to staffing. However, the COVID–19 PHE also highlighted the long-standing concerns with inadequate staffing in LTC facilities and we reiterate that evidence has shown that appropriate staffing made a crucial difference in quality of care as part of the overall response to the COVID–19 PHE in LTC facilities (see 88 FR 61356).

In the proposed rule, we outlined the need for a minimum nurse staffing standard noting the consequences of inadequate staffing, such as poor resident outcomes, adverse events, and delayed or omitted basic care tasks (88 FR 61355). We also included in the proposed rule an impact analysis for public comment and responses to comments received can be found in section VI., ''Regulatory Impact Analysis,'' of this final rule. We maintain that chronic understaffing continues in LTC facilities and evidence demonstrates the benefits of increased nurse staffing in these facilities. Indeed, a number of the comments we received on the proposed rule further highlighted the danger from a lack of sufficient

staffing for residents as well as the negative effects that chronic understaffing has on the nursing workforce. As such, we believe that requiring a Federal minimum nurse staffing standard will create a consistent floor (baseline) across all facilities and reduce the variability in the nurse staffing HPRD across States. In tandem, we believe policies finalized and discussed in this rule will help to advance equitable, safe, and quality care for all residents by reducing the risk of residents receiving unsafe and low-quality care. Therefore, we are finalizing our proposal to establish minimum nurse staffing standards for LTC facilities as discussed in this final rule.

We recognize the concerns raised by commenters regarding the cost of this rule, requests for additional funding, and workforce challenges. In light of these concerns, CMS announced a national campaign to support staffing in nursing homes.[59] As previously discussed, CMS will work to develop programs that make it easier for individuals to enter careers in nursing homes, investing over $75 million in financial incentives such as tuition reimbursement. In addition, the implementation of the requirements in this final rule are phased-in to allow all facilities the time needed to prepare and comply with the new requirements specifically to recruit, retain, and hire nurse staff as needed. Finally, the rule also finalizes requirements that will allow for a hardship exemption in limited circumstances. While we fully expect that LTC facilities will be able to meet our requirements, we recognize that external circumstances may temporarily prevent a facility from achieving compliance despite a facility's demonstrated best efforts. Details regarding the finalized implementation timeframe and exemption framework are discussed in sections II.B.5 and II.B.7 of this rule, respectively (that is, a phased implementation up to 5 years for rural facilities and up to 3 years for non-rural facilities).

Comment: Some commenters suggested that the timeframe used to determine compliance with the minimum HPRD should be set for at least one year from the date of the survey for which the compliance is being determined. Specifically, commenters suggested that the lookback period should cover a full annual certification period and emphasized that facilities should be held accountable for staffing decisions through an entire certification period. Comments also suggested that compliance should be determined by reviewing the facility's quarterly average HPRD and the lookback period should be no longer than 1 year. For example, one commenter stated that a quarterly average of a facility's HPRD for nurse staffing would align more closely to what consumers see on CMS Care Compare and what is used in the CMS Five-Star Quality System. They note that this type of consistency helps consumers and providers understand the requirements and monitor performance.

Response: We agree that creating consistency between what is publicly reported can better inform consumers and help facilities' understanding of the compliance requirements. As such, we are not finalizing our proposal to limit determinations of compliance with hours per resident day requirements to the most recent available quarter of PBJ System data submitted in accordance with § 483.70(p). We envision compliance will be assessed by using a combination of PBJ data and surveyor review and observations. We note that CMS already uses PBJ in the existing survey process, and we instruct surveyors to review a report of each facility's most recent quarter of PBJ data (or additional quarters if warranted), to help target their investigations of compliance. CMS intends to calculate each facility's staffing hours per resident per day based on data required to be submitted to CMS, such as existing data required at § 483.70(p) (as redesignated in this final rule) for electronic submission of staffing information (which is submitted through the PBJ system). As with all regulations, CMS publishes information on how compliance will be assessed in the State Operations Manual, appendix PP, and in the survey procedure documents found on the CMS web page for nursing home surveys.[60] Similarly, we will publish more details on how compliance will be assessed after the publication of this final rule in advance of each implementation date for the different components of the rule.

Comment: In addition to the proposed requirements, we also solicited comments on the following issues:

- The benefits and trade-offs associated with different staffing standards;
- Use of case-mix adjusted staffing HPRD for each facility (rather than solely the facility's self-reported staffing information) to assess compliance with the minimum staffing standards, steps CMS can take to support LTC facilities in predicting what their case-mix adjusted staff might be and hire in expectation of that adjusted staffing level, and any resources facilities will need to proactively calculate their existing HPRD for nursing staff;
- Alternative policies or strategies we should consider to ensure that we enhance compliance, safeguard resident access to care, and minimize provider burden.

We received few comments related to the specific benefits and trade-offs associated with different staffing standards. Commenters stated that a requirement with individual staffing levels for specific nurse types reduces flexibility, which may result in non-compliance with the staffing requirements. In contrast, a total nurse staffing standard or combined total standard with individual thresholds for specific nurse types offers the facility the flexibility to adjust as needed to day-to-day shifts in staffing. Moreover, commenters noted concerns about complying with minimum staffing standards that differ significantly from State staffing requirements. We also received very few comments related to adopting a case-mix adjusted staffing HPRD for each facility to assess compliance with the minimum staffing standards. However, commenters who provided feedback shared concerns with adopting case-mix adjustments to staffing HPRD standards, noting that the adjusted HPRD is derived from MDS data that offers a snapshot of the past and does not predict future staffing needs. Another commenter also shared concerns that the data currently used to determine case-mix adjustments is flawed and should not be used to create acuity-adjusted staffing requirements.

Response: We thank commenters for their thoughtful feedback in response to our comment solicitations. We agree that there are varying approaches to establishing a minimum staffing standard that would create greater flexibility, such as a implementing a total nurse staffing standard with individual staffing levels for specific nurse staff. As discussed, we are modifying our proposal to finalize a higher total standard that will increase improvements in quality and safety while providing flexibility for providers in meeting the minimum standard. We agree with commenters who indicated that there are several factors to consider when making case-mix adjustments to assess compliance with the minimum HPRD staffing standards, including the

[59] *https://www.cms.gov/newsroom/fact-sheets/medicare-and-medicaid-programs-minimum-staffing-standards-long-term-care-facilities-and-medicaid.*

[60] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.*

need to ensure that facilities are able to proactively predict and calculate what their case-mix adjusted HPRD for staff might be. We believe that additional consideration is needed to analyze the use of case-mix adjusted staffing HPRD for each facility to assess compliance with the minimum staffing standard and will keep this suggested approach in mind for future rulemaking.

Comment: We solicited comments on evidence that States relied on when they adopted their specific minimum nurse staffing standards and the rate of compliance with the State's staffing standards. We did not receive comments that provide the evidence that States relied on when they adopted specific minimum nurse staffing standards, however we did receive very few comments on the impact of the minimum nurse staffing standards that States adopted. One commenter stated that overall number of nursing staff in nursing homes influences quality in nursing homes. Another commenter noted that ''Washington State already has established staffing minimums. They are effective, they are enforced, and there is an established process for waivers.''

We also received very few comments on rates of compliance with State staffing mandates. For example, one commenter stated that nearly 30 percent of their State's nursing homes have difficultly complying with their minimum staffing requirement. Another commenter noted that their State successfully improved compliance with minimum staffing requirements as a result of the implementation of administrative penalties for facilities that failed to comply with the State's minimum HPRD staffing requirement, citing public health data following the implementation of State's requirements.[61]

Response: We appreciate the comments received on compliance with State minimum staffing requirements, which appears to vary. We believe that establishing a national floor (baseline) for nurse staffing in nursing homes will lead to improvements in quality across all States and reduce disparities in care. However, as mentioned previously, the provisions of this rule are not intended to, and do not preempt the applicability of any State or local law providing a higher standard (in this case, a higher HPRD requirement for total nurse staffing, RNs and/or NAs, an RN coverage requirement in excess of at least one RN on site 24 hours per day, 7 days a week) than required by this final rule.

Final Rule Action: We are modifying our proposal and finalizing a requirement for facilities to provide a minimum total nurse staffing standard of 3.48 HPRD that must include at least 0.55 HPRD of RNs and 2.45 HPRD of NAs. We are not finalizing our proposal to limit determinations of compliance with hours per resident day requirements to the most recent available quarter of PBJ System data submitted in accordance with § 483.70(p).

4. Registered Nurse 24 Hours per Day, 7 Days a Week (§ 483.35(b)(1))

The existing LTC facility staffing regulations require an RN to be onsite 8 consecutive hours a day, 7 days a week (§ 483.35(b)(1)).[62] In other words, an RN is required to be onsite for a total of 8 consecutive hours out of 24 hours a day. The LTC facility may decide to allocate all 8 consecutive hours of RN time to one day shift or an evening shift for a 24-hour day, similarly to the HPRD proposed for RNs. To address health and quality of care concerns and to avoid placing LTC facility residents at risk of preventable safety events due to the absence of an RN, we proposed to revise § 483.35(b)(1) to require LTC facilities to have an RN onsite 24 hours a day, 7 days a week.

An existing statutory waiver for Medicare SNFs, set out at section 1819(b)(4)(C)(ii) of the Act and implemented at § 483.35(f), permits the Secretary to waive the requirements of § 483.35(b) to provide the services of a RN for more than 40 hours a week, including the director of nursing. We proposed that facilities would use this process to pursue a waiver of the 24 hours a day, 7 days a week requirement.

In addition to proposing the 24-hour, 7 days a week requirement for an RN, we noted that the separate existing requirement for the director of nursing (DON) at § 483.35(b)(2) would remain. Specifically, all LTC facilities are required to designate an RN to serve as the DON on a full-time basis (§ 483.35(b)(2)). The current rule stipulates that the DON can serve as a charge nurse only if the facility has an average daily occupancy of 60 or fewer residents (§ 483.35(b)(3)). Since the DON must be an RN, the DON is included in the proposed nurse minimum staffing requirements as an RN. All RNs with administrative duties, including the DON, should be available for direct resident care when needed. However, the DON, as well as other nurses with administrative duties, would likely have limited time to devote to direct resident care. We are concerned that for some LTC facilities having the DON as the only RN on site might be insufficient to provide safe and quality care to residents. This concern was also expressed in the NASEM 2022 publication discussed in the proposed rule, in which the NASEM recommended that the DON not be counted in the requirement for an RN 24 hours, 7 days a week.[63] Hence, in the 2023 proposed rule we also solicited comments on the following specific questions:

- Does your facility, or one you are aware of, have an RN onsite 24 hours a day, 7 days a week? If not, how does the facility ensure that staff with the appropriate skill sets and competencies are available to assess and provide care as needed?
- If a requirement for a 24 hour, 7 day a week onsite RN who is available to provide direct resident care does not seem feasible, could a requirement more feasibly be imposed for a RN to be ''available'' for a certain number of hours during a 24 hour period to assess and provide necessary care or consultation provide safe care for residents? If so, under what circumstances and using what definition of ''available''?
- Should the DON be counted towards the 24/7 RN requirement or should the DON only count in particular circumstances or with certain guardrails?
- Are there alternative policy strategies that we should consider to address staffing supply issues such as nursing shortages?

We received numerous comments regarding this proposal. Upon reviewing and analyzing these comments, we are finalizing a revision of the proposal as described in the responses below:

Comment: Many commenters, including some professional provider organizations, advocacy groups, and labor organizations supported the proposed requirement for an RN to be onsite 24 hours a day, 7 days a week that is available for direct resident care. Some of these commenters also noted that other experts and organizations have for many years been supporting a requirement for at least one RN on site at a LTC facility 24 hours a day, 7 days

[61] California Department of Public Health, 3.2 Nursing Hours Per Patient Day data as of November 6, 2019.

[62] 42 CFR 483.35, *https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.*

[63] National Academies of Sciences, Engineering, and Medicine. 2022. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff, Recommendation 2B.*

a week. One commenter noted that it was the RN that put the ''skilled'' into ''skilled nursing care'' that residents require for a stay in a LTC facility. Some of these commenters stated that the current requirement was not only insufficient but put residents at risk of preventable safety events. Some commenters also supported the proposal for a 24/7 RN due to the increased acuity of residents and their complex medical, physical, and behavioral health care needs. As commenters noted, LTC facilities are caring for residents with complex medical and behavioral health needs. They are also caring for a growing population of short-term residents recovering from serious health care issues, surgery, or other injuries. Other commenters pointed out the improved outcomes to residents that result from greater RN staffing. Commenters also pointed out that greater RN staffing levels are associated with positive quality measures and fewer quality of care deficiencies, such as, fewer pressure ulcers; lower restraint use; decreased infections, including urinary tract infections (UTIs); less pain and the need for pain medication; improved activities of daily living (ADLs); less weight loss and dehydration, less use of antipsychotic medication; more morning care; and lower mortality rates.

Many other commenters, including some industry and provider organizations, supported the 24/7 RN requirement but were very concerned about some LTC facilities' ability to comply with this requirement. Other commenters, for the same reasons, opposed the 24/7 RN requirement. Some commenters contended that the requirement was too expensive and was an unfunded mandate. While others contended that the requirement was not feasible due to a lack of available staff. As noted previously, however, some commenters denied there was a staffing shortage noting that the ''shortage'' could be resolved by higher pay and better working conditions.

Response: As demonstrated by the comment summary, we received an abundance of comments expressing diverse views on the 24/7 RN requirement. We appreciate the support for the proposal. We agree that an RN's education, training, and scope of practice is necessary to provide the skilled care that LTC facility residents require for safe and quality care. The increased acuity of residents, both short and long-term, with their correspondingly complex medical, physical, and behavioral health care needs requires an RN's expertise. In addition, the literature clearly demonstrates improvement in resident outcomes when there is an increase in RN staffing. While we acknowledge the assertions by the commenters who were either concerned about the feasibility of the proposal or opposed to the proposal, we believe that the benefits of improving resident health and limiting preventable safety events by a stronger RN presence are vital. Therefore, we are finalizing the 24/7 RN proposal with revisions as detailed below.

Comment: Some commenters stated that a 24/7 RN was unnecessary for resident care. They pointed out that the residents are sleeping during the night and do not require an RN's services. They also asserted that the care staff at most SNFs can provide quality care by following care plans and initiating the protocols established by the RN during the day without the RN being on site 24 hours a day. They contended that the only facility where RNs are needed around the clock are hospitals, especially in the areas of critical care. One organization noted that according to its members the majority of LTC facilities do not have an RN on site 24/7.

Response: We agree with the commenters that LPN/LVNs and NAs can provide quality care by following the care plans and protocols established by an RN. However, it is the RN's education, training, and scope of practice, especially in nursing assessment, that is missing from resident care when an RN is not readily available. Residents can have changes in their physical and behavioral health at any time of the day. These changes could possibly require that the nursing staff assess the resident to determine whether there needs to be a change to a resident's care, such as the administration of some pro re nata or PRN [64] medications; whether consultation with another health care provider, such as a physician is required; or whether the resident requires care beyond what the LTC facility could provide, requiring a transfer to another facility such as an acute care hospital. It is an RN whose education, training, and scope of practice includes the nursing assessment skills needed to make these determinations and the training and expertise to provide the quality of nursing care residents require in such circumstances.

Comment: Some commenters not only supported the proposal for an RN 24/7 but also recommended that the requirement be strengthened. Many commenters were concerned about LTC facilities only being required to have the RN ''available'' to provide direct resident care and not requiring the RN to be ''providing'' direct resident care. These commenters recommended that the requirement be strengthened to require that the RN be providing direct resident care as that is the level of care that should be provided in a LTC facility. These commenters agreed with the 2022 Nursing Home Study that more RN staff should result in fewer deficiencies in care; however, they also insist that the RN cannot be simply ''present'' in the LTC facility. They contend that while having an RN onsite 24/7 in LTC facilities is important for resident care quality and safety, it is the active contributions and clinical expertise of RNs that ensures the delivery of skilled quality care for residents. Other commenters recommended that there be more than one RN onsite. For example, some commenters recommended one RN for every 100 residents.

Response: We appreciate the commenters support for the 24/7 RN proposal. Regarding the commenters that recommended strengthening the requirement by requiring one RN for every 100 residents, we do not agree with those comments. We believe that having a RN onsite 24/7 to help with preventable issues and creating a specific standard to ensure residents receive on average at least 0.55 hours of RN care per day is a stronger approach to improve resident health and safety than requiring one RN for every 100 residents. We are thus finalizing a total nurse staffing requirement of 3.48 HPRD that must include RN direct care levels of at least 0.55 HPRD. Although this does not go as far as requiring direct care from a 24/7 RN would, it will still provide for greater required RN direct care than current standards do. These requirements are set forth at § 483.35(b)(1) as finalized in this rule. Thus, the RN direct care staff requirement will be adjusted according to the number of residents in the facility. Regarding the commenters who recommended changing the proposed requirement that an RN be ''available to provide direct care,'' to require the RN ''providing direct resident care'', we are not modifying the proposed requirements to incorporate that comment. The total nurse staffing requirement finalized in this rule

[64] PRN medications are medications that are given as needed when certain circumstance occur. Those circumstances would be indicated in the medication order. For example, a PRN medication could be given when a resident has a temperature over a certain degree or for agitation. In a LTC facility, it would generally be a licensed nurse who makes the determination to give a PRN medication.

contains an RN direct care level of at least 0.55 HPRD. This requirement along with the requirement for a 24/7 RN available to provide direct resident care should provide the high-quality, safe care that residents need.

Comment: In the proposed rule, we specifically solicited comments on whether the DON should be counted towards the 24/7 RN requirement or should the DON only count under specific circumstances. Commenters were divided on this question. Many commenters opposed the DON being counted towards the 24/7 RN requirement, as well as any other RN that is assigned to administrative duties. They contended that only RNs providing direct resident care should be counted towards the requirement. Still other commenters thought the DON should be included since they would be onsite at the LTC facility and could provide direct resident care, if needed. However, other commenters did not oppose including the DON in the requirement, especially if the resident census was below 30 residents.

Response: As discussed in the previous comment, we are finalizing the 24/7 RN requirement to require that the RN is available to provide direct resident care as proposed. Therefore, if the DON is a RN and is available to provide direct resident care, then the DON will count towards this requirement. We are not establishing a specific resident census for this requirement because we have no reliable evidence upon which to base a specific number of residents for this requirement.

Comment: Many commenters were concerned about the statutory waivers cited in the proposed rule and CMS's assertion that the statutory waiver would apply to the proposed 24/7 RN requirement. They contended that these waivers diminished the requirement for a 24/7 RN and would result in a reduced quality of care for residents. Other commenters also noted that these statutory waivers were difficult to operationalize and were rarely granted. Specifically, commenters noted that the requirements for the statutory waiver were difficult for many LTC facilities to meet, such as the requirement for SNFs to be in a rural area. Some commenters thought these waivers could actually undermine the 24/7 RN requirement by enabling too many LTC facilities to avoid the requirement. At least one commenter recommended that LTC facilities use the same exemption criteria proposed as § 483.35(g) (finalized at § 483.35(h) as discussed in this rule), which would be applied to hardship exemptions for the minimum nurse HPRD standards set forth at proposed § 483.35(b)(1) (finalized at § 483.35(c)(1) as discussed in this rule).

However, other commenters contended that it was unnecessary for the RN to even be on site at the LTC facility 24/7. These commenters stated that part of the 24 hours could be satisfied through some type of ''virtual'' presence by an RN. Commenters suggested that an RN could be available by phone, internet, or be able to get to the LTC facility within a certain amount of time, such as 30 minutes. Commenters stated that a one-size-fits-all approach was unnecessary, and requirements should be based on resident acuity. Commenters insisted that by allowing for a part of the 24/7 RN coverage to be virtual, each LTC facility could determine if their resident population needs an RN on site 24/7 or whether the RN could be virtually present during a part of the day. Some commenters specifically recommended that an RN could virtually support LPNs on the evening and night shifts. There were also commenters who noted that while there was a process for obtaining a hardship exemption to the minimum nurse staffing requirement, there was no waiver or exemption process for the 24/7 RN requirement.

Response: The current requirement is that the LTC facility provide 24 hours of licensed nursing services (RN or LPN/LVN) and RN services 7 days a week for 8 consecutive hours per day as set forth at existing sections § 483.35(a) and (b). There are two waivers discussed in § 483.35 of the LTC participation requirements that are set forth in paragraphs (e) and (f) (redesignated in this final rule as paragraphs (f) and (g), respectively). The requirements for these waivers come directly from the statute, specifically section 1819(b)(4)(C)(ii) and 1919(b)(4)(C)(ii) of the Act, respectively. Since these two waivers are statutory, the waivers can only be removed or modified in detail by legislation. Thus, the waivers in existing § 435.35(e) and (f) (redesignated as paragraphs (f) and (g) in this final rule) will not be changed except for conforming changes, which we will discuss further, to ensure that the statutory waivers do not conflict with the regulatory flexibilities finalized in this final rule at § 483.35(h). To assist readers and provide clarity, table 2 provides an overview of the differing requirements for the statutory waiver at § 483.35(e) and (f) (finalized as paragraphs (f) and (g) in this rule).

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While the details of the statutory waivers, described in table 2, can only be modified by legislation, we agree with the commenters that LTC facilities

Table 2: Requirements for the LTC Staffing Statutory Waivers by Facility Type

Facility Type*	NFs*	SNFs*
Statutory Citation	Section 1919(b)(4)(C)(ii) of the Act	Section 1819(b)(4)(C)(ii) of the Act
Regulatory Citation and requirements for participation that can be waived	§ 483.35(e) Nursing services. Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis (*final rule redesignates this paragraph as paragraph (f)*)) The State can waive the following requirements: 1. The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans. 2. The facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week *(final rule revises to must have a RN onsite 24 hours per day, for 7 days a week).*	§ 483.35(f) Nursing services. SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week. *(final rule redesignates this paragraph as (g) and revises title)* The Secretary can waive the following requirement: 1. The facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week *(final rule revises to must have a RN onsite 24 hours per day, for 7 days a week).*
Criteria that must be met to be eligible for the statutory waiver	1. The facility must demonstrate to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel. 2. The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility. 3. The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility. 4. A waiver is subject to annual State review. 5. In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel. 6. The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the	1. The facility is located in a **rural area** and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area. 2. The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week. 3. The facility either— • Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period, **OR** • Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty; 4. The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the

need to have some flexibility with the 24/7 RN requirements. We are especially concerned about those LTC facilities that meet the requirements for hardship exemptions. If a LTC facility is unable to meet the minimum staffing requirements as set forth at § 483.35(b) (as finalized in this rule), it also might not be able to comply with the 24/7 RN requirement because this could be an indication of the LTC facility's difficulty in obtaining staff in general. Conversely, if a LTC facility does not meet the requirements for a hardship waiver, it should be able to comply with the 24/7 RN requirement by the required implementation deadlines. Thus, we are finalizing an additional exemption for facilities that experience a hardship complying with the 24/7 RN requirement. This exemption will be in addition to the existing statutory waiver process set forth at § 483.35(e) and (f) (finalized in this rule as paragraphs (f) and (g)). Specifically, we are revising the requirements at proposed § 483.35(b) (finalized at § 483.35(c)(1) as discussed in this rule) to indicate that facilities must have a RN onsite 24 hours per day, 7 days a week that is available to provide direct resident care, except when this requirement is waived in accordance with the existing statutory waivers at § 483.35(e) and (f) (redesignated as paragraphs (f) and (g) as discussed in this rule) or exempted in accordance with the criteria for regulatory flexibilities at § 483.35(h). Section 483.35(h) specifies that a facility may qualify for a hardship exemption of 8 hours a day from the 24/7 RN requirement if the facility is located in an area where the RN to population ratio is a minimum of 20 percent below the national average, as calculated by CMS, by using data from the Bureau of Labor Statistics and Census Bureau. The finalized regulatory flexibilities and criteria for eligibility at § 483.35(h), including the basis for why such eligibilities have been set at current thresholds, are discussed in detail in the next section, section II.B.5. of this rule. We expect that those facilities currently meeting the 24/7 RN staffing requirement will continue meeting the requirement.

Furthermore, we are adding a requirement to specify that for any periods when the onsite RN requirements are exempted in accordance with the exemption criteria at § 483.35(h), facilities must have a registered nurse, nurse practitioner, physician assistant, or physician available to respond immediately to telephone calls from the facility. At existing § 483.35(e) (finalized at § 483.35(f)) we are modifying the heading of the paragraph to read ''Nursing facilities: Waiver of requirement to provide licensed nurses and a registered nurse on a 24-hour basis''. This paragraph applies to NFs only and the modified heading helps to clarify those requirements that are applicable to the waiver set out at section 1919(b)(4)(C)(ii) of the Act. In addition, we are modifying the language at existing § 483.35(f) (finalized at § 483.35(g)) to revise the heading of the paragraph to read ''SNFs: Waiver of the requirement to provide services of a registered nurse for at least 112 hours a week''. This paragraph would be applicable to facilities that meet the statutory qualifications for the waiver set out at section 1819(b)(4)(C)(ii) of the Act.

Given that this rule finalizes an additional regulatory flexibility for facilities to receive an exemption of 8 hours per day of the 24/7 RN requirement, we want to clarify that facilities who may also meet the requirements for the statutory waivers as detailed at existing sections § 483.35(e) and (f) (finalized as paragraphs (f) and (g) in this rule) will still have the ability to choose which process they want to pursue to achieve regulatory flexibility from the 24/7 RN requirement. For example, a SNF may be exempted from 8 hours per day of the 24/7 RN requirement if they meet the criteria specified in § 483.35(h). If this SNF is rurally located, then in accordance with existing § 483.35(f) (finalized in this rule at paragraph (g)) this facility may choose to instead pursue the statutory waiver for SNFs to achieve greater flexibility from the 24/7 RN requirement based on their specific situation and ability to meet the criteria outlined by the statute for the waiver rather than pursue the 8 hours per day exemption provided under new § 483.35(h).

Final Rule Action: We are finalizing with revisions the proposed requirement for an RN to be onsite 24 hours a day, 7 days a week and available to provide direct resident care. The RN can be the DON; however, they must be available to provide direct resident care. Also, LTC facilities that qualify for a hardship exemption to the minimum nurse staffing requirement set forth at § 483.35(b)(1)(i) in accordance with the criteria outlined at § 483.35(h) (as finalized in the rule) may also request an exemption of 8 hours per day of the 24/7 RN requirement. We have added this as we believe that additional flexibility is needed for facilities as they adopt the 24/7 RN requirement. We have added a requirement at § 483.35(c)(2) to specify that for any periods when the onsite RN requirements in are exempted in accordance with § 483.35(h), facilities must have a registered nurse, nurse practitioner, physician assistant, or physician available to respond immediately to telephone calls from the facility. In addition, we are modifying the language at existing § 483.35(e) (finalized at § 483.35(f)) to revise the heading of the paragraph to read ''Nursing facilities: Waiver of requirement to provide licensed nurses and a registered nurse on a 24-hour basis''. We are also, modifying the language at existing § 483.35(f) (finalized at § 483.35(g)) to revise the heading of the paragraph to read ''SNFs: Waiver of the requirement to provide services of a registered nurse for at least 112 hours a week''.

5. Hardship Exemptions From the Minimum Hours per Resident Day Requirements (§ 483.35(g))

We proposed at new § 483.35(g), that facilities could be exempted from the 0.55 HPRD of RNs and/or 2.45 HPRD of NAs requirements if they were found non-compliant with the HPRD requirements and met four eligibility criteria, based on location, good faith efforts to hire, disclosure of financial information, and were not excluded based on the prior year's citations, failure to submit data to the PBJ, or having been designated as a Special Focus Facility. We stated that determinations regarding exemptions would be made during a survey. We also proposed that facilities could only receive an exemption from the proposed minimum HPRD requirements and not the proposed 24/7 RN requirements. We noted that a waiver of the proposed 24/7 RN requirements must be granted in accordance with the existing statutory waivers at § 483.35(e) and (f). We further proposed that the Secretary, through CMS or the applicable State Agency, would make the determination about exemption from the HPRD requirements and that such exemptions would be in effect for one year and renewable annually if facilities continued to meet the exemption requirements. We received a large number of comments that addressed exemptions. Comments ranged from robust objection to any exemptions, to support for exemptions as proposed or in concept, with both opposing and supporting commenters recommending a wide variety of specific changes to revise and improve our proposal. These comments reflected disparate and often opposing views on the provision of exemptions. In addition to proposing specific exemption criteria,

we also solicited comment on several specific questions related to exemptions.

We discuss and respond to these comments and responses to our questions in detail below.

Comment: Many commenters objected to allowing any exemption from the HRPD requirements. Some commenters stated that understaffing results in falls, injuries, and even death. Some commenters stated that the proposed exemptions would normalize inadequate staffing, depress wages, and would be dangerous and undermine or jeopardize the health and safety of residents. Other commenters stated that every nursing home resident deserved high quality care, regardless of their geographic location or other factors. One commenter stated that CMS must stop putting the financial priorities of the nursing home industry above the basic needs and dignity of nursing home residents. Some commenters suggested that certain facilities, including rural facilities, should be given special consideration, while others suggested that no facility should be given special consideration. Several commenters stated that they believed there should be progressive enforcement of the requirement, with reduced penalties in clear instances of a good faith effort to meet the staffing standards.

Response: We appreciate all of the commenters' concerns and suggestions. Our goal is to promote safe, high-quality care for all residents. We also recognize the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing, particularly in rural areas. We have decided to retain the availability of exemptions under certain circumstances for select facilities, which would include some that are rural, after consideration of the comments, recognition of both quality of care and access to care concerns. We note the continued availability of recourse when there is a quality of care concern, including those that may be related to safety and staffing availability, such as complaints to survey agencies, QIOs, and State long-term care ombudsman programs. Exemptions may remain in place only until the next standard survey, and we expect any LTC facility receiving an exemption to work toward full compliance with the staffing standards.

Comment: Some commenters stated that any exemptions should be limited in number and frequency and must be paired with specific elements of heightened scrutiny and transparency. Furthermore, the commenters asserted that the need for such an exemption must be compelling. One commenter stated that only if facilities, at their current staffing ratios, are performing well on outcomes such as hospital readmission rates, nurse turnover, facility acquired injuries, anti-psychotic medication use, would there be a logical justification to give them a waiver. Commenters also recommended concrete standards and clear, measurable, and rigorous criteria for receiving an exemption. One commenter recommended that CMS narrowly tailor the workforce shortage exemption. Other commenters suggested many specific changes, such as:

- Capping the number of exemptions a facility can receive, to avoid facilities that are perpetually exempted;
- Prohibiting any facility that does not meet the staffing requirements from admitting new residents;
- Disqualifying facilities operating under an exemption from any type of value-based purchasing initiatives within either the Medicare or Medicaid programs;
- Requiring facilities with an exemption to demonstrate progress on reducing turnover and increasing wages;
- Appointing an independent entity to monitor performance of any facility with an exemption;
- Ensuring transparency around exemptions through such tools as prominent display of exemption status on Nursing Home Compare with a warning about the possible consequences of nursing understaffing, posted notice within the facility, and specific notice to any individual/family residing in or seeking admission, as well as the Long-Term Care Ombudsman Program;
- Requiring that the facility's staffing plans demonstrate consideration of nationally recognized best practices, such as PHI's 5 Pillars of Direct Care Job Quality; and that the facility provide evidence related to best practices beyond offering prevailing wages, such as enhanced benefits, expanded training programs, worker surveys to inform workplace improvements, improved scheduling policies, participation in job fairs, and partnerships with schools;
- Requiring ''good faith efforts to hire and retain staff'' to include documentation of recruiting efforts, a specific method for calculating and reporting staff turnover, and an explicit target and plan for reducing turnover, including regular reporting to CMS;
- Requiring ''documentation of financial commitment to staffing'' that includes investments in recruiting and retention, and evidence of increased wages;
- Requiring an alternate viable plan for meeting the needs of the residents in their care, not solely on financial difficulties;
- Establishing a sunset date for hardship exemptions; and
- Placing nursing homes granted an exemption on a 'do not refer' list that is distributed to area hospitals and other providers.

Response: We thank the commenters for their suggestions. The exemption framework provides qualifying LTC facilities with the opportunity to receive time-limited flexibility upon completion of several essential documentation and transparency requirements. We considered each option suggested. While we are not implementing all of them at this time, we have included some, including around transparency and we may consider them in future rulemaking. In response to the concerns raised, we have made some revisions. Specifically, we have removed the distance criterion and narrowed the availability of exemptions to those facilities in staff shortage areas where the supply of applicable healthcare staff (RN, NA, or combined licensed nurse, which includes both RNs and LVN/LPNs, and nurse aide) is not sufficient to meet area needs as evidenced by the applicable provider-population ratio for nursing workforce that is a minimum of 20 percent below the national average for the applicable exemption (RN, NA, or combined licensed nurse and nurse aide), as calculated by CMS, by using the Bureau of Labor Statistics and Census Bureau data. The area is the geographical area defined as the metropolitan statistical area (MSA) or nonmetropolitan statistical area (non-MSA) where the LTC facility is located using data from the U.S. Bureau of Labor Statistics (available at *https://www.bls.gov/oes/current/msa_def.htm*). Furthermore, we agree that transparency to current and potential residents, as well as the State Long Term Care Ombudsman Program is a necessary element. We are therefore adding transparency requirements in order to receive an exemption. First, a facility must post in a prominent, publicly viewable location in the facility a notice of the facility's exemption status, the extent to which the facility does not meet the minimum staffing requirements, and the timeframe during which the exemption applies. Second, a facility must provide a similar notice to each resident or resident representative, and to each prospective resident or prospective resident representative, that includes a statement reminding residents of their rights to contact advocacy and oversight entities, as

provided in the notice provided to them under § 483.10(g)(4). Finally, the facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman. Exemption information will also be publicly available on Care Compare. We considered capping the number of exemptions or establishing escalating requirements for subsequent exemptions, but at this time, find that the underlying requirements to obtain an exemption are sufficient to encourage ongoing good faith efforts to meet the new requirements, to evaluate facilities quality of care prior to granting each exemption, and to ensure that residents and their representatives are aware of the exemption status of the facility.

Comment: Many commenters stated that the proposed exemption process was unfair and unworkable. Others described it as not meaningful or too burdensome and limited to be useful. Other commenters supported the proposed process. One commenter noted that the proposed staggered implementation dates and exemption criteria reflect a nuanced understanding of the challenges faced by LTC facilities and called the exemption criteria reasonable. Another stated that the exemption process would only postpone the challenges of meeting the minimum staffing standards. Some stated that small, rural facilities most in need of an exemption would not be able to meet the criteria to qualify while others suggested that few facilities at all would be able to qualify, stating that the criteria will be difficult if not impossible for most nursing homes to meet in all but the extreme circumstances. Some commenters urged CMS to streamline the exemption requirements to offer greater flexibility. Some commenters stated that the process should not be punitive, but should help facilities comply with the rule or that the process should protect facilities from monetary penalties and have checks and balances to ensure facilities are not punished for not meeting unattainable goals. One commenter recommended that CMS create a waiver process that is available to all facilities without exclusions; does not entail citation; is attainable by any facility that is in need and that is making good faith efforts (reasonable process); and includes support from a QIO or another party to assist facilities in securing support resources to meet applicable needs. Some commenters stated that disparities between criteria for exemptions or waivers should be minimized and should be ''somewhat uniform'' since they relate to the issue of insufficient workforce. One commenter stated that any exemption should be based on the availability of workers, compensation offered, and working conditions. Other commenters recommended adding an exemption for unforeseen circumstances, temporary weather-related staffing reductions, or exigent circumstances. One commenter noted that their State considers extraordinary circumstances such as natural disaster, catastrophic event or a national or State-declared emergency; location in a region that the health commissioner has declared is experiencing an acute labor shortage; and a verifiable union dispute as mitigating factors for understaffing. Another recommended that CMS create a protocol for State agencies to implement to ensure consistency and provided details of how their State implemented exemptions to State requirements. Finally, one commenter stated that they were pleased that compliance with the 24/7 RN requirement did not imply compliance with the minimum staffing HPRD standard and that the hardship exemption process cannot be used to circumvent that [24/7 RN] requirement. Another stated that adding additional requirements that already have a foundation in regulations is illogical and risks further erosion of an already fragile system.

Response: We appreciate the comments in support of the exemption process and have considered the concerns raised about it. We have determined, in the interest of resident health and safety, that it is not acceptable to significantly expand the exemption process. However, based on the feedback from commenters and concerns raised regarding access to care, as discussed previously we have modified our proposal to allow facilities that can demonstrate a limited supply of RNs (based on a provider-to-population ratio 20 percent below the national average) and meet the exemption criteria to receive an exemption from 8 hours per day of the 24/7 RN requirement. In keeping with the comments regarding uniformity and exemptions based on worker availability, we are also finalizing, as part of the exemption process, a comparable exemption criterion for determining the workforce unavailability criterion for the total nurse staffing 3.48 HPRD standard that we are finalizing. Specifically, we will incorporate a provider to population ratio for combined licensed nurse and nurse aide workforce into the exemption requirements where such a ratio must be at least a minimum of 20 percent below the national average. As explained in the proposed rule (88 FR 61378), to calculate whether a LTC facility is in an area with a shortage of RNs or NAs, we first use the Care Compare data to identify the State and county where each LTC facility is located. We then combine these data with information from the U.S. Bureau of Labor Statistics (available at *https://www.bls.gov/oes/* on the counties in each MSA and non-MSA to identify the MSA or non-MSA where each LTC facility is located. Next, we identify the total number of RNs and NAs in each MSA and non-MSA using the Bureau of Labor Statistic's Occupational Employment and Wage Statistics Query System (available at *https://data.bls.gov/oes/#/home*). Afterwards, we calculate the population for each MSA or non-MSA using population estimates from the United States Census Bureau by summing the population for all counties in the MSA or non-MSA (available at *https://www.census.gov/data/tables/time-series/demo/popest/2020s-counties-total.html#v2022*). Finally, we calculate whether the LTC facility is located in an MSA or a non-MSA with a medium or low provider-to-population ratio by comparing the area's provider-to-population ratio to the average provider-to-population ratio for the United States. We note that facilities that do not receive an exemption will have the opportunities afforded by the enforcement process to address any noncompliance deficiency citations, such as informal dispute resolution processes and administrative and judicial appeals. We have determined that this is the appropriate set of criteria to use for exemptions from both the 24/7 RN requirement and the 3.48 total staffing standard as it is appropriate to apply the same criteria for workforce insufficiency (20 percent below the national average for the applicable staff category) across all exemptions.

Comment: Many commenters suggested that facilities that receive an exemption should have to demonstrate progress on staffing related issues. For example, one commenter recommended we add a provision to require the facility to increase retention to 75 percent or higher if the facility will utilize an exemption, as there are many methods that can be utilized to increase staff retention, including flexible work schedules, bonuses, well-trained managers/supervisors, incentive programs and much more. This commenter stated that reducing turnover rates will significantly increase resident care/safety as well as reduce

the recruitment burden on managers. Several commenters mentioned turnover rates in the context of retention and recruiting, and one suggested that, for RNs and/or CNAs and other nursing staff, if the turnover rate is higher than 35 percent, a facility should not meet the good faith effort requirement for an exemption. Another commenter suggested adding a provision that would bar nursing homes with a turnover rate higher than the State median from receiving hardship exemptions.

Response: We thank commenters for these suggestions. At this time, we are not adding additional requirements related to turnover to qualify for an exemption. The facility's staffing plan in accordance with § 483.71(b)(4), however, requires the facility to develop and maintain a staffing plan to maximize recruitment and retention of direct care staff, and is considered part of a demonstration of a good faith effort to hire. Retention and turnover may thus be considered in evaluating whether a facility is complying with its staffing plan in seeking exemption. We also note that information on turnover is publicly available on Care Compare. In 2022, CMS began posting levels of weekend staffing and rates of staff turnover and using these metrics in the Five Star Quality Rating System to help provide more useful information to consumers. In addition, CMS is adopting the Nursing Staff Turnover Measure for the SNF VBP program beginning with the FY 2026 program year. This is a structural measure that has been collected and publicly reported on Care Compare and assesses the stability of the staffing within an SNF using nursing staff turnover. This is part of the Administration's focus to ensure adequate staffing in long-term care settings and delivers on a commitment included in the President's Executive Order 14070, Increasing Access to High-Quality Care and Supporting Caregivers. Facilities would begin reporting for this measure in FY 2024, with payment effects beginning in FY 2026. While we are not adopting these suggestions at this time, we may consider them for future rulemaking.

Comment: Several commenters objected to the demonstration of financial commitment as an exemption criterion. Some commenters felt that this criterion was duplicative of the information that would be provided in the good faith effort to hire criterion. One noted that the framework for exemptions was likely to encourage the use of temporary staffing and that, given the cost of temporary labor, this may create a wrong impression while accelerating predatory temporary labor pricing. Another comment recommended requiring facilities that intend to utilize a staffing exemption provide full disclosure of all financial documents, including ownership, related parties, profits, tax and corporate filings, audits, and financial statements and requiring that these documents be made available within 10 days of the request to residents, resident responsible parties, executors/trustees of resident estates, advocates, and regulatory agencies. One commenter suggested that in order to qualify for an exemption, a facility must demonstrate that its owners and management are not profiting from the nursing home or any company that is paid by the facility. Another stated that any exemption related to claimed financial constraints must be considered with far more robust transparency requirements. One commenter stated that the requirement is vague. In response to our question regarding a spending threshold, several commenters recommended that CMS establish that facilities must spend 80 percent of revenue on direct care services, similar to the proposed CMS requirements for HCBS services [65] and requirements in four States (New Jersey, New York, Massachusetts, and Pennsylvania). Another commenter recommended 75 percent as a threshold, with independent confirmation. One commenter stated that CMS must either conduct or direct the State survey agency to conduct an audit of the nursing home's finances.

Response: We thank commenters for these suggestions. We have considered both the comments supporting and the comments objecting to the financial commitment criterion. We recognize that the requirement we are finalizing only requires the facility to document and provide information when needed to receive an exemption. We believe that the financial commitment criterion will lead facilities to evaluate their financial commitment to staffing while leading CMS to better understand facility investment in staffing and the implications of expanding the requirement by establishing a threshold, requiring additional documentation, or other modifications. While we are not adopting these suggestions at this time, we will consider them for future rulemaking.

Comment: Some commenters specifically objected to the exemption determination being made after a facility is surveyed and determined to be out of compliance with the HRPD staffing requirement. Several commenters indicated that being cited and fined before getting an exemption was unreasonable. One suggested that extensions of the exemption period should be automatic ''if conditions persist.'' Many commenters felt that facilities should proactively be able to apply for an exemption through the submission of documentation. One commenter was concerned that the process requires facilities to open themselves up to additional scrutiny to qualify and that this could mean a provider opens themselves up to exclusion if a surveyor determines their insufficient staffing has resulted in harm or inaccurately cites the PBJ tag. Another commenter stated that facilities are already heavily penalized for not submitting PBJ data, and this exclusion should be limited to allow for a temporary lapse, especially when it results from emergent reasons, such as a disaster that the facility didn't report or when a facility is unable to submit data, despite trying, due to technical portal issues. One commenter noted that this would increase the workload on already over-burdened and underfunded State survey agencies. Others noted that States already have significant backlogs of surveys and facilities should not be penalized for that. One commenter recommended that CMS develop a streamlined process to apply for an exemption without requiring an onsite survey and noted that the exemption request process must be simple and not burdensome.

Response: We thank commenters for their feedback. We believe that the exemption criteria recognizes that some facilities may have difficulty meeting the new requirements and therefore may obtain an exemption if they meet the qualifications. However, this is balanced by the need to ensure residents' health and safety. With respect to a survey preceding the granting of an exemption, we note that facilities cannot request, and a State would not conduct, a survey specifically for the purpose of granting an exemption, but rather that facilities would be evaluated during a survey, such as the standard recertification survey, to determine if they were eligible for an exemption. A survey preceding any determination regarding an exemption would identify any other deficiencies of the facility, including those that could disqualify a facility from receiving an exemption and help ensure that safety and quality of care is maintained. As mentioned previously, we will publish more details on how compliance will be assessed after publication of this final rule in advance

[65] *https://www.cms.gov/newsroom/fact-sheets/ensuring-access-medicaid-services-cms-2442-p-notice-proposed-rulemaking.*

of each implementation date for the different components of the rule. We intend to use the traditional process of communication of information via CMS QSO memoranda and publication of information in the State Operations Manual.

Comment: Some commenters recommended that specific types of LTC facilities be exempt from the HRPD requirements. One commenter recommended that Life Plan Communities (similar to Continuing Care Retirement Communities) be exempt. Some commenters suggested that all Tribal facilities be exempt from the HRPD requirements. Other commenters suggested that some specialized facilities (subacute units, hospital-based SNFs, and distinct part units of hospitals, any facility in an auto-HPSA) also be exempt from the HRPD requirements. One commenter recommended exempting nursing homes in States that have existing staffing ratio requirements for licensure. Others suggested that facilities with high quality measures at their current staffing levels be automatically exempted or be qualified to request an exemption. Some commenters said that they found the lack of flexibility, waiver, or leniency for communities taking good faith efforts to comply unfair. Finally, one commenter suggested that all rural facilities should be exempt.

Response: We thank commenters for these suggestions. As noted earlier, our goal is to promote safe, high-quality care for all residents. We also recognize the need to strike an appropriate balance that considers the current challenges some LTC facilities are experiencing, particularly in rural areas. We considered establishing categories for blanket exemptions, but are not adopting any at this time. Blanket exemptions for an entire category of facilities lacks the facility-specific assessment required under our proposal. In particular, we are finalizing a process under which any facility granted an exemption must have a preceding survey to determine its compliance with the requirements. However, such compliance determinations would not be conducted if we were to establish blanket exemptions. At this time, we want to ensure we are aware of any quality of care concerns at the individual facility level prior to granting an exemption. As we gain insight into facility compliance with the staffing minimums and in the application of the exemption process, we can consider suggestions to tighten the exemption process in future rulemaking. We note that hospital providers of long-term care services (swing-beds) are not subject to the Nursing Services requirements under § 483.35, but instead are subject to the hospital conditions of participation, including staffing (§ 482.23), as well as specific provisions of 42 CFR part 483 identified in § 482.58.

Comment: Some commenters objected to using location as an exemption criterion, while others supported a location criterion. Many responded to our question regarding the ''right distance'' from another facility to warrant a hardship exemption, often suggesting an alternative or stating that mileage is not an indicator of hardship and objecting to any mileage-based criterion. One commenter stated that the mileage-based criterion was arbitrarily set and did not account for multiple facilities in the same area needing to apply for an exemption. Commenters noted a variety of BLS limitations, geographic features, and transit system considerations that made the location criteria problematic. Several commenters suggested that a provider to population ratio does not reflect the true availability of the workforce, and that this must be considered when determining eligibility for waivers and exemptions. One commenter supported the location criterion as proposed but wanted it to also be applied to the statutory waiver for RNs/licensed nurses; other commenters voiced similar concerns about the existing RN/licensed nurse waiver. Some commenters suggested removing the provider to population ratio, and reducing the mileage criteria to 10 or 15 miles. One commenter noted that the presence of a CAH near an LTC facility also impacted staff availability, even in the face of collaborative efforts. One commenter also suggested the mileage-based criterion be clarified for Tribal facilities to state that for Tribal facilities, it must be another Tribal facility within 20 miles. A different commenter suggested the mileage criterion should be 50 miles, stating that the average daily commute in the United States is 37 miles one-way (per U.S. Department of Transportation) and that it is not appropriate to jeopardize the health and welfare of a nursing facility resident with a staffing exemption for 20 miles when that is 17 miles less than the average commute of the staff who work at care facilities. Fifty miles was also suggested by another commenter who also felt the provider to population ratio should be changed to a more stringent 50 percent below the national average. Another supported 40 percent below the national average as the requirement. Other commenters stated HPSA data is not a good criterion to determine exemption status, as the data only shows how many licensed nurses are in an area and does not consider how many of those nurses are willing to work in an LTC facility and that availability should take into consideration competition from other types of providers. One commenter pointed out problems with urban/rural definitions and further encouraged including urban facilities in eligibility for exemptions. Another commenter stated that the proposed method to determine a workforce shortage area is unworkable and inaccurate, because it is based on an already depressed national average. One commenter who objected to any exemptions stated that every nursing home resident deserved high-quality care, regardless of their geographic location or other factors. Many commenters who supported the need for staffing requirements also objected to exemptions, noting that all residents, regardless of zip code, are entitled to appropriate professional nursing care. One commenter recommended re-evaluating these criteria every six months and one year after implementation and annually.

Response: We thank commenters for these suggestions. We have considered the many perspectives and potential alternatives presented. Given that there was not a public consensus on the appropriate distance and considering the general opposition received in establishing this specific criterion, we have revised our proposal. We are only finalizing the applicable provider-population ratio for nursing workforce (RN, NA, or combined licensed nurse and nurse aide) in the facility area as a location criterion, removing the additional mileage-based criterion. As a threshold for determining a workforce shortage, given concerns raised about workforce unavailability, and in light of eliminating the distance criterion, we concluded that finalizing the moderate standard is appropriate. Therefore, we are finalizing that the provider-population ratio must be a minimum of 20 percent below the national average, as calculated by CMS, by using the Bureau of Labor Statistics and Census Bureau data.

Comment: One commenter objected to the use of the term ''good faith effort'' as too subjective and recommended that any term used must be objectively measurable. Several commenters were concerned with the term 'prevailing wage' and one suggested CMS should define the term ''prevailing wage'' in a manner that is more consistent with its use elsewhere in Federal law and

regulations. This commenter recommended looking to collectively bargained wage rates as a source of data on competitive wage levels, counting benefits as well as wages in the determination, and taking into account wage levels for jobs in other industries with similar entry requirements and for nursing positions in hospitals, staffing agencies, and other settings in determining the prevailing wage.

Response: We appreciate these comments and concerns. After considering all of the information and suggestions presented, we are finalizing the proposal regarding ''good faith efforts'' and ''prevailing wages'' as published. The language about prevailing wages is consistent with the statutory language in section 1919(b)(4)(C)(ii) of the Act in establishing requirements for facility waivers, which states that 'the facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel,' Therefore, we believe that the language used is appropriate. However, while we are not adopting these suggestions at this time, we may consider them for future rulemaking.

Comment: In response to CMS's question about additional hardships that CMS should consider in providing exemptions, some commenters supported adding financial difficulties/constraints. Commenters noted that many facilities receive most of their revenue from Medicaid, which commenters characterized as inadequate in many States to cover the daily costs of care for the resident. According to commenters, these facilities would not be able to afford the increased staffing requirements and would most likely reduce the number of beds, lower the number of Medicaid residents they admit, or close, leaving many residents without housing because hospitals and other high-quality facilities may not admit residents who pose a high risk for negative outcomes. A commenter suggested that CMS provide exemptions based on financial hardship such as changes in financial performance as it relates to provision of care and services to residents, including financial exemptions based on customary accounting measurements such as changes in operating income, variances versus annual budget or prior year performance, and changes in cash flow. Others objected to a hardship exemption based on the financial condition of the provider. One commenter stated that we do not allow car manufacturers in financial distress to produce vehicles without seatbelts or with less effective crumple zones in front-end bumpers; we do not allow airlines in financial distress to fly without stewards or qualified pilots and that adequate staffing should be a core element of any nursing home's financial plans rather than an extra for those facilities that can afford it.

Response: We thank commenters for their concerns and suggestions. We have considered all of the information submitted and, given the competing nature of those comments and information, it would be challenging to define exactly what constitutes a financial challenge. Therefore, we are not at this time including an exemption criterion based on financial need but are maintaining a criterion based on a provider to population ratio. We note that facilities will be required to demonstrate through documentation the amount of financial resources that the facility expends on nurse staffing relative to revenue prior to being granted an exemption. While we are not adopting these suggestions at this time, we may consider them for future rulemaking.

Comment: Some commenters objected to the exclusion criterion for exemptions, either suggesting less restrictive or more restrictive exclusion criteria. A commenter stated that CMS should remove all the proposed exclusion criteria because all facilities should be afforded an opportunity for an exemption. Another commenter stated that facilities should not be required to be cited for staffing noncompliance before being eligible for an exemption and that facilities should be eligible to apply for an exemption based on the workforce supply and the facility's good-faith efforts to hire and retain staff—no exceptions. Some commenters supported the exclusion criteria and one commended CMS for not considering HPRD exemptions for providers with a history of staffing concerns, poor care delivery, or harm or abuse to residents to whom they are entrusted to provide care. In response to our question about additional exclusions, some commenters felt CMS should expand exclusions to include Special Focus Facility Candidates (not just SFFs) and perennial 1-star rated facilities. Another suggested expanding the criteria that makes a facility ineligible for an exemption to include facilities that have recently been cited for failing to meet staffing standards and/or abuse or neglect of residents. A commenter suggested that CMS give States the option to tailor the exemption process to align with their existing frameworks if those States have existing staffing standards and exemption. Another asked CMS to clearly indicate that the final rule will not preempt any higher State standards or State consumer protection and Medicaid Fraud Control Unit's (''MFCUs'') efforts related to staffing or quality of nursing care in LTC facilities.

Response: CMS has considered these suggestions, balanced these noted concerns, and determined that, at this time, we will finalize our proposed exclusion criteria without modification. We note that it is a long-standing requirement that all facilities must comply with both State and Federal standards, and therefore, would be held to any higher standards imposed by a State.

Comment: One commenter specifically supported the 1-year time frame for exemptions. Many commenters noted that there are not enough surveyors or that surveys do not occur exactly 1 year apart.

Response: We thank commenters for their support and for voicing their concerns about the timing of surveys. In response, we are revising the timeframe for exemptions under § 483.35(h) from 1 year, to the next standard recertification survey. Thus, no matter when the exemption is initially approved following a survey, it is in effect until the next standard survey, unless it is removed as a result of a facility falling into the exclusion category. The exemption can be removed any time a facility develops any one of the exclusions. Waivers under §§ 483.35(f) (Medicaid nursing facilities) and 483.35(g) (Medicare skilled nursing facilities) are subject to annual review or renewal, respectively, pursuant to the waiver language set out in the Social Security Act.

Final Rule Action: After consideration of the comments, we received on the proposed rule, we are finalizing our proposal for hardship exemptions to the HRPD requirements with the following modifications:

- We have redesignated the proposed hardship exemption from the minimum hours per day requirements at § 483.35(g) as new paragraph (h) in this final rule and revised the heading to also include a hardship exemption from the ''registered nurse onsite 24 hours per day, for 7 days a week requirements''.
- We have revised the location criteria at newly redesignated § 483.35(h)(1) (proposed § 483.35 (g)(1)) to eliminate the 20 mile criterion and remove all references to a 40 percent below national average provider-to-population ratio. We are finalizing at

newly redesignated § 483.35 (h)(1) (proposed § 483.35 (g)(1)) the requirement that the facility be located in an area where the supply of applicable healthcare staff (RN, or NA, or total nurse staffing) is not sufficient to meet area needs as evidenced by the applicable provider-to-population ratio for nursing workforce(RN, NA, or combined licensed nurse and nurse aide) that is a minimum of 20 percent below the national average, as calculated by CMS, by using the Bureau of Labor Statistics and Census Bureau data.

• We have modified the requirements at § 483.35(h)(1) to specify that a facility can receive an exemption from one, two, or all three of the following requirements, as follows:

(1) The facility may receive an exemption from the total nurse staffing requirement of 3.48 hours per resident day at § 483.35(b)(1) if the combined licensed nurse, which includes both RNs and LVN/LPNs, and nurse aide to population ratio in the area is a minimum of 20 percent below the national average.

(2) The facility may receive an exemption from the RN 0.55 hours per resident day requirement (§ 483.35(b)(1)(i)) and an exemption of 8 hours a day from the RN on site 24 hours per day, for 7 days a week requirement (§ 483.35(c)(1)) if the RN to population ratio in the area is a minimum of 20 percent below the national average.

(3) The facility may receive an exemption from the NA 2.45 hours per resident day requirement at § 483.35(b)(1)(ii) if the NA to population ratio in the area is a minimum of 20 percent below the national average.

• We have added new requirements at § 483.35(h)(4), *Disclosure of exemption status,* to require that the facility:

(1) Posts, in a prominent location in the facility, and in a form and manner accessible and understandable to residents, and resident representatives, a notice of the facility's exemption status, the extent to which the facility does not meet the minimum staffing requirements, and the timeframe during which the exemption applies; and

(2) Provides to each resident or resident representative, and to each prospective resident or resident representative, a notice of the facility's exemption status, including the extent to which the facility does not meet the staffing requirements, the timeframe during which the exemption applies, and a statement reminding residents of their rights to contact advocacy and oversight entities, as provided in the notice provided to them at § 483.10(g)(4); and

(3) Sends a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

• We are not finalizing paragraph (g)(5)(iv) due to changes made to exemptions for the 24/7 RN requirement.

• We are finalizing, as proposed, requirements for good faith efforts to hire (§ 483.35(h)(2)) and demonstrated financial commitment (§ 483.35(h)(3)).

• We renumbered proposed paragraphs (g)(4) through (6) as paragraphs (h)(5) through (7) in the section accordingly.

• We have revised paragraph (h)(7) to provide that the term for a hardship exemption under § 483.35(h) is from grant of exemption until the next standard recertification survey, unless the facility becomes an Special Focus Facility, or is cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm, is or cited at the immediate jeopardy level of severity with respect to insufficient staffing as determined by CMS, or fails to submit Payroll Based Journal data in accordance with § 483.70(p). A hardship exemption may be extended on each standard recertification survey, after the initial period, if the facility continues to meet the exemption criteria in § 483.35(h)(1) through (5), as determined by the Secretary.

6. Facility Assessment (Proposed § 483.71)

Facility assessments play an important role in ensuring that LTC facilities develop thoughtful, informed staffing plans to meet the needs of their specific residents based on case mix and other factors. The current requirements for the facility assessment are set forth at § 483.70(e) and require each LTC facility to conduct and document a facility-wide assessment to determine what resources are necessary to care for its resident population competently during both day-to-day operations and emergencies. It must be reviewed and updated annually, as necessary, and whenever the facility plans for or has any change in its facility or population that would require a substantial change to any part of the assessment. The assessment must address or include evaluation of the resident population, the facility's resources, and a facility-based and community-based risk assessment that utilizes the all-hazards approach. For the reasons set forth in the proposed rule, we proposed to redesignate (that is, relocate or move) the existing requirements for the facility assessment to its own standalone section from § 483.70(e) to proposed § 483.71. We also proposed technical changes throughout the CFR to replace references to § 483.70(e) with § 483.71 based on this proposed change. We also proposed technical changes throughout the CFR to replace references to § 483.70(e) with § 483.71 based on this proposed change. For organizational purposes, we proposed to redesignate the stem statement for current § 483.70(e) to the stem statement for proposed § 483.71 and existing § 483.70(e)(1) through (3). We proposed to redesignate § 483.70(e)(1) through (3) as proposed § 483.71(a)(1) through (3), respectively.

At new § 483.71(a)(1)(ii), we proposed to clarify that facilities would have to address in the facility assessment details of its resident population, including the care required by the resident population, using evidence-based, data driven methods that consider the types of diseases, conditions, physical and behavioral health issues, cognitive disabilities, overall acuity, and other pertinent facts that are present within that population, consistent with and informed by individual resident assessments as required under existing § 483.20, ''Resident Assessment.'' Specifically, we proposed to revise this paragraph by specifying the ''use of evidence-based, data driven methods'' and create a link to the requirements for the resident assessment. Facilities are expected to update their facility assessment as needed, no less than annually, using evidence-based, data-driven methods, that consider the needs of their residents and the competencies of their staff.

We also proposed to revise this paragraph to add ''behavioral health issues'' to clarify that LTC facilities must consider their residents' physical and behavioral health issues. At new § 483.71(a)(1)(iii), we proposed to add ''and skill sets'' so the requirement reads: ''The staff competencies and skill sets that are necessary to provide the level and types of care needed for the resident population.'' At new § 483.71(a)(3), we proposed to add a cross-reference to the existing requirements for facilities to conduct a facility and community-based risk assessment as part of their emergency planning resources.

At new § 483.71(a)(4), we proposed to require facilities to include the input of facility staff, including but not limited to categories such as nursing home leadership, management, direct care staff and their representatives, and staff providing other services.

We proposed at new § 483.71(b)(1) to require facilities to use the facility assessment to inform staffing decisions to ensure appropriate staff are available with the necessary competencies and skill sets necessary to care for its residents' needs as identified through resident assessments and plans of care as required in § 483.35(a)(3).

In addition, we proposed a new § 483.71(b)(2) to require facilities to use the facility assessment to assess the specific needs for each resident unit in the facility, and to adjust as necessary based on any significant changes in the resident population. Facilities would also be required, at proposed § 483.71(b)(3), to consider the specific staffing needs for each shift, such as day, evening, night, weekends, and to adjust as necessary based on any significant changes to the resident population.

We proposed at new § 483.71(b)(4) that LTC facilities would have to use their facility assessment to develop and maintain a staffing plan to maximize recruitment and retention of nursing staff. We did not propose to specify how the staffing plan should be developed or what it must contain. We solicited comments on the operational challenges or burdens of this proposed provision, as well as how CMS could best provide oversight of this proposed requirement.

We proposed at § 483.71(b)(5), to require facilities to use the facility assessment to inform contingency planning for events that do not necessarily require the activation of the facility's emergency plan but do have the potential to impact resident care.

Based upon our review and analysis of the comments, we are finalizing the proposed requirements as proposed with some revisions. The language we are finalizing and the reasons for those changes are detailed in the comments and responses below.

Comment: A few commenters supported the move to relocate the current requirements at § 483.70(c) (Facility assessment to a standalone) to § 483.71 (Facility assessment). However, other commenters opposed any changes to the current facility assessment requirements as unnecessary.

Response: We acknowledge that relocating the facility assessment requirements might not appear to be a substantial change. However, the facility assessment requirements are the foundation for any LTC facility's planning for the staffing and other resources that are necessary to provide the appropriate care required for its resident population. This merits a separate requirement and also emphasizes the importance of the facility assessment. Hence, we are finalizing this redesignation as proposed.

Comment: Some commenters were supportive of the proposed changes to the facility assessment requirements. Several commenters were particularly supportive of the insertion of ''behavioral health issues'' in § 483.35(a)(1)(ii) in describing the factors the LTC facility's assessment must address regarding its resident population. One commenter even stated that the proposed changes to the facility assessment requirement were one of the most important changes that were proposed. However, there were also many commenters that opposed the proposed changes. Some commenters thought that the requirement was formulaic and many LTC facilities just ''sleepwalked'' through the process. Some opposed the proposed changes contending that they would only result in more paperwork and take direct care staff away from resident care. They contended that there was little, if any, evidence that the current requirements in any way benefitted residents, especially regarding nurse staffing. Other commenters noted that the facility assessment requirement has been essentially ignored by both LTC facilities and surveyors. They noted that from FY 2021 to FY 2023, there had only been 592 deficiencies cited regarding the facility assessment requirement and in only 10 of these cases was it even likely a financial penalty would be imposed. However, other commenters indicated that the proposed changes were not necessary because the vast majority of LTC facilities were already in substantial compliance with the current requirements.

Response: The comments received regarding facility assessment demonstrated a diversity of opinions on the proposed changes. We agree that the proposed changes will strengthen the overall facility assessment, which we have long viewed as a foundational element to care and resource planning in LTC facilities. The facility assessment is an important complement to the minimum staffing requirements finalized as part of this rule as it sets standards that must be met for staffing based on actual resident case-mix, not just the floor (baseline) created by the minimum staffing requirements. We agree with the commenters that the addition of ''behavioral health issues'' is an important change and emphasizes the need to consider these issues in the facility assessment. Thus, we are finalizing the addition of ''and behavioral health'' at § 483.35(a)(1)(ii) as proposed.

However, we disagree with commenters about the meaning of the number of deficiencies cited by surveyors. While the number of deficiencies is relatively low, this is not an indication that the requirement is being ignored or dismissed by the LTC facilities or surveyors. As some commenters indicated, the vast majority of LTC facilities are complying with the facility assessment requirement. Also, some surveyors might choose to cite a deficiency based on a requirement set out elsewhere in the LTC participation requirements instead of the facility assessment requirement. For example, a surveyor might cite a noncompliance deficiency for the sufficient nurse staffing requirement set forth at § 483.35(a)(1) rather than the facility assessment requirement. Regarding the commenters who opined that LTC facilities were only ''sleepwalking'' through the process, the governing body is responsible for the quality of care provided to residents and how the LTC facility's policies are established and implemented (§ 483.70(d)(a)). The medical director is responsible for the implementation of resident care policies; and the coordination of medical care in the facility (§ 483.70(h)). Hence, it is the responsibility of both the governing body and the medical director to ensure that requirements, including the facility assessment requirement, are complied with at their facility to ensure that residents receive quality, safe care. To address this concern, we are finalizing at § 483.71(b) a requirement that the LTC facility must ensure the active participation of a member of the governing body and the medical director in the facility assessment process. This is discussed in more detail below.

Comment: Many commenters supported the proposed facility assessment changes and recommended the requirement be strengthened. Some recommended that a tool be developed for LTC facilities to follow in conducting their facility assessments. Others recommended that LTC facilities could be required to follow a prescribed method or specific methodologies to provide some uniformity in the facility assessments and focus the assessments on resident acuity. They also suggested that the facility assessments should be reviewed and updated more often, such as quarterly. A few commenters recommended that the facility assessment either be included in or structured similarly to the quality assessment and program improvement (QAPI) program. Some others wanted to

require an evaluation of all of the training programs in the facility assessment process.

Response: CMS thanks the commenters for their recommendations. However, we will not finalize any of these recommendations as requirements in this rule. We will continue to evaluate these suggestions and consider these comments if there is future rulemaking regarding the facility assessment requirement. Regarding an evaluation of training programs in the facility assessment, at § 483.95 we require LTC facilities to develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. LTC facilities are required to determine the amount and type of training necessary based on their facility assessment as now set forth at new § 483.71. Hence, part of developing or reviewing and updating the facility assessment would include determining the amount of and type of training each individual providing services to residents should receive.

Comment: Several commenters were concerned about the proposed staff required to be involved in the facility assessment process, although many other commenters supported the idea that direct care staff should be closely involved in creating the facility assessments. Some commenters wanted to specifically name RNs and all other levels of nursing staff to ensure their input on staffing was included in the facility assessment. They contended that RNs were in the best position to determine staffing levels for the various units in the LTC facility. Other commenters contended that Nas should be specifically named since they provide most of the direct resident care. Some commenters were very supportive of our proposal because they believed the LTC facility's Medical Director should be actively involved in the facility assessment process. A few also suggested that the governing board be included in the process. However, other commenters opposed expanding the requirements for who should be involved in this process, especially in requiring non-staff or other third parties in the facility assessment process. Commenters contended that this would be inappropriate since it is an operational document for the facility. They suggested that the inclusion of third parties, especially union representatives, could be disruptive, divisive, and render the facility assessment ineffective. In addition, there are concerns that third parties, especially union representatives, would not be primarily concerned about the residents' care and well-being but the workers they represent. Specifically, they raised their concerns that union representatives would be concerned with their members' compensation, benefits, and working conditions and not the care provided to residents. To address this concern, a few commenters recommended that any representatives of direct care workers also be an employee of the LTC facility. These commenters contended that only another employee would have the knowledge of the facility and its operations to provide beneficial input into the facility assessment. Other commenters noted that the guidance contained in the State Operation Manual that is used for surveys already indicates that LTC facilities should seek input from residents, resident representatives, resident families, and family councils.[66]

Response: The staff involved in the facility assessment are essential to the quality and comprehensiveness of the assessment. We agree with the commenters that all levels of the nursing staff need to be included in the facility assessment process so that the final product is comprehensive and provides the maximum benefit to the residents and the LTC facility. As discussed above, it is the governing body that is responsible for establishing and implementing the policies (§ 483.70(d)(a)) and the medical director is responsible for the implementation of that these individuals would also be essential to the facility assessment process. The most contentious comments generally regarded the proposal for representatives of direct care staff. We thank commenters for their suggestions. We agree the purpose of the facility assessment is to identify the resources and supports needed to safely care for residents. However, we also believe that individuals other than facility staff could offer beneficial input for the process. Input from the representatives of direct care staff, for example, third-party elected local union representatives, business agents, safety and health specialists, or a non-union worker's designated representatives from a worker advocacy group, community organization, local safety organization, or labor union, could be especially important. Direct care staff may be hesitant to criticize staffing decisions of management or fear retaliation. Their representatives would generally be able to speak more freely and can reflect concerns that they have heard across a number of staff members. We agree that representatives who are not themselves employees may not have the knowledge of the facility or its operations as an employee would; however, it is the representatives' ability to provide input that employees might be hesitant to provide themselves that could be valuable input.

We want to clarify that the requirement for ''direct care staff'' means more than RNs, LPNs/LVNs, and Nas alone. We encourage LTC facilities to solicit input or even active participation from other direct care staff, especially physicians, nurse practitioners, physician assistants, social workers, activity directors, dieticians/nutritionists, and other therapists. Also, if the LTC facility has specialized units, such as, memory care, behavioral health, sub-acute, or ventilator/trach dependent, we encourage the inclusion or input of staff from those units. Due to the care provided by these specialized units, their staff could provide valuable input into the staffing and other resource requirements needed for the residents care for in units.

We also want to clarify our expectations regarding ''active participation'' for the staff identified in this requirement. LTC facilities need flexibility in how they conduct, develop, and implement their facility assessments. Hence, ''active participation'' does not require that all identified staff or their representatives are at every meeting or discussion or must approve the final facility assessment. However, at a minimum, all identified staff should have the opportunity to present their views and have those views considered by the other staff that are actively participating in the process. LTC facilities should determine the level of active participation for each individual thereafter. For example, if some meetings would focus on nurse staffing, the LTC facility would not necessarily have to require a physical therapist or a member of the food and nutrition staff to attend. Also, the LTC facility could limit the staff who would be responsible for the final approval of the facility assessment. In addition, individuals could participate in-person or virtually. For example, the medical director or member of the governing body could participate by phone in meetings or provide their input and comments on drafts in written form. Regarding those individuals whose input should be

[66] State Operations Manual, appendix PP Guidance to Surveyors for Long Term Care Facilities (Rev. 211, 02–03–23), Tag F838, Guidance sec. 483.70(e) (Rev.: 173, Issued: 11–22–17, Effective 11–28–17, Implementation: 11–28–17).

solicited and considered if received, the LTC facility should actively solicit input from identified participants. The LTC facility should determine the best way to contact these individuals to solicit their input. The input should then be shared with all of the individuals who are actively participating in the facility assessment process in time for there to be a discussion of the received input. The time period for providing input should be reasonable. The individuals from whom input is being sought would likely need more than a few days or a week to contemplate what input they want to provide.

Hence, we are revising § 483.71(b)(1) to require that the LTC facility require the active participation of the nursing home leadership and management including but not limited to, a member of the governing body, the medical director, an administrator, and the director of nursing; and, direct care staff, including but not limited to, RNs, LPNs/LVNs, Nas, and representatives of direct care staff, if applicable. The LTC facility must also solicit and consider input received from residents, resident representatives, family members.

Comment: Some commenters contended that the proposed requirements conflicted with each other, especially the minimum nurse staffing and 24/7 RN requirements. They also noted concerns about how the facility assessment requirement worked with these requirements.

Response: All of the requirements in this finalized rule are designed to both function independently and work together to ensure that LTC facility residents receive the quality care required for their health and safety needs. The minimum nurse staffing requirement as set forth in § 483.35(a)(1) requires LTC facilities to have a minimum total nurse staffing of 3.48 HPRD with a minimum 0.55 HPRD for RNs, and a minimum total of 2.45 HPRD for Nas. Unless a LTC facility is exempted as described in § 483.35(h), each LTC facility must comply with the requirement. The 24/7 RN requirement is in addition to the minimum nurse staffing requirement; however, each RN that is on duty and providing direct resident care also counts towards both requirements. Hence, there is no conflict between these requirements. The facility assessment requirement as set forth at § 483.71 is a separate requirement that is designed to ensure that each LTC facility has assessed its resident population to determine the resources, including direct care staff, their competencies, and skill sets, the facility needs to provide the required resident care. If the facility assessment indicates that a higher HPRD for either total nursing staff or an individual nursing category is necessary for ''sufficient staffing'', the facility must comply with that determination to satisfy the requirement for sufficient staffing as set forth at § 483.35(a)(1). The facility assessment requirement ensures that each LTC facility assesses the needs of its resident population to determine the resources it needs to provide the care its residents require. However, if the facility assessment indicates that a lower HPRD or that a 24/7 RN is not required to care for their resident population, the LTC facility must still comply with those minimum staffing requirements. Hence, these requirements do not conflict with each other. Each requirement works independently to achieve the separate goals of a minimum nurse staffing requirement and an assessment of the resources that are required to care for the LTC facility's resident population. They also work together to ensure that each LTC facility is providing the quality, safe care required for their resident population.

Comment: Some commenters questioned the usefulness of the facility assessment regarding determinations of daily staffing needs. They contended that the facility assessment is more global rather than granular, that is, it cannot assist with the daily changes in resident acuity.

Response: We acknowledge that resident acuity and daily staffing needs can vary. LTC facilities must already contend with and adjust for these changes daily. However, if the facility assessment was conducted according to the requirements finalized in this rule, LTC facilities should know the number of staff, the competencies, skills sets they need, and the other resources needed to care for residents in their facilities. This should enable LTC facilities to adjust their staffing and other resources to compensate for resident acuity and changes needed in daily staffing.

Comment: In the proposed rule, we discussed some of the reasons input from representatives of direct care representatives could be important for the facility assessment process. One statement was, ''[a]longside direct care employees, their representatives *may also help ensure facility assessments are up-to-date and used to inform facility staffing*'' (emphasis added) (88 FR 61375). Several commenters disagreed with the part of the statement emphasized in italics above. These commenters contended the enforcement role belongs exclusively to State and Federal surveyors and is never the domain of a third-party representatives.

Response: We agree with the commenters that the enforcement of the LTC participation requirements is not within the scope of participation of third-party representatives. However, the referenced statement in the proposed rule located at 88 FR 61375 is not referring to any enforcement role. As stated in the proposed rule, the input from representatives of direct care workers could be beneficial, especially when the direct care workers are hesitant to raise concerns with their employers about the current staffing in the facility. In such instances, representatives can provide the LTC facility with assessments and recommendations anonymously from direct care workers free from the fear of retaliation, which could assist LTC facilities in ensuring their facility assessments are up to date and accurately inform facility staffing without retaliation. Ultimately, we believe that this type of input can positively impact staff leading to better and safer care for residents. Hence, we are finalizing a requirement that LTC facilities ensure the active participation of direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs, and representatives of direct care staff, if applicable.

Comment: Some commenters contended that the proposed changes constitute a one-size-fits-all approach that is inconsistent with the goals of the facility assessment. They contend that the individual needs of the residents and LTC facilities are not being considered or acknowledged in the proposed rule.

Response: We do not agree that these requirements utilize a ''one-size-fits-all'' approach. The minimum nurse staffing requirement as set forth in § 483.35(b)(1) requires LTC facilities to have a minimum total nurse staffing of 3.48 HPRD with a minimum 0.55 HPRD for RNs, and a minimum total of 2.45 HPRD for NAs. Because HPRD involves an assessment of the total number of hours worked by each type of staff compared to the actual number of residents in the facility, it is automatically adjusted for size of facility. With the facility assessment requirement, each individual LTC facility assesses its own resident population and the resources needed to care for them, which will often result in facilities needing to staff higher than the minimum staffing requirements. Thus, neither of these requirements is ''one-size-fits-all'' because they are tailored to each LTC facility. The only requirement that is the same regardless of the LTC facility or its

resident population is the 24/7 RN requirement. However, this requirement is designed to reduce the occurrence of preventable safety events for residents, as well as address health and quality concerns, which requires at least one RN providing direct resident care throughout the day. LTC facilities are expected to increase RN coverage as needed to comply with the minimum nurse staffing requirements and their facility assessment. The minimum nurse staffing and 24/7 RN requirements are not justifications for any LTC facility to fail to provide the direct care staff with the appropriate competencies and skill sets and other resources required to appropriately care for its resident population.

Comment: Some commenters were supportive of the requirement for certain individuals to be involved in the facility assessment process but recommended more time to comply with the requirement. These commenters noted that it would be difficult to assemble the staff required, develop the facility assessment, and a staffing plan in the usual time allotted after a final rule is published. One commenter recommended 120 days after the final rule was published, and another recommended two years.

Response: All LTC facilities should already have a facility assessment. While it should not take an extended period of time to do so, CMS is concerned that some LTC facilities might need more time to comply with the requirements finalized in this rule. For example, some LTC facilities might need additional time due to staffing issues or a lack of previous documentation. Hence, we are finalizing a longer implementation date for the facility assessment requirements in this rule to allow more time for LTC facilities to come into compliance. We proposed a 60-day implementation date for the facility assessment requirements, however, we are modifying our proposal to require implementation of the facility assessment requirements 90 days after publication of this final rule. LTC facilities should be using the facility assessment to determine appropriate staffing needs based on their resident population's care needs and meet these requirements in an accelerated manner.

Comment: Commenters were divided on the proposed requirement that set forth how LTC facilities were to use their facility assessments. Many commenters opined that additional requirements were unnecessary, burdensome, and would also be taking direct care staff away from resident care. There were also many commenters that were supportive, especially regarding the requirement that the LTC facility use their facility assessment in making staffing decisions and in developing and implementing the staffing plan. One commenter was grateful that this section was clarifying how the facility assessment should be used and indicated that this made it more meaningful. Other commenters recommended that the requirement be strengthened to increase its effectiveness. Some commenters recommended a requirement for an assessment committee. Other commenters recommended a requirement on specific items that should be considered or included in the staffing plan, such as compensation and training for direct care staff.

Response: The new requirement at § 483.71(c) is intended to provide clarification on how LTC facilities are to use their facility assessments. While some commenters might argue that it is unnecessary, we disagree. The facility assessment is the foundation for LTC facilities to assess their resident population and determine the direct care staffing and other resources, to provide the required care to their residents. The facility assessment must be conducted and developed with the intent of using it to inform decision making, especially about staffing decisions. The facility assessment must be used to develop and maintain the staffing plan or the plan to maximize recruitment and retention of direct care staff. The facility assessment should identify the numbers of staff, types of staff, the required competencies and skill sets that staff require to care for the resident population. Thus, the facility assessment would inform the staffing plan the LTC facility requires. The facility assessment must also be used to inform contingency planning. LTC facilities will likely encounter different events that have the potential to affect resident care. These events, however, do not necessarily require activation of the facility's emergency plan. The facility assessment should be used to inform contingency planning to address these types of events. For example, direct care staff will call in sick some days. LTC facility must have contingency plans for when direct care staff cannot come into work. Hence, we are finalizing § 483.71(c) as proposed.

Comment: Some commenters opposed facility assessment requirements being used to cite for deficiencies during a survey. Commenters asserted that surveyors could not determine the quality of the facility assessment or the staffing plan. Also, they noted that even if the staffing plan was well developed, its effectiveness depended on so many factors that LTC facility should not be responsible for any results.

Response: We agree with the commenters that surveyors cannot determine the quality of the facility assessment. Surveyors determine whether or not the LTC facility has complied with the facility assessment requirements as set forth at new § 483.71. Therefore, an LTC facility could be cited for non-compliance if its facility assessment failed to contain all the requirements set forth in new § 483.71 and failed to determine a direct care staffing plan consistent with facility resident acuity levels.''

Comment: Some commenters were concerned about the potential of direct care staff, especially nurses, encountering retaliation as a result of participation in the facility assessment process. These staff might hesitate to criticize the LTC facility's staffing policies or make recommendations about staffing that they know will not be endorsed by the management. Some commenters recommended that nurses have some protections, such as whistleblower protections.

Response: RNs, LPNs/LVNs, and NAs are critical to a comprehensive and effective facility assessment. We encourage all direct care staff involved in the facility assessment process to provide thoughtful and honest feedback when participating in the facility review and development process for the assessment. Similarly, management should not punish or retaliate against direct care staff for providing honest input. In this rule, we are finalizing a requirement for facilities to ensure active participation from representatives of direct care staff, if applicable, as such we encourage staff, especially those who may be concerned about potential retaliation, to communicate with and utilize their representatives as a resource for sharing input. In addition, the Occupational Safety and Health Administration (OSHA) has resources to help employers learn about recommended practices to keep their workplaces free of illegal retaliation.[67]

Final Rule Action: We are finalizing as proposed the relocation of § 483.70(e) to a standalone section, § 483.71. We are finalizing as proposed the addition of ''behavioral health issues'' to § 483.71(a)(1)(ii); the addition of ''and skill sets'' to § 483.71(a)(1)(iii); and the addition of ''as required'' in § 483.73(a)(1) through (3). We are also finalizing our proposal to redesignate the stem statement for current § 483.70(e) to the stem statement for

[67] *https://www.osha.gov/sites/default/files/publications/OSHA3905.pdf.*

proposed § 483.71 and existing § 483.70(e)(1) through (3) as proposed § 483.71(a)(1) through (3), respectively. We are finalizing as revised § 483.71(b) to require that the LTC facility actively require the participation of the nursing home leadership and management, including but not limited to, a member of the governing body, the medical director, an administrator, and the director of nursing; and, direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs, and representatives of direct care staff, if applicable. The LTC facility must also solicit and consider input received from residents, resident representatives, family members, and representatives of direct care staff. We are also finalizing as proposed § 483.71(c) that sets out the activities for which the LTC facility must use the facility assessment, including making staffing decisions, developing and maintaining a plan to maximize recruitment and retention of direct care staff, to inform contingency planning for events that do not necessarily require activation of the facility's emergency plan.

7. Implementation Timeframe

We proposed to implement the 0.55 RN and 2.45 NA HPRD, the RN onsite 24 hours a day, 7 days a week, and facility assessment requirements in three phases, to avoid any unintended consequences or unanticipated risks to resident care when a facility is developing new policies and procedures necessary to comply with these requirements. This would give facilities significant time to recruit additional staff needed to meet the requirements.

In addition, we anticipate that additional time would be needed to develop revised interpretive guidance and survey processes, conduct surveyor training on the changes, and implement the changes in the Long-Term Care Survey Process system.

For facilities located in urban areas, we proposed that implementation of the final requirements be achieved in three phases, over a 3-year period. Specifically, we proposed that—

- Phase 1 would require facilities to comply with the facility assessment requirements (§ 483.71) 60-days after the publication date of the final rule.
- Phase 2 would require facilities to comply with the requirement for a RN onsite 24 hours a day, 7 days a week (§ 483.35(b)(1)) 2 years after the publication date of the final rule.
- Phase 3 would require facilities to comply with the minimum staffing requirement of 0.55 and 2.45 HPRD for RNs and NAs respectively (§ 483.35(a)(1)(i) and (ii)) 3 years after the publication date of the final rule.

For facilities located in rural areas, we proposed the implementation of the final requirements be achieved in three phases, over a 5-year period. Specifically, we proposed that—

- Phase 1 would require facilities to comply with the facility assessment requirements (§ 483.71) 60-days after the publication date of the final rule.
- Phase 2 would require facilities to comply with the requirement for a RN onsite 24 hours a day, 7 days a week (§ 483.35(b)(1)) 3 years after the publication date of the final rule.
- Phase 3 would require facilities to comply with the minimum staffing requirement of 0.55 and 2.45 HPRD for RNs and NAs respectively (§ 483.35(a)(1)(i) and (ii)) 5 years after the publication date of the final rule.

For purposes of the implementation timeframe, we proposed to define ''rural'' in accordance with the Census Bureau definition. ''Rural'' encompasses all population, housing, and territory not included within an urban area[68] We also solicited public comments on whether a different definition should be used. We noted that the final regulations would be effective 60 days following the publication of the final rule in the **Federal Register** and solicited public comments.

We received the following comments in response to this solicitation.

Comment: Many commenters supported a single implementation timeframe for both rural and urban LTC facilities. They expressed concerns that workforce shortages existed in both urban and rural areas regardless of facility location. One commenter stated that the separate phase-in timeframes would foster competition between urban and rural facilities, that nursing staff would be recruited away from rural areas to fulfill the needs of urban areas first, and when it became time for rural areas to recruit, they would find themselves competing to bring staff back. Many commenters noted that an extended implementation timeframe for rural areas would exacerbate existing disparities in the quality of care for rural residents. Moreover, commenters emphasized that residents in rural LTC facilities were entitled to the same quality of care as those in urban and underserved areas. Some commenters expressed concerns that the proposed implementation timeframe favored rural areas as they would have not only an extended phase-in timeframe but also would be able to utilize the exemptions.

Response: We agree that residents in both urban and rural LTC facilities deserve access to safe and high-quality care and are finalizing for all LTC facilities, regardless of location, minimum nurse staffing standards along with a 24 hour per day, 7 day per week requirement for an RN to be onsite and available to provide resident care. We also agree with commenters that workforce shortages exist regardless of facility location, which is why we are finalizing exemption criteria that focus on the provider-to population ratio rather than on a facility's rural status alone. Equal access to exemptions from the requirements of this rule based on a pronounced unavailability of registered nurses and nurse aides will address this concern. We do not agree that a staggered implementation will result in potential employees being recruited away by facilities in urban areas, as there is no regulation that would prohibit any rural LTC facility from recruiting and retaining all nursing staff at any time, including those times when non-rural facilities are actively increasing their own staffing levels to comply with the requirements of this final rule. However, we recognize that there is a possibility that potential employees may opt to relocate if employers offer a more competitive salary. Additionally, all LTC facilities are required to comply with the facility assessment requirements at § 483.71 within the same timeframe, regardless of their location, effective 90 days after publication of this final rule. As part of the facility assessment, LTC facilities must develop and maintain a plan to maximize recruitment and retention of direct care staff.

We continue to recognize that rural areas face myriad challenges ranging from worker housing shortages to severe transportation challenges for remote facilities that are unique to their location. We are thus finalizing, in addition to an exemption framework, a staggered implementation timeline that allows additional time for rural facilities to comply with the requirements of this rule.

Comment: Many commenters expressed concerns that the proposed U.S. Census Bureau definition of ''rural'', for purposes of the proposed implementation timeframe, does not accurately represent rural areas. In 2022, the U.S. Census Bureau published updated criteria on how it will define

[68] *https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html#:~:text=Rural%20encompasses%20all%20population%2C%20housing,and%2For%20population%20density%20requirements.*

urban areas.[69] An urban area is comprised of a densely settled core of census blocks that meet minimum housing unit density and/or population density requirements. To qualify as an urban area, the territory identified according to criteria must encompass at least 2,000 housing units or have a population of at least 5,000 and rural consists of all territory, population, and housing units located outside urban areas.[70] Commenters expressed concern that the revised definition is too narrow, would exclude many areas that historically have qualified as rural or areas that fall under other Federal or State definitions of ''rural'' and that as a result, many LTC facilities in such areas would not qualify for the proposed extended implementation timeframe for rural areas. Numerous commenters suggested a wide variety of sources for alternative definitions of ''rural'' that CMS should consider using. A few commenters suggested aligning the definition of ''rural'' with other Medicare programs in order to promote consistency and assure access to services in rural communities that depend on LTC facilities for care delivery.

Specifically, these commenters suggested using the ''rural'' definitions from the Medicare Rural Hospital Flexibility Program, or the CMS–SNF–IRF wage index. Numerous other commenters suggested that CMS use an alternative definition that is used by other Federal programs and agencies. Commenters suggested these alternative definitions to address concerns that the current definition is not sufficiently accurate. Commenters suggested using definitions from the Office of Management and Budget (OMB),[71] or the Federal Office of Rural Health Policy (FORHP.)[72]

Response: We appreciate the varied comments received on the proposed ''rural'' definition. While most commenters did not support the use of the Census Bureau's definition of ''rural'' and suggested using alternative definitions, there was not a consensus about which definition of ''rural'' would be most appropriate to use for the rule. However, we do acknowledge that using the Census Bureau definition of ''rural'' for this rule could mean that counties that were considered rural prior to the Census Bureau updates in 2022 or under alternative Federal definitions such as the Office of Management and Budget (OMB), would now be considered urban. For example, if we were to use the Census Bureau's definition of ''urban'', 2,645 counties would be classified as urban,[73] while if we were to use OMB's definition of ''urban'', 1,252 counties would be considered ''urban.''[74] Furthermore, the 2022 urban area delineations issued by U.S. Census Bureau removed the subcategories of urbanized areas (encompasses a population of 50,000 or more people) and urban clusters (encompasses a population of at least 2,500 and less than 50,000 people).[75] This means that towns as small as 5,000 people are delineated as urban areas with no differentiation between small towns and large cities.

We agree that the definition used in the rule should be consistent with the definition used in other Medicare programs and note that the definition of ''rural'' from OMB has been used by the critical access hospital requirements (see 42 CFR 485.610[76]), and rural emergency hospital requirements (see section 1886(d)(2)(D) of the Act[77] and 42 CFR 485.506[78]).

Based on the considerations of the comments and suggested alternatives, we are finalizing to define ''rural'' in accordance with the OMB definition. OMB designates counties as Metropolitan (metro), Micropolitan (micro), or neither. ''A Metro area contains a core urban area of 50,000 or more population, and a Micro area contains an urban core of at least 10,000 (but less than 50,000) population. All counties that are not part of a Metropolitan Statistical Area (MSA) are considered rural.''[79]

Comment: Many commenters stated that the adoption of a final rule establishing minimum staffing in LTC facilities was essential. However, the commenters suggested various implementation timeframes. Many commenters recommended that CMS shorten the implementation timeframe to less than five years, with some suggesting that a shorter implementation timeframe would motivate facilities to begin recruiting and retaining staff to meet the finalized requirements as soon as possible. A commenter suggested that the LTC facilities would be able to meet the standards in a shorter phase-in because the proposed minimum nursing standards were relatively low and that the nursing staff needed would not need more than two hours of training.

Conversely, numerous other commenters suggested that CMS implement a phase-in timeframe of more than five years for all LTC facilities. One commenter expressed that the proposed phase-in timeframes did not allow sufficient time to recruit, train and graduate enough RNs due to the shortage of available seats in nursing schools. The commenter suggested that an unintended consequence of the proposed rule would be to force LTC facilities to hire nurses that might not be qualified and the LTC facilities would not have the time to train new staff ''to ensure competency'' and as a result, the LTC facilities would meet the minimum nursing requirement, but the residents would still be at risk due to the untrained staff. A commenter expressed that the additional time would allow facilities the time and financial support needed to ''build out the necessary education and workforce infrastructure, so that hiring of the additional staff can happen.'' Moreover, one commenter suggested that CMS delay the implementation timeframe of all LTC facilities ''to at least 5 years after the date of the final rule, with an additional at least 36-month allowance period for facilities to hire staff once the workforce is available''.

Response: We agree with the commenters that the minimum staffing requirements are essential and are finalizing them with the revisions described in this rule. In determining the question of the appropriate timeline for implementing these changes, we sought to strike a balance between ensuring a higher level of resident safety through earlier implementation and assuring that the implementation of these changes is not so aggressive as to result in unintended facility closures or resident census reductions, both of which could negatively impact the

[69] 87 FR 16706, March 24, 2022 (*https://www.federalregister.gov/documents/2022/03/24/2022-06180/urban-area-criteria-for-the-2020-census-final-criteria*).

[70] *https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html#:~:text=Rural%20encompasses%20all%20population%2C%20housingand%2For%20population%20density%20requirements.*

[71] *https://www.ruralhealthinfo.org/topics/what-is-rural.*

[72] *https://www.hhs.gov/guidance/document/defining-rural-population.*

[73] A list of all 2020 Census Urban Areas from the U.S., Puerto Rico, and Island Areas sorted by Urban Areas Census (UACE): *https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html.*

[74] *Core Based Statistical Areas (CBSAs), Metropolitan Divisions, and Combined Statistical Areas (CSAs): https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html.*

[75] *https://www.ruralhealthinfo.org/topics/what-is-rural.*

[76] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-F/section-485.610.*

[77] *https://www.ssa.gov/OP_Home/ssact/title18/1886.htm.*

[78] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-485/subpart-E.*

[79] *https://www.hhs.gov/guidance/document/defining-rural-population.*

ability of residents to receive care in a location that is close to their loved ones. In addition to considering comments regarding the exact implementation timeframe, we also considered the totality of the many flexibilities that are included in this final rule, including finalization of the proposed exemptions to the NA and RN HPRD requirements, and the addition of exemptions for the total nurse 3.48 HPRD requirement and for the 24 hours per day, 7 days per week RN requirement. As such, we are finalizing the implementation timeframe as proposed for all non-rural LTC facilities to complete implementation 3 years after the publication date of this final rule and all rural facilities will complete implementation 5 years after the publication date of this final rule. We believe that this is the most appropriate approach to implementation in light of the conflicting public comments on the subject of the implementation timeframes, the many revisions that we have made to the policies within this rule, and our policy goal of improving the care of all LTC facility residents while avoiding unintended consequences. We strongly encourage all LTC facilities to begin working towards full compliance as quickly as possible.

Comment: Numerous commenters suggested that CMS outline interim milestones gradually increasing each year until LTC facilities meet the final RN and NA HPRD requirements. They stated that this approach would allow for LTC facilities to slowly adapt to the new minimum staffing requirements while continuing to provide safe and quality care. In addition, this approach would discourage last-minute hiring practices by LTC facilities.

Response: Taking into consideration conflicting comments, we have structured the implementation of the final policy discussed in this rule to occur in three phases; Phase 1 requires facilities to comply with the facility assessment requirements; Phase 2 requires facilities to comply with the requirement for a facility to provide 3.48 HPRD of nursing care and to have a RN onsite 24 hours a day, 7 days a week; and Phase 3 requires facilities to comply with the minimum staffing requirements of 0.55 and 2.45 HPRD for RNs and NAs respectively. We are phasing in the 3.48 HPRD total staffing requirements during Phase 2 as we expect LTC facilities will be able to comply quickly with this requirement since facilities may use any combination of nursing staffing types (RN, LPN/LVN, or NA), rather than using specific nursing staffing types to meet this requirement. However, we expect LTC facilities that are currently staffing in excess of 3.48 HPRD of total nursing care will not reduce their total nurse staffing HPRD when the 3.48 HPRD for total nurse staffing requirement is implemented. LTC facilities should continue using the facility assessment to determine staffing needs above the finalized minimum standards to provide safe and quality care based on resident acuity.

Beyond these phases, we do not agree that it is appropriate to specify additional interim milestones. We believe that milestones should be specific to the needs of each facility and as part of the facility assessment, a LTC facility must have a facility-wide assessment to determine what resources are necessary to care for its residents. That assessment should consider, among other things, the facility's resident population, staff competencies and necessary skill set, its resources, and other factors that may affect the care it provides. The facility must use this facility assessment to inform staffing decisions to ensure that there are a sufficient number of staff with the appropriate competencies and skill sets necessary to care for residents' needs and to develop and maintain a plan to maximize recruitment and retention of direct care staff. The facility assessment will drive the interim steps that need to occur at each facility in preparation for complying with the requirements of this final rule.

Comment: A commenter suggested that we delay the implementation of the requirements until CMS has completed a pilot program first.

Response: We appreciate this suggestion. However, we believe that the minimum staffing requirements need to be implemented as soon as possibly feasible to ensure residents receive safe and quality care in LTC facilities. Therefore, CMS will not proceed with a pilot program.

Comment: Commenters expressed that there is not a need for a longer implementation timeframe for other underserved communities, as there is no evidence available to show that LTC residents in underserved communities have lesser needs than LTC residents in other areas. They stated that it would only perpetuate poor quality care for underserved communities, especially among racial and ethnic minorities.

Response: We agree with the commenters. Residents in LTC facilities should have access to safe and quality care, regardless of location. Therefore, we are not extending the implementation timeline for medically underserved communities.

Comment: A commenter recommended that we consider ways to incentivize nursing homes to meet the minimum nursing requirements on an accelerated timeline.

Response: In the FY 2023 SNF Prospective Payment System (PPS) Rule final rule (87 FR 47570 through 47576), we adopted the Total Nursing Hours per Resident Day Staffing (Total Nursing Staffing) measure for the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program-beginning with the FY 2026 program year. LTC facilities that have SNF beds participate in the SNF VBP Program and are subject to payment incentives under the program. Therefore, these LTC facilities will be incentivized to comply with the minimum staffing requirements because as their performance on the Total Nursing Staffing measure for the SNF VBP Program improves, those facilities may receive more favorable payment adjustments. Specifically, the LTC facilities that increase their staffing levels in FY 2025 and FY 2026 may receive either increased improvement or achievement scores under the SNF VBP Program. CMS awards achievement points to facilities that perform higher than the 25th percentile of national SNF performance on program measures and awards improvement points to facilities that have shown improvements in the measure performances from the baseline period to the performance period. Performance on the Total Nurse Staffing measure in the FY 2025 and FY 2026 performance year will affect payment adjustments in FY 2027 and FY 2028 program years respectively. LTC facilities that focus early on increasing their nurse staffing levels and otherwise improving performance on quality measures, such as the Total Nurse Staffing measure would have the opportunity to identify areas for further improvements and to take the necessary steps to address them. This could result in higher scores for the Total Nurse Staffing measure and subsequent increases in payment adjustments.

Regardless of these incentives, LTC facilities should use the facility assessment to determine appropriate staffing needs based on their resident population and their needs and meet these requirements in an accelerated manner to ensure timely and quality care to residents.

Comment: Some commenters recommended that we provide technical assistance to help LTC facilities meet the minimum staffing requirements within the proposed timeframe.

Response: As noted previously, CMS is launching an initiative to help increase the LTC workforce by committing over $75 million in financial incentives, such as tuition

reimbursement, to support the recruitment, training, and retention of nursing staff.[80] CMS is also exploring the potential to provide technical assistance to LTC facilities through the Quality Improvement Organizations and additional opportunities to provide technical assistance to those facilities impacted by this final rule. CMS will release interpretative guidance following the publication of the rule ahead of each implementation phase.

Comment: A few commenters expressed that State governments must plan for and readjust funds in order to meet the increased expense that hiring staff will require. According to the commenters, currently most State Medicaid rates do not cover the daily cost of care for residents and will not be able to cover the increased cost of labor this minimum staffing requirement will incur. Commenters suggested working with State Medicaid officials and managed care plans to ensure appropriate reimbursement rates while a commenter recommended that we establish advance funding for State governments.

Response: While the actions of State governments, including Medicaid rates, are not within the scope of this rule, we note that the policies in this rule will be phased in over a period of up to 5 years.

Final Rule Action: After consideration of the comments, we received on the proposed rule, we are finalizing the following implementation timeframe as follows:

- Rural facilities (as defined by OMB):

++ The requirement related to the Facility assessment at § 483.71 must be completed 90-days after the publication date of this final rule.

++ The requirement related to providing 3.48 HPRD for total nurse staffing at § 483.35(b)(1) and the requirement related to 24/7 onsite RN at § 483.35(c)(1) must be implemented 3 years after the publication date of this final rule.

++ The requirements related to providing 0.55 RN and 2.45 NA HPRD at § 483.35(b)(1)(i) and (ii) must be implemented 5 years after the publication date of this final rule.

- Non-rural facilities:

++ The requirement related to the Facility assessment at § 483.71 must be completed 90 days after the publication date of this final rule.

++ The requirement related to providing 3.48 HPRD for total nurse staffing at § 483.35(b)(1) and the requirement related to 24/7 onsite RN at § 483.35(c)(1) must be implemented 2 years after the publication date of this final rule.

++ The requirements related to providing 0.55 RN and 2.45 NA HPRD at § 483.35(b)(1)(i) and (ii) must be implemented 3 years after the publication date of this final rule.

These regulations are effective 60-days following the publication of the final rule in the **Federal Register**. The implementation date for the specific requirements are listed in detail in tables 3 and 4.

Table 3: Implementation Timeframes for Facilities in Rural Areas

Regulatory Section(s)	Implementation Date
§ 483.71	*Phase 1*: 90-days after the publication date of the final rule
§ 483.35(b)(1) and (c)(1)	*Phase 2*: 3 years after the publication date of the final rule
§ 483.35(b)(1)(i) and (ii)	*Phase 3*: 5 years after the publication date of the final rule

Table 4: Implementation Timeframes for Facilities in Non-Rural Areas

Regulatory Section(s)	Implementation Date
§ 483.71	*Phase 1*: 90-days after the publication date of the final rule
§ 483.35(b)(1) and (c)(1)	*Phase 2*: 2 years after the publication date of the final rule
§ 483.35(b)(1)(i) and (ii)	*Phase 3*: 3 years after the publication date of the final rule

C. Severability Clause

Finally, we stated and continue to affirm that, to the extent a court may enjoin any part of the rule, the Department of Health and Human Services intends that other provisions or parts of provisions should remain in effect. Any provision of this final rule held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this final rule and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances. For instance, the specific HPRD and 24 hour, 7 day a week RN staffing requirements finalized at § 483.35(b)(1) and (c)(1) could independently make improvements in the number of staff present at a LTC facility—the continuity of any one of the numeric standards would be helpful, and they do not require enforcement of the others to improve conditions at LTC facilities. We also note that the Medicaid reporting provisions of this final rule regarding the percent of payments spent on compensation for direct care and support staff workforce operate independently of mandated levels of nurse staffing—this is a reporting requirement, and the information about Medicaid expenditures on compensation for direct care and support staff workforce is important for CMS and the public in helping determine whether Medicaid service payments are economic and efficient, as well as adequate to support sufficient access for beneficiaries to high quality care.

[80] FACT SHEET: Biden-Harris Administration Takes Steps to Crack Down on Nursing Homes that Endanger Resident Safety | The White House: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/01/fact-sheet-biden-harris-administration-takes-steps-to-crack-down-on-nursing-homes-that-endanger-resident-safety/.*

D. Consultation With State Agencies and Other Organizations

Section 1863 of the Act (42 U.S.C. 1395z), requires the Secretary to consult with appropriate State agencies and recognized national listing or accrediting bodies, and appropriate local agencies, in relation to the determination of conditions of participation for providers of services. We held two listening sessions on June 27, 2022, and August 29, 2022, to allow all stakeholders, including State agencies and other organizations, to voice their concerns about the impact of a staffing standard, and took into consideration comments provided by State agencies.

Pursuant to section 1863 of the Act, in addition to publishing the proposed rule in order to solicit the views of States, we received comments from 11 State and local government organizations.

III. Medicaid Institutional Payment Transparency Reporting Provision (§§ 438.72 and 442.43)

A. General

In response to concerns about transparency in the use of Medicaid payments and chronic understaffing in Medicaid institutional services (discussed in detail in our proposed rule at 88 FR 61381 through 61384), we proposed new Federal requirements to promote public transparency around States' statutory obligation under section 1902(a)(30)(A) of the Social Security Act (the Act) and around the quality requirements in section 1932(c) of the Act for services furnished through managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs) under our authority under section 1902(a)(4) of the Act.[81] Specifically, we proposed to add new Federal requirements to promote better understanding and transparency related to the percentages of Medicaid payments for nursing facility and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) services that are spent on compensation to direct care workers and support staff. As noted in 88 FR 61382, this proposal was specific to nursing facility and ICF/IID services, which we at times may refer to collectively in this preamble as ''institutional services.'' We also noted in 88 FR 61382 that unlike in sections I. and II. of this rule, we will not be referring to LTC facilities, as this section (section III. of the final rule) focuses on Medicaid-certified nursing facilities and ICFs/IID, which are not referred to as LTC facilities. As discussed in the proposed rule at 88 FR 61383, we relied on several sections of the Act for our authority to propose these reporting requirements. Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may find necessary to assure the correctness and verification of such reports.

Under our authority at section 1902(a)(6) of the Act, and consistent with section 1902(a)(30)(A) of the Act, we proposed at § 442.43 to newly require that State Medicaid agencies report, at the facility level, on the percent of payments for nursing facility and ICF/IID services that are spent on compensation for the direct care and support staff workforce. While some States have voluntarily established similar transparency policies or initiatives, we noted our belief that a Federal requirement is necessary and would be more effective to generate more meaningful and comparable data and support transparency nationwide.

As discussed in our proposed rule at 88 FR 63184, we proposed that the reporting requirement at § 442.43 would apply not only to services provided under a fee for service (FFS) delivery system, but also when long-term services and supports (LTSS) systems are covered through managed care. For States that contract with MCOs and PIHPs to cover services delivered by nursing facilities and ICFs/IID, we proposed that States report annually on the percent of payments made to nursing facilities and ICFs/IID that is spent for compensation to direct care workers and support staff. Section 1932(c) of the Act lays out quality assurance standards with which States must comply when delivering Medicaid services through MCOs. This includes services delivered by MCOs authorized under section 1932(c), which requires the Secretary to both monitor States and consult with States on strategies to ensure quality of care. Additionally, based on our authority under section 1902(a)(4) of the Act to specify methods of administration that are necessary for proper and efficient administration of the State plan, we also proposed to apply the requirement to services delivered by PIHPs.

In addition, while we noted in the proposed rule at 88 FR 61383 that our proposal focused on institutional services, this proposal (which is being finalized in this rule) is consistent with efforts to address the sufficiency of payments for HCBS to direct care workers and access to and the quality of services received by beneficiaries of HCBS finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**.

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: A number of commenters expressed broad support for the proposal to require States to report on the percent of Medicaid payments that nursing facilities and ICFs/IID are spending on compensation to direct care workers and support staff, and to make this information publicly available. Many of these commenters expressed concerns about low worker wages and chronic understaffing; a few commenters noted that low wages to institutional direct care workers and support staff have a disproportionate impact on women and people of color who make up a large proportion of this workforce. Many supportive commenters noted that collecting these data will help demonstrate the links between Medicaid payment rates, worker compensation, staffing levels, and quality of care. Commenters noted that more transparency and accountability in the use of Medicaid funds may address public mistrust of how facilities are spending Medicaid payments, empower beneficiaries to advocate for more investment in quality care, and ensure public resources are being allocated for adequate staffing levels, wages, and benefits.

A few commenters provided anecdotal examples of when facilities have received temporary or long-term rate increases, but the increases were not passed along to staff. A few commenters noted that while interested parties might cite low Medicaid payment rates as a barrier to fair compensation, there is inadequate evidence to support this statement due to the lack of transparent and uniform reporting on Medicaid payment rates; these commenters indicated that a reporting requirement could help clarify concerns regarding the sufficiency of Medicaid payment rates.

A few commenters noted that this information could be useful to

[81] Throughout this section, section III. of the final rule, the use of the term ''managed care plan'' means managed care organization (MCOs) and prepaid inpatient health plans (PIHPs).

researchers and policymakers. One commenter noted this proposal would create a better understanding around compensation differences across States, which will help to inform future policy improvements and help policymakers better understand where to target interventions for facilities that are outliers in terms of workforce compensation that may affect the quality and quantity of care provided to residents.

Response: We thank commenters for their support.

Comment: A number of commenters did not support finalizing the proposed reporting requirement, although many expressed general support for the principle of payment transparency. Many of these commenters indicated that the reporting requirement would pose an unreasonable burden on State Medicaid agencies and nursing facilities and ICFs/IDD. One commenter noted that the requirements might have a disproportionate negative impact on smaller facilities that have fewer streamlined administrative processes.

A number of commenters representing both nursing facilities and ICFs/IID raised concerns that the proposal did not directly address Medicaid payment rates, which commenters believed are insufficient to support high-quality care or increases in direct care worker and support staff compensation; some of these commenters asked that we not finalize this proposal and instead propose requirements that States must regularly review Medicaid payment rates. Some of these commenters also suggested that without an increase in Medicaid payment rates to help offset the additional administrative burdens associated with reporting, facilities may have to redirect resources away from training and supervision, or some facilities may close.

A few commenters noted that the requirements as proposed, particularly the definition of direct care worker and reporting timeframes, do not align with current reporting requirements in the commenters' respective States. The commenters asked that we either not finalize the proposed provision or that we analyze existing State reporting requirements to ensure that any new Federal reporting requirements are not duplicative or misaligned with State reporting.

A few commenters representing ICFs/IID suggested finalization of the proposed requirements be delayed until we take into consideration differences between ICFs/IID and nursing facilities. These commenters stated that differences include variations in size, location, and physical layout; staff responsibilities; and services offered to residents, including active treatment and community engagement. A few commenters suggested that ICFs/IID should be exempted from the requirements if they are finalized.

Response: We acknowledge that complying with this reporting requirement will necessitate the use of resources and time on the part of providers and States. We believe that the value of the data collected through their efforts makes this use of resources and time worthwhile. As discussed further in this section, we are finalizing our definitions of compensation and direct care workers at § 442.43(a) with modifications to better account for the costs of clinical supervision, training, and other expenses that are essential to high-quality care. Additionally, as discussed further in this section, we are finalizing our proposal at § 442.43(b) to require only aggregated data reported at the facility level and by worker category (direct care worker or support staff), which we believe will limit burden on both providers and States.

We believe that, generally speaking, States and providers should already have information about the amount of Medicaid payments providers receive for specific services, and that providers likely already track expenditures for wages and benefits for their workers. We also believe that the aggregated reporting will be easier for States to validate and incorporate into their existing auditing processes.

While section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate methodologies, section 1902(a)(30)(A) of the Act does provide us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.

For managed care, section 1932(c)(1)(A)(ii) of the Act similarly does not speak explicitly to Medicaid provider payment rates but requires that States' quality strategies include an examination of other aspects of care and service directly related to the improvement of quality of care. Further, section 1932(c)(1)(A)(iii) of the Act authorizes the proposals being finalized in this section of this final rule, which enable States to compare payment data among managed care plans in their program; this could provide useful data to fulfill their statutory obligations for monitoring and evaluating quality and appropriateness of care. This authority under section 1932(c)(1)(A)(ii) and (iii) of the Act is extended to PIHPs through our authority under section 1902(a)(4) of the Act.

We will be making the reporting methodology and reporting template for the requirements finalized at § 442.43 available for public comment through the Paperwork Reduction Act notice and comment process, which will give the public the opportunity to provide specific feedback and help us align the methodology and reporting process with existing State practices to the greatest extent possible. However, we acknowledge that because State processes, timelines, and definitions vary, it may not be possible to align all details of the reporting process with existing practices in multiple States. We therefore plan to provide technical assistance, as needed, to facilitate further alignment with States' current reporting practices, to the greatest extent possible.

We decline to exclude ICFs/IID from the reporting requirement, as we do not believe such an exclusion would be warranted. We note that specific concerns related to ICF/IID reporting are addressed throughout section III. of this final rule.

Comment: One commenter stated that we already collect multiple data sets that could be used to approximate the information that would be subject to the proposed reporting requirement, including: direct care salary, benefits, and hours for freestanding nursing facilities using the Medicare Cost Report; Medicaid fee-for-service per diems in upper payment limit reporting; and quarterly supplemental payment information through the Medicaid Budget and Expenditure Systems (MBES) and in CMS–64 reports. This commenter stated that we should use existing Federal data to approximate the proposed metrics, which the commenter believed would reduce administrative burden and ensure consistent calculations across Medicaid programs. A few commenters noted that facilities already complete cost reports and suggested that researchers and regulators interested in Medicaid expenditures could obtain spending information from these cost reports.

One commenter stated that Medicaid wage and benefit data are available in some States while Medicaid financial data are not available in other States; the commenter stated that while it would be ideal to have more detailed information on wages and benefits, the commenter did not believe that most State Medicaid programs would have this information available without developing a more

comprehensive financial reporting system.

Response: We disagree that these data are readily available from existing data sources currently collected by CMS. The data sources that the commenter listed would not provide information about Medicaid revenues at the facility level. We note, for instance, that the Medicare Cost Reports do not break out Medicaid revenues, nor are they completed by providers who do not bill Medicare. Other data sources cited by the commenters, such as the upper payment limit (UPL) reporting and quarterly supplemental payment information are data collection efforts related to provider payments that are intended for a different purpose and do not provide the information we intend to capture with the reporting requirement at § 442.43. We also note the supplemental payment reporting data does not capture the whole provider payment (that is, base plus supplemental payments). Additionally, the UPL reporting provides estimates of Medicaid payments to facilities; States have flexibility in how they calculate their UPL, using the best and most recent data available to the State either through Medicare cost reports or State-specific cost reports.

We also disagree that nationally comparable data could be extrapolated from current cost reports, given the variations among cost reporting forms, practices, and delivery systems. A number of States do not make cost reporting data readily available to the public in a way that facilitates easy analysis.

We agree with the commenter who observed that data are not consistently available from all States. As discussed throughout this section (section III. of the final rule), we have designed the requirement to promote greater consistency and transparency while also attempting to minimize burden for States, particularly those States with less experience collecting and tracking wage data, as well as for providers.

Comment: A few commenters did not believe that the reporting requirement as proposed would yield consistent or fully transparent data, given the differences among facilities, their payment models, current reporting practices, case mixes, size, geographical location, staffing requirements, and staff roles. A few commenters also noted that States have different wage laws that could impact the percent of Medicaid payments that facilities allocate to direct care worker and support staff compensation.

Response: We believe the diversity among facilities and State reporting practices and employment laws is why a broad, national reporting requirement is necessary to help establish baseline data measuring investment in the direct care and support workforce. We note that the requirement is constructed so that States will report an aggregate percentage that will allow for national comparisons, as well as facility-level data that will allow for more granular differences among facilities to be identified.

Comment: A few commenters expressed concern that the reporting requirement would result in the generation of misleading data and perpetuate the idea that facilities' expenditures on any expenses other than direct care worker compensation are invalid or go only to profit. A few of these commenters suggested that facilities use Medicaid payments for a variety of expenses such as providing residents with private rooms, improving facility ventilation, evaluating and testing emergency preparedness plans, and other non-compensation activities that improve residents' care and safety. These commenters expressed concerns that reporting on the percent of Medicaid payments going only to compensation for direct care workers or support staff would lead policymakers to draw erroneous conclusions about facilities' expenditures and discourage increased investment in long-term care or the raising of Medicaid rates. One commenter expressed opposition to what they regarded as an underlying assumption that facilities are not allowed to be profitable.

Response: The purpose of this requirement is not to suggest that all non-compensation facility expenditures (including profits that may incentivize the operation of a facility) are invalid, or that any particular such expenditure is not worthwhile. Specifically, we are not suggesting that by designating certain activities as administrative and by not considering certain expenditures as compensation under this rule, they are inessential. Rather, we believe, as has been discussed at length in the proposed rule at 88 FR 61381 through 61382, that understaffing in facilities is well-documented and chronic and poses a risk to the quality of care. As a result, we have made addressing compensation for institutional direct care workers and support staff a particular focus of this requirement. We also remind commenters that the purpose of this rule is to create a reporting requirement, not to require that a certain amount of the Medicaid payment be allocated to compensation. We believe that gathering data on what percent of Medicaid payments facilities are spending on compensation will help us understand what percent of Medicaid payments is also needed for non-compensation costs, which we understand includes many essential activities.

Comment: A few commenters expressed concerns that residents would not find the data helpful in making decisions about their long-term care and that beneficiaries and residents can already get valuable information about nursing facilities from Nursing Home Compare.

Response: We disagree that beneficiaries would not find the data helpful and note that some commenters expressed the contrary view that these data can help beneficiaries advocate for high-quality care. While we agree that Nursing Home Compare provides beneficiaries with useful information about nursing facilities, Nursing Home Compare does not include data on how much facilities spend on compensation to direct care workers and support staff.[82] We believe that facility-level data on the percent of Medicaid payments spent on direct care worker and support staff compensation will be a useful complement to the facility-level quality data in Nursing Home Compare and help make available more comprehensive information on nursing facilities for beneficiaries and other members of the public.

Comment: One commenter requested that this requirement be made a Condition of Participation for nursing facilities to encourage compliance and to allow the information to be included in Nursing Home Compare.

Response: We decline to make the reporting requirement a Condition of Participation at this time. We note that the provision being finalized at § 442.43 is a requirement that must be followed by States and does not directly impose requirements on providers. We believe it is important to first develop the reporting process and acclimate States and providers to this requirement before considering making it a Condition of Participation for providers, although we may consider proposing to do so at a later time.

Comment: A few commenters noted that the proposed requirement could help assess the extent to which facilities with a large Medicaid population have challenges achieving compliance with the minimum staffing standards finalized in section II. of this final rule.

Response: We agree that facility-level data reported by States could help

[82] To view what information is available on Nursing Home Compare, visit the Nursing Home Compare website at: *https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome.*

identify facilities that are outliers in terms of allocating Medicaid payments for compensation for direct care workers and support staff, which could be relevant when examining understaffing or staff turnover at certain facilities. We also note that our intention with the reporting requirement at § 442.43 is to align with a similar reporting requirement focused on the percent of Medicaid payments for certain home and community-based services (HCBS) spent on compensation for direct care workers finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. These aligned requirements will provide a more consistent picture of compensation to the direct care workforce providing services to individuals receiving Medicaid-covered LTSS across settings.

Comment: One commenter asked that ICFs/IID be exempted from the minimum staffing standards.

Response: We clarify that while the provision at § 442.43 being finalized in this section (section III. of this final rule) applies to ICFs/IID, the minimum staffing standards being finalized in section II. of this final rule do not apply to ICFs/IID.

B. Definition of Compensation

At § 442.43(a)(1), we proposed to define compensation to include salary, wages, and other remuneration, as those terms are defined by the Fair Labor Standards Act (FLSA) and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we proposed to define compensation to include the employer share of payroll taxes for direct care workers and support staff delivering Medicaid-covered nursing facility and ICF/IID services (which, while not necessarily paid directly to the workers, is paid on their behalf). We considered whether to include training or other costs in our proposed definition of compensation. However, we believed that a definition that more directly addresses the financial benefits to workers would better measure the portion of the payment for services that went to direct care workers and support staff, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We were also concerned that requesting providers to quantify and include costs of non-financial benefits in their reporting would prove burdensome and could introduce a lack of uniformity in determining and reporting related costs. We requested comment on our proposed definition of compensation, particularly whether the definition of compensation should include other specific financial and non-financial forms of compensation for the workers included in the proposed provisions.

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: Several commenters supported our definition of compensation.

Response: We thank the commenters for their support.

Comment: One commenter suggested that we align the definition with items normally reported on Internal Revenue Service (IRS) form W–2.

Response: We decline to make modifications to the proposed definition of compensation based on this comment. We believe the proposed definition encompasses the relevant compensation items that would be captured on a W–2 form, including the employee's salary, wages, other remuneration, benefits, and information about payroll taxes.

Comment: One commenter suggested we add differential pay and incentives to the definition of compensation.

Response: We are not certain what type of ''incentives'' the commenter was referring to. Our definition of compensation as proposed at § 442.43(a)(1) includes salary, wages, and other remuneration as defined by the FLSA and its regulations. The Department of Labor has advised that shift differential pay and nondiscretionary bonuses in health care settings are included within the definition of salary, wages, and other remuneration under the FLSA.[83] Non-discretionary bonuses [84] include those that are announced to employees to encourage them to work more steadily, rapidly or efficiently, and bonuses designed to encourage employees to remain with a facility.[85] Generally, we intended for the definition at § 442.43(a)(1) to include most types of payments made directly to direct care workers or support staff as salary, wages, and remuneration; we will provide technical assistance as needed for questions regarding specific types of payments.

Comment: One commenter, while expressing support for the proposed definition of compensation, noted the importance of including medical, dental, and vision benefits, and retirement plans. A few commenters suggested we add paid leave and vacation time to the definition of compensation.

Response: We believe that all the items identified by these commenters—medical, dental and vision benefits, retirement, and paid time off—are either explicitly included in the proposed definition or would be reasonably considered part of benefits for the purpose of compensation.

In its glossary, the Bureau of Labor Statistics (BLS) defines compensation as ''employer costs for wages, salaries, and employee benefits,'' and notes that the National Compensation Survey includes the following categories in employee benefits: insurance (life insurance, health benefits, short-term disability, and long-term disability insurance); paid leave (vacations, holidays, and sick leave); and retirement (defined benefit and defined contribution plans).[86] We believe the items suggested by the commenters align with our intent and are reflected by a common understanding of ''benefits'' as exemplified in the BLS glossary.

We are finalizing the definition of ''benefits'' at § 442.43(a)(1)(ii) with several modifications that we believe will help clarify what is included in the definition, will better align the definition with what is referenced in the BLS glossary, and will align this definition with a definition of compensation in a similar compensation reporting requirement finalized at § 441.311(e) as part of the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. The purpose of aligning these requirements is to provide a more consistent picture of investment in the direct care workforce providing Medicaid-covered LTSS across settings.

We are retaining ''health and dental benefits'' but also adding to the list ''life and disability insurance'' to reflect the examples of insurance included in the BLS glossary. (We are using ''disability insurance'' to refer to short- or long-term disability insurance.) We note that the proposed definition at § 441.43(a)(1)(ii) already included health insurance, which we believe can be regarded as the same as medical benefits. The proposed definition also already included dental benefits. While we decline to specify vision benefits in this definition, which

[83] Refer to U.S. Department of Labor, Fact Sheet #54—The Health Care Industry and Calculating Overtime Pay. *https://www.dol.gov/agencies/whd/fact-sheets/54-healthcare-overtime.*

[84] The Department of Labor has advised that few bonuses are discretionary under the FLSA. *Id.*

[85] See regulations 29 CFR 778.200 and 778.208 for more information.

[86] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

were not included in the proposal and is not part of the BLS glossary definition as a separate item from ''health benefits,'' we note that the list of benefits provided in § 442.43(a)(1)(ii) is not exhaustive, and that vision benefits, when offered by an employer, would reasonably be considered as part of compensation.

We are also changing ''sick leave'' to the broader term ''paid leave,'' as this should be understood to cover any time for which the employee is paid, whether it be for sick leave, holidays, vacations, and so forth. We are also adding retirement, which we believe is also a useful blanket term for different types of retirement plans or contributions on the employee's behalf.

Thus, § 442.43(a)(1)(ii) as finalized in this final rule specifies that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

Comment: A few commenters, while not clearly requesting that these benefits be added to the definition of compensation, noted a number of benefits that employers may offer that may be difficult to quantify if they were to be included in reporting. These benefits included: recruitment and retention activities, gym fees, pet insurance, employee wellness programs, childcare support, nutrition programs, and assistance for staff experiencing financial shortfalls.

One commenter believed that including additional benefits in the definition of compensation would undermine the purpose of the requirement, which the commenter believed should focus on direct payments to workers.

Response: We are not making additional modifications to the benefits definition listed at § 442.43(a)(1)(ii) beyond what we described in the prior response. When proposing that benefits be included in the definition of compensation, we intentionally included the phrase ''such as'' when describing benefits to indicate that the example of benefits provided in the definition is not exhaustive. We did not attempt to list all possible benefits in the regulatory definition, as we run the risk of creating a definition that is too narrow.

However, we note that some of the items listed previously, such as employee wellness programs, which make available non-financial assistance to all employees (rather than being a specific financial benefit for the employee) would qualify as administrative expenses.[87] We plan to provide technical assistance to States to help ensure that States understand what are considered administrative expenses versus compensation expenses.

Comment: A few commenters noted specific support for including the employer share of payroll taxes in the compensation definition, as this is also an important component of the full compensation cost. One commenter suggested that the definition should include worker's compensation taxes.

Response: It is our intention to include employers' payroll tax contributions for worker's compensation (as well as other payments required by the Federal Insurance Compensation Act) under § 442.43(a)(1)(iii) (and thus as part of the definition of compensation). While not necessarily paid directly to the workers, these expenses are paid on their behalf. We also note, for instance, that per the BLS, the National Compensation Survey calls payroll taxes for worker's compensation ''legally mandated employee benefits'' and includes them as part of the definition of ''employee benefits'' for the purposes of determining compensation.[88] We decline to make changes in this final rule based on these comments, but we plan to provide technical assistance to States on how to help ensure that providers are including payroll tax contributions for worker's compensation, as well as contributions for other payroll taxes such as unemployment insurance, when reporting on compensation to workers.

Comment: A few commenters suggested that we add training costs to the definition of compensation, and a few commenters expressed specific concerns that the cost of specialized training for ICF/IID staff was not included in the definition of compensation. Commenters noted that training is a critical element of providing care.

In contrast, a commenter noted that attempting to disclose and quantify non-financial compensation forms would make reporting confusing and cumbersome and could lead to variations in reporting among States that would undermine the goal of uniform reporting. Another commenter agreed that we should not include training costs in the definition of compensation; the commenter noted that nursing facilities are generally required to pay the costs for training required for certification of nurse aides but may then be reimbursed for the costs through a variety of payment methods or State grants. The commenter also noted that some facilities may choose to offer additional training as part of a collective bargaining agreement or to help reduce worker turnover, but did not believe the related costs should be considered part of the compensation package for workers.

A commenter asked that we add mileage reimbursement to cover the costs to deliver services in various locations.

Response: We clarify that the time direct care workers spend in training would already be accounted for in the definition of compensation. We agree with commenters that training is critical to the quality of services, and that some facilities, due to the needs of the residents, may require specialized training. We do not want to encourage providers to reduce training to cut administrative costs. We also agree that training costs may be difficult to standardize and are further complicated by the fact that some facilities may receive funding for training of some staff from sources other than their Medicaid payments.

We remain reluctant, upon considering comments, to treat all training costs as ''compensation'' to the direct care worker or support staff. Trainings are often required as part of the job and may vary depending on the services or the needs of the beneficiaries they serve. We are concerned that including training costs in the definition of compensation could mean that direct care workers with higher training requirements would see more of their ''compensation'' going to training expenses, which could cause them to be regarded as more highly compensated while receiving lower take-home pay than colleagues with fewer training requirements.

Rather than include training costs in the definition of ''compensation,'' we are creating a new § 442.43(a)(4) for the purposes of the reporting requirement in § 442.43 to define ''excluded costs.'' Excluded costs are those that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers and support staff. We are specifying at § 442.43(a)(4)(i) that required training costs (such as costs for qualified trainers and training materials) reasonably associated with Medicaid-covered nursing facility or ICF/IID services are excluded from the calculation of the percent of Medicaid

[87] *See* 29 CFR 778.224(b) (describing various workplace perks which are not considered employee compensation when calculating overtime pay under the FLSA, such as the cost to an employer that provides gym memberships, wellness programs, or nutrition programs).

[88] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

payments to providers that is spent on compensation for direct care workers and support staff. This means that, unless providers receive payment for trainings from sources other than their Medicaid payments for nursing facility or ICF/IID services, providers could deduct the total eligible training expenses for direct care workers and support staff reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services from the provider's total Medicaid payments before the compensation percentage is determined. We note that in facilities that also serve residents whose services are covered by non-Medicaid payment sources, we expect that the facility would calculate the excluded costs by estimating the percent of total eligible training expenses reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services, based on the percent of the facility's residents whose care is primarily paid for by Medicaid.

Similarly, we do not agree that mileage reimbursement or travel should be considered compensation to direct care workers and support staff. Since the reporting provision at § 442.43 pertains to facility-based services, we do not believe that travel expenses for direct care workers and support staff are necessarily high for a significant portion of facilities. However, we also acknowledge that there are reasons why facilities may need to require staff to travel as part of their duties, particularly in rural or smaller facilities or some ICFs/IID, which might require staff to transport beneficiaries to activities and appointments, assist beneficiaries in the community, or travel between facilities that are operated by the same provider. In these cases, the travel would not be for the direct care worker or support staff's personal benefit.[89] We also agree that travel costs will vary significantly by facility, depending on the facility size, staff makeup, nature of the services provided, and the beneficiaries served. We are concerned that including travel in the definition of compensation could mean that direct care workers or support staff with higher travel demands would see more of their compensation going to travel, which could cause them to be regarded as more highly compensated while receiving lower take-home pay than colleagues with lower travel demands.

To preserve beneficiary access to services (and access to the community for facility residents) and avoid burden or disparate impact on beneficiaries, direct care workers, support staff, and providers in rural or underserved areas, we are excluding travel costs reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services in this final rule from the calculation of the percent of Medicaid payments for nursing facility or ICF/IID services going to compensation for direct care workers and support staff. This means that providers could deduct the total eligible travel costs for direct care workers and support staff reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services from the provider's total Medicaid payments before the compensation percentage is determined. We note that in facilities that also serve residents whose services are covered by non-Medicaid payment sources, we expect that the facility would calculate the excluded costs by estimating the percent of total eligible travel expenses reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services, based on the percent of the facility's residents whose care is primarily paid for by Medicaid.

To reflect the exclusion of travel costs from the payment calculation, we are adding a new § 442.43(a)(4)(ii) that specifies that travel costs for direct care workers and support staff (such as mileage reimbursements and public transportation subsidies) are considered an excluded cost for the purposes of the calculation at § 442.43(c).

We note that the finalization of excluded costs for training and travel at § 442.43(a)(4) aligns with the definition of excluded costs finalized at § 441.311(e)(1)(iii) as part of the Ensuring Access to Medicaid Services published elsewhere in this **Federal Register**. This definition also excludes training and travel costs from the calculation of the percentage of Medicaid payments for certain HCBS being spent on compensation for direct care workers. We reiterate that we believe alignment between these reporting provisions in §§ 442.311(e) and 442.43 is important to provide a more consistent picture of investment in the direct care workforce providing Medicaid-covered LTSS across settings.

Comment: While not necessarily asking that we account for personal protective equipment (PPE) in the reporting requirement, many commenters wrote about the importance of PPE in facility-based settings. Many of these commenters were self-identified direct care workers or other staff working in facilities and shared frustrations with not having sufficient PPE during (and even after) the COVID–19 Public Health Emergency (PHE). A few of these commenters also noted specific concerns regarding administrative staff's access to PPE; one commenter, who self-identified as a receptionist in a nursing facility, shared an experience of being asked to interact with residents during the COVID–19 PHE without being provided PPE.

Response: We believe that these comments serve as an important reminder, especially given the recent experience with the COVID–19 PHE, that PPE should be treated as essential to supporting direct care workers and support staff's ability to perform their duties on par with training and travel. Providing direct care workers and support staff with adequate PPE is critical for the health and safety of both the workers and the beneficiaries they serve. We also do not believe that direct care workers or support staff should have to pay for PPE out-of-pocket or that it should be considered part of their compensation. We also note that due to the enclosed environment of many facilities, providing PPE to all staff is critical for maintaining health and safety for all staff and beneficiaries.

Similar to our approach with travel and training, we are also finalizing a new § 442.43(a)(4)(iii) to exclude costs for PPE reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services. We note that this is consistent with an exclusion of PPE costs finalized at § 441.311(e)(1)(iii) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**.

We are excluding PPE costs for facility staff reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services in this final rule from the calculation of the percent of Medicaid payments for nursing facility or ICF/IID services going to compensation for direct care workers and support staff. This would mean that providers could deduct the total eligible PPE expenses for their facilities reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services from the provider's total Medicaid payments before the compensation percentage is determined. We note that in facilities that also serve residents whose services are covered by non-Medicaid payment sources, we expect that the facility would calculate the excluded costs by estimating the percent of total eligible PPE expenses reasonably associated with providing Medicaid-covered nursing facility or ICF/IID services, based on the percent of the facility's residents whose care is primarily paid for by Medicaid.

[89] *See* 29 U.S.C. 207(e)(2) (permitting employers to exclude ''reasonable payments for traveling expenses'' when determining an employee's regular rate of pay under the FLSA); *see also* 29 CFR 778.217 (same).

To reflect the exclusion of PPE costs from the payment calculation, we are adding a new § 442.43(a)(4)(iii) that specifies that a provider's PPE costs reasonably associated with providing Medicaid-covered nursing facility and ICF/IID services may be considered excluded costs for the purposes of the calculation at § 442.43(c).

After consideration of the comments, we are finalizing § 442.43(a)(1)(i) and (iii) as proposed. We are finalizing § 442.43(a)(1)(ii) with modifications to specify that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

We are also finalizing a new definition at § 442.43(a)(4) to define excluded costs, which are costs reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers and support staff. Such costs are limited to: costs of required trainings for direct care workers and support staff (such as costs for qualified trainers and training materials); travel costs for direct care workers and support staff (such as mileage reimbursement or public transportation subsidies); and costs of personal protective equipment for facility staff.

C. Definitions of Direct Care Workers and Support Staff

At § 442.43(a)(2), for the purposes of the proposed reporting provision at § 442.43(b), we proposed to define direct care workers to include: nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving nursing facility and ICF/IID services; certified nurse aides who provide such services under the supervision of one of the foregoing nurse provider types; licensed physical therapists, occupational therapists, speech-language pathologists, and respiratory therapists; certified physical therapy assistants, occupational therapy assistants, speech-language therapy assistants, and respiratory therapy assistants or technicians; social workers; personal care aides; medication assistants, aides, and technicians; feeding assistants; activities staff; and other individuals who are paid to provide clinical services, behavioral supports, active treatment (as defined at § 483.440), or address activities of daily living (such as those described in § 483.24(b), which includes activities related to mobility, personal hygiene, eating, elimination, and communication), for individuals receiving Medicaid-covered nursing facility and ICF/IID services. Our proposed definition of direct care worker was intended to broadly define such workers to ensure that the definition appropriately captured the diversity of roles and titles that direct care workers may have. For the reasons discussed in the proposed rule (88 FR 61385), our proposed definition of direct care worker differs from the definition of direct care staff in LTC facilities at § 483.70(q)(1), which was established for the PBJ reporting program at § 483.70(q). We requested comment on whether we should adopt the definition of direct care staff at § 483.70(q)(1), instead of our proposed definition of direct care worker.

We requested feedback on our proposed definition of direct care worker at § 442.43(a)(2). We specifically requested whether there are categories of staff we should add to, or remove from, our proposed definition. We requested feedback from the public as to whether our proposed definition appropriately included workers who are instrumental in helping residents achieve the level of health or develop skills needed to transition from facility settings back into the community, assess residents for readiness for transition, and support in discharge planning, or if these workers should be included as a separate category.

At § 442.43(a)(3), for the purposes of the proposed reporting requirement at § 442.43(b), we proposed to define support staff to include individuals who are not direct care workers and who maintain the physical environment of the care facility or support other services (such as cooking or housekeeping) for residents. Similar to our proposed definition of direct care worker, our proposed definition of support staff was intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles that such workers may have. Specifically, we proposed to define support staff to include: housekeepers; janitors and environmental services workers; groundskeepers; food service and dietary workers; drivers responsible for transporting residents; and any other individuals who are not direct care workers and who maintain the physical environment of the care facility or support other services for individuals receiving Medicaid-covered nursing facility and ICF/IID services. We requested comment on whether there are other specific types of workers, such as security guards, who should be included in the definition. We also solicited comment on whether any of the types of workers listed in this proposal should be excluded from the definition of support staff. We also requested comment, generally, on our proposal to include support staff in this proposed reporting requirement.

We also proposed in both § 442.43(a)(2) and (3) to define direct care workers and support staff, respectively, to include individuals employed by or contracted or subcontracted with a Medicaid provider or State or local government agency. This proposal was in recognition of the varied ownership and employment relationships that can exist in Medicaid institutional services. For instance, differences may include: institutions that are privately owned and operated or facilities owned and operated by a local or State government; facilities that are partially or wholly staffed through a third-party staffing organization through a contractual arrangement; or staff who are employed directly or as independent contractors. Additionally, a facility may contract with, for example, a third-party transportation company to provide transportation services to residents. We solicited comment on whether this component of our proposed definition adequately captures the universe of potential employment or contractual relationships between institutional facilities and relevant direct care workers and support staff.

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: A few commenters expressed support for the definition of direct care worker. A commenter noted that the definition appears to capture most, if not all, positions that provide direct care to residents. Another commenter supported the definition because they believed it includes only the staff who provide direct care services to residents.

A commenter responded to our comment solicitation on using the definition of direct care staff at § 483.70(q)(1); this commenter did not support using the definition of direct care staff at § 483.70(q)(1) because it did not align with the duties and responsibilities of staff in ICFs/IID.

Response: We thank commenters for their support. With the exception of a few modifications noted later in this section, we are finalizing the definition of direct care worker that we proposed at § 442.43(a)(2).

Comment: A commenter noted that the examples of workers included in the direct care worker definition include

many workers who complement or supplement shortfalls in registered nurses and other long-term care staffing and contribute to the quality of care. This commenter supported the broad definition of direct care worker proposed at § 442.43(a)(2), and believed that for consistency throughout this final rule, these staff should count towards any minimum staffing requirement (which is discussed in section II. of this final rule). Another commenter requested that we clarify that the direct care worker definition at § 443.42(a)(2) is broader than that used in the proposed minimum staffing standard and therefore is for the purposes of this section only. A commenter expressed concern that this definition will lead some facilities to treat the workers included in this direct care worker definition interchangeably, such as asking skilled clinicians to perform unskilled services such as meal delivery or personal hygiene services. The commenter also raised a concern that some facilities might inappropriately substitute one type of clinical specialty for another if a broad direct care worker definition fails to recognize the unique clinical skills of each member of the multidisciplinary care team.

Response: We clarify that the definition proposed at § 442.43(a)(2) is only for the purposes of the reporting requirement being finalized in § 442.43 and is not to be used for the purposes of the minimum staffing requirements being finalized in section II. of this final rule. We also note that the intent of this requirement is to list the different staff whose compensation must be included in the numerator of the reported percent of Medicaid payments being spent on compensation. The intent is not to define a single category of interchangeable workers.

Comment: A commenter requested that we clarify that the definition excludes nurses who perform primarily administrative tasks. A commenter supported excluding administrative staff who are primarily in a supervisory position (such as a director of nursing) or primarily completing paperwork (such as nurses assigned to complete Minimum Data Set paperwork) and stated that the definition should include only the services of hands-on, direct care workers.

A commenter suggested we include physicians and physician assistants in the definition of direct care workers, given the importance of these staff to nursing facilities' patient care. A commenter stated that while they are not recommending we add physicians and physician assistants to the definition, they would like to know the purpose of the data to understand why these roles were excluded. A few commenters also suggested we add pharmacists.

Response: Consistent with the proposed rule, our definition is intended to exclude staff who perform administrative tasks (such as overseeing business operations) and whose primary duty is to provide non-clinical supervision to other staff.

Upon further consideration, we are modifying our definition of direct care worker at § 442.43(a)(2) to clarify that the definition includes nurses or other staff providing clinical supervision. This modification is in recognition of the importance of clinical supervision in facility settings and to align with a similar modification made to the direct care worker definition finalized at § 441.311(e) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. (As noted in our proposed rule at 88 FR 61385, we believe it is important to keep the definitions of direct care workers in this rule and the Ensuring Access to Medicaid services rule as closely aligned as possible.) We clarify that nurses or other staff who provide clinical oversight and training for direct care staff (as allowed by their professional license), participate in activities directly related to provision of beneficiary care (such as completing or reviewing documentation of care), are qualified to provide services directly to beneficiaries, and periodically interact with beneficiaries should be included in the definition of direct care worker. In some instances, this may also pertain to physicians, physician assistants, or pharmacists that meet the elements of this description of nurses or other staff who provide clinical supervision. We decline to add physicians, physician assistants, or pharmacists as additional categories in the definition of direct care worker because we want to keep the definition focused on the staff that commonly provide most of the direct care in facilities.

We reiterate that our intention is to align the reporting requirement at § 442.43 with similar reporting requirements finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**, which focuses on compensation rates for direct care workers providing Medicaid HCBS. The purpose of these aligned requirements is to provide a more consistent picture of the investment in the direct care workforce providing Medicaid-covered LTSS across settings.

Comment: One commenter requested clarification on whether Certified Medication Aides were included in the definition of direct care worker, and suggested we add this job duty if it was not included.

Response: We believe that a Certified Medication Aide would likely fall under the definition of direct care worker as proposed at § 442.43(a)(2)(vii), which specifies a medication assistant, aide, or technician. We note that job titles at facilities may vary, and States should apply their best judgment when determining if certain titles fit within the definition of direct care worker at § 442.43(a)(2). We will also supply technical assistance as needed.

Comment: A number of commenters representing ICFs/IID were concerned that Qualified Intellectual Disability Professionals (QIDPs) were not included in the definition. Commenters noted that, in addition to being a required position in ICFs/IID, QIDPs have specialized training and are responsible for care coordination and assessing, monitoring, documenting, and ensuring the provision of quality care to ICF/IID residents.

Response: We acknowledge that ICFs/IID are required at § 483.430(a) to be staffed by a QIDP, who may be doctors, nurses, or other professionals described at § 483.430 with specialized training in care for people with intellectual and developmental disabilities. It is our understanding that QIDPs' roles may vary in different States or even among different facilities within a State. For instance, some QIDPs may actively participate in direct care while others may take on more of an administrative or care coordination role. We note that the proposed definition of direct care worker included a broad category proposed at § 442.43(a)(2)(x) (but being finalized at § 442.43(a)(2)(xi), as discussed below), which specifies any other individual who is paid to provide clinical services, behavioral supports, active treatment (as defined at § 483.440), or address activities of daily living (such as those described in § 483.24(b)) for Medicaid-eligible individuals receiving Medicaid services under this part. We defer to States to determine if the QIDPs working in their ICFs/IID meet this definition or other elements of the definition of direct care worker at § 442.43(a)(2), and we have not added this position explicitly to the definition.

Comment: A number of commenters representing ICFs/IID expressed concern that Direct Support Professionals (DSPs) were not included in the definition of direct care worker. Commenters noted that in many States, ''Direct Support

Professional'' is a typical professional designation and a critical position in ICFs/IID; DSPs are often the staff that provide direct, daily support to ICF/IID residents. Commenters asked that we add DSPs to the definition of direct care worker at § 442.43(a)(2).

A few commenters noted that it may cause confusion to exclude DSPs from the definition of direct care worker in § 442.43(a)(2) when DSPs were included in the definition of direct care worker in the Ensuring Access to Medicaid Services rule (as the definition was proposed at 88 FR 27984). One commenter recommended we include DSPs in the definition at § 442.43(a)(2) to align the definitions in the two rules and acknowledge the role that DSPs play in providing LTSS care across settings.

Response: We are persuaded both by the characterization of DSPs as direct care workers and the concern that omitting DSPs in the definition of direct care worker at § 442.43(a)(2) would misalign the definition with the definition of direct care worker finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. We reiterate, as noted in prior responses, that our intention is to align the reporting requirement at § 442.43 with similar reporting requirements finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**, which focuses on compensation rates for direct care workers providing HCBS. The purpose of these aligned requirements is to provide a more consistent picture of the direct care workforce for individuals receiving Medicaid-covered LTSS across settings.

After consideration of the commenters received, we are modifying the definition of direct care worker at § 442.43(a)(2) to include DSPs.

Comment: A few commenters responded to our comment solicitation regarding whether we should add to the definition staff who can be instrumental in helping residents achieve the level of health or develop skills needed to transition from nursing facilities back into the community, assess residents for readiness for transition, and support in discharge planning. A commenter agreed that these staff duties should be added to the definition. Another commenter, however, stated that these staff should only be added to the definition if they are in a separate category from direct care workers. The commenter noted that these workers are providing important services to improve the residents' health, safety, and autonomy, but the job duties vary much more broadly than in the case of the direct care workers identified in § 442.43(a)(2).

Response: Based on the comments received, we are not modifying the definition of direct care staff at § 442.43(a)(2) to include a specific category of staff who provide transition supports. Although a few commenters were supportive of their inclusion as a separate category, we were not persuaded by the balance of the comments that staff who provide these supports are not already reflected in the different categories of workers contained in the definition. We also want to ensure that the definition focuses on workers who provide direct care, rather than what in some cases could be primarily administrative support.

We note that the proposed definition of direct care worker included a broad category at § 442.43(a)(2)(x) (being finalized at § 442.43(a)(2)(xi)), which specifies any other individual who is paid to provide clinical services, behavioral supports, active treatment (as defined at § 483.440), or address activities of daily living (such as those described in § 483.24(b)) for Medicaid-eligible individuals receiving Medicaid services under this part. We defer to States to determine if staff who provide discharge planning or other transition supports in facilities meet this definition or other elements of the definition of direct care worker at § 442.43(a)(2).

Comment: A number of commenters requested that we divide the definition of direct care worker into two categories: a direct care worker category and a category referred to as either ''ancillary staff'' or ''licensed staff.''

One group of commenters advocated restricting the definition of direct care workers to nursing staff and recommended defining direct care workers as registered nurses, licensed practical nurses, and certified nursing assistants—a list they believed would align with the staff addressed by the minimum staffing requirements proposed in section II. of this final rule. Some of these commenters suggested this alignment would aid in interested parties' ability to draw inferences from the data regarding the impact of the minimum staffing requirements proposed in section II. of this final rule. A few commenters suggested retaining nurse practitioners and clinical nurse specialists, in addition to registered nurses, licensed practical nurses, and certified nursing assistants. A commenter suggested that restricting the definition of direct care workers to nursing staff would aid in data consistency among States because, while every facility employs nursing staff, there may be more variation among States and facilities in the types of the other workers; the commenter provided the example that some States recognize feeding and medication assistants, and others do not. Commenters who recommended limiting the definition of direct care worker to nursing staff suggested that a second category, ''ancillary staff,'' should be defined to include the other staff listed in § 442.43(a)(2) such as physical therapists, occupational therapists, speech-language pathologists, and therapy aides; some of these commenters also suggested adding physicians, physician assistants, and pharmacists to this category.

Other commenters advocated for limiting the definition of direct care workers to certified nursing assistants and, where relevant, personal care aides and home health aides. One of these commenters also suggested retaining feeding assistants in the definition. These commenters suggested that these roles are responsible for providing most of the direct care to nursing facility and ICF/IID residents, particularly in regard to activities of daily living. A few of these commenters suggested that these roles would align more closely with the definition of direct care worker in the Ensuring Access to Medicaid Services rule (as the definition was proposed at 88 FR 27984) and the way that the term direct care worker has been used by other Federal agencies such as the Administration for Community Living. Commenters also believed this would allow for the transparent reporting of compensation paid to workers who typically receive lower pay. Commenters expressed concerns that if compensation to these workers were reported together with the compensation paid to typically higher-paid workers, this would obscure the ''unique contributions and challenges of these roles.'' A few commenters suggested other staff listed in § 442.43(a)(2) should be included in an ''ancillary staff'' category. A commenter suggested that, rather than an ancillary staff category, we create a ''licensed staff'' category that includes all of the staff that typically require licensure.

Response: We decline to create a new category of ancillary or licensed staff apart from the direct care worker category. We note that there was not consensus among commenters that the definition of direct care workers should be limited to staff with nursing duties, staff without professional licenses, or staff who typically receive lower pay. We believe the category of direct care

workers as proposed at § 442.43(a)(2) is appropriately broad to capture a spectrum of workers who provide direct care to residents.

Limiting the definition of direct care workers to nursing staff does not align with our intention to examine expenditures for all staff who provide direct care to residents receiving Medicaid institutional LTSS. We also note that the reporting requirement we proposed (and are finalizing in this final rule) includes ICFs/IID, which do not necessarily focus on nursing services to the same extent as nursing facilities do. We agree with the commenter who noted that there might be variation in the types of non-nursing staff in nursing facilities, but we note that there is variety in the roles of *all* staff across facilities. Attempting to parse the direct care workforce into additional categories for reporting purposes not only adds administrative burden, it also could undermine our goal of creating simple, nationally comparable baseline data.

We continue to believe it is appropriate to include licensed professionals in the definition of direct care worker. There is a shortage of nurses and other clinicians delivering LTSS, and we believe it is important to support these members of the LTSS workforce especially, as they also work directly with residents. We disagree with commenters who stated that restricting the definition of direct care workers to certified nursing assistants, personal care aides, and feeding assistants would align the definition with the definition of direct care workers in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**. We note that the definition finalized at § 441.311(e), like the definition at § 442.43(a)(2), includes both licensed clinicians and other unlicensed direct care workers.

We also decline to add home health aides to the definition of direct care worker at § 442.43(a)(2). We agree with commenters that home health aides are part of the definition of direct care workers finalized in the reporting requirement at § 441.311(e) in the Ensuring Access to Medicaid Service final rule published elsewhere in this **Federal Register**. However, while we intend to align these definitions as much as possible to provide a complete picture of compensation for all direct care workers providing Medicaid LTSS, we also believe it is important to adapt each definition to their respective settings. We do not believe home health aides typically provide services in institutional facilities. In a situation where care might be provided by someone described as a home health aide, we believe this role would be addressed by the category proposed at § 442.43(a)(2)(ix) (being finalized at § 442.43(a)(2)(xi)), which specifies inclusion of any other individual who is paid to provide clinical services, behavioral supports, active treatment (as defined at § 483.440), or address activities of daily living (such as those described in § 483.24(b)) for Medicaid-eligible individuals receiving Medicaid services under this part.

Comment: A number of commenters supported our definition of support staff and agreed that the definition was broad enough to include the workers responsible for supporting residents' health, safety, quality of care, and, in ICFs/IID, active treatment. A few commenters expressed specific support for including compensation for support staff in the reporting requirement.

Response: We thank commenters for their support.

Comment: A few commenters responded positively to our comment solicitation regarding the inclusion of security guards in the list of support staff, agreeing that these workers should be added to the list in § 442.43(a)(3). One commenter noted that some ICFs/IID that serve residents with aggressive behavior may be required to have security guards as part of their licensure.

Commenters suggested that we include the following workers in the definition of support staff: administrative staff (including billing staff); receptionists; information technology (IT) staff; central supply staff who purchase and distribute food, supplies, and materials for providers who maintain multiple facilities; staff who provide laundry or linen service; and transportation drivers.

A commenter noted that every employee who works in a facility contributes, in some way, to the care of those residents. The commenter stated that all persons contributing to the care of the residents, whether directly employed by the facility or through contract with an outside entity, should be included as either direct care or support staff.

Response: Based on feedback from commenters, we will modify the definition of support staff at § 442.43(a)(3) to include security guards. We believe that security guards provide important services that support the safety of staff and beneficiaries in facilities, but that these services may not intuitively fall under any of the other categories already included in the definition of support staff. Thus, we believe it is important to explicitly include security guards as a category of worker included in the definition finalized at § 442.43(a)(3).

We decline to make other modifications to the definition based on comments. We believe laundry services are already included in the definition of support staff at § 442.43(a)(3)(i) as part of housekeeping duties, and thus, we decline to add that as a separate category in the definition. Transportation drivers are addressed in the proposed definition (and the definition we are finalizing) at § 442.43(a)(3)(v).

We believe the other specific positions described by commenters are administrative roles and would not be included in our definition of support staff at § 442.43(a)(3). We agree that all staff, including those who provide administrative support, are critical to the functioning of a facility. We also believe, as has been discussed at length in the proposed rule at 88 FR 61381 through 61383, that direct care worker understaffing in facilities is well-documented and chronic and poses a risk to the quality of care. As a result, we have made addressing compensation for institutional direct care workers and support staff a particular focus of this requirement.

Comment: A number of commenters, particularly those representing ICFs/IID, expressed concern that some staff may have duties that encompass components of both the direct care worker definition in § 442.43(a)(2) and the support staff definition in § 442.43(a)(3), such as DSPs who also provide services such as cooking, housekeeping, or maintaining the physical environment of an ICF/IID. Commenters expressed concern that this overlap in duties would create inconsistent reporting, confusion, or additional administrative burden if facilities had to report portions of the same staff's compensation in two categories. A commenter suggested we resolve this overlap by allowing the full compensation for these DSPs to be included in the direct care worker cost category.

One commenter also noted that the definitions of direct care worker and support staff do not address universal care workers who provide both nursing services and support services.

Response: We believe that for reporting purposes, compensation for staff that act as direct care workers and support staff should be reported according to the staff's primary job duties. We do not expect the calculations of the percent of payments for nursing facility and ICF/IID services that are spent on compensation for the

direct care and support staff workforce to allocate compensation across direct care and support staff categories based on the proportion of time an individual worker performs specific tasks.

Comment: A few commenters specifically noted support for the inclusion of third-party contracted and subcontracted staff in the definitions of direct care workers and support staff at § 442.43(a)(2) and (3). A commenter noted that if we were to exclude contracted staff from the reporting requirement, we would be missing critical information on staff compensation expenditures and create an incentive for facilities to rely even more heavily on contracted staff to avoid having to report on payments to these staff.

A few commenters suggested that we expand the definitions of direct care workers and support staff as they relate to the inclusion of third-party contracted staff. These commenters noted that nursing facility ownership structures have become extremely complicated and that organizations can engage with facilities in a variety of ways including complicated related-party transactions. These commenters recommended we expand the direct care worker and support staff definitions to include all individuals or entities providing services under contract, subcontract, or other related agreement, in whole or in part, with an organization or provider that provides goods or services to the facility through contract, subcontract, or other related agreement, in-whole or in-part. This includes direct care workers, ancillary services staff, and support staff providing goods or services to the facility under a contract, subcontract, or other related agreement, in-whole or in-part, and regardless of whether the individual receives a W–2 from either the contracted organization or the facility.

A few commenters observed that many facilities use contract labor (in which the contract price includes wages, benefits, and administrative costs) and all-inclusive contracts (in which a facility pays a monthly rate for labor, supplies, and other items). A commenter suggested that we modify the definition of compensation or benefits to clarify that the definition excludes any payment that is not directly received by the worker or excludes any payment that is retained by a related party or contracted agency. A commenter requested we issue guidance requiring facilities to report only the portion of contracted costs that are actually related to compensation; this commenter suggested that if it is not possible for facilities to report only the portion of contracts related to compensation, that we require States to discount costs for payments to agencies and contractors by an amount that represents the average percentage of these payments that is not related to actual worker compensation, based on a State examination of a sample of such payments.

A number of commenters representing ICFs/IID noted that ICFs/IID often contract for many services. These commenters stated that obtaining compensation information from third-party organizations may be burdensome, might require obtaining confidential or proprietary information, discourage third party entities from contracting with ICFs/IID, create administrative burden and complexity, and open ICFs/IID to penalties if they are unable to track down this information. Some of these commenters specified concern about the impact of the requirement on ICFs/IID that contract with HCBS providers to allow the ICF/IID residents to attend community day programs. Relatedly, a few commenters noted that ICFs/IID may contract with other community organizations to provide ICF/IID residents access to, for example, YMCA programs, bowling alleys, or other recreational activities. These commenters were concerned that these community providers or organizations would not accept the ICF/IID residents if they were required to report on compensation to their staff. A few commenters expressed concern that States would reduce ICF/IID services or that ICFs/IID would stop offering community engagement activities or feel penalized for offering community engagement if presented with increased reporting burden.

To address the potential complexity of reporting on third-party contracted staff, a commenter suggested we allow the full cost of contracts to be reported separately, based on the general type of service being delivered, which the commenter believed aligns with most States' current ICF/IID cost reporting. Similarly, another commenter noted that in the commenter's State, Medicaid cost reports separate agency (contract) spending from compensation paid to employed workers and suggested that we adopt the same approach.

Response: We decline to modify the definitions of direct care worker or support staff in response to these comments. We agree that it is important to report on the compensation paid to contracted staff, not the value of the entire contract to a third-party. As noted by commenters, the value of the entire contract may include administrative or other costs that would fall outside the definition of compensation and inflate the reported percentage of compensation. We also agree with commenters that excluding contracted staff would not provide accurate insight into allocation of Medicaid payments to the workers providing direct care and support to residents. We believe that the language in the definitions of direct care worker and support staff at § 442.43(a)(2) and (3) already indicates that it is compensation to workers employed as part of a contract, not the value of an entire contract for services, that should be included in the reporting.

We are concerned that some of the alternate language proposed by commenters might alter the definition in ways beyond what we intended for the definitions of direct care worker and support staff. For instance, we are uncertain what commenters meant in their proposed alternative definition by individuals who provide services ''in-whole or in-part.'' If this is a reference to workers who provide services on less than a full-time basis, then we believe these individuals are already included in our definitions of direct care worker and support staff at § 442.43(a)(2) and (3), as these definitions do not specify whether a worker is employed on a part- or full-time basis. We are concerned that the language suggested by commenters could be interpreted as including compensation to individuals who, while supporting an organization that provides contracted services to residents, do not themselves provide services specifically for the residents.

We also note that the definitions of direct care workers and support staff that we proposed (and are finalizing, with modifications, in this final rule) are meant to capture employees and contracted staff who provide services, not goods, to facility residents. We would not, for instance, expect the compensation of staff working for a wholesale grocer that supplies food to a facility to be included in the reported compensation.

We acknowledge that some facilities may rely on a number of contracts to provide services for residents (including contracts with HCBS providers or other entities in the community). We do not believe the compensation of all workers employed by a contractor or subcontractor will be relevant to the reporting requirement. Given the variety of contracting models we will provide subregulatory guidance to States on how to approach reporting on compensation to contracted and subcontracted staff.

Comment: One commenter noted that HCBS providers providing contracted services for ICF/IID residents may face additional, duplicative, or conflicting

reporting requirements, due to finalization of compensation-related reporting requirements in the Ensuring Access to Medicaid Services rule.

Response: As finalized at § 441.311(e) in the Ensuring Access to Medicaid Services rule published elsewhere in this **Federal Register**, HCBS providers that provide homemaker, home health aide, personal care, or habilitation services will be required to report on the percent of Medicaid payments going to direct care worker compensation. We will provide subregulatory guidance on how States should approach reporting by HCBS providers who fall within the reporting requirement at § 441.311(e) and who also provide contracted services to nursing facility or ICF/IID residents to minimize reporting burden on these providers.

After consideration of the comments received, we are finalizing the definition of direct care worker at § 442.43(a)(2) with a modification to add DSPs and to include nurses or other staff who provide clinical supervision. We are finalizing the definition of support staff at § 442.43(a)(3) with a modification to add security guards.

D. Reporting Requirement

Based on our authority at sections 1902(a)(6) and 1902(a)(30)(A) of the Act with respect to FFS, and sections 1902(a)(4) and 1932(c) of the Act with respect to managed care plans (that is, MCOs and PIHPs), we proposed new reporting requirements at § 442.43(b) to require States to report annually, by delivery system (if applicable) and by facility, on the percent of Medicaid payments for nursing facility and ICF/IID services that is spent on compensation for direct care workers and on compensation for support staff, at the time and in the form and manner specified by CMS. As noted in our responses previously, and as discussed in the proposed rule at 88 FR 61386, we believe that this information will help identify national trends and also help States identify facilities that appear to be outliers in terms of the amount of Medicaid payment going to direct care worker and support staff compensation. We believe that contextualizing direct care worker and support staff compensation information in this manner will help States understand whether current payment rates for nursing facility and ICF/IID services are consistent with economy, efficiency, and quality, and sufficient to ensure meaningful beneficiary access.

We proposed that the reporting to CMS would be for all Medicaid payments made to nursing facility and ICF/IID providers receiving payment under FFS or managed care delivery systems. As discussed in 88 FR 61387, for FFS payments, this would include base payments and supplemental payments for nursing facility and ICF/IID services. For FFS base and supplemental payments, we are relying on the definition of supplemental payments provided in section 1903(bb)(2) of the Act, which defines supplemental payments as Medicaid payments to a provider that are in addition to any base payment made to providers under the State plan or under demonstration authority. As discussed in guidance released in 2021, we interpret base payment (as used in the definition of supplemental payment in section 1903(bb)(2)(A) of the Act) to refer to a standard payment to the provider on a per-claim basis for services rendered to a Medicaid beneficiary in an FFS environment. The base payment can include: (1) any payment adjustments; (2) any add-ons; and/or (3) any other additional payments received by the provider that can be attributed to services identifiable as having been provided to an individual beneficiary, including those that are made to account for a higher level of care, complexity, or intensity of services provided to an individual beneficiary.[90] We solicited comment on whether, for FFS payments, we should instead require reporting on only the percent of base payments spent on such compensation, or separate reporting on the percent of base payments and on the percent of aggregated payments (base plus supplemental payments) spent on such compensation.

We also proposed at § 442.43(b) that, for States that contract with MCOs and/or PIHPs to cover services delivered by nursing facilities and/or ICFs/IID, States report on the percent of payments made by the MCO or PIHP to nursing facilities and ICFs/IID that is spent for compensation to direct care workers and support staff. For these managed care plans, payments would include the managed care plan's contractually negotiated rate, State directed payments defined in § 438.6(a), pass-through payments defined in § 438.6(a) for nursing facilities, and any other payments from the MCO or PIHP to the nursing facility or ICF/IID.

We also proposed to require that, if States deliver the relevant services through both FFS and managed care, the States report separately for each delivery system.

We proposed that the reporting be performed annually. We solicited comment on this timeframe. We requested comment on whether annual reporting is reasonable, or if we should reduce the frequency of reporting to every other year or every 3 years.

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: A number of commenters recommended that instead of, or in addition to, our proposed reporting requirements we implement the Medicaid transparency recommendations of the March 2023 Medicaid and CHIP Payment and Access Commission (MACPAC).[91] The MACPAC recommendations call for State Medicaid programs to make nursing facility payment and cost data publicly available for each nursing facility in a standard format that includes: (1) FFS base Medicaid payments, FFS supplemental payments, managed care State directed payments, and beneficiary contributions to their share of costs; (2) the amount of provider contributions to the non-Federal share of Medicaid payments to calculate net payments to providers; (3) expenses for wages and benefits separately for nursing, ancillary, and support services as well as administrative staff and other employees; (4) expenses for direct care including staffing costs for nursing, ancillary, and support services; (5) expenses for administration, property, and profits; and (6) detailed expenses for related-party transactions, real estate ownership, and disallowed costs. These commenters believed that unless Medicaid programs are required to provide more comprehensive data on rates and payments as well as expenses, we will not be able to draw any useful conclusions from the proposed transparency requirement.

Response: We defer to States as to whether they wish to make this information available to the public. While we agree that this level of granular detail would generate a great deal of potentially useful information, we strongly disagree with commenters that reporting on higher-level aggregated data would not yield useful information. We note that the reporting requirement at § 442.43 will provide data on the

[90] Centers for Medicare & Medicaid Services, State Medicaid Directors Letter # 21–006, New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021, December 10, 2021. *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

[91] Medicaid and CHIP Advisory Committee, *March 2023 Report to Congress on Medicaid and CHIP.* See specifically ''Chapter 2: Principles for Assessing Medicaid Nursing Facility Payment Policy.'' Available at: *https://www.macpac.gov/publication/principles-for-assessing-medicaid-nursing-facility-payment-policies/.*

percent of Medicaid payments (including FFS base payments, FFS supplemental payments, managed care State directed payments, and beneficiary contributions) that is being spent on compensation for direct care and support staff as well as other payments that may not all be captured in the MACPAC recommendations, such as other payments in managed care delivery systems, including contractually negotiated rates, pass-through payments, and any other payments from the MCO or PIHP in managed care delivery systems. As noted in a prior response, we decline to subdivide direct care workers into nursing and ancillary staff categories. We believe that this reporting requirement will result in nationally comparable baseline data that will allow for inferences regarding investment in the direct care and support staff workforce. While we will take the other recommendations under consideration, at this time we do not intend to increase administrative burden on States and providers by requiring Federal reporting on additional categories that fall outside of our focus on the direct care and support staff workforce.

We also point commenters to the Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities final rule (88 FR 80141) published on November 17, 2023, which implements portions of section 6101 of the Patient Protection and Affordable Care Act requiring the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities. Some of the commenters' additional concerns regarding facility ownership structures may be addressed by the requirements in that rule.

Comment: A few commenters noted support for requiring reporting of both FFS base and supplemental payments, pointing out that supplemental payments contribute to total revenue in the same way that base rates do and should not be treated differently or excluded.

One commenter noted that in the commenter's State, facilities do not receive FFS supplemental payments but rather receive varying FFS base payments depending on the acuity of the residents. This commenter stated that requiring reporting on total payments would result in better comparisons across States. A few commenters stated that FFS payment base rates do not fluctuate drastically year-to-year without changes to the State plan, and thus believed that including both FFS base and supplemental payments would not be burdensome and would provide a comprehensive picture of nursing facilities' expenditures on compensation. A few commenters also noted support for requiring reporting on all payments from an MCO or PIHP, including State directed payments made by these managed care plans.

One commenter, on the other hand, supported reporting on FFS base and supplemental payments separately. The commenter stated that separate reporting would illustrate the separate roles of the FFS base payment and supplemental payments, which in turn would be important to understanding how Medicaid payments support nursing facility staffing and ensure supplemental payments were also being used to support worker compensation.

Response: We are finalizing the substantive language at § 442.43(b) specifically requiring reporting on Medicaid FFS base and supplemental payments as proposed. (We note that we are finalizing § 442.43(b) with some non-substantive technical modifications to improve the overall clarity of the requirement.) We agree with commenters that requiring reporting on both Medicaid FFS base and supplemental payments (added together) strikes the right balance of providing a complete picture of Medicaid FFS payments while minimizing administrative burden to the greatest extent possible.

Upon further consideration, we are finalizing § 442.43(b) with a modification to remove the specification that reporting is ''by delivery system.'' We continue to expect that services delivered under a managed care delivery system will be part of the reporting requirement. We do not, however, intend to require that States report data to us separately by delivery system. We note that commenters did not express specific support for this separate reporting, and we are concerned that this separate reporting may increase administrative burden in States that provide services through both FFS and managed care delivery systems. We also note that the compensation reporting requirement (reporting on the percent of Medicaid payments made to direct care workers providing Medicaid HCBS) finalized at § 441.311(e) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register** does not require separate reporting by delivery system. We intend to align these reporting requirements to the greatest extent possible.

Comment: A commenter requested that CMS clarify what payments are required to be reported in accordance with § 442.43(b) for providers that are network providers for an MCO or PIHP.

Response: We point readers to the language being finalized at § 442.43(b), which states that the Medicaid payments that must be included in the State reporting include the contractually negotiated rate, State directed payments, pass-through payments, and any other payments from the MCO or PIHP for nursing facility and ICF/IID providers.

Comment: Several commenters supported requiring reporting at least annually for both FFS and managed care delivery systems, which commenters believed would aid in tracking trends in worker compensation across facilities and States. One commenter noted that an annual frequency appropriately balances the need for actionable information with administrative burden. One commenter noted that timely data on Medicaid is critical as rates can be too low and not updated frequently, which can have a negative impact on providers and on beneficiaries' access to care. One commenter noted that frequent public reporting can be a critical element to promoting policy change and improving health care quality.

A few commenters, however, while stating that they found the annual reporting frequency to be reasonable, noted that States have many reporting burdens and asked that we remain receptive to alternative frequencies proposed by States. One of these commenters noted that some States may need more time than others to come into compliance with the requirement and suggested that we allow for some flexibility to accommodate different States' circumstances or allow States to determine their own timeframe.

A few commenters, citing concerns about the burden associated with collecting and analyzing reimbursement streams and worker compensation data, as well as competing reporting priorities and limited staff resources, suggested we require reporting every 3 years. One of these commenters noted that some of the wage and benefit information that would be required is not readily available to some Medicaid agencies, not all cost reports have this information, and providers do not typically report this type of information to their State Medicaid agencies.

Response: We are finalizing the annual reporting frequency as proposed. We agree with commenters that receiving timely reporting data is critical, and we are concerned that if too much time elapses between each

reporting period, the reports, when released, will become quickly out of date. Additionally, as discussed further in this section, we are finalizing at § 442.43(f) an applicability date that will give States 4 years to comply with this reporting requirement. Once States that do not currently collect these data update their systems appropriately, we believe the reporting will become routine and the initial administrative burden will lessen. We will provide technical assistance to States as needed as they develop their reporting capacity.

After consideration of the comments received, we are finalizing a modification to § 442.43(b) to strike ''by delivery system'' from the reporting requirement.

We are also finalizing § 442.43(b) with minor modifications to clarify that the Medicaid payments used in the calculation required at § 442.43(b) do not include excluded costs (which are being finalized at § 442.43(a)(4), as discussed in section III.B. of this final rule.) Additionally, we are finalizing the regulatory text at § 442.43(b) with technical modifications to aid with clarity and correct minor grammatical errors.

E. Exclusion of Certain Payments

We proposed at § 442.43(b)(1) to require reporting for payments, including FFS base and FFS supplemental payments, and payments from managed care plans, to nursing facilities and ICFs/IID for Medicaid-covered services, with the exception of services offered in swing bed hospitals (as described in § 440.40(a)(1)(ii)(B)). We proposed to exclude swing bed hospitals, as we do not want to pose a burden on rural hospitals that provide LTSS to a comparatively small number of beneficiaries. We solicited comment on this proposal.

For reasons described in the proposed rule at 88 FR 61387, at § 442.43(b)(2), we proposed that States exclude from the reporting payments for which Medicaid is not the primary payer, meaning that States would exclude payments for services for residents who are dually eligible for Medicare and Medicaid and whose skilled nursing care services are paid for by Medicare. We solicited feedback from the public on whether including cost-sharing payments for services that were primarily paid for by Medicare would provide a more accurate picture of the relationship between Medicaid payments and worker compensation. We also requested comment on whether excluding cost-sharing payments would increase or decrease burden on States and providers.

For reasons discussed at 88 FR 61387, we did not propose to exclude beneficiary contributions to their care when Medicaid is the primary payer of the services.

We considered whether to allow States, at their option, to exclude, from their reporting, payments to providers that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, the number of Medicaid beneficiaries receiving the service, or other Medicaid utilization data including but not limited to Medicaid bed days. We considered this option as a way to reduce State, managed care plan, and provider data collection and reporting burden based on the experience of States that have implemented similar reporting requirements. However, we were concerned that such an option could discourage providers from serving Medicaid beneficiaries or increasing the number of Medicaid beneficiaries served. We requested comment on whether we should allow States the option to exclude, from their reporting to us, payments to providers that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, the number of Medicaid beneficiaries receiving the service, or other Medicaid utilization data including but not limited to Medicaid bed days. We also requested comment on whether we should establish a specific limit on such an exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms of Medicaid revenues for the service, number of Medicaid beneficiaries served, or other Medicaid utilization data (including but not limited to Medicaid bed days).

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: A few commenters supported our decision to exclude payments to swing beds from the reporting in the proposed rule. These commenters noted that swing bed hospitals utilize different accounting systems for their expenditures and thus should not be included in nursing facility reporting. One commenter agreed that swing bed hospitals should be excluded to avoid placing a burden on rural facilities that serve a relatively low number of nursing facility residents.

Response: We thank commenters for their support. We are finalizing the exclusion of payments to swing bed hospitals at § 442.43(b)(1) as proposed.

Comment: A few commenters agreed with excluding payments for services in which Medicaid is not the primary payor. One commenter specifically agreed that this exclusion would reduce burden on States and providers and that payments from other payors would not provide meaningful insight into the allocation of Medicaid payments for compensation of workers. However, a number of commenters recommended we require that reporting be for the percent of all revenue spent on compensation (and not limited just to the percent of Medicaid payments). Commenters believed this would further aid in transparency and oversight of how facilities allocate their revenue. A few commenters also stated that requiring only reporting on payments for which Medicaid is the primary payer actually increases burden and recommended that reporting be on the percentage of all revenues that are spent on compensation. Commenters noted that nursing facilities receive revenue from many sources apart from Medicaid payments and pay direct care workers and support staff compensation from a pool comprised of all revenue sources.

A number of commenters recommended we expand this requirement to include Medicare as well as Medicaid payments. A few of these commenters disagreed with our statement that including Medicare payments was out of scope. These commenters stated that not only is including Medicare payments within our authority, not doing so ignores our legal obligations under the Nursing Home Reform Act (specifically, 42 U.S.C. 1396r(f)(1)) to protect residents and make sure that public funding is effectively and efficiently used, as well as our obligations under section 6104 of the Affordable Care Act (requiring that skilled nursing facilities receiving Medicare payments disclose wages paid to direct care staff on their cost reports).

Response: We decline to modify the requirements to require reporting for all revenue or for Medicare revenue, as this would be out of scope for the proposal. We believe that States and facilities are aware of the amount of Medicaid payments received by each facility. We understand that all revenue received by a facility ultimately gets pooled together for the purposes of paying worker compensation and that facilities often serve a mix of residents with different payers and different needs. As discussed further in this section, we will provide a methodology that will allow States to make a reasonable calculation of what percent of a facility's direct care and support staff

workforce was paid from Medicaid revenues.

As discussed in the proposed rule at 88 FR 61383, we proposed these reporting requirements in part using our authority under section 1902(a)(30)(A) of the Act, which requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe section 1902(a)(30)(A) of the Act speaks specifically to Medicaid payments, not to all payments received by providers. We will take under advisement commenters' recommendations regarding reporting on all revenue but cannot pursue such a requirement in this rule.

We also reiterate that our intention is to align the reporting requirement at § 442.43 with similar reporting requirements finalized in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**, which focuses on the percent of Medicaid payments for certain HCBS going to compensation for the direct care workforce. The purpose of these aligned requirements is to provide a consistent picture of the percent of Medicaid payments going to compensation for the direct care workforce for Medicaid-covered LTSS across settings. Not only would adding reporting on Medicare payments be out of scope for this reporting requirement, we believe that doing so would obscure data on the allocation of Medicaid payments. We thank commenters for their feedback and will consider a reporting requirement for Medicare payments for future rulemaking.

Comment: A few commenters agreed that beneficiary contributions, such as co-pays (to the extent they exist) should also be included in the revenue side of the calculation. A few commenters noted that because beneficiary contributions can fluctuate, they can have an impact on the resources available for compensation to staff and thus should be included in the reporting.

One commenter asked for clarification on which beneficiary contributions should be included. The commenter noted that in the proposed rule we mentioned deductibles and coinsurance but did not mention resident contributions to the cost of their care as a result of Medicaid rules for post-eligibility treatment of income (PETI). The commenter expressed concern that we had not listed all types of beneficiary contributions in the regulatory text.

Response: We thank commenters for their support. We clarify that beneficiary contributions, including contributions to the cost of their care as a result of Medicaid rules for PETI, are part of Medicaid total payments for the purposes of this reporting requirement. We decline to specify beneficiary contributions in the regulatory text because we believe these are already understood to be part of total Medicaid payments. As noted in the proposed rule at 88 FR 61387, § 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the [State] plan to be paid by the individual.'' For managed care delivery systems, although the term ''payment-in-full'' as defined at § 447.15 is not applicable, for consistency between FFS and managed care delivery systems, any deductible, coinsurance, or copayment required to be paid by the individual would similarly be included in the total amount used to determine the percent of Medicaid payments for nursing facility and ICF/IID services under managed care delivery systems that is spent on compensation for direct care workers and support staff.

Comment: Most commenters who responded to our comment solicitation on small provider exemptions did not support exempting small providers from the reporting requirement because a complete picture of Medicaid spending on compensation in all nursing facilities and ICFs/IID is critically needed. A few commenters agreed with the reasons we cited in the proposed rule, that excluding certain providers would create the potential for disincentivizing providers to accept Medicaid patients. A commenter noted that ICFs/IID in particular tend to be small, so excluding small providers could mean a significant number (if not all) of some States' ICF/IID providers might be exempted.

One commenter did support excluding certain providers, noting that providers with a low number of nursing beds or extremely high or extremely low Medicaid utilization will typically not have operating costs that reflect the average for the industry and as such may change the State reported averages. The commenter proposed that providers should be excluded from reporting information required by this rule if they have any of the following characteristics during the reporting period: (1) Medicaid utilization based on census of 30 percent or less; (2) Medicaid utilization based on census of 80 percent or more; or (3) 40 or fewer Medicaid-certified beds. One commenter recommended excluding payments for out-of-State single-case agreements, due to the difficulties collecting data from out-of-State facilities.

Response: We thank commenters for their feedback regarding concerns related to offering exemptions from the reporting requirement. We agree that offering exemptions would create disincentives to serve Medicaid beneficiaries and would not provide a comprehensive picture of compensation for the direct care and support staff workforce. We also note that we are especially interested in the expenditures of facilities serving a high percentage of Medicaid beneficiaries and, thus, would not wish to exclude them from this reporting. We will not modify this reporting requirement to add exemptions for providers. We will provide technical assistance as needed to address payments for Medicaid beneficiaries in out-of-State facilities.

Comment: One commenter expressed concern about the impact of dually eligible individuals on cost calculations, as Medicaid does not bear the cost of therapy provision or prescription drugs for dually eligible nursing facility residents.

Response: As discussed in the proposed rule at 88 FR 61386, States would exclude Medicaid payments to cover only cost-sharing payments on behalf of residents who are dually eligible for Medicare and Medicaid and whose skilled nursing care services are paid for by Medicare. We will provide technical assistance on how to calculate costs for dually eligible residents whose nursing facility care is being covered by Medicaid, but some aspects of their care are paid for by Medicare.

After consideration of the comments received, we are finalizing the requirements at § 442.43(b)(1) and (2) as proposed.

We are also finalizing at new § 442.43(b)(3) an exemption of data from Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641. During our finalization of the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**, it came to our attention that requirements potentially affecting IHS or Tribal provider expenditures would conflict with 25 U.S.C. 1641, governing how IHS and Tribal health programs may use Medicare and Medicaid funds, and other applicable laws providing for Tribal self-governance and self-determination. Although we are not finalizing a requirement in this final rule to require that providers spend a

minimum percentage of their Medicaid payments for nursing facility or ICF/IID services on direct care worker and support staff compensation, we have left open the possibility that the data collected under § 442.43 could help inform a minimum performance proposal in future rulemaking. Given the conflict between such a minimum performance requirement and the statutory requirements at 25 U.S.C. 1641, we will be unable to use data from IHS and Tribal health programs to inform future policy making related to direct care worker and support staff compensation. We believe that requiring States to report on data from IHS and Tribal programs would create unnecessary burden and (given their current allocation requirements) might skew the other data States would collect and report to CMS. Further, we note that finalizing an exemption for IHS and Tribal programs at § 442.43(b)(3) aligns with an exemption in the compensation reporting requirement finalized at § 442.311(e)(2) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register**.

F. Report Contents and Methodology

At § 442.43(c)(1), we proposed that the reporting must provide information necessary to identify, at the facility level, the percent of Medicaid payments spent on compensation to: direct care workers at each nursing facility, support staff at each nursing facility, direct care workers at each ICF/IID, and support staff at each ICF/IID. We anticipate that States and providers would be able to obtain the information needed to calculate the percent of Medicaid payments made to direct care workers and support staff using data used in rate setting, internal wage information, cost reports, and resident census numbers (which would indicate the number of days residents had Medicaid-covered stays during the year). However, we solicited comment on our proposal that information be reported at the facility level, particularly on any concerns about potential burden on providers and States.

We proposed to include in the reporting requirement the percentages of Medicaid payments to each nursing facility or ICF/IID that are going towards compensation to direct care workers and support staff at those facilities. However, we stated in the proposed rule at 88 FR 61387 that we would consider adding to the proposed reporting requirements additional elements for States to report on median hourly compensation for direct care workers and median hourly compensation for support staff, in addition to the percent of Medicaid payments going to overall compensation for these workers. We requested that commenters also provide feedback on whether the reporting should be on salary/wages or on total compensation (salary/wages and other remuneration, including employer expenditures for benefits and payroll taxes) and whether the information should be calculated for all direct care workers and for all support staff or further broken down by the staff categories specified in our proposal at § 442.43(a)(2) and (3).

At § 442.43(c)(2), we proposed that States must report the information required at § 442.43(c)(1) (the percent of Medicaid payment going to compensation for direct care workers and support staff and, if added to the provision, median hourly wages) according to a methodology that we provide. For reasons discussed in the proposed rule at 88 FR 61387 through 61388, we did not propose to codify a specific reporting methodology. In the proposed rule at 88 FR 61387, we stated that if this proposal is finalized, we would specify a reporting methodology as part of the reporting instrument, which would be submitted separately for formal public comment under the processes set forth by the Paperwork Reduction Act. We solicited initial suggestions for an appropriate methodology for identifying the percentage of Medicaid payment that has gone to direct care worker and support staff compensation. We also solicited initial suggestions about whether separate methodologies would be appropriate for FFS base payments and supplemental payments and if so, suggestions for each. Commenters who supported adding a requirement to report median hourly wages were also asked to provide suggestions for a methodology for those calculations.

To support our goal of transparency, we considered adding a provision requiring that States make publicly available information about the underlying FFS payment rates themselves for nursing facility and ICF/IID services. For the reasons discussed in 88 FR 61388, we considered adding to the proposed reporting provisions a requirement that, as applicable, States report a single average Statewide FFS per diem rate (one reported rate for nursing facility services and one reported rate for ICF/IID services). We also requested comment on whether the reported average should be the average of only the per diem FFS base payment rates or the average of the per diem FFS base payment rates plus FFS supplemental payments.

Finally, as discussed in 88 FR 61388, in consideration of potential future rulemaking, we requested comment on whether we should require that a minimum percentage of the payments for Medicaid-covered nursing facility services and ICF/IID services be spent on compensation for direct care workers and support staff. We also requested comment on whether such a requirement would be necessary to ensure that payment rates and methodologies are economic and efficient and consistent with meaningful beneficiary access to safe, high-quality care, or otherwise necessary for the proper and efficient operation of the State plan. Additionally, we requested suggestions on the specific minimum percentage of payments for Medicaid-covered nursing facility services and ICF/IID services that should be required to be spent on compensation to direct care workers and support staff. If a minimum percentage was recommended, we requested that commenters provide separate recommendations for nursing facility services and ICF/IID services and the rationale for each such minimum percentage that is recommended. We requested that commenters provide data or evidence to support such recommendations, which we will review as part of our consideration of policy and rulemaking options.

We received comments on our proposal. The following is a summary of these comments and our responses.

Comment: A few commenters expressed support for the requirement that States collect data at the facility level. A commenter noted specific support for including both privately- and publicly owned facilities.

A few commenters noted that facility-level reporting may be burdensome. One of these commenters asked for clarification as to whether the reporting will be by provider or by facility; the commenter noted that some providers operate multiple individual facilities and that requiring reporting at the facility level rather than the provider level will increase burden.

Response: As stated in our proposed requirement at § 442.43(c), the reporting gathered by the State should be at the facility level (but reported to CMS, for each nursing facility, as a single aggregated percentage for direct care worker compensation and, separately, a single aggregated percentage for support staff compensation and, for each ICF/IID, a single aggregated percentage for direct care worker compensation and, separately, a single aggregated percentage support staff compensation). We will provide technical assistance to

States on how to collect data from providers that operate multiple facilities to minimize administrative burden.

Comment: Many commenters supported disaggregating the reporting requirements by job duty or title, rather than reporting a percentage for direct care workers and a percentage for support staff. Several commenters also supported requiring reporting on median hourly wages (again, disaggregated by job duty). These commenters noted that wages for different types of direct care workers and support staff are wide ranging, and commenters were concerned that posting broad categorical percentages or median hourly wages for a range of job classifications would not provide transparency regarding how the facility is staffed and how each type of worker is compensated.

Other commenters did not support reporting on median hourly wages. A commenter, representing a number of State Medicaid agencies, stated that while some Medicaid agencies agreed that this data would help evaluate the impact of rate increases on staff wages, others were strongly opposed to additional reporting due to the increased administrative burden on States and providers. A commenter noted that the cost reports in the commenter's State do not currently include median hourly wages and that having to obtain that information from facilities would significantly increase burden.

A few commenters believed that if median hourly wage was reported, it should be reported for total compensation. One of these commenters observed that facilities might have to make changes to their facility's human resources or accounting software to accommodate further disaggregation of wage reporting. The commenter also noted that the wide variety of salary or wage types and pay systems would make data disaggregated beyond total compensation difficult to compare among States and across providers.

A few commenters suggested that this reporting be disaggregated by the subcategories of compensation listed in the definition of compensation at § 442.43(a)(1). A few commenters suggested that the subcategories should be further disaggregated, such as requiring reporting separately on overtime payments, the cost of paid time off, and the cost of health benefits.

A few commenters suggested we require disaggregation beyond compensation subcategory or job duty. A commenter suggested we require disaggregating median wage by part- and full-time status, as well as by contracted and employee status, which the commenter believed would allow policymakers to better understand the relationships between Medicaid payment, provider employment practices, and quality of care. A commenter, making a similar suggestion to require separate reporting of contracted staff, also suggested we require that facilities report whether they have an ownership interest in the third-party entity providing the contracted services. A few commenters suggested we require separate reporting on wages paid to new staff, to ensure facilities were appropriately investing in increasing staffing levels. A commenter suggested reporting on whether a facility offers health and retirement benefits and the percent of workers enrolling in those benefits. A few commenters also recommended we encourage States to collect data that would demonstrate racial, gender, and career advancement disparities.

A few commenters suggested that reporting be disaggregated by rate component. A commenter explained that due to the large variations between the Medicaid reimbursement systems used in the States and territories, reporting by rate component would allow for a variety of percentage of payment calculations by individual rate component and in total.

Response: We are finalizing the Federal reporting requirement as proposed (to require aggregated reporting of direct care worker compensation and support staff compensation) and without requiring reporting on median hourly wages.

In previous comment summaries and responses, we discussed concerns about variations in job titles and duties and are concerned that requiring payment broken down by job title may make national comparisons difficult, and significantly increase the reporting burden. For similar reasons, we decline at this time to require reporting on median hourly wage. As noted by commenters, there are variations among State and local wage laws and cost of living that would make meaningful comparisons of median hourly wages difficult at a national level. We believe it is important to first establish competency with collecting and reporting broad baseline data before requiring more granular reporting, although we recognize there could be value to collecting more granular data, including on median wages, in the future.

Additionally, upon consideration of the comments, we have identified no compelling reason to implement a Federal requirement for disaggregating the data by compensation category. We believe that employee benefits, in addition to wages, are also integral to the compensation of direct care workers and support staff. The third component of compensation—employers' share of payroll taxes—is a fixed percentage of the employee's wages set by law.

We thank commenters for their thoughtful feedback and suggestions for additional reporting components or metrics. We note that States may, at their discretion, require additional disaggregated data that they feel would be helpful in tracking local trends in workforce compensation and providing oversight and transparency.

Comment: Many commenters recommended that nursing homes should be required to detail other expenses, including any payments to related parties. These commenters believed that this would support greater financial transparency. One commenter recommended that both Medicare and Medicaid cost reports be made publicly available to disclose the total amount of spending on nursing, ancillary, and support services compared with spending on administration, property, profits, related party transactions, and disallowances.

One commenter recommended that additional data be collected on other outcome measures, including staffing levels for direct care workers and workers who provide indirect care (such as housekeeping or food services); the number of short- and long-stay residents; payer distribution of residents; quality measures constructed from the Minimum Data Set; safety measures constructed from health inspection data collected from nursing homes during on-site inspection surveys; medical outcomes from Medicare data, including hospital admissions, emergency department visits, mortality, hospital readmissions, and successful community discharge (short stay); and results from surveys of residents, family, and staff.

Response: We thank commenters for their suggestions but note that recommendations regarding reporting on expenditures other than compensation are out of scope for this rule, as are requests that we create and finalize requirements regarding cost reports. As stated in prior responses, the purpose of this requirement is not the granular tracking of all facility expenditures. As discussed at length in the proposed rule at 88 FR 61831 through 61833, understaffing in facilities is well-documented and chronic and poses a risk to the quality of care, and thus we have made addressing compensation for

institutional direct care workers and support staff a particular focus of this requirement. We recognize the role of related-party and other transactions in affecting the overall costs and profits of nursing facilities, and in turn the amount of funding available for direct care and administrative staffing; we will examine this issue and its impacts on quality in the future.

We also note that Nursing Home Compare contains a great deal of information regarding quality measures for nursing facilities.

Comment: Although they did not necessarily provide recommendations for a methodology, some commenters expressed concerns about how the required information will be calculated. These concerns include:

- For facilities that accept payments from multiple payers, identifying the amount of compensation for services provided to residents with stays covered by Medicaid;
- Accounting for variations in beneficiary acuity, which can impact both the amount of Medicaid payments and the facility resources allocated to the beneficiaries;
- Accounting for third party contracts in which (1) the contract price includes wages, benefits, and administrative costs, or (2) all-inclusive contracts (in which a facility pays a monthly rate for labor, supplies, and other items);
- Calculating the percent of Medicaid payments going to compensation if the Medicaid payment is less than the facility's standard rate; and
- Determining a reporting period (such as provider fiscal year, State fiscal year, or calendar year) that promotes consistency without creating administrative burden or confusion for providers.

A few commenters made specific suggestions regarding methodology and the reporting period. A commenter recommended the percentage be calculated by determining (a) a per diem salary cost amount (compensation costs divided by total patient days) and (b) a per diem revenue amount (Medicaid payments divided by Medicaid days), and dividing amount (a) by amount (b). The commenter cautioned, however, that this method will not provide information about whether revenues are being diverted away from patient care.

A commenter noted that a potential challenge could arise when accounting for payment adjustments that occur in one year that are paid in a different year, which could either under-report or over-report the payments to providers. To address this, the commenter suggested that States be required to report payments based on actual dates of service, not the dates payments are made to providers.

A commenter recommended that the reporting period should be the facility's fiscal year or cost report year, but that changes in the reporting period should be allowed if the facility changes ownership. A commenter suggested we allow States to determine the reporting period.

A few commenters suggested we develop a reporting methodology based on a review of current nursing facility and ICF/IID cost reports or other State-level reporting practices.

Response: We thank commenters for their feedback, which we will take into consideration when developing the reporting methodology and reporting template (including reporting period), that we will be making available for public comment through the Paperwork Reduction Act notice and comment process. This will give the public the opportunity to provide specific feedback and help us align the methodology and reporting process with existing State practices to the greatest extent possible.

We received public comment on our solicitation regarding whether we should require State reporting on per diem Medicaid FFS payment rates for nursing facilities and ICFs/IID. A few commenters wrote in support of adding this requirement to the reporting requirement at § 442.43(c). However, we have finalized a requirement at § 447.203(b)(1) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register** requiring State agencies to publish all Medicaid FFS fee schedule payment rates on a website that is accessible to the general public. We are not finalizing a reporting requirement at § 442.43(c) that would largely duplicate the reporting requirement at § 447.203(b)(1).

We received responses to our request for comment on whether, as part of future rulemaking, we should require that a minimum percentage of the payments for Medicaid-covered nursing facility services and ICF/IID services be spent on compensation for direct care workers and support staff. We received comments both in support of and in opposition to the idea of requiring a minimum threshold. We did not receive comments providing data supporting a specific minimum threshold. We thank commenters for their feedback and will take these comments into consideration in pursuing any future rulemaking on this issue.

After consideration of the comments received, we are finalizing § 442.43(c)(1) and (2) as proposed.

G. Website Posting

Based on our authority in sections 1902(a)(6) and 1902(a)(30)(A) of the Act with respect to FFS and sections 1902(a)(4) and 1932(c) of the Act with respect to managed care plans, we proposed new requirements to promote public transparency related to the administration of Medicaid-covered institutional services. For the reasons discussed in 88 FR 613888 and 61389 we proposed at § 442.43(d) to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the results of the newly proposed reporting requirements in § 442.43(b). We requested comment on whether the proposed requirements at § 435.905(b) are adequate to ensure the availability and the accessibility of the information for people receiving LTSS and other interested parties. We noted that the accessibility and availability requirements set forth in § 435.905(b) focus on whether the language used on a website is accessible to computer users with disabilities or limited English proficiency.

At § 442.43(d)(1), we proposed to require that the data and information that States are required to report in § 442.43(b) be provided on one website, either directly or by linking to relevant information on the websites of the managed care plan(s) that is contracted to cover nursing facility or ICF/IID services. We explained our intent for the States to be ultimately responsible for ensuring compliance with the proposal, including to ensure through contractual arrangements with managed care plans, as applicable, that the proposed requirements are satisfied when required information is provided on websites maintained by these plans. Proposed § 442.43(d) contemplates that some States that provide nursing facility or ICF/IID services through a managed care delivery system may decide to work with their managed care plans to make the reporting information available on the managed care plans' websites, rather than replicating the information directly on the State's website. We requested comment on whether States should be permitted to link to websites of these managed care plans and, if so, whether we should limit the number of separate websites that a State could link to in place of directly reporting the information on its own website; or whether we should require that all the required information be posted directly on a website maintained by the State.

At § 442.43(d)(2), we proposed to require that the website include clear

and easy to understand labels on documents and links. At § 442.43(d)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. The intent of § 442.43(d)(3) is to require that States ensure that the reporting information on their own website is up to date. We would also expect, if the State is linking to a managed care plan's website, that the State ensure on at least a quarterly basis that the links are operational and continue to link to the information States are required to report in § 442.43(b). We did not propose to direct that managed care plans must also review their websites quarterly, but rather we expect that States would develop a process with their managed care plans to ensure that any reporting information contained on a managed care plan website is timely and accurate. If a State obtains information that a managed care plan website to which the State links as a means of publishing the required reporting information is not being maintained with timely updates for ongoing accuracy, we expect that the State would work with the relevant managed care plan to correct the situation and, if unsuccessful, cease linking to that managed care plan's website and begin posting the required reporting information on a State-maintained website. We requested comment on this proposal, including whether this timeframe for website review is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

At § 442.43(d)(4), we proposed to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost to the public. We also proposed to require that States include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. We requested comment on whether these requirements would be sufficient to ensure the accessibility of the information for people receiving nursing facility or ICF/IID services and other interested parties.

We also proposed at § 442.43(e) that we must report on our website (Medicaid.gov or a successor website) the information reported by States to us under § 442.43(b). Specifically, we envision that we would update our website to provide information reported by each State on the percent of payments for Medicaid-covered services delivered by nursing facilities and ICFs/IID that is spent on compensation to direct care workers and support staff (and, if added to the provision, information on median hourly wages) which would allow the information to be compared across States and providers. We also envisioned using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard.[92] In the proposed rule at 88 FR 61389, we noted that if, based on public comment, we add a requirement that States provide information about their payment rates for nursing facility and ICF/IID services, we would provide this information on our website as a way of providing easy-to-find context for the other payment information reported by States. We currently do not intend to include the information on payment rates in the CMS Medicaid and CHIP Scorecard.

We received public comment on these proposals. The following is a summary of these comments and our responses.

Comment: A few commenters stated that they supported requiring States to have only one website with all the data and information related to reporting requirements. A commenter noted that this makes accessing data much easier and more accurate than external links to managed care plans' websites. A commenter requested we also require that data be in a downloadable format that supports use of the data, to support analysis by the public, researchers, and other interested parties.

Response: We decline to make modifications to this requirement. We agree with commenters that having one website on which the public may access data is a good practice. However, we have finalized a requirement at § 441.313(a)(1) in the Ensuring Access to Medicaid Services final rule published elsewhere in this **Federal Register** that gives States flexibility to maintain either a single website or link to managed care plan websites. To provide parity for both HCBS and institutional Medicaid services, we are finalizing the substantive requirement at § 442.43(d) as proposed, allowing States to meet this requirement by linking to individual MCO or PIHP websites. (We note that we are finalizing § 442.43(d) with technical modifications to correct a grammatical error.)

Although we decline to add technical specifications for the data format to the regulatory text, we do expect that States (or managed care plans, as applicable) will make this information available in a format that is accessible, downloadable, and otherwise usable for members of the public.

Comment: A commenter noted support for the requirement that language on the website be clear and easy to understand.

Response: We thank the commenter for their support. We are finalizing the requirement at § 442.43(d)(1) as proposed.

Comment: A few commenters supported quarterly review of the website. A commenter suggested we require that missing or inaccurate information be remedied within 2 weeks of the review. The commenter stated that delayed reviews can lead to the posting of inaccurate data, which hampers transparency initiatives. A commenter, noting the importance of transparency in reporting, stated that States should expect managed care plans to review their websites on a monthly basis at a minimum.

Response: We are finalizing the review requirement at § 442.43(d)(2) as proposed. We agree with commenters that quarterly review is an appropriate review frequency that balances oversight with administrative burden, given that the data itself are updated annually. We note that States or managed care plans have discretion to review the website more frequently as needed. We also decline to require a specific deadline by which outdated or erroneous data or broken links are to be updated, noting that issues might take different amounts of time to resolve. We expect that States will ensure that outdated or erroneous information, or broken links, will be remedied as promptly as possible. In addition, if a State becomes aware that posted information is outdated or erroneous and the issue cannot be addressed very rapidly, we expect that the State (or managed care plan) will publish a notice on the web page identifying the information concerned and stating that revised information is expected to be published in the future, giving the timeframe if available, so that the public will be appropriately cautioned not to rely on the outdated or erroneous information.

Comment: A few commenters stated that the accessibility standards outlined in the proposal appear sufficient to ensure access and availability of information, including to people with disabilities, people with limited English proficiency, and people who require the information in other languages. A few commenters also supported the requirement requiring prominent language that additional assistance is

[92] CMS's Medicaid and CHIP Scorecard. Accessed at *https://www.medicaid.gov/state-overviews/scorecard/index.html.*

available at no cost, with clear instructions for requesting assistance or additional accommodations. A commenter suggested that the website include the contact information for a ''designated individual within the State Medicaid agency responsible for nursing facility oversight who is available to address any accessibility concerns.'' One commenter recommended we require the website include the State Medicaid agency contact information so that members of the public can contact someone with questions about the data.

Response: We are finalizing the accessibility requirements at § 442.43(d) introductory text and (d)(3) as proposed. We decline to formalize any additional requirements in the regulatory text but agree that including relevant contact information on the website is important for ensuring the information is available and accessible to the public. We also note that having contact information on the website for a relevant contact at the State Medicaid agency would aid in the quarterly review finalized at § 442.43(d)(2) by allowing the public to notify the State of any errors or operational issues with the website. We encourage States to implement this practice, even though we are not formally requiring its adoption.

Comment: A commenter did not support requiring the public posting of facilities' cost data. The commenter noted that this may be particularly problematic for ICFs/IID, which range in size and can be quite small. The commenter was concerned that publicizing facilities' cost data could lead to inaccurate (presumably negative) conclusions being drawn about the facilities.

Response: The requirement is only for States to publish the percent of a facility's Medicaid payments that are going to worker compensation, not more detailed cost data (such as the amount of Medicaid payments or the amount paid to workers). While States may, at their discretion, decide to publish more detailed information, we believe the Federal requirement strikes a balance between promoting transparency and allowing for the sharing of aggregated (rather than granular) data about facilities' financial activities.

We did not receive comments on our proposal at § 442.43(e).

After consideration of the comments received, we are finalizing § 442.43(d) with minor technical modifications to change ''MCO and PIHP websites'' to ''MCO's and PIHP's websites.'' We are finalizing § 442.43 (e) as proposed.

H. Applicability Date and Application to Managed Care

For reasons discussed in 88 FR 61389 through 61390, we proposed, at § 442.43(f), to provide States with 4 years to implement these requirements in FFS delivery systems following the effective date of the final rule. This proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations, policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We invited comments on whether this timeframe is sufficient, whether we should require a shorter or longer timeframe (such as 3 or 5 years) to implement these provisions, and if a shorter or longer timeframe is recommended, the rationale for that shorter or longer timeframe.

In the context of Medicaid coverage of nursing facility and ICF/IID services, we believe that the foregoing reasons for the reporting requirements proposed in this rule apply to the delivery of these services regardless of whether they are covered directly by the State on an FFS basis or by a managed care plan for its enrollees. Accordingly, we proposed to apply the requirements at § 442.43 to both FFS and managed care delivery systems through adoption by reference in a new regulation in 42 CFR part 438, which generally governs Medicaid managed care programs. Specifically, we proposed to add a cross-reference to the requirements in proposed § 438.72(a) to be explicit that States that include nursing facility and/or ICF/IID services in their MCO or PIHP contracts would have to amend their contracts to the extent necessary to comply with the requirements at § 442.43 and proposed at § 442.43(b) that payments from MCOs and PIHPs count as Medicaid payments for purposes of those requirements. We believe this would make the obligations of States that implement LTSS programs through a managed care delivery system clear and consistent with the State obligations for Medicaid FFS delivery systems. Additionally, for States with managed care delivery systems under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include coverage of nursing facility services and/or ICF/IID services in the MCO's or PIHP's contract, we proposed to provide States until the first managed care plan contract rating period that begins on or after the date that is 4 years after the effective date of the final rule to implement these requirements. We solicited feedback on the proposed application of the reporting requirement to managed care delivery systems, and the proposed timeframe for compliance. We also invited comments on whether the proposed effective date timeframe is sufficient, whether we should require a longer timeframe (such as 5 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

We received comments on these proposals. The following is a summary of these comments and our responses.

Comment: A few commenters suggested that we shorten the timeframe for compliance, especially given the importance of the data being collected and the urgency of the understaffing in facilities. A commenter stated that 4 years was unnecessarily long and recommended 2 years as a reasonable alternative. A few commenters recommended 3 years, stating that States and facilities should already have much of the required data available.

A few commenters recommended a longer timeframe than 4 years, such as 6 or 7 years. These commenters cited challenges such as limited State staff and financial resources to dedicate to completing this reporting requirement; obligations to comply with other new reporting obligations; a backlog of eligibility determinations following the end of the COVID–19 Public Health Emergency; support needed to help providers, especially smaller providers, update their systems to report the necessary data; and time and resources needed to update States' systems to collect, process, and audit the required data.

One commenter supported the 4-year applicability date if the rule is finalized as proposed.

Response: We are finalizing the 4-year applicability date that we proposed at § 442.43(f). We believe that 4 years strikes an appropriate balance between obtaining these data as quickly as possible and acknowledging that some States and providers will need time to update systems. As noted in prior responses, we also intend to make the reporting methodology and reporting format available to the public through the Paperwork Reduction Act notice and comment process. We believe the 4-year delayed applicability date provides sufficient time for this process, as well as any subregulatory guidance or technical assistance needed to assist States to prepare for and be in compliance with the requirements.

We did not receive specific comments on the proposal to add a cross-reference at § 438.72(a) to apply the reporting requirements finalized at § 442.43 to

managed care plans and the associated applicability date for MCOs and PIHPs.

After consideration of the comments received, we are finalizing the substance of § 442.43(f) as proposed, but with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 442.43(f) *Applicability date* (rather than *Effective date*). We are also modifying the language at § 442.43(f) to specify that States must comply with the requirements in § 442.43 beginning 4 years from the effective date of this final rule, rather than stating that § 442.43 is effective 4 years after the effective date of the final rule.

Additionally, we are finalizing both §§ 442.43(f) and 438.72(a) with technical modifications (discussed in the next paragraph) regarding the applicability date for States providing nursing facility and ICF/IID services through managed care plans. The purpose of these modifications is to streamline § 438.72(a) and consolidate all applicability dates in § 442.43(f). We also believe these modifications better align the structure of §§ 438.72(a) and 442.43(f) with similar requirements finalized at § 438.72(b) and a number of applicability dates in the Ensuring Access to Medicaid Services Final Rule published elsewhere in this **Federal Register**.

As proposed, § 438.72(a) included a requirement that States that included nursing facility or ICF/IID services in their MCO and PIHP contracts must comply with § 442.43, as well as specifying that States must comply with § 442.43 by the first rating period for contracts with the MCO or PIHP beginning on or after 4 years after the effective date of the final rule. We are striking the applicability date language from § 438.72(a) and finalizing § 438.72(a) with modified language that simply specifies that the State must comply with requirements at § 442.43 for nursing facility and ICF/IID services. We are finalizing § 442.43(f) with a modification to add (with minor modifications) the language that had been originally proposed at § 438.72(a), specifying that in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes nursing facility services or ICF/IID services, States must comply beginning the first rating period for contracts with the MCO or PIHP beginning on or after 4 years after the effective date of the final rule.

I. Future Guidance and Interested Parties Advisory Group Comment Solicitation

As noted in the proposed rule at 88 FR 61390, as a result of finalizing the proposals as discussed, we will establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements, and establish new templates consistent with requirements under the Paperwork Reduction Act. We invited comment on this approach, particularly regarding any additional guidance we would need to provide or actions we would need to take to facilitate States' implementation of these proposed provisions.

Finally, in consideration of potential future rulemaking, we requested comment on whether we should propose that States implement an interested parties' advisory group in parallel with proposed requirements at § 447.203(b)(6) finalized in the Ensuring Access to Medicaid Services rule published elsewhere in this **Federal Register**, which requires States to establish an interested parties advisory group to advise and consult on the sufficiency of FFS rates paid to direct care workers providing certain HCBS. We solicited comment from the public on whether we should consider developing requirements for States to establish a similar group to advise and consult on nursing facility and ICF/IID service rates.

We received a few comments from the public that supported this proposal. We thank commenters for their feedback and will take the comments into consideration should we pursue rulemaking in the future.

IV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions of the September 6, 2023, proposed rule with the following modifications:

- In § 442.43(a)(1), we modified paragraph (a)(1)(ii) to specify that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.
- In § 442.43(a)(2), we redesignated paragraphs (a)(2)(vi) through (x) as paragraphs (a)(2)(vii) through (xi), respectively, and added a new paragraph (a)(2)(vi) to include direct support professionals to the definition. Additionally, we are finalizing the newly redesignated paragraph (a)(2)(xi) with a modification to include nurses and other staff that providing that clinical supervision.
- In § 442.43(a)(3), we redesignated paragraph (a)(3)(vi) as paragraph (a)(3)(vii) and added a new paragraph (a)(3)(vi) to add security guards to the definition of support staff.
- We are finalizing a new definition of excluded costs at § 442.43(a)(4), which are costs reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers and support staff. Such costs are limited to: (1) costs of required trainings for direct care workers and support staff (such as costs for qualified trainers and training materials); (2) travel costs for direct care workers and support staff (such as mileage reimbursements and public transportation subsidies); and (3) costs of personal protective equipment for facility staff.
- In § 442.43(b), we removed ''by delivery system and,'' added language specifying that the Medicaid payments used in the required calculation do not include excluded costs, and added a cross-reference to § 442.43(b)(3). We are also finalizing technical modifications to improve clarity and correct grammatical errors.
- We are finalizing a new § 442.43(b)(3) to specify that States must exclude data from Indian Health Service and Tribal health program providers subject to 25 U.S.C. 1641.
- In § 442.43(d), we made minor technical modifications for grammar and readability, including changing ''MCO and PIHP websites'' to ''MCO's and PIHP's websites.''
- In § 442.43(f), we retitled the requirement *Applicability date* and made minor modifications to the language to specify that States must comply with § 442.43 beginning 4 years after the effective date of this final rule. We also added to § 442.43(f) language (with minor modifications) that had been proposed in § 438.72(a) specifying that in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes nursing facility services or ICF/IID services, States must comply beginning the first rating period for contracts with the MCO or PIHP beginning on or after 4 years after the effective date of the final rule.
- In § 438.72(a), we struck the language specifying an applicability date; the substance of this language was added to § 442.43(f). We streamlined the language at § 43.72(a) to specify that States must comply with requirements

at § 442.43 for nursing facility and ICF/IID services.

• Throughout chapter 42 of the CFR we have updated references to ''§ 483.70(e)'' to replace them with ''§ 483.71'', as appropriate to reflect the new designation for the facility assessment requirements.

• In § 483.35, we redesignated the updates to existing paragraph (a)(1) as a new paragraph (b) entitled ''Total nurse staffing (licensed nurses and nurse aides)'' and renumbered the existing paragraphs in § 483.35 accordingly.

• In § 483.35, we added a requirement at new paragraph (b)(1) for facilities to meet a minimum of 3.48 HPRD for total nurse staffing. Requirements at new paragraphs (b)(1)(i) and (ii) require facilities to also have a minimum of RN HPRD of 0.55 and NA HPRD of 2.45. In this redesignated paragraph we also are not including the proposed requirement for determinations of compliance with HPRD requirements to be made based on the most recent available quarter of PBJ system data submitted in accordance with § 483.70(p).

• In § 483.35, we revised newly redesignated paragraph (c)(1) to add that facilities may be exempted from 8 hours per day of the 24/7 RN onsite requirement if they meet the exemption criteria outlined in new paragraph (h).

• In § 483.35, we added a new paragraph (c)(2) to require that during any periods when the onsite RN requirements in paragraph (c)(1) are exempted under paragraph (h), facilities must have a registered nurse, nurse practitioner, physician assistant, or physician available to respond immediately to telephone calls from the facility.

• In § 483.35, we redesignated existing paragraphs (e) and (f) as paragraph (f) and (g), respectively. In newly redesignated paragraph (f), we revised the heading to read ''Nursing facilities: Waiver of requirement to provide licensed nurses and a registered nurse on a 24-hour basis.'' In newly redesignated paragraph (g), we revised the heading to read ''SNFs: Waiver of the requirement to provide services of a registered nurse for at least 112 hours a week''.

• In § 483.35, we redesignated proposed new paragraph (g) as a new paragraph (h) and revised the heading to read ''Hardship exemptions from the minimum hours per resident day and registered nurse onsite 24 hours per day, for 7 days a week''.

• In § 483.35, we revised new paragraph (h) to add that a facility may be exempted from both the minimum hours per resident day required in paragraph (b) and 8 hours per day of the 24/7 RN onsite requirement at paragraph (c)(1).

• In § 483.35, we revised new paragraph (h) to withdraw the 20 mile distance qualifier for an exemption from the minimum hours per resident day requirement. Qualifying location criteria to be eligible for an exemption is based on workforce unavailability only.

• In § 483.35, we revised new paragraph (h) to modify the transparency requirements that a facility must meet to receive an exemption from the minimum hours per resident day and 8 hours of the 24/7 RN onsite requirements. In addition to demonstrating a good faith effort to hire and identifying the annual amount of funds dedicated to hiring efforts, facilities must also post in the facility and provide notices to residents and the LTC ombudsman of their exemption status and inability to comply with the minimum staffing requirements, including the degree to which they do not meet the staffing requirements.

• In new § 483.71, we modified the proposal at paragraph (b) to clarify the required involvement of specific staff in the development of the facility assessment. LTC facility staff, including nursing home leadership (governing body, etc.) and direct care staff (RNs; LPN/LVNs; NAs; representatives of direct care staff, if applicable; and other specialties) must be offered the opportunity to actively participate. Facilities must also solicit and consider input from residents, and resident representatives.

• We revised the implementation timeframe to reflect the following:

++ Non-rural Facilities

++ Phase 1 (90 days after publication)—Facility Assessment Updates (§ 483.71)

++ Phase 2 (2 years after publication)—Minimum 3.48 HPRD for total nurse staffing and 24/7 RN Requirements (§ 483.35(b)(1) and (c)(1))

++ Phase 3 (3 years after publication)—Minimum .55 RN and 2.45 NA HPRD Requirements (§ 483.35(b)(1)(i) and (ii))

++ Rural Facilities (as defined by OMB)

—Phase 1 (90 days after publication)—Facility Assessment Updates (§ 483.71)

—Phase 2 (3 years after publication)—Minimum of 3.48 HPRD for total nurse staffing HPRD and 24/7 RN Requirements (§ 483.35(b)(1) and (c)(1))

—Phase 3 (5 years after publication)—Minimum .55 RN and 2.45 NA HPRD Requirements (§ 483.35(b)(1)(i) and (ii))

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comments before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In analyzing information collection requirements (ICRs), we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2022 National Occupational Employment and Wage Estimates, BLS at *https://www.bls.gov/oes/current/oes_nat.htm.* We have calculated the estimated hourly rates in this rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. The HHS wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for including these overhead and fringe benefit costs.

Table 5 presents the BLS occupation code and title, the associated LTC facility staff position in this regulation, the estimated average or mean hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs). Where available, the mean hourly wage for Nursing Care Facilities (Skilled Nursing Facilities) [93] was used.

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Table 5: Summary Information of Estimated Hourly Costs

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1141	Registered Nurses (Nursing Care Facilities (Skilled Nursing Facilities))	Registered Nurse	$37.11	$74
11-9111	Medical and Health Services Managers (Nursing Care Facilities (Skilled Nursing Facilities))	Director of Nursing (DON) and Administrator	$49.91	$100
29-1216	General Internal Medicine Physicians (General Medical and Surgical Hospitals)	Medical Director	$93.90	$188
43-6013	Medical Secretaries and Administrative Assistants (General Medical and Surgical Hospitals)	Administrative Assistant	$20.30	$41
29-1229	Physician, All Other (Specialty (except Psychiatric and Substance Abuse))	Medical Director	$135.86	$272
29-1031	Dieticians and Nutritionists (Nursing Care Facilities (Skilled Nursing Facilities))	Food and Nutrition Manager	$31.63	$63
11-3013	Facilities Manager	Facilities Manager	$50.95	$102
29-2061	Licensed Practical and Licensed Vocational Nurses (Nursing Care Facilities (Skilled Nursing Facilities))	Licensed Nurse	$28.10	$56
31-1131	Nursing Assistants (Nursing Care Facilities (Skilled Nursing Facilities))	Certified Nursing Assistance (CNA)	$16.90	$34

We solicited public comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs). Based upon our analysis of comments received, we are revising our burden estimates and adding a burden estimate for LTC facilities (LTCFs) to solicit and consider any input received by residents, resident representatives, and family members. These revisions and the addition are detailed below:

[93] *https://www.bls.gov/oes/current/naics4_623100.htm.*

A. ICRs Regarding § 483.35 Nursing Services

At § 483.35(a), we proposed that each LTC facility would have to provide 0.55 HPRD for RNs and 2.45 HPRD for NAs.

In the proposed rule, we analyzed the COI requirement as indicated below.

These proposed requirements would require each LTC facility to review and modify, as necessary, its policies and procedures regarding nurse staffing. The review and modifications to the necessary policies and procedures would require activities by the director of nursing (DON), an administrator, and an administrative assistant. The DON and the administrator would need to review the requirements, as well as the facility assessment, to determine if any changes are necessary to the policies and procedures and, if so, make those necessary changes. The DON would then need to work with a medical administrative assistant to ensure that those changes were made to the appropriate documents and ensure that all appropriate individuals in the facility were made aware of the changes. We estimated that these activities would require 2 burden hours for an administrator at a cost of $200 ($100 × 2 hours), 3 hours for the DON at a cost of $300 ($100 × 3 hours), and 1 hour for the administrative assistant at a cost of $41 ($41 × 1 hour). Hence, for each LTC facility the burden estimate would be 6 hours (2 + 3 + 1) at a cost of $ 541 ($200 + $300 + $41). There are currently 14,688 LTC facilities. Thus, the burden for all LTC facilities would be 88,128 (14,688 × 6 hours) hours at a cost of $7,946,208 ($541 × 14,688 LTCFs).

Comment: Numerous commenters generally contended the proposed requirements were too burdensome and expensive. One provider organization stated that the estimate for the ICR burden that included two hours for an administrator, three hours for the DON, and one hour for an administrative assistant were grossly underestimated. The commenter asserted that LTC facilities would be required to review and modify nurse staffing policies and procedures to become compliant with the requirements, develop and modify contracts with staffing agencies, engage in budget modification and staffing model reevaluations based on the staff available to meet the new requirements, and determine appropriate resident placement efforts when the facility cannot be compliant with the requirements. The commenter also noted that there were likely other activities that would be required as well.

Response: We agree with the commenter that the burden estimated in the proposed rule for proposed § 483.35(a) was understated. We note that as discussed in section II.B.3. of this rule, we are finalizing at § 483.35(b) to require LTC facilities to provide a minimum total nurse staffing requirement of 3.48 HPRD (paragraph (b)(1) introductory text), which includes 0.55 HPRD of RNs (paragraph (b)(1)(i)) and 2.45 HPRD of NAs (paragraph (b)(1)(ii)).

We are revising and increasing the burden estimate particularly to account for additional activities addressed by the commenters, including the review and modification of contracts, staffing models, and contingency planning to address when staffing or other resource issues arise. Thus, we are revising our burden estimate to allow for 8 hours at a cost of $800 ($100 × 8) for the administrator, 7 hours at a cost of $700 ($100 × 7 hours) for the DON, and 4 hours at a cost of $164 ($41 × 4 hours) for the administrative assistant. Hence, the total estimated burden for each LTC facility would be 19 hours at cost of $1,664. For all 14,688 LTC facilities, the total estimated burden would be 279,072 hours (19 hours × 14,688) at a cost of $24,440,832 ($1,664 × 14,688).

B. ICRs Regarding § 483.71 Facility Assessment

At § 483.71 Facility assessment, we proposed to relocate the existing requirements at § 483.70(e) Facility assessment to the new § 483.71. We also proposed to modify certain specific requirements and add a third section that will set forth the activities for which we expect LTC facilities to use their facility assessments.

We proposed to relocate current § 483.70(e)(1)(i) through (v) to § 483.71(a)(1)(i) through (v). This section sets forth what the facility assessment must address or include, but is not limited to, regarding the facility's resident population. At § 483.71(a)(1)(ii), we proposed to add ''using evidence-based, data-driven methods'' (such as the MDS resident assessments or data from QAPI activities) and ''behavioral health issues'' so that the requirement would then read, ''The care required by the resident population, using evidence-based, data driven methods that consider the types of diseases, conditions, physical and behavioral health issues, cognitive disabilities, overall acuity, and other pertinent facts that are present within that population.'' At § 483.71(a)(1)(iii), we proposed to add ''and skill sets'' so the requirement would read, ''The staff competencies and skill sets that are necessary to provide the level and types of care needed for the resident population.'' These modifications constitute clarifications in the requirements and are not new requirements for which the LTC facilities must comply. Hence, we will not be analyzing any new or additional burden related to those changes.

We proposed to relocate the current requirements at § 483.70(e)(2)(i) through (vi) to § 483.71(a)(2)(i) through (vi). At § 483.71(a)(2)(iii), we proposed to add ''behavioral health'' so that the requirement would read, ''Services provided, such as physical therapy, pharmacy, behavioral health, and specific rehabilitation therapies.'' Behavioral health services requirements are set forth at § 483.40 and are integral to the health of residents. All LTC facilities should be considering the behavioral health care needs of their residents. Hence, this change does not constitute a new requirement but a clarification. Hence, we did not analyze any new or additional burden related to this change.

We proposed to add a new requirement at § 483.71(a)(4) for LTC facilities to incorporate the input of facility staff and their representatives into their facility assessment. These staff categories included, but were not limited to, nursing home leadership, management, direct care staff and representatives and other service workers. LTC facilities already include many of these categories of individuals when they conduct or update their facility assessments. Thus, this requirement constitutes a clarification and not a new requirement. Hence, we did not analyze any new or additional burden related to this change.

We proposed to add new requirements at § 483.71(b). These requirements set forth specific activities for which the LTC facilities would be expected to use their facility assessments. These assessments would inform staffing decisions to ensure that a sufficient number of staff with the appropriate competencies and skill sets necessary to care for its residents' needs as identified through resident assessments and plans of care as required in § 483.35(a)(3); consider specific staffing needs for each resident unit in the facility, and adjust as necessary based on changes its to resident population; consider specific staffing needs for each shift, such as day, evening, night, and adjust as necessary based on any changes to its resident population; and, develop and maintain a plan to maximize recruitment and retention of direct care staff.

LTC facilities are either already using their facility assessments for these activities or will be based upon the other requirements in the proposed rule, except for using their facility assessments to develop and maintain a plan to maximize recruitment and

retention of direct care staff. Based upon our experience with LTC facilities, these facilities are already working on recruitment and retention of direct care staff. However, these facilities would need to review their current efforts to determine if there are opportunities to improve their efforts and, if so, decide how to do so. The LTC facility's facility assessment would require the development of a plan to maximize recruitment and retention and accomplish the associated tasks and would also be an invaluable tool in assessing and maintaining sufficient staff for their facility.

The staff involved in developing this plan would vary by the type of care and services provided by the individual facilities. Some LTC facilities might have various therapists on staff, such as physical and occupational therapists. Others might employ psychologists, social workers, or complementary medicine or American Indian/Alaska Native Traditional Healers who provide behavioral health services to residents. When developing a recruitment and retention plan, we encourage LTC facilities to include participation and input from the various types of direct care staff in their facilities and representatives of these workers. We note that the time spent by these staff to participate in the facility assessment process should not be substituted for the direct care minimums for RNs and NAs required under this rule. All LTC facilities provide 24-hour nursing services and the direct care nursing staff would include RNs, other licensed nurses (LPNs or LVNs), and nursing assistants (NAs). For the purpose of estimating the burden for developing a recruitment and retention plan, we estimated the burden for an administrator, the DON, and one individual from each of the nursing categories, an RN, LPN/LVN, and NA to develop the plan. These individuals would have to meet to develop a plan and then the administrator will need to obtain approval for the plan from the governing body. During the development process and after approval, an administrative assistant would need to provide support and ensure the plan is disseminated and saved appropriately in the facility's records. We estimated that developing a recruitment and retention plan would require 6 hours for an administrator at a cost of $600 ($100 × 6 hours); 6 hours for the DON at a cost of $600 ($100 × 6 hours); 4 hours for a RN at a cost of $296 ($74 × 4 hours); 2 hours for a LPN/LVN at a cost of $112 ($56 × 2 hours); 2 hours for a nursing assistant at a cost of $68 ($34 × 2); and, 2 hours for an administrative assistant $82 ($41 × 2 hours). Thus, the burden for each LTC facility is 22 (6 + 6 + 4 + 2 + 2 + 2) hours at an estimated cost of $1,758 ($600 + $600 + $296 + $112 + $68 + 82). For all 14,688 LTC facilities the burden would be 323,136 hours (14,688 LTCFs × 22 hours) at an estimated cost of $25,821,504 ($1,758 × 14,688 LTCFs).

Comment: Numerous commenters generally contended the proposed requirements regarding the facility assessment were too burdensome and expensive. One provider organization stated that the estimate of 22 staff hours for the facility assessment requirement grossly underestimated the burden to a LTC facility. One provider organization stated that complying with this requirement would require multiple staff members a significant amount of time to comply. Also, compliance would require an ongoing effort by multiple staff members. The commenter acknowledged that estimating the burden is complicated since it depends upon the number of revisions and is influenced by the changes in the resident population and staff in each facility.

Response: We agree with the commenter that there are more activities related to complying with the facility assessment requirement than were considered in the proposed rule. As discussed in detail in section II.B.6. of this rule, we are finalizing as proposed all of the proposed changes regarding the facility assessment, except for § 483.71(b) that has been revised to require LTC facilities to require the active participation of the nursing home leadership and management, including but not limited to, a member of the governing body, the medical director, an administrator and the director of nursing; and direct care staff, including but not limited to, RNs, LPNs/LVNs, and NAs, and representatives of the direct care staff, if applicable. The LTC facility must also solicit and consider input received from residents, resident representatives, and family members.

Based upon our review and analysis of comments related to this estimated burden and our substantive revisions in this final rule, we have revised the estimated burden for the facility assessment requirement as detailed below.

In the proposed rule, for the development of this staffing plan the estimated burden was 22 hours at a cost of $1,758. Based upon the comments received and further analysis, we now estimate that developing a recruitment and retention plan would require 10 hours for an administrator at a cost of $1000 ($100 × 10 hours); 10 hours for the DON at a cost of $1000 ($100 × 10 hours); 8 hours for a RN at a cost of $592 ($74 × 8 hours); 4 hours for a LPN/LVN at a cost of $224 ($56 × 4 hours); 5 hours for a nursing assistant at a cost of $170 ($34 × 5 hours); and, 3 hours for an administrative assistant $123 ($41 × 3 hours). Thus, the burden for each LTC facility is 407 (10 + 10 + 8 + 4 + 5 + 3 = 40) hours at an estimated cost of $ 3,109 ($ 1000 + $1000 + $592 + $224 + $170 + 123). For all 14,688 LTC facilities the burden would be 587,520 hours (14,688 LTCFs × 40) at an estimated cost of $45,664,992 ($3,109 × 14,688 LTCFs).

In addition, this rule finalizes revisions to the facility assessment that would also require additional burden. For § 483.71(b), we proposed that LTC facilities would be required to include the input of facility staff, including, but not limited to nursing home leadership, management, direct care staff, the representatives of direct care employees, and staff providing other services. We did not assess a burden for this proposal because it was a clarification and not a new requirement. However, as finalized by this rule, § 483.71(b) now requires that the LTC facility ensure the active involvement of nursing home leadership and management, including but not limited to, a member of the governing body, the medical director, an administrator and the director of nursing; and, direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs; and, representatives of direct care staff, if applicable. The LTC facility must also solicit and consider input from residents, resident representatives, and family members. We believe that many of the specifically named staff positions are already included by most LTC facilities in their facility assessment development, review, and updating process. We are also not estimating a burden for the active participation of representatives of direct care staff, if applicable, because assisting those they represent already falls within their responsibilities. If any of the direct care staff have representatives, the LTC facility should be aware of those individuals. However, soliciting and considering any input received by residents, resident representatives, family members is a new requirement. We are not estimating a burden for reviewing the input since this would be part of the facility assessment process. Thus, a burden estimate is being assessed for the activities required to comply with that requirement. These revisions are detailed below.

For a LTC facility to solicit input from residents, resident representatives, and family members would require the LTC facility to identify all of these individuals, make them aware of the facility assessment process, and then solicit their input. LTC facilities would differ in how they communicate to the named individuals. Although LTC facilities are not required to establish resident or family groups, residents do have the right to organize and participate in resident groups (§ 483.10(f)(5)). If residents do form resident or family groups, the LTC facility must provide the group(s) with private space for them to meet and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner. Based upon our experience, most LTC facilities have established resident or family groups. LTC facilities could easily use these established communications pathways, as well as posting notices and sending emails to solicit input for the facility assessment from the named individuals. To comply with the requirement to solicit the input of these individuals identified in the facility assessment requirement, we estimate this would require an administrator 1 hour at $100 per hour ($100 × 1 hour = $100) to draft the text of the communication and then an administrative assistant 2 hours at $41 per hour ($41 × 2 hours = $82) to forward the communication to the required individuals. The text of the communication should include a brief description of the facility assessment process, the opportunity to submit input, how that input can be submitted, and the deadline to submit the input. This would likely include posting of a notice in the LTC facility and forwarding the communication to the facility's resident or family group(s). The consideration of this input would then be part of the facility assessment review and updating process.

Hence, the burden for each LTC facility would be 3 hours (1 + 2 = 3) at an estimate cost of $182 ($100 + $82 = $182). For all 14,688 LTC facilities, the total estimated burden would be 44,064 hours (14,688 LTCFs × 3 hours = 44,064) at a cost of $2,673,216 ($182 × 14,688 LTCFs = 2,673,216).

The total estimated burden for the ICRs in part 483 is 910,656 (279,072 + 587,520 + 44,064) hours at a cost of $72,779,040 ($24,440,832 + $45,664,992 + 2,673,216).

TABLE 6: Total Burden for Part 483 ICRs

LTC Requirements Section	Burden Hours Per LTCF	Cost Estimate Per LTCF	Burden Hours For all LTCFs	Cost Estimate For all LTCFs
§ 483.35 Policies and Procedures Nursing Services	19	$1,664	279,072	$24,440,832
§ 483.71 Facility assessment – Recruitment and Retention Plan	40	$3,109	587,520	$45,664,992
§ 483.71 Soliciting input	3	$182	44,064	$2,673,216
Totals	62	$4,955	910,656	$72,779,040

The burden will be included in this revised Information Collection Request under the OMB control number 0938–1363; Expiration date: April 30, 2026.

C. ICR Related to Medicaid Institutional Payment Transparency

1. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics (BLS) May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). In this regard, table 7 presents BLS's mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Table 7: National Occupational Employment and Wage Estimates

OCCUPATION TITLE	OCCUPATION CODE	MEAN HOURLY WAGE ($/HR)	FRINGE BENEFITS AND OVERHEAD ($/HR)	ADJUSTED HOURLY WAGE ($/HR)
Administrative Services Manager	11-3012	55.59	55.59	111.18
Chief Executive	11-1011	118.48	118.48	236.96
Compensation, Benefits, and Job Analyst	13-1141	36.50	36.50	73.00
Computer Programmer	15-1251	49.42	49.42	98.84
General and Operations Manager	11-1021	59.07	59.07	118.14
Management Analyst	13-1111	50.32	50.32	100.64
Training and Development Specialist	13-1151	33.59	33.59	67.18

For States and the private sector, our employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To estimate the financial burden on States related to the finalized Medicaid Institutional Payment Transparency Reporting provisions (discussed below), it was important to consider the Federal Government's contribution to the cost of administering the Medicaid program. The Federal Government provides funding based on a Federal medical assistance percentage (FMAP) that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes. For Medicaid, all States receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. Taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimating State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be smaller given that some States contributions will be less than 50 percent. We requested comment on our estimated number of burden hours for the proposal for each of the activities and total annual burden and cost for each facility. We did not receive specific comments on these burden estimates.

3. Information Collection Requirements (ICRs)

The following finalized changes will be submitted to OMB for their approval when our survey instrument has been developed; we are using feedback received during public comment on the proposed rule to inform the development of the survey instrument. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of estimating the impact of this finalized rule. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10851 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new information collection request. Note that we intend that the following finalized changes associated with § 442.43(b), (c), and (d), discussed later in this section, will be submitted to OMB for review as a single PRA package under control number 0938–TBD (CMS–10851).

a. State and Provider Burden Under § 442.43(b) and (c)—Payment Transparency Reporting

As discussed in section III. of this final rule, under our Medicaid authority at sections 1902(a)(6) and 1902(a)(30)(A) of the Act with respect to FFS delivery systems, and sections 1902(a)(4) and 1932(c) of the Act with respect to managed care delivery systems, we proposed and are finalizing new reporting requirements at § 442.43(b) for States to report annually on the percent of payments for Medicaid-covered services delivered by nursing facilities and ICFs/IID that are spent on compensation for direct care workers and support staff. (Our definitions of who is included in direct care workers and support staff, finalized at § 442.43(a)(2) and (3), respectively, are discussed in the preamble in section III. of this rule.) The intent of this requirement is for States to report separately, at the facility level, on the percent of payments for nursing facility services that are spent on compensation to direct care workers, the percent of payments for nursing facility services that are spent on compensation to support staff, the percent of payments for ICF/IID services that are spent on compensation to direct care workers, and the percent of payments for ICF/IID services that are spent on compensation to support staff. We proposed and are finalizing a cross-reference to the requirements in § 438.72 to specify that States that include nursing facility and ICF/IID services in their contracts with managed care organizations (MCOs) or prepaid inpatient health plans (PIHPs) would have to comply with the requirements at § 442.43(b). Where they appear, references to the requirements at

§ 442.43(b) apply to both FFS and managed care delivery systems.

We considered, but are not finalizing, additional requirements that States report on median hourly compensation for direct care workers and median hourly compensation for support staff, in addition to the percent of Medicaid payments going to overall compensation for these workers. We considered, but are not finalizing, adding at § 442.43(c) a provision requiring that States make publicly available information about the underlying FFS payment rates themselves for nursing facility and ICF/IID services. We note that our cost estimates in the proposed rule included estimated costs for both of these additional reporting requirements and are no longer reflected in this ICR. We also note that we are finalizing an additional requirement (discussed in section III. of this final rule) that will allow providers to exclude certain costs (such as certain costs related to training, travel, and PPE) from their Medicaid payments when calculating the percent of Medicaid payments spent on compensation to direct care workers and support staff. We anticipate that this may lead to a slight increase in the State's burden to develop guidance for providers on how to apply these excluded costs in facility settings and have adjusted the ICR accordingly.

(1) State Institutional Payment Transparency Reporting Requirements and Burden

The burden associated with the reporting requirements finalized in this rule would affect all 51 States (including Washington, DC). While not all States cover ICF/IID services (because it is an optional Medicaid benefit), all States must offer Medicaid nursing facility services (because it is a mandatory Medicaid benefit). Thus, we anticipate that all 51 States (including Washington, DC) would participate in the reporting requirements proposed at § 442.43(b). Additionally, three territories (Guam, Puerto Rico, and the U.S. Virgin Islands) are required to include nursing facility services in their State plans, and thus are included in these calculations as well.[94] While we included these territories in our cost estimates, we continue to refer to the affected entities collectively as ''States''. We estimated both a one-time and ongoing burden to States to implement these requirements at the State level.

One-Time Reporting Requirements and Burden (§ 442.43(b)): States

Under finalized § 442.43(b) and (c), we anticipate as a one-time burden that States, through their designated State Medicaid agency, would have to: (1) draft new policy describing the State-specific reporting process (one-time); (2) update any related provider manuals and other policy guidance, including guidance on excluded costs (one-time); (3) build, design, and operationalize an electronic system for data collection and aggregation (one-time); and (4) develop and conduct an initial training for providers on the reporting requirement and State-developed reporting system (one-time). We note that we are not requiring that States update their Medicaid State plans as part of this reporting requirement, and thus we did not estimate a burden associated with State plan amendments.

With regard to this one-time burden for States, we estimate it would take: 40 hours at $111.18/hr. for an administrative services manager to draft new policy describing the State-specific reporting process; 40 hours at $100.64/hr. for a management analyst to update any related provider manuals and other policy guidance; 40 hours at $98.84/hr. for a computer programmer to build, design, and operationalize an electronic system for data collection on the percent of Medicaid payments going to compensation; 30 hours at $67.18/hr. for a training and development specialist to develop and conduct training for providers on the reporting requirement and system; 3 hours at $118.14/hr. for a general and operations manager to review and approve policy updates, provider agreement updates, and training materials; and 1 hour at $236.96/hr. for a chief executive to review and approve all operations associated with this requirement.

In addition to these activities outlined above, States may also have to update managed care contracts to reflect the new reporting requirement and provide managed care-specific guidance on the reporting requirement. Recent data indicates that 24 States provide at least some long-term services through a managed care delivery system.[95] For the managed care-specific burden, we estimate 10 hours at $111.18/hr. for an administrative services manager to draft updates to managed care plan (that is, MCO and/or PIHP) contracts. (We anticipate that all other State activities associated with managed care plans would be reflected in the activities described previously in this section.)

In aggregate, we estimate a one-time burden of 6,926 hours [(164 hours × 54 States) + (10 × 24 States)]. We estimate a cost of $811,792 (54 States × [(40 hr. × $111.18) + (40 hr. × $100.64) + (25 hr. × $98.84) + (30 hr. × $67.18) + (3 hr. × $118.14) + (1 hr. × $236.96)]), with an additional $26,683 for managed care-related costs (24 States × [10 hr. × $111.18]). The total cost is estimated at $838,475 ($811,792 + $26,683). Taking into account the Federal contribution to Medicaid administration, the estimated State share of the cost would be $419,237 ($838,475 × 0.50).

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[94] Note that due to waiver under section 1902(j) of the Social Security Act, American Samoa and the Commonwealth of the Northern Marianas Islands are not required to include nursing facility services in their State plans and thus are not included in these estimates. Additionally, no territory currently includes the optional ICF/IID benefit in their State plan.

[95] Data taken from Centers for Medicare & Medicaid Services, ''Managed Long Term Services and Supports (MLTSS) Enrollees,'' available at *https://data.medicaid.gov/dataset/5394bcab-c748-5e4b-af07-b5bf77ed3aa3*.

Table 8: Summary of One-Time Burden for States for the Medicaid Institutional Payment Transparency Reporting Requirements at § 442.43(b)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Draft new policy describing the State-specific reporting process	54	54	Once	40	2,160	111.18	240,149	120,074
Update any related provider manuals and other policy guidance	54	54	Once	40	2,160	100.64	217,382	108,691
Build, design, and operationalize an electronic system for data collection, aggregate, and stratify reporting	54	54	Once	40	2,160	98.84	213,494	106,747
Develop and conduct training for providers on the reporting requirement and system	54	54	Once	30	1.62-	67.18	108,832	54,416
Review and approve policy updates and training materials	54	54	Once	3	162	118.14	19,139	9,569
Review and approve all operations associated with this requirement	54	54	Once	1	54	236.96	12,796	6,398
Draft contract modifications for managed care plans	24	24	Once	10	240	111.18	26,683	13,342
Total	Varies	348	Once	164	6,936	Varies	838,475	419,237

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Ongoing Reporting Requirements and Burden (§ 442.43(b)): States

Under finalized § 442.43(b), we estimate as ongoing burdens that States would: (1) notify and train nursing facility and ICF/IID providers about the annual reporting requirement, including the State-level process for collecting data (ongoing); (2) collect information from providers annually (ongoing); (3) aggregate or stratify data as needed (ongoing); (4) derive percentages for compensation (ongoing); and (5)

develop a report for CMS on an annual basis (ongoing).

With regard to the ongoing burden, we estimate it would take: 8 hours at $67.18/hr. for a training and development specialist to notify and train providers about annual reporting requirement; 2 hours at $100.64 for a management analyst to review and make any needed updates to guidance for nursing facility and ICF/IID services; 6 hours at $98.84/hr. for a computer programmer to collect information from providers, aggregate data as needed, derive percentages for compensation, and develop a report for the State; 2 hours at $118.14/hr. by a general and operations manager to review, verify, and submit the report to CMS; and 1 hour at $236.96/hr. for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate an ongoing burden of 1,026 hours (19 hours × 54 States) at a cost of $97,470 (54 States × [(8 hr. × $67.18) + (2 hr. × $100.64) + (6 hr. × $98.84) + (2 hr. × $118.14) + (1 hr. × $236.96)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $48,735 ($97,470 × 0.50) per year.

Table 9: Summary of Ongoing Burden for States for the Medicaid Institutional Payment Transparency Reporting Requirements at § 442.43(b)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Notify and train providers about annual reporting requirement	54	54	Annually	8	416	67.18	29,022	14,511
Review and make any needed updates to nursing facility and ICF/IID provider guidance and manuals	54	54	Annually	2	108	100.64	10,869	5,435
Collect information from providers; aggregate data as required; derive an overall percentage for compensation; and develop report for State	54	54	Annually	6	312	98.84	32,024	16,012
Review, verify, and submit report to CMS	54	54	Annually	2	104	118.14	12,759	6,380
Review and approve all operations associated with this requirement	54	54	Annually	1	52	236.96	12,796	6,398
Total	54	54	Annually	Varies	1,026	Varies	97,470	48,735

(2) Nursing Facility and ICF/IID Institutional Payment Transparency Reporting Requirements and Burden

The burden associated with this final rule would affect nursing facility and ICF/IID providers in both FFS and managed care systems. We estimate both a one-time and ongoing burden to implement the reporting requirement finalized at § 442.43(b).

To estimate the number of nursing facility and ICF/IID providers that are being impacted by this rule, we used data from the CMS Quality Certification and Oversight Reports (QCOR) system (*qcor.cms.gov*) to identify the total number of Medicaid-certified nursing facilities and ICFs/IID in all States (including Washington, DC) and the three territories that are required to include nursing facility services in their State plan. Data from QCOR indicates that in FY 2022, there were 14,194 freestanding Medicaid-certified nursing facilities (including facilities dually certified for both Medicare and Medicaid, and Medicaid-only facilities). Additionally, in FY 2022, there were 5,713 ICFs/IID. In total, we estimate 19,907 Medicaid-certified nursing facilities and ICFs/IID are impacted by this finalized reporting requirement and may need to provide data to the State on what percentage of their Medicaid reimbursements for nursing facility and ICF/IID services went to direct care worker and support staff compensation.

Under finalized § 442.43(b), we anticipate that nursing facilities and ICFs/IID would need to: (1) learn the State-specific reporting policies and process (one-time); (2) calculate compensation for each direct care worker and support staff if they do not

already have that information readily available (one-time); and (3) build, design and operationalize an internal system for developing the report for the State (one-time).

One-Time Reporting Requirements and Burden (§ 442.43(b)): Nursing Facility and ICF/IID Providers

With regard to the one-time burden for providers, we estimate it would take: 10 hours at $73.00/hr. for a compensation, benefits, and job analysis specialist to learn the State-specific reporting policy and calculate compensation for each direct care worker and support staff; 10 hours at $98.84/hr. for a computer programmer to build, design, and operationalize an internal system for developing the report for the State; and 1 hour at $118.14/hr. for a general and operations manager to review and approve the reporting system. In aggregate, we estimate a one-time burden of 418,047 hours (19,907 facilities × 21 hours) at a cost of $36,560,002 (19,907 providers × [(10 hr. × $73.00) + (10 hr. × $98.84) + (1 hr. × $118.14)].

Table 10: Summary of One-Time Burden for Nursing Facilities and ICFs/IID for the Medicaid Institutional Payment Transparency Reporting Requirements at § 442.43(b)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Learn State-specific reporting policy; calculate compensation for each direct care worker and support staff	19,907	19,907	Once	10	199,070	73.00	14,532,110	n/a
Build, design, and operationalize an internal system for developing the report for the State	19,907	19,907	Once	10	199,070	98.84	19,676,079	n/a
Review and approve reporting system	19,907	19,907	Once	1	19,907	118.14	2,351,813	n/a
Total	19,907	59,721	Once	Varies	418,047	varies	36,560,002	n/a

Ongoing Reporting Requirements and Burden (§ 442.43(b)): Nursing Facility and ICF/IID Providers

With regard to the ongoing burden, we anticipate nursing facilities and ICFs/IID will have to: (1) update compensation calculations to account for on-going staffing changes among direct care workers and support staff (in other words, ensure their system includes newly hired direct care workers or support staff and takes into account staff departures); (2) calculate the aggregated compensation of direct care workers and support staff as a percentage of their annual Medicaid claims (ongoing); and (3) report the information to the State annually (ongoing).

We estimate it would take 8 hours at $73.00/hr. for a compensation, benefits, and job analysis specialist to update compensation calculations to account for staffing changes; 2 hours at $98.84/hr. for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 1 hour at $118.14/hr. for a general and operations manager to review, approve, and submit the report to the State. In aggregate, we estimate an on-going burden of 218,977 hours (19,907 providers × 11 hours) at a cost of $17,912,717 (19,907 facilities × [(8 hr. × $73.00) + (2 hr. × $98.84) + (1 hr. × $118.14)].

Table 11: Summary of Ongoing Burden for Nursing Facility and ICFs/IID for the Medicaid Institutional Payment Transparency Reporting Requirements at § 442.43(b)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Account for staffing changes among employees and contracted employees	19,907	19,907	Annually	8	159,256	73.00	11,625,688	n/a
Calculate compensation, aggregate data, and report to the State	19,907	19,907	Annually	2	39,814	98.84	3,935,216	n/a
Review, approve, submit report to the State	19,907	19,907	Annually	1	19,907	118.14	2,351,813	n/a
Total	19,907	59,721	Annually	Varies	218,977	varies	17,912,717	n/a

b. State Website Posting Requirements and Burden (§ 442.43(d))

At § 442.43(d), we are finalizing the requirement for States to operate a website that meets the availability and accessibility requirements at 42 CFR 435.905(b) and that provides the results of the finalized reporting requirements in § 442.43(b). We also are finalizing at § 442.43(d) that States must verify, no less than quarterly, the accurate function of the website and the timeliness of the information and links.

As noted previously, we anticipate that this provision will affect all 51 States (including Washington, DC) and the territories required to have nursing facility services in their State plans which we refer to collectively as ''States.'' We estimate both a one-time and ongoing burden to implement these requirements at the State level, which would be the same regardless of whether the State offers nursing facility and ICF/IID services through FFS or managed care systems. In developing our burden estimate, we assumed that States would provide the data and information that States are required to report under newly proposed § 442.43(d) by adding to an existing website, rather than developing an entirely new website to meet this requirement. We note that we are not requiring that States update their Medicaid State plans as part of this reporting requirement and are not estimating a burden associated with State plan amendments.

One Time Website Posting Requirements and Burden (§ 442.43(d)): States

With regard to the one-time burden, based on the website requirements, we estimate it would take: 10 hours at $111.18/hr. for an administrative services manager to determine the content of the website; 30 hours at $98.84/hr. for a computer programmer to develop the website; 1 hour at $118.14/hr. for a general and operations manager to review and approve the website; and 1 hour at $236.96/hr. for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 2,268 hours (54 States × 42 hours) at a cost of $239,333 (54 States × [(10 hr. × $111.18) + (30 hr. × $98.84) + (1 hr. × $118.14) + (1 hr. × $236.96)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $119,667 ($239,333 × 0.50) per year.

Table 12: Summary of the One-Time Burden for States for the Website Posting Requirements at § 442.43(f)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)/year
Determine content of website	54	54	Once	10	540	111.18	60,037	30,019
Develop website	54	54	Once	30	1,620	98.84	160,121	80,060
Review and approve the website at the management level	54	54	Once	1	54	118.14	6,380	3,190
Review and approve the website at the executive level	54	54	Once	1	54	236.96	12,796	6,398
Total	54	216	Once	Varies	2,268	Varies	239,333	119,667

Ongoing Website Posting Requirements and Burden (§ 442.43(d)): States

With regard to the States' ongoing burden related to the website requirement, per quarter we estimate it would take: 2 hours at $111.18/hr. for an administrative services manager to provide any updated data and information for posting and to verify the accuracy of the website; 8 hours at $98.84/hr. for a computer programmer to make any needed updates to the website; 1 hour at $118.14/hr. for a general and operations manager to review and approve the website; and 1 hour at $236.96/hr. for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 2,592 hours (12 hours × 54 States × 4 quarters) at a cost of $295,527 (54 States × 4 quarters × [(2 hr. × $111.18) + (8 hr. × $98.84) + (1 hr. × $118.14) + (1 hr. × $236.96)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $147,764 ($295,527 × 0.50) per year.

Table 13: Summary of the Ongoing Burden for States for the Website Posting Requirements at § 442.43(f)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr.)	Total Time (hr.)	Wage ($/hr.)	Total Cost ($)	State Share ($)
Provide updated data and information for posting and verify the accuracy of the website	54	216	Quarterly	2	432	111.18	48,030	24,015
Update website	54	216	Quarterly	8	1,728	98.84	170,796	85,398
Review and approve website at the management level	54	216	Quarterly	1	216	118.14	25,518	12,759
Review and approve website at the executive level	54	216	Quarterly	1	216	236.96	51,183	25,592
Total	54	864	Quarterly	Varies	2,592	Varies	295,527	147,763

4. Burden Estimate Summary

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Table 14: Summary of Annual Burden Estimates

Regulation Section(s)/ICR Provision	Number of Respondents	Number of Responses	Time per Response (hrs.)	Total Time (hr.)	Hourly Labor Rate ($/hr.)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§ 442.43(b) One-Time Burden to States (Table 8) (Payment Transparency Reporting)	Varies	348	Varies	6,936	Varies	838,475	419,237	0
§ 442.43(b) Ongoing Burden to States (Table 9) (Payment Transparency Reporting - Annual)	54	270	Varies	1,026	Varies	97,470	48,735	0
§ 442.43(b) One-Time Burden to Providers (Table 10) (Payment Transparency Reporting)	19,907	59,721	Varies	418,047	Varies	36,560,002	n/a	0
§ 442.43(b) Ongoing Burden to Providers (Table 11) (Payment Transparency Reporting - Annual)	19,907	59,721	Varies	218,977	Varies	17,912,717	n/a	0
§ 442.43(f) One-Time Burden to States (Table 12) (Website Posting)	54	216	Varies	2,268	Varies	239,333	119,667	0
§ 442.43(f) Ongoing Burden to States (Table 13) (Website Posting - Quarterly)	54	864	Varies	2,592	Varies	295,527	147,764	0
TOTAL	Varies	121,140	Varies	649,306	Varies	55,943,524	735,403	0

VI. Regulatory Impact Analysis

A. Statement of Need

1. Minimum Nurse Staffing

With respect to the requirements for minimum nurse staffing in LTC facilities, sections 1819 and 1919 of the Act authorize the Secretary to issue requirements for participation in Medicare and Medicaid, including such regulations as may be necessary to protect the health and safety of residents (sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act). Such regulations are codified in the implementing regulations at 42 CFR part 483, subpart B.

Approximately 1.2 million Americans are residents in LTC facilities each day with Medicare and Medicaid serving as the payor for most residents.[96] As we discussed in detail in detail in sections II. and III, a large body of quantitative and qualitative research suggests that adequate nurse staffing is vital for ensuring residents' health and safety. More specifically, there is a positive association between the number of hours of care that a resident receives each day and resident health and safety.[97] [98] [99] Research also suggests that there is a relationship between inadequate staffing and nursing staff burnout, which can lead to high employee turnover.[100] High employee turnover, in turn, can lead to lower continuity of resident care.

During our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we have observed that all these interested parties routinely express the concern that chronic understaffing in LTC facilities is making it difficult for residents to receive high quality care. Low quality care also has a negative impact on the Medicare and Medicaid programs, leading to higher spending due to more hospitalizations and unplanned Emergency Department visits.[101] [102] [103] The available evidence suggests that various types of requirements for LTC facility staff could increase the quality of care in LTC facilities. We also recognize, however, that staffing in the long-term care sector is still recovering from the COVID–19 pandemic that saw a large number of employees leave the sector, leading to concerns about resident access to care. In response to these concerns, and after evaluating a wide range of research and stakeholder feedback, we are finalizing a 24/7 on-site RN requirement, minimum RN and NA HPRD requirements, and a total nurse staffing requirement or 3.48 HPRD, all of which aim to increase resident safety and quality of care while preserving resident access to care.

Specifically, we are requiring that LTC facilities provide RN coverage onsite 24 hours per day, 7 days a week (24/7 RN). In addition, we are requiring that they provide a minimum of 0.55 RN and 2.45 NA HPRD, and 3.48 total nurse staff HPRD. While the 0.55 RN HPRD, 2.45 NA HPRD, and 3.48 total nurse staff HPRD standards were developed using case-mix adjusted data sources, the standards themselves will be implemented and enforced independent of a facility's case-mix. In other words, facilities must meet the 0.55 RN, 2.45 NA, and 3.48 total nurse staff HPRD standards, regardless of the individual facility's patient case-mix. Requiring 24/7 RN and a minimum number of hours of care for each resident will help protect resident health and safety by ensuring that all facilities provide a minimal level of staff care to address residents' health and safety needs. These standards reflect only the minimum level of staffing required and all LTC facilities must provide adequate staffing to meet their specific population's needs based on their facility assessments. In many cases, facilities will need higher levels of staffing as a result.

2. Medicaid Institutional Payment Transparency Reporting

In response to concerns about the chronic understaffing and low wages for the institutional workforce (discussed in detail in our proposed rule at 88 FR 61398 and 61399), we proposed new Federal reporting requirements that are intended to promote public transparency. States have a statutory obligation under section 1902(a)(30)(A) of the Act and the quality requirements in section 1932(c) of the Act for services furnished through managed care organizations (MCOs) (as well as for prepaid inpatient health plans (PIHPs), under our authority at section 1902(a)(4)), to make Medicaid payments that are sufficient to enlist enough providers so that high-quality LTSS are available to the beneficiaries who want and require such care. We also relied on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

As discussed in section III. of this final rule, we are finalizing (with some modifications) our proposal to require that State Medicaid agencies report annually, at the facility level, on the portion of payments to nursing facility and ICF/IID services that are spent on compensation for the direct care and support staff workforce.[104] We also proposed, and are finalizing, that States make this information available to the public by posting the information on a website. As discussed in the proposed rule at 88 FR 61399, we developed the requirement to focus on compensation because many direct care workers and support staff earn low wages and receive limited benefits.[105] Evidence suggests that there is a connection between wages and high rates of turnover among

[96] *https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/cms-program-statistics-medicare-skilled-nursing-facility.*

[97] Ochieng, N., Chidambaram, P., Musumeci, M. Nursing Facility Staffing Shortages During the COVID–19 Pandemic. Apr 04, 2022. Kaiser Family Foundation. Accessed at *https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staffing-shortages-during-the-covid-19-pandemic/.*

[98] Harrington, C., Carrillo, H., Garfield, R., Squires, E. Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016. Apr 03, 2018. Kaiser Family Foundation. Accessed at *https://www.kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2016-staffing-levels/.*

[99] Min A, Hong HC. Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A Cross-sectional study using the U.S. Nursing Home Compare database. Geriatr Nurs. 2019 Mar-Apr;40(2):160–165. doi: 10.1016/j.gerinurse.2018.09.010. Epub 2018 Oct 4. PMID: 30292528.

[100] Kelly LA, Gee PM, Butler RJ. Impact of nurse burnout on organizational and position turnover. Nurs Outlook. 2021 Jan-Feb;69(1):96–102. doi: 10.1016/j.outlook.2020.06.008. Epub 2020 Oct 4. PMID: 33023759; PMCID: PMC7532952.

[101] Ochieng, N., Chidambaram, P., Musumeci, M. Nursing Facility Staffing Shortages During the COVID–19 Pandemic. Apr 04, 2022. Kaiser Family Foundation. Accessed at *https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staffing-shortages-during-the-covid-19-pandemic/.*

[102] Harrington, C., Carrillo, H., Garfield, R., Squires, E. Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016. Apr 03, 2018. Kaiser Family Foundation. Accessed at *https://www.kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2016-staffing-levels/.*

[103] Min A, Hong HC. Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A Cross-sectional study using the U.S. Nursing Home Compare database. Geriatr Nurs. 2019 Mar-Apr;40(2):160–165. doi: 10.1016/j.gerinurse.2018.09.010. Epub 2018 Oct 4. PMID: 30292528.

[104] Throughout this discussion, we use the term ''States'' to include all States, Washington, DC, and any territories that include nursing facility services or ICF/IID services in their State plan.

[105] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

some workers in the institutional workforce.[106] To develop relevant policies to support high quality care for Medicaid beneficiaries, we first need clear, consistent data from States and facilities about the current percent of Medicaid payments going to the compensation of direct care workers and support staff. Data regarding the percent of Medicaid payments going to compensation of direct care workers and support staff are not currently being reported to CMS.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Public Law 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for regulatory actions with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking.

For this final rule, we have calculated the annual cost of the minimum staffing requirements in table 22 based on hours per resident day in CY 2021 dollars, assuming the implementation and enforcement of these hours per resident day requirements as being applied independent of a facility's case-mix. We estimate that the aggregate impact of the staffing-related provisions in this rule, which includes a phased-in implementation of the requirement for 24 hours per day, 7 days per week RN onsite coverage, the 0.55 RN and 2.45 NA minimum HPRD requirements, and the 3.48 HPRD total nurse staff requirement will result in an estimated cost of approximately $53 million in year 1, $1.43 billion in year 2, $4.38 billion in year 3, with costs increasing to $5.76 billion by year 10. We estimate the total cost over 10 years will be $43.0 billion with an average annual cost of $4.30 billion.

There is uncertainty about the degree to which LTC facilities would bear the cost of meeting the minimum staffing and 24/7 RN requirements and how much of the costs would be passed onto payors (including Medicaid, Medicare, private insurers, and nursing facility residents). We expect LTC facilities would generally have 3 possible approaches to addressing the increased costs associated with the higher staffing levels: (1) reduce their margin or profit; (2) reduce other operational costs; and (3) increase prices charged to payors. LTC facilities may use some combination of these approaches, and those approaches could vary by facility and over time. These decisions could depend on a number of factors, including: the current margin levels of a facility; the cost increase due to the staffing requirements relative to current costs and revenues; the current level of operational costs; and the ability to negotiate prices with payors.

With regards to payors, we have facility level data on the percentage of resident days paid for by Medicaid, Medicare, and other payors for the estimates in this RIA. We used these data to estimate the potential share of costs for each payor by weighting each facility's increased costs by the percentage of resident days paid for by each payor type. As we show in table 23, the potential Medicaid share of costs excluding collection of information costs is 67 percent—that is, if all of the costs of the staffing requirements were passed on to payors, Medicaid could be expected to pay about two-thirds of the total costs. Similarly, as we show in table 24, the potential Medicare share of costs is approximately 11 percent of the total costs, with other payors potentially bearing the other 22 percent of the total costs. As we note in our analysis below, however, our cost estimates assume that LTC facilities and not payors will bear the rule's costs.

Additionally, we have estimated in table 21 the economic impact of the requirement that States report, by facility and by delivery system (if applicable), on the percentage of Medicaid payments being spent on compensation for direct care workers and support staff delivering Medicaid-covered nursing facility and ICF/IID services. Under this final rule the requirements become effective in 4 years. We estimate an initial implementation cost of $9,355,472 for years 1 to 4 (resulting in total initial implementation costs of $37,421,888) and ongoing annual costs of $18,305,713 per year starting in year 5.

In response to the proposed rule (88 FR 61352–61429), we received approximately 46,520 total comments, of which more than 16,000 included comments related to the content of the regulatory impact analysis related to the minimum staffing standards. Commenters included numerous individuals who were LTC residents/families/caregivers/staff, industry, national advocates, national professional organizations, labor unions, and academic researchers. In this final rule, we provide a summary of the public comments received and our responses to them, including relevant changes in the RIA methodology and estimate.

Comment: Many commenters expressed concern about the cost estimates and the estimates of the number of employees that facilities would need to hire to meet the proposed requirements, as well as the assumptions underlying these estimates. Some commenters stated CMS overestimated the cost of implementing the requirements since it assumed that nursing homes will retain LPNs/LVNs when the commenters expect that nursing homes will actually lay off

[106] Sharma, H. and Liu, X. Association between wages and nursing staff turnover in Iowa. Innov Aging. 2022; 6(4): igac004. Published online 2022 Feb 5. doi: *10.1093/geroni/igac004.*

LPNs/LVNs and replace them with lower paid NAs to meet the 2.45 NA HPRD requirement, significantly reducing this requirement's cost. They also suggested that the cost of meeting the 24/7 RN and 0.55 RN HPRD requirements would be much lower than estimated since nursing homes would similarly lay off LPNs/LVNs and replace them with RNs, rather than maintaining LPN/LVNs at current level. These commenters noted that the rule's requirement would cost only a small portion of the industry's revenues and suggested that CMS should implement an even a higher minimum staffing standard of 4.2 HPRD, with one outside study showing a 4.2 HPRD requirement including 0.75 RN HPRD, 1.4 license nurse HPRD, and 2.8 NA HPRD, would cost $7.25 billion annually.

Other commenters stated that CMS underestimated the costs for the requirements in the proposed rule and the number of nurse staff necessary to meet the requirements. Several commenters cited high growth in staff costs for the individual facilities in which they work or manage over the past few years, especially during the public health emergency (PHE). Commenters stated that Medicare and Medicaid reimbursement rates have not kept pace with rising costs. Other commenters suggested that CMS consider including the cost of using agency/contract staff in the impact analysis and consider not increasing staffing minimums but rather mandating the wages that staffing agencies can charge so that nursing homes are able to succeed financially. Other commenters stated that CMS used wage labor data from 2019 that is no longer current to what facilities are paying and that assuming a 2.31 percent increase in real wage rates was underestimating future wage increases.

Other commenters cited individual analyses they had done of staffing and cost data, which showed different costs than we estimated with estimates ranging from $4 billion to $7.1 billion annually. Many commenters cited an analysis of the proposed rule done by CliftonLarsonAllen (CLA), which estimated that the proposed 24/7 RN requirement, 0.55 RN HPRD requirement, and the 2.45 NA HPRD requirement would cost a total cost of $6.8 billion annually, even with exclusion of increases in real wage rates and higher wage rates for contract employees. This analysis also estimated that more RNs and NAs would need to be hired than what our analysis estimated. A large number of commenters also cited an analysis done by Leading Age, which estimated a total cost of $7.1 billion annually.

One commenter indicated that they had been involved with creating the Leading Age cost estimate and, writing in a personal capacity, noted that a central reason for the difference in costs was due to growth in wage rates from 2021 to 2023 and that this $7.1 billion cost estimate is based on daily rather than quarterly nurse staffing data from the Payroll Based Journal (PBJ). This commenter also stated that CMS cost estimates failed to include a provider-based adjustment to account for the use of contract staff and that our estimated wage growth of 2.31 percent was too low. They suggested using more recent Medicare cost data and other wage source data and highlighted the need for a SNF-specific wage index based on audited cost reports. Finally, they noted that the cost estimate excludes some nursing homes where cost or staffing data were unavailable, including nursing homes in Guam and Puerto Rico, leading to an underestimation of the actual cost. Other commenters stated that the CMS analysis assumed no costs for facilities prior to each requirement going into effect and ignored the potential impact of these costs on Medicare, Medicaid, and non-Medicare/Medicaid payors.

Response: We appreciate the commenters sharing their insights into the costs that their facilities have accrued to hire staff in recent years, as well as the comments highlighting how using differing data sources, such as contract nursing wage rates, and assumptions, such as using daily rather than quarterly nurse staffing data from the PBJ, influence the estimated cost and the number of employees facilities would need to hire.

We appreciate the commenters sharing their various hiring practices and information about their costs for hiring nurse staff in recent years. As we highlighted in the proposed rule through various breakdowns of the data by state, facility size, geographical location (rural vs. urban), and whether the facility is certified by Medicare, Medicaid, or dual certified, the cost for facilities to meet the 24/7 RN and HPRD requirements varies.

We also appreciate the commenters referring us to the CLA and Leading Age analyses showing an estimated $6.8 billion and $7.1 billion annual cost, respectively, when the rule is fully in effect and providing a copy of these analyses. In reviewing these alternative cost estimates, we have identified key differences between our estimation strategy and these estimation strategies that appear to have led to differing estimates and we provide additional information regarding why we have decided to retain our estimation strategy and model assumptions.

CLA's $6.8 billion cost estimate indicates that it calculates the rule's cost using the median, or the wage rate including salaries and allocated benefits for the single employee who earns middle wage rate, for each staff type from Medicare cost reports released as of July 2023 using form S–3, Part V, column 5. We would note, however, that column 5 contains the loaded mean, or average wage rate including allocated benefits for the employee type. For example, for NAs, it contains the average loaded salaries for all NAs that the facility employs. In light of this inconsistency, we are unsure how this outside analysis calculated median wage rate using Medicare cost reports. Calculating the median hourly wage rate for each nurse staff type requires obtaining wage data on every NA, LPN/LVN, and RN in every facility, or alternatively, having each of the more 14,000 nursing homes share the data for the RN, LPN/LVN, and NA in their facility who earns the middle wage among all RNs, LPNs/LVNs, and NAs they employ. We do not have these data and do not know of a source that provides it. As such, we continue to use the loaded mean hourly wage to calculate costs for the final rule.

In reviewing the $6.8 billion estimate, the provided documentation indicates that it is based on wage rates only for employees. In contrast, our estimate, as well as the Leading Age estimate, calculates costs based on average hourly wage rates for employees and contractors. Calculating costs based only on employee wages requires an assumption that hours that contract employees are currently working would not count toward the minimum requirements and lead to facilities needing to hire more staff to meet the requirement. This assumption leads to a higher cost for meeting the requirements. We would note, however, that all hours worked by both employees and contract staff count toward the requirements we are finalizing. In addition, including costs for both employees and contract staff provides a more accurate picture of the average hourly wage that each facility is paying to their nurse staff. As a result, in this final rule, we are maintaining the inclusion of all nursing hours worked by employees and contract staff to calculate additional employees needed and continue to use overall average hourly rates to calculate the cost.

The CLA estimate indicates that the $6.8 billion cost was calculated based

on a combination of 2021 and 2022 Medicare cost reports, without specifying the share of reports that come from each fiscal year. Our analyses and all costs are measured in FY 2021 US dollars and costs each year are provided in real 2021 US dollars rather than nominal dollars. Adjusting for general inflation, $6.8 billion in 2022 Dollars is approximately $6.3 billion in 2021 US dollars.[107] For Leading Age's $7.1 billion annual estimate, the authors indicate that it is based on 2023 US dollars, which they calculate by increasing costs from the 2021 cost reports by 13 percent to account for inflation. In 2021 US dollars this would similarly be $6.3 billion.

In reviewing the CLA's $6.8 billion estimate, the authors indicated that using Q1 2023 PBJ data, nearly 80 percent of nursing homes would need to hire staff to meet the 24/7 RN requirement based on daily data. Our review of Nursing Home Care Compare data from March 2023, however, shows that for the facilities for which RN hours per day data are available, only 24.5 percent of facilities, or 3,578 facilities, would need to hire RNs using the following formula: Total RN Hours per Resident Day = Reported RN Staffing Hours per Resident Day × Average Number of Residents per Day. The same analysis of Nursing Home Care Compare data from January 2024 similarly shows that only 22.1 percent, or 3,202 facilities would need to hire RNs to meet this requirement. For Leading Age's $7.1 billion cost estimate, one commenter, writing in a personal capacity, indicated that they were involved in calculating this estimate and that the higher cost came by analyzing daily, rather than quarterly, data from the PBJ. While there may be days within a particular quarter where a nursing home that meets the requirements overall based on quarterly data did not meet it on an individual day, we estimate that they would reallocate their existing staffing resources to ensure compliance with the rule on a continual basis and to reflect resident census changes. As such, we disagree with the estimate that nearly 80 percent of nursing homes would need to hire staff to meet the 24/7 RN requirement. Our analysis estimates that only 22.2 percent of nursing homes would need to hire staff to meet the 24/7 RN requirement. We also assume that they would reallocate staff hours during the week to meet the 0.55 RN, 2.45 NA, and 3.48 total nurse staff HPRD requirements.

We appreciate the comment about adjusting the cost based on the share of contract staff that a facility uses and taking into consideration the need to use contract staff to meet the requirements. We also appreciate the comment about taking into account facilities for which there are no salary or staffing data. As we have noted above, all cost estimates calculate facility wage rates for each nurse type based on wages for both employee and contract staff in each nurse (RNs, LPNs/LVNs, and NAs) type. With regards to missing facilities, we note that our analysis includes data from all available facilities where there was staffing information available in the October 2021 Nursing Home Compare dataset. This included 14,688 facilities out of 15,270 facilities, or approximately 96.1 percent (14,688/15,270). We believe, therefore, that the cost estimate would remain similar even if these additional nursing homes, for which staffing data were unavailable, were included in the analysis. We are, however, adding additional language in the detailed economic analysis below to clarify that wages are based on costs for both contract staff as well as employees, as well as to clarify how we imputed any missing data.

We appreciate the commenters feedback on expected increase in wage rates for nurse staff. We note that all cost estimates are provided in 2021 US dollars and the growth in wage rates we use, are real wage rate growth. That is, the estimates take into account annual inflation and assume that wages are meaningfully increasing above inflation. Over 10 years, we are estimating a nearly 23 percent increase in real wage rates. We note that between 2001 and 2017, a 16-year period, real wage rates for nurses increased by only 9.92 percent.[108] Reviewing Bureau of Labor Statistics data for more recent years also suggests that our estimated increase is reasonable. Between 2019 and 2022, average hourly nominal wages for NAs increased from $14.77 to $17.41, or 17.8 percent, while average hourly nominal wages for RNs increased from $37.24 to $42.80, or 7.6 percent. Taking into account inflation, however, real wages increased by approximately 3 percent for NAs and declined by 0.37 percent for RNs. As such, we believe that our estimate of a 23 percent increase in real wage rates for nurse staff in 10 years does not underestimate growth in wage rates and we maintained this wage rate increase as cited in the proposed rule. In addition, we continue to use cost data from 2021 Medicare cost reports since our analysis provides all costs in 2021 US dollars addressing concerns that more recent wage data would provide a higher cost estimate in 2021 US dollars.

We appreciate the opportunity to provide clarification regarding costs that facilities may incur to hire staff prior to each requirement's effective date since facilities will likely start hiring staff to meet the requirements before the effective date. In the proposed rule, as well as this final rule, the cost estimates for each requirement includes costs that facilities may incur in the year before each requirement going into effect as they hire employees in anticipation of the requirement. For example, in the proposed rule, we proposed that for facilities located in urban areas, the 24/7 RN requirement would go into effect 2 years after the date of publication. This means that these facilities would be required to meet the requirement starting 2 years, or 24 months, from the date of publication. In the cost analysis, both in the proposed rule, as well as this final rule, however, we included costs for facilities to meet the 24/7 RN requirement during all of year 2 (12–24 months) after the date of publication, or 1 year before the requirement went into effect. We included costs for facilities prior to the requirement date to acknowledge that facilities will likely need to hire RNs for this requirement before 2 years after the date of publication, rather than instantaneously hiring them 2 years after the date of publication. We appreciate the commenter bringing this issue to our attention and have provided this clarification below in the detailed economic analysis.

Finally, we acknowledge that costs could in theory be much lower than we estimated if, as suggested by some commenters, facilities transitioned away from LPNs/LVNs when hiring nurses to meet the proposed requirements. We would note, however, that there are transition costs of hiring and firing that have not been quantified. We would also note that facilities have the option to use any nurse staff type, including LPNs/LVNs, to meet the 3.48 total nurse staff HPRD requirement included in the final rule, which would reduce any incentive to transition from LPNs/LVNs to NAs and our intent is for facilities already meeting the minimum staffing requirements not to scale down or adjust staffing types as a result of this rule. As such, we believe that there is a low likelihood that facilities will

[107] Federal Reserve Bank of Minneapolis. Inflation Calculator. Accessed February 26, 2024. *https://www.minneapolisfed.org/about-us/monetary-policy/inflation-calculator.*

[108] Barry J. Real wage growth in the U.S. health workforce and the narrowing of the gender pay gap. Human Resources for Health. 2021;19: 105. doi: 10.1186/s12960–021–00647–3.

transition away from LPNs/LVNs to meet the requirements in this rule and of course, expect that facilities will not lay off staff necessary to serve patients with their existing case mix. We do not believe that we could accurately predict facility behaviors with respect to LPNs/LVNs. Due to the role that LPNs/LVNs can play in meeting the 3.48 HPRD requirement and the related reduced likelihood of nursing homes ending employment of LPNs/LVNs in light of this policy change, it would understate the effects of the final rule to attempt to reduce overestimation of effects of the rule as proposed and thus we have decided to retain our assumption that facilities will retain LPNs/LVNs at their current level. Given these factors, we are retaining our estimation methodology as we believe it provides an accurate estimate of the rule's estimated economic cost. We would note, however, that we have modified the formula to estimate the cost over 10 years since in the proposed rule the cost estimate provided for the alternative policies that we are now finalizing was based on the 3.48 HPRD requirement going into effect the same time as the 0.55 RN HPRD and 2.45 NA HPRD requirements. Since this final rule requires facilities located in urban areas to meet the 3.48 HPRD requirement 2 years following publication of this rule, which is 1 year prior to the implementation date of the 0.55 RN HPRD and 2.45 NA HPRD requirements, and for rural facilities to meet the 3.48 HPRD requirement 2 years prior to the implementation date of the 0.55 RN and 2.45 NA HPRD requirements, we modified the formula to take into account that nurse staff hired to meet the 3.48 total nurse HPRD requirement can also count toward meeting the individual NA requirement that will be implemented in future years. We detail these changes below in the detailed economic analysis section.

Comment: Multiple commenters provided feedback on other effects apart from increased costs and the need to hire new nurse staff that would emerge from the staffing requirements. Some commenters said that nursing homes may lay off non-nurse staff members and cut resident activities, such as bingo night, which contribute to patients' quality of life, to fund the requirements since nursing homes are already struggling financially with the rising costs of inflation, food, insurance, and an already increased payroll. One commenter stated that the rule may also increase operating expenses more generally. Other commenters expressed concern that without additional Medicare and Medicaid funding, which varies by state, the rule could result in access to care issues, especially in rural and underserved communities. Specifically, commenters noted that the staffing requirements' costs could lead some facilities to close and other facilities to limit the numbers of residents they admit due to insufficient nurse staff to accept more residents. Commenters stated that this effect would likely be higher for nursing homes with a larger share of residents utilizing Medicaid, which are more likely to need to hire staff to meet one or more of the requirements, as well as nursing homes in rural areas that may have difficulty attracting nurse staff or contract employees. Commenters noted that for some rural communities, the closure of facilities could have far reaching impacts on the community leading individuals to leave or forcing nurse home employees to commute long distance to other cities for work, negatively impact the local economy and community life. Commenters suggested analyzing potential bed losses due to the rule, which in turn, could have adverse effects on hospitals who would be unable to discharge patients, leaving them with less space for new patients and increasing the government's cost for patients whose care was covered by Medicare or Medicaid. Commenters also suggested it could have a negative impact on other health care facilities, such as inpatient rehabilitation facilities, which could see greater struggles to find nursing home bed space for their patients. Commenters noted that facility closures could lead residents to be placed further away from the families negatively impacting their overall well-being, or alternatively, nursing homes could pass on the cost to consumers reducing consumers' savings and leading them to use Medicaid. Commenters also suggested that nursing homes may stop accepting patients using Medicaid due to low reimbursement rates, negatively impacting patients who utilize Medicaid.

Other commenters challenged the idea that the rule will be a burden for facilities. They stated that many facilities are diverting funds away from resident care and toward corporate profits. As such, commenters suggested that CMS should not assume that facilities will have challenges meeting the staffing standard and additional actions should be taken to create transparency regarding facility spending. Some commenters expressed concern that phasing-in the nurse staffing requirements would negatively impact patients and staff members, specifically that phasing-in the requirements means a delay in improved quality of care for residents negatively affecting their health, safety, and quality of life. Commenters also suggested that low staffing levels will lead to continued employee burnout, making them more likely to quit resulting in increased difficulty for facilities to meet the requirements. Finally, multiple commenters noted that the rule does not include increased Medicare or Medicaid reimbursement rates for nursing home residents and that current reimbursement rates have not kept pace with rising costs in recent years. These commenters said that Medicaid reimbursement rates should be increased to ensure access to care and to pay staff a wage that can support a family. Other commenters noted that there is wide variation in Medicaid reimbursement rates across states and asked CMS to consider how this variation will impact facilities' ability to meet the requirements. Finally, some commenters said that they would be forced to hire agency staff at an inflated cost with no guarantee of quality care or positive patient outcomes.

Response: We appreciate the thoughtful and insightful comments regarding additional effects that could emerge from the staffing rule. CMS requires facilities to provide appropriate staffing and extracurricular activities to ensure the highest quality of care for residents in accordance with resident assessment, care plans, and resident preferences (see existing requirements at § 483.24(c)). In developing this rule, we sought to ensure resident health and safety while also maintaining access to care. While CMS agrees with commenters highlighting that phasing-in the requirements could lead to a delay in residents receiving higher quality care, as well as continued staff burnout, these effects are difficult to quantify and must be balanced with challenges associated with more rapid implementation of these requirements. As such, we have maintained our regulatory approach that phases in the different staffing requirements over 5 years.

Taken broadly, access to care comments addressed two main issues: finding sufficient staff and the cost for hiring staff. According to the U.S. Bureau of Labor Statistics, in 2022 there were 3,072,700 RNs in the United States.[109] As finalized, the rule would

[109] U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2022: 29–1141 Registered Nurses. Accessed February 26, 2024. *https://www.bls.gov/oes/current/oes291141.html.*

require the hiring of approximately 16,000 RNs to meet both the 24/7 RN requirement and the 0.55 RN HPRD requirement. This is approximately 0.5 percent of all non-self-employed RNs in the labor force. HRSA's National Center for Health Workforce Analysis uses a Health Workforce Simulation Model to project the supply and demand for health workers, including RNs.[110] The National Center projects a 10 percent shortage of RN in 2026 and 2031, that will be reduced to 9 percent by 2036.[111] Projected supply adequacy of RNs varies considerably across States, ranging from a shortage of 29 percent in Georgia to a projected 42 percent oversupply in North Dakota in 2036.

Hiring necessary for facilities to meet the NA HPRD requirement will represent a larger portion of NAs available nationwide, and this rule has taken three steps to minimize the impact on access to care and to prevent the closure of facilities due to inadequate staff availability.

The first is to allow facilities located in areas with nurse staff shortages to apply for an exemption from the staffing requirements. Facilities located in areas with nurse staff shortages, as defined in the regulatory text at § 483.35(h), are eligible for exemptions that include: an 8-hour per day exemption from the 24/7 RN requirement, an exemption from the 0.55 RN HPRD requirement, an exemption from the 2.45 NA HPRD requirement, and an exemption from the 3.48 total nurse staff HPRD requirement. These exemptions could reduce both the rule's cost as well as the number of nurse staff needed helping to ensure continued access to care. Based only on being located in an area with nurse staff shortage, a preliminary analysis of the data suggests that more than 29 percent of facilities would be eligible for an 8-hour exemption from the 24/7 RN requirement and the 0.55 RN HPRD requirement, 23 percent of facilities would be eligible for an exemption from the 2.45 NA HPRD requirement, and 22 percent of facilities would be eligible for an exemption from the total nurse staff requirement. Among rural facilities, more than 67 percent of facilities would be eligible for an 8-hour exemption from the 24/7 RN requirement and a total exemption from the 0.55 RN HPRD requirement, 19 percent would be eligible for an exemption from the 2.45 NA HPRD requirement, and 40 percent would be eligible for an exemption from the 3.48 total nurse staff HPRD requirement. Since facilities would also need to meet all other requirements to obtain an exemption, however, these numbers are not reflective of the number of facilities estimated to fully qualify for the exemptions as they only describe the number of facilities that would satisfy the workforce availability criterion. Second, CMS is launching an initiative to provide over $75 million in financial incentives, such as scholarships and tuition reimbursement, to make it easier for nurses to enter careers in nursing homes. CMS is also exploring the potential to provide additional technical assistance to LTC facilities regarding staffing through the Quality Improvement Organizations. Finally, rather than requiring facilities to immediately meet the staffing requirements, we have taken a phased-in approach to the requirements to help ensure that an adequate workforce is available and to reduce the cost. For facilities located in urban areas, the requirements will be phased in over 3 years. Specifically, these facilities will have 2 years to comply with the 3.48 total nurse HPRD and the 24 hours per day, 7 days a week RN requirement and have 3 years to comply with the 0.55 RN and 2.45 NA HPRD requirements. For facilities located in rural areas, requirements will be phased in over 5 years. Specifically, these facilities will have 3 years to comply with the 3.48 total nurse HPRD and the 24 hours per day, 7 days per week RN requirement and will have 5 years to comply with the 0.55 RN and 2.45 NA HPRD requirements. While we view the exemptions and the phasing in of the nurse staff requirements as necessary to ensure access to care, we acknowledge that they do come with negative effects for residents and staff. Specifically, exemptions and phasing in of the individual staffing requirements will result in residents residing in nursing homes, which are not currently meeting these requirements, in receiving either less nurse care or a longer delay in receiving the full hours of care per day. Similarly, nursing home staff may experience a heavier workload, leading to higher burnout. As such, we believe that there will be minimum negative impact on workforce availability throughout the care continuum, minimal impact on nursing home bed availability, and minimal increased costs for Medicare and Medicaid due to hospitals being unable to discharge patients.

We note that Medicare and Medicaid payment rates for nursing home care are outside the scope of this rule. With regards to a SNF-specific wage index, we refer commenters to the text regarding this issue and its feasibility on page 61411 in the proposed rule (88 FR 61410). Specifically, we note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) gave the Secretary the discretion to establish a geographic reclassification procedure specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. To date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. Adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors (MACs), potentially far in excess of those required under the IPPS, given that there are nearly five times as many SNFs as there are IPPS hospitals. We continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, but we do not believe this undertaking is feasible at this time (88 FR 53212).

Finally, while some commenters have questioned whether agency contract staff will increase quality care or positive patient outcomes and said that they may be forced to hire any available staff to meet the requirement, we would note that all nurse staff are required to meet applicable state requirements to be a nurse and are able to have a positive impact on patient health and quality of care. We would continue to encourage facilities to ensure that they are utilizing contract staff in a manner that best improves patient care. In addition, all other requirements governing LTC facilities continue to apply, and we expect facilities to deliver safe and high-quality care to all residents, regardless of the employment arrangement that nursing home use to procure staff.

Comment: A few commenters, including the Small Business Administration's Office of Advocacy, suggested that CMS erroneously certified that the rule will not have a

[110] Department of Health and Human Services, Health Resources and Services Administration, Health Workforce Projections. Available at *https://data.hrsa.gov/topics/health-workforce/workforce-projections.* April 2024.

[111] Nurse Workforce Projections, 2021–2036 (hrsa.gov) *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/nursing-projections-factsheet.pdf.* March 2024.

significant economic impact on a substantial number of small entities and is violating the Regulatory Flexibility Act (RFA), which requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Specifically, commenters pointed to an outside analysis by CLA estimating that the rule's actual annual cost will be closer to $6.8 billion when all requirements are in effect and when compared to revenues for skilled nursing facilities (NAICS 6231) and intellectual and developmental disabilities facilities (NAICS 6232) from the 2017 Economic Census, would exceed the 3 to 5 percent threshold that HHS qualifies as economically significant. They also noted that the CMS should have included other LTC facilities that rely on nurses in the RFA certification. These include residential mental health and substance abuse facilities (NAICS 62322), Continuing Care Retirement Communities and Assisted Living Facilities for the Elderly (NAICS 6233), Continuing Care Retirement Communities (NAICS 623311), Other Residential Care Facilities (NAICS 62399), and Services for the Elderly and Person with Disabilities (NAICS 62412). Finally, they noted that costs should have been analyzed on a per small entity basis to make it easier to understand the rule's true impact.

Response: We appreciate the comments provided. We have discussed in detail in our comment response above regarding our estimated cost, and why we think that our estimate provides a more accurate calculation of the likely cost, and henceforth, are using it as the basis for our conclusion. In summary, the higher estimate from CLA uses median wages for nursing homes, which are not data that are publicly available and do not appear on Medicare cost reports, it does not appear to include hours worked by contract employees in the estimates, and it calculates costs in 2022 US dollars while we calculate costs in 2021 US dollars. Meanwhile, the higher estimate from Leading Age appears to calculate costs based on daily nurse staff levels and assumes that nursing homes would not reassign staff to different days in the week to meet the requirements and provides estimates in 2023 US dollars. We would also note that while one commenter indicated the wages from the CLA estimate were from 2023 when wages were higher, this is not the case. Rather, as the CLA document provided indicates, this $6.8 billion cost estimate is based on a combination of facility wage data from 2021 and 2022. We believe that they confused the Leading Age and CLA estimates.

The rule also includes exemptions for facilities that are located in areas with nurse staff shortages that would allow facilities to receive an 8 hour a day exemption from the 24/7 RN requirement, as well as exemptions from the 0.55 RN HPRD requirement, the 2.45 NA requirement, and the 3.48 total nurse staff HPRD requirement. These exemptions could reduce both the rule's cost as well as the number of staff that will need to be hired and thus help supported continued access to care. Given these changes in the requirements, we maintain our certification that this final rule will not have a significant economic impact on a substantial number of small entities and do not analyze options for regulatory relief of small entities beyond the exemptions we have already finalized in this rule.

With regards to the per facility analysis, we would note that the proposed rule provided multiple per facility cost analyses for facilities needing staff by state that include costs for (1) rural compared to urban facilities, (2) facilities of different sizes (<50 beds, 50 to 100 beds, and >100 beds, and (3) Medicare, Medicaid, and Dual Acceptance Status. We would also note that analyzing the cost on a per facility basis would lead to the same percentage as we have estimated, since costs were calculated based on all facilities.

We appreciate some commenters noting that our estimates of share of revenues were based on 2017 dollars that do not take into account cost increases. Therefore, to more accurately, estimate the estimated costs as a share of revenues, we take into account increases in the Consumer Price Index to more accurately measure annual revenues, which results in annual revenues rising to approximately $179 billion in 2021 US dollars. We also appreciate the suggestion to include other long term care facilities that rely on nurses in the analysis. We believe, however, that the impact on these other facility types would be minimal since the requirements of this rule do not apply to these other facility types. Moreover, we would note that including these additional facility types, with the exception of ''other residential care facilities'' that do not utilize significant amounts of nursing staff, in the analysis would increase total revenues for affected industries to approximately $275 billion in 2021 US dollars, which would not change the analysis that the rule does not have a significant economic impact on a substantial number of small entities.

Comment: A few commenters expressed concern that CMS erroneously certified that the rule did not violate the Unfunded Mandates Reform Act (UMRA) since Tribal governments own nursing homes that this rule would affect.

Response: We recognize that Tribal governments own nursing homes, as do states and local governments. As we have noted in the regulatory impact analysis for the proposed rule, this rule does not require Tribal governments to provide additional financial resources to meet any of the staffing requirements in this rule. As such, we maintain our certification that the rule will not impose new requirements for Tribal governments.

Comment: A few commenters stated that CMS violated Federal law by not engaging in meaningful discussion or consult with Tribes before releasing the proposed regulation that affects tribally operated nursing homes in Indian Country. They indicate that CMS seems to have ignored detailed comments that Tribal leaders and the CMS Tribal Technical Advisory Group (TTAG) submitted in response to CMS' Request for Information last year.

Response: Consistent with the CMS Tribal Consultation Policy, CMS seeks the guidance of Tribal leaders on the delivery of health care for American Indians/Alaska Natives (AI/AN) served by the Marketplace, Medicare, Medicaid, Children's Health Insurance Program, or any other health care program funded by CMS. We believe that we have followed the CMS Tribal Consultation Policy by engaging in meaningful discussions on this regulation that affects tribally-operated nursing homes. CMS reviewed and took into consideration all comments provided in the FY 2023 SNF PPS RFI, including those comments specific to the impact of any staffing rule on Tribal nursing homes. As we outlined in the proposed rule, we held two listening sessions on June 27, 2022, and August 29, 2022, to allow all stakeholders, including those with concerns about the impact that a staffing standard will have on tribally-owned nursing homes, the opportunity to provide feedback on the approach utilized for establishing a minimum staffing standard (88 FR 61364). In addition, we attended the CMS Tribal Technical Advisory Group (TTAG) quarterly meeting on October 18–19, 2023, to provide an overview of the NPRM and respond to questions and comments from the TTAG. We encouraged the TTAG to submit written comments as outlined in the proposed

rule and we have reviewed and considered those comments in issuing this final rule. Consistent with the government-to-government relationship, CMS is available to continue its dialogue with Tribal governments and the CMS TTAG and to provide technical assistance as needed in the implementation of this rule impacting Tribal nursing homes.

Comment: One commenter noted that they believe that this policy has federalism implications and should be subject to applicable federalism requirements since the proposed rule is intended to and would preempt the applicability of any State or local law providing for a maximum staffing level, to the extent that such a State or local maximum staffing level would prohibit a Medicare and Medicaid certified LTC facility from meeting the minimum HPRD ratios and RN coverage levels. They also note that facilities would be required to meet applicable state and Federal staffing laws and that CMS failed to consult with state agencies and other organizations in violation of section 3(b) of Executive Order 13132.

Response: As we noted in the federalism analysis section, to the extent Federal standards exceed State and local law minimum staffing standards, no Federal pre-emption is implicated because facilities complying with Federal law would also be in compliance with State law. We are not aware of any State or local law providing for a maximum staffing level. This final rule, however, is intended to and would preempt the applicability of any State or local law providing for a maximum staffing level, to the extent that such a State or local maximum staffing level would prohibit a Medicare, Medicaid, or dually certified LTC facility from meeting the minimum HPRD requirements and RN coverage levels finalized in this rule or from meeting higher staffing levels required based on the facility assessment provisions finalized in this rule. As we outlined in the proposed rule (88 FR 61364), we held two listening sessions on June 27, 2022, and August 29, 2022, to allow all stakeholders, including state agencies and other organizations to voice their concerns about the impact that a staffing standard, and took into consideration comments provided by state agencies.

C. Detailed Economic Analysis

1. Impacts for LTC Minimum Staff Requirement

a. Nursing Services (§ 483.35)

We are finalizing two changes to the existing requirements for Nursing Services for LTC facilities at § 483.35. We are requiring facilities to provide RN coverage onsite 24 hours per day, 7 days a week and to meet a minimum staffing standard of 0.55 RN, 2.45 NA, and 3.48 HPRD for total nurse staffing. We note that these estimates do not include adjustments for any exemptions that we may provide, which could reduce the rule's cost (including cost associated with potential LTC facility closure or reduction in patient load capacity per facility) and benefits, based on the frequency of exemptions.

(1). RN Onsite 24 Hours a Day, 7 Days a Week (24/7 RN)

To estimate the cost to the industry of full implementation of the requirement that a facility have an RN on site 24 hours a day, 7 days a week (24/7 RN), we first summed the current annual RN salary cost for each facility. We then subtracted this amount from the estimated annual RN salary cost that the facility will incur to meet the new requirement.

To measure the current RN staff cost to the industry, we estimated the total number of RNs currently employed in LTC facilities and their loaded respective labor wages using data from the 2022 Nursing Home Staffing Study, which has information on 14,688 LTC facilities. This study uses the *2021 SNF—Medicare Cost Report* data set to find the total facilities, the total number of reported LTC specific RNs and their loaded mean annual salaries, defined as salary and fringe benefits. Specifically, we calculated mean hourly wages for both employees and agency staff by using Column 3 in Worksheet S–3, Part V and dividing it by the sum of reported paid hours for RNs using data from Column 4 in Worksheet S–3, Part V.[112] For nursing homes with missing or extreme values for hourly wages, we imputed the wage rate based on the state-level weighted hourly wage of non-outlier nursing homes within the state. Using this dataset, we were able to estimate the aggregate RN loaded salary costs and the cost per facility, including the cost for contract RNs.

To estimate the RN cost per resident census, we used the October 2021 *Care Compare* data set that calculates average hours per resident day (HPRD) for RNs using the PBJ System data from 2021 Q2. Hours per resident day is defined as the average hours of RN care that each resident in the facility receives per day. For example, a facility that has an average HPRD of 0.5 for RNs would provide, on average, 0.5 hours (30 minutes) of RN care for each resident. We linked this dataset using the facility unique ID variable with the *2021 SNF—Medicare Cost Report* data set to create a complete dataset. Using this combined dataset, we were also able to view the impact by resident census as well as the impact by LTC facility characteristics such as facility ownership, bed size, Five-Star Quality Rating System staffing ratings, payer mix, and location. This complete dataset helped provide an understanding of which types of LTC facilities would bear the largest cost burden of a new Federal 24/7 RN requirement.

For each facility, we first calculated the total number of hours each day that an RN is on site by multiplying the average RN hours per resident day by the average number of residents in the facility (daily hours of RN care = RN HPRD × Residents in Facility). We then estimated the number of additional hours of RN care that facility would need to meet the 24/7 RN requirement by subtracting the current daily hours of RN care from 24 hours (additional daily RN hours needed = 24 − current daily hours of RN care). We then calculated the total number of additional RN hours needed per year by multiplying this amount by 365 (additional yearly RN hours needed = additional daily RN hours needed × 365). Finally, we estimated each facility's yearly cost for meeting the requirement by multiplying the total number of the yearly hours needed by the loaded hourly wage (yearly 24/7 RN cost = additional yearly RN hours needed × facility RN wage rate).

For example, if a facility had an average of 0.4 RN HPRD and had 50 residents it would provide 20 hours of total RN hours per day (0.4 HPRD × 50 residents = 20 total RN hours per day). To meet the 24/7 RN requirement, this facility would have to increase its total RN hours per day by 4 hours (24 hours needed − 20 hours current RN care = 4 hours needed) and 1,460 hours (4 hours per day × 365 days/year) annually. Using the loaded mean hourly wage cost of $44 per hour, this facility would spend $64,240 per year ($44 × 4 RN hours per day × 365 day per year = $64,240) to be in compliance with the 24/7 RN requirement.

After estimating each facility's cost for meeting the 24/7 RN requirement, the next step was to sum the additional cost for all LTC facilities to meet the 24/7 RN requirement for an aggregate cost to the industry of $349 million per year. We also found approximately 78 percent of LTC facilities had 24/7 RN coverage

[112] The cost report data utilized were from October 18, 2022, and are available at *https://www.cms.gov/httpswwwcmsgovresearch-statistics-data-and-systemsdownloadable-public-use-filescostreportscost/2021-1*.

within a 90-day window based on PBJ System data from 2021 Q2, showing that they provided at least 24 hours of RN care per day. We assumed this estimate for all quarters, for an annual estimate of approximately 22 percent (100 percent − 78 percent = 22 percent) or 3,261 LTC facilities (0.222 × 14,688 LTC facilities = 3,261 LTC facilities) that would need to increase their RN staffing to comply with the 24/7 RN requirement. Among this 22 percent of facilities needing to increase RN staffing, there was an average of 0.43 hours of RN care per resident day.

Table 15 summarizes the average annual cost for LTC facilities to meet the 24/7 RN Staffing Requirement over a 10-year period, which includes any associated collection of information costs as described in section IV. In estimating the cost, we take into account expected growth in wages that will result from greater demand for RNs in LTC facilities to meet the proposed 24/7 RN requirement, as well as the 0.55 RN hours per resident day requirement that we discuss in more detail later in the analysis. All costs are reflected in 2021 US dollars.

There is uncertainty about how much RN wages will change over the next 10 years due to changes in demand for RNs emerging due to both this final rule, as well as broader patterns of healthcare use in the United States. A 2009 study [113] examined minimum licensed nurse (RN/LPN) staffing standards in California for acute care hospitals that went into effect in March 2004. The authors found that compared to metropolitan areas outside of California that did not have the regulation, RN wage growth in California increased 12.8 percent more between 2000 and 2006. A more recent study [114] found that real nurse wage rates increased by nearly 10 percent between 2001 and 2017, with changes in rates varying during years of U.S. economic growth and recession. During its strongest growth between 2001 and 2004, real wages increased at an average rate of 2.41 percent annually. Given the uncertainty in growth and increased demands for RNs, we assumed that real wages each year will increase at 2.31 percent.

We provide separate cost estimates for facilities in rural and urban areas since facilities in rural areas would have to meet the requirement 3 years after the final rule publication. Facilities in urban areas, in contrast, would need to meet the requirement 2 years after the final rule publication. This resulted in an average annual cost of approximately $366 million in 2021 US dollars without considering exemptions.

Table 15: Annual Cost for 24/7 RN Requirement

Year	Collection of Information Costs for 24/7 RN (§483.35 Nursing services)	24/7 RN Requirement (Urban Facilities)	24/7 RN Requirement (Rural Facilities)	Total Cost
1	$24,440,832.00	$0.00	$0.00	$24,440,832.00
2	$25,005,415.00	$213,764,107.41	$0.00	$238,769,522.41
3	$25,583,040.00	$218,702,058.29	$146,603,030.04	$390,888,128.33
4	$26,174,009.00	$223,754,075.83	$149,989,560.03	$399,917,644.86
5	$26,778,628.00	$228,922,794.98	$153,454,318.87	$409,155,741.85
6	$27,397,214.00	$234,210,911.55	$156,999,113.64	$418,607,239.19
7	$28,030,090.00	$239,621,183.61	$160,625,793.16	$428,277,066.77
8	$28,677,585.00	$245,156,432.95	$164,336,248.98	$438,170,266.93
9	$29,340,037.00	$250,819,546.55	$168,132,416.34	$448,291,999.89
10	$30,017,792.00	$256,613,478.07	$172,016,275.15	$458,647,545.22
10 Year Total Cost	$271,444,644	$2,111,564,589	$1,272,156,756	$3,655,165,989.00

(2) RN on Site 24 Hours a day, 7 Days a Week (24/7 RN)—State Level Analysis

To provide a more in-depth understanding of the financial and staffing effects of the 24/7 RN requirement, we examined its impact for different groups of LTC facilities in each State, as well as Washington DC and Puerto Rico. We first assessed how many full-time RNs LTC facilities will need to hire to meet the finalized requirement. In this analysis, we defined a full-time employee as an employee who worked 1,950 hours per year. This definition was based on a full-time employee working 5 days per week, 8 hours per day, with a 30-minute break (37.5 hours/week × 52 weeks/year). To meet the 24/7 RN requirement, each facility will need to provide a minimum of 8,760 hours (24 hours/day × 365 days) of RN care annually since we did not include any facility exemptions in these calculations. All calculations used the October 2021 *Nursing Home Care Compare* data set that provides each nursing home's average daily resident census and HPRD for RNs using the PBJ system data for 2021 Q2.

For each facility, we first calculated the total number of full-time RNs in the facility using the following formula: (facility specific RN HPRD x average daily resident census × 365)/1,950. For example, if a facility has 100 residents and provides an average of 0.2 RN HPRD, then during the year, it will provide a total of 7,300 hours of RN care (0.2 RN HPRD × 100 residents × 365 days = 7,300 hours) yearly and have 3.74 full-time RNs. We then calculated the number of additional full-time RNs needed by subtracting the total hours of RN care that the facility currently provides yearly from the 8,760 hours needed to ensure 24/7 RN coverage and dividing by 1,950, which is the number

[113] Mark B, Harless DW, and Spetz J. California's Minimum-Nurse Staffing Legislation and Nurses' Wages. Health Affairs. 2009;28 Supplement 1, w326-w334. *doi: 10.1377/hlthaff.28.2.w326.*

[114] Barry J. Real wage growth in the U.S. health workforce and the narrowing of the gender pay gap. Human Resources for Health. 2021;19: 105. *doi: 10.1186/s12960–021–00647–3.*

of hours of yearly care provided by a full-time RN. Continuing with our example in this section, the nursing home will need to provide 1,460 additional RN hours per year (8,760 hours − 7,300 hours = 1,460 hours) and hire 0.75 additional full-time RNs.

Table 16 shows the total number of RNs currently employed by LTC facilities in each State's urban and rural areas, the number of full-time RNs that LTC facilities will need to hire, and the percent increase in RNs that LTC facilities in each State will need to meet the proposed minimum staffing standard barring any exemptions. Oklahoma will need the largest increase in RNs in percentage terms for rural facilities, needing to increase the size of its RN workforce by 27 percent. Meanwhile, for urban facilities, the largest percentage increase in RNs will be in Louisiana at 17.6 percent. Facilities in Texas will need to hire the most overall RNs with the State needing 653 additional full-time RNs. Across the United States, however, the number of RNs that facilities will need to meet the requirement varies widely with several States, including Florida and Illinois, needing to increase the size of their LTC facilities' RN labor force by less than 1 percent.

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State	Existing Full-Time RNs in Rural Areas	Additional RNs Needed in Rural Areas	% Increase in RNs Needed in Rural Areas	Existing Full-Time RNs in Urban Areas	Additional RNs Needed in Urban Areas	% Increase in RNs Needed in Urban Areas
Oklahoma	437	118	27.0	568	83	14.6
Oregon	158	5	3.2	762	29	3.8
Pennsylvania	1,026	1	0.1	7,575	9	0.1
Puerto Rico	0	0	--	29	0	0.0
Rhode Island	0	0	--	947	0	0.0
South Carolina	279	8	2.9	1,325	26	2.0
South Dakota	488	19	3.9	240	4	1.7
Tennessee	683	28	4.1	1,693	25	1.5
Texas	1,138	250	22.0	4,451	403	9.1
Utah	122	2	1.6	926	8	0.9
Vermont	250	4	1.6	72	1	1.4
Virginia	574	6	1.0	1,951	22	1.1
Washington	193	3	1.6	1,967	5	0.3
West Virginia	399	10	2.5	682	2	0.3
Wisconsin	1,142	11	1.0	2,214	20	0.9
Wyoming	245	5	2.0	85	0	0.0
United States	26,708	1,358	5.1	108,220	1,909	1.8

State	Existing Full-Time RNs in Rural Areas	Additional RNs Needed in Rural Areas	% Increase in RNs Needed in Rural Areas	Existing Full-Time RNs in Urban Areas	Additional RNs Needed in Urban Areas	% Increase in RNs Needed in Urban Areas
Oklahoma	437	118	27.0	568	83	14.6
Oregon	158	5	3.2	762	29	3.8
Pennsylvania	1,026	1	0.1	7,575	9	0.1
Puerto Rico	0	0	--	29	0	0.0
Rhode Island	0	0	--	947	0	0.0
South Carolina	279	8	2.9	1,325	26	2.0
South Dakota	488	19	3.9	240	4	1.7
Tennessee	683	28	4.1	1,693	25	1.5
Texas	1,138	250	22.0	4,451	403	9.1
Utah	122	2	1.6	926	8	0.9
Vermont	250	4	1.6	72	1	1.4
Virginia	574	6	1.0	1,951	22	1.1
Washington	193	3	1.6	1,967	5	0.3
West Virginia	399	10	2.5	682	2	0.3
Wisconsin	1,142	11	1.0	2,214	20	0.9
Wyoming	245	5	2.0	85	0	0.0
United States	26,708	1,358	5.1	108,220	1,909	1.8

We then assessed the financial cost for facilities to implement the 24/7 RN requirement. To estimate the yearly cost per State, we used the formulas described in section VI.C.1.(a) of this rule to first estimate each facility's yearly cost to meet the requirement. We also assumed that LTC facilities exceeding the minimum requirements for RNs will not reduce RNs to the minimum required level or lay off other staff to reduce costs. We then calculated the average cost per resident day by summing the total cost of meeting the requirement for all facilities in the State and dividing it by the total number of resident days for *all facilities needing additional RNs.* We estimated the average cost per resident day only for facilities needing staff to provide a more complete picture of the burden that the rule will impose on these facilities.

Table 17 provides the yearly Statewide cost to implement the requirement, as well as the average cost per resident day for facilities in rural and urban areas that will need to hire additional staff to meet the requirement. Delaware has the highest cost per resident day with a single facility that is not meeting the 24/7 RN requirement and will need to spend $87.45 per resident day. The highest overall cost occurs in Texas where facilities will need to collectively spend more than $84 million to meet the minimum staffing requirement. The cost also varied across urban and rural areas. In New Hampshire, LTC facilities in urban areas that need staff will need to spend an average of $8.95 per resident day to meet the requirement, while in Hawaii, Puerto Rico, and Wyoming these facilities will occur no cost. Nevada will have the highest average cost for rural LTC facilities at $21.81 per resident day.

Table 17: LTC Facilities in Each State Needing RNs and the Average Cost per Resident Day by Rural and Urban Location to Satisfy 24/7 RN Requirement (Absent an Exemption)

State	Yearly Statewide Cost ($ Million)	Average Cost per Resident Day (Statewide)	Urban LTC Facilities Needing RNs	Average Cost per Resident Day (Urban Areas)	Rural LTC Facilities Needing RNs	Average Cost per Resident Day (Rural Areas)
Alabama	1.1	$3.25	12	$3.86	6	$2.14
Alaska	0.2	$20.75	0	$0.00	2	$20.75
Arizona	1.1	$5.09	12	$5.80	1	$0.28
Arkansas	8.8	$3.62	64	$3.00	50	$4.59
California	44.5	$7.96	280	$7.81	20	$10.42
Colorado	1.8	$9.13	0	$0.00	17	$9.13
Connecticut	0.2	$6.24	2	$1.22	1	$19.09
Delaware	0.3	$87.45	1	$87.45	0	$0.00
District of Columbia	0.0	$0.0	0	$0.00	--	--
Florida	2.4	$5.04	21	$4.92	8	$5.31
Georgia	13.0	$4.91	58	$4.54	66	$5.27
Hawaii	0.1	$10.08	0	$0.00	1	$10.08
Idaho	0.9	$6.34	5	$8.38	8	$5.04
Illinois	14.4	$6.95	55	$6.15	68	$7.86
Indiana	10.9	$5.87	74	$5.16	46	$7.48
Iowa	10.0	$6.18	37	$5.37	99	$6.51
Kansas	9.0	$7.14	38	$6.72	71	$7.41
Kentucky	1.2	$4.63	9	$3.01	8	$7.12
Louisiana	23.1	$4.43	134	$4.16	49	$5.34
Maine	0.8	$6.55	4	$5.55	8	$7.19
Maryland	0.6	$6.20	9	$6.20	0	$0.00
Massachusetts	3.1	$7.23	29	$7.23	0	$0.00
Michigan	4.2	$5.38	32	$5.89	12	$3.69
Minnesota	1.6	$5.05	14	$5.91	19	$4.39
Mississippi	2.3	$3.68	16	$3.81	21	$3.57
Missouri	23.5	$5.83	114	$5.29	114	$6.46

State	Yearly Statewide Cost ($ Million)	Average Cost per Resident Day (Statewide)	Urban LTC Facilities Needing RNs	Average Cost per Resident Day (Urban Areas)	Rural LTC Facilities Needing RNs	Average Cost per Resident Day (Rural Areas)
Montana	1.7	$6.16	6	$4.62	15	$6.96
Nebraska	5.6	$8.28	4	$5.50	58	$8.47
Nevada	0.7	$21.81			4	$21.81
New Hampshire	0.8	$8.54	7	$8.95	1	$6.61
New Jersey	1.7	$4.41	22	$4.41	0	$0.00
New Mexico	0.8	$5.00	4	$4.57	8	$5.34
New York	2.7	$5.57	21	$5.35	5	$6.75
North Carolina	5.6	$4.63	46	$5.15	19	$3.51
North Dakota	0.7	$6.94	0	$0.00	9	$6.94
Ohio	17.9	$4.94	142	$4.83	74	$5.23
Oklahoma	26.2	$7.77	83	$6.85	118	$8.54
Oregon	3.7	$8.78	29	$8.43	5	$11.97
Pennsylvania	0.7	$5.75	9	$7.44	1	$1.65
Puerto Rico	0.0	$0.00	0	$0.00	0	$0.00
South Carolina	2.8	$4.77	26	$4.73	8	$4.93
South Dakota	1.6	$5.62	4	$7.36	19	$5.23
Tennessee	4.2	$4.13	25	$4.32	28	$3.94
Texas	84.6	$6.28	403	$5.48	250	$7.95
Utah	0.7	$4.98	8	$5.79	2	$1.83
Vermont	0.3	$5.42	1	$0.65	4	$5.97
Virginia	2.1	$3.92	22	$3.87	6	$4.12
Washington	0.8	$6.76	5	$7.00	3	$6.41
West Virginia	1.1	$6.52	2	$5.81	10	$6.62
Wisconsin	2.6	$7.30	20	$7.42	11	$7.10
Wyoming	0.4	$8.60	0	$0.00	5	$8.60
United States	349.0	$5.97	1,909	$5.55	1,358	$6.71

Table 18 shows the average cost per resident day to implement the requirement for facilities in each State that will need additional RNs, dividing facilities based on their size into three groups: less than 50 beds, 50 to 100

beds, and more than 100 beds. Within each group of LTC facilities, the cost varied widely by number of beds and State. In West Virginia, the average cost per resident day for facilities that have more than 100 beds and need additional RNs will be $0.72, while in North Carolina, the average cost per resident day for facilities with fewer than 50 beds will be $29.19.

Table 18: Number of LTC Facilities in Each State Needing to Hire RNs and Average Cost per Resident Day by Facility Size to Satisfy 24/7 RN Requirement (Absent an Exemption)

	LTC Facilities Needing RNs	Yearly Statewide Cost ($ Million)	Average Cost per Resident Day (Statewide)	Cost -<50 Beds	Cost - 50 to 100 Beds	Cost > 100 Beds
Alabama	18	$1.10	$3.25	$0.94	$3.59	$2.09
Alaska	2	$0.20	$20.75	$20.75	$0.00	$0.00
Arizona	13	$1.10	$5.09	$11.17	$5.02	$4.23
Arkansas	114	$8.80	$3.62	$0.00	$4.63	$2.75
California	300	$44.50	$7.96	$17.35	$6.39	$3.33
Colorado	17	$1.80	$9.13	$15.46	$5.82	$5.67
Connecticut	3	$0.20	$6.24	$14.21	$0.00	$0.52
District of Columbia	0	$0.00	$0.00	$0.00	$0.00	$0.00
Delaware	1	$0.30	$87.45	$0.00	$87.45	$0.00
Florida	29	$2.40	$5.04	$11.73	$4.14	$2.25
Georgia	124	$13.00	$4.91	$13.29	$5.37	$3.42
Hawaii	1	$0.10	$10.08	$10.08	$0.00	$0.00
Idaho	13	$0.90	$6.34	$7.54	$4.57	$6.57
Illinois	123	$14.40	$6.95	$13.93	$8.19	$4.02
Indiana	120	$10.90	$5.87	$12.74	$5.69	$2.33
Iowa	136	$10.00	$6.18	$7.92	$4.85	$2.24
Kansas	109	$9.00	$7.14	$8.26	$5.75	$2.62
Kentucky	17	$1.20	$4.63	$3.37	$5.41	$0.16
Louisiana	183	$23.10	$4.43	$10.25	$7.00	$3.85
Maine	12	$0.80	$6.55	$6.55	$6.56	$0.00
Maryland	9	$0.60	$6.20	$6.96	$2.13	$0.00
Massachusetts	29	$3.10	$7.23	$12.58	$7.42	$2.06
Michigan	44	$4.20	$5.38	$11.66	$4.50	$2.81
Minnesota	33	$1.60	$5.05	$5.61	$3.97	$0.00
Mississippi	37	$2.30	$3.68	$9.72	$3.25	$1.50
Missouri	228	$23.50	$5.83	$11.26	$7.32	$3.61
Montana	21	$1.70	$6.16	$12.26	$3.78	$8.19

	LTC Facilities Needing RNs	Yearly Statewide Cost ($ Million)	Average Cost per Resident Day (Statewide)	Cost -<50 Beds	Cost - 50 to 100 Beds	Cost > 100 Beds
Nebraska	62	$5.60	$8.28	$10.60	$6.54	$4.94
Nevada	4	$0.70	$21.81	$24.40	$17.35	$0.00
New Hampshire	8	$0.80	$8.54	$12.34	$6.50	$4.07
New Jersey	22	$1.70	$4.41	$16.27	$2.60	$2.06
New Mexico	12	$0.80	$5.00	$7.70	$4.13	$5.28
New York	26	$2.70	$5.57	$6.83	$7.70	$1.77
North Carolina	65	$5.60	$4.63	$29.19	$3.66	$1.52
North Dakota	9	$0.70	$6.94	$6.42	$11.09	$0.00
Ohio	216	$17.90	$4.94	$9.75	$4.33	$3.71
Oklahoma	201	$26.20	$7.77	$18.00	$9.45	$5.09
Oregon	34	$3.70	$8.78	$12.43	$7.35	$9.33
Pennsylvania	10	$0.70	$5.75	$9.19	$3.19	$1.65
Puerto Rico	0	$0.00	$0.00	$0.00	$0.00	$0.00
South Carolina	34	$2.80	$4.77	$10.48	$4.78	$1.76
South Dakota	23	$1.60	$5.62	$7.27	$2.54	$0.00
Tennessee	53	$4.20	$4.13	$12.27	$4.54	$2.01
Texas	653	$84.60	$6.28	$10.93	$8.11	$5.01
Utah	10	$0.70	$4.98	$3.58	$6.01	$0.00
Vermont	5	$0.30	$5.42	$9.82	$2.01	$0.00
Virginia	28	$2.10	$3.92	$12.31	$3.44	$0.73
Washington	8	$0.80	$6.76	$14.04	$6.41	$1.42
West Virginia	12	$1.10	$6.52	$13.74	$3.98	$0.72
Wisconsin	31	$2.60	$7.30	$13.32	$5.52	$9.19
Wyoming	5	$0.40	$8.60	$17.49	$2.22	$0.00
United States	3,267	$349.0	$5.97	$11.17	$6.25	$4.07

In table 19, we calculated the average cost by State for facilities needing staff to meet the minimum staffing requirement based on whether the facility accepted patients with Medicare, Medicaid, or both Medicare

and Medicaid. The highest per resident day cost will be for 14 Medicaid-only facilities in Illinois that will need to spend an average of $29 per resident day to meet the staffing requirement. The lowest per resident day cost for facilities needing staff will be for a single Medicaid-only facility in South Dakota that will need to spend $0.33 per resident day to meet the requirement.

Table 19: Number of LTC Facilities in State Needing to Hire Staff and Average Cost per Resident Day by Medicare, Medicaid, and Dual Acceptance Status to Satisfy 24/7 RN Requirement (Absent Exemption)

State	Medicaid Only Facilities Needing RNs	Medicaid Only Facilities Cost per Resident Day	Medicare Only Facilities Needing RNs	Medicare Only Facilities Cost per Resident Day	Medicare and Medicaid Facilities Needing RNs	Medicare and Medicaid Facilities Cost per Resident Day
Alabama	2	$5.10	1	$0.94	15	$3.14
Alaska	0	$0.00	0	$0.00	2	$20.75
Arizona	0	$0.00	2	$34.70	10	$3.75
Arkansas	1	$3.76	0	$0.00	111	$3.61
California	11	$9.11	13	$20.26	273	$7.54
Colorado	3	$23.37	0	$0.00	13	$6.41
Connecticut	0	$0.00	0	$0.00	3	$6.24
Delaware	0	$0.00	1	$87.45	0	$0.00
District of Columbia	0	$0.00	0	$0.00	0	$0.00
Florida	0	$0.00	2	$10.71	24	$3.81
Georgia	1	$26.52	2	$34.37	121	$4.75
Hawaii	0	$0.00	0	$0.00	1	$10.08
Idaho	0	$0.00	1	$1.86	12	$6.68
Illinois	10	$5.35	0	$0.00	113	$7.10
Indiana	4	$7.88	2	$20.15	112	$5.50
Iowa	2	$5.26	1	$12.90	129	$6.09
Kansas	19	$10.72	0	$0.00	89	$6.52
Kentucky	0	$0.00	1	$0.68	15	$4.78
Louisiana	0	$0.00	6	$6.74	170	$4.48
Maine	0	$0.00	0	$0.00	10	$5.38
Maryland	0	$0.00	4	$7.68	4	$5.23
Massachusetts	0	$0.00	2	$10.03	25	$6.58
Michigan	1	$14.48	0	$0.00	42	$5.42
Minnesota	3	$8.26	0	$0.00	28	$4.75
Mississippi	5	$4.45	1	$23.67	31	$3.31
Missouri	6	$11.30	2	$3.08	219	$5.68

State	Medicaid Only Facilities Needing RNs	Medicaid Only Facilities Cost per Resident Day	Medicare Only Facilities Needing RNs	Medicare Only Facilities Cost per Resident Day	Medicare and Medicaid Facilities Needing RNs	Medicare and Medicaid Facilities Cost per Resident Day
Montana	0	$0.00	0	$0.00	21	$6.16
Nebraska	5	$13.34	0	$0.00	53	$7.28
Nevada	0	$0.00	0	$0.00	4	$21.81
New Hampshire	0	$0.00	0	$0.00	8	$8.54
New Jersey	0	$0.00	2	$5.28	19	$4.38
New Mexico	1	$5.96	0	$0.00	11	$4.95
New York	0	$0.00	0	$0.00	26	$5.57
North Carolina	0	$0.00	8	$70.04	56	$3.24
North Dakota	0	$0.00	0	$0.00	9	$6.94
Ohio	0	$0.00	4	$12.33	208	$4.81
Oklahoma	5	$18.96	1	$0.01	191	$7.58
Oregon	3	$4.27	2	$23.40	29	$8.89
Pennsylvania	0	$0.00	2	$21.85	8	$3.66
Puerto Rico	0	$0.00	0	$0.00	0	$0.00
Rhode Island	0	$0.00	0	$0.00	0	$0.00
South Carolina	0	$0.00	10	$12.96	23	$3.43
South Dakota	4	$5.18	0	$0.00	19	$5.70
Tennessee	4	$14.91	2	$4.78	47	$3.51
Texas	14	$9.00	11	$9.40	620	$6.18
Utah	2	$3.04	1	$8.08	7	$5.34
Vermont	0	$0.00	0	$0.00	5	$5.42
Virginia	4	$7.68	3	$2.82	20	$2.88
Washington	0	$0.00	0	$0.00	8	$6.76
West Virginia	3	$19.82	0	$0.00	7	$5.00
Wisconsin	1	$26.97	2	$12.89	27	$6.73
Wyoming	0	$0.00	0	$0.00	5	$8.60
United States	114	$9.22	89	$13.44	3,003	$5.72

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(3). Minimum Nurse Staffing Requirement of 3.48 Total Nurse Staffing HPRD, 0.55 RN HPRD, and 2.45 NA HPRD

To estimate the incremental impact of the minimum nurse staffing requirement requirements of 2.45 NA HPRD, 0.55 RN HPRD, and 3.48 total nurse staffing HPRD, we first estimated the industry's aggregate annual cost for nurse staff (RNs, LPNs/LVNS, and NAs) at current staffing levels. We then estimated the aggregate annual cost for nurse staff (RNs, LPNs/LVNs, and NAs) for all facilities to meet these requirements. We note that these HPRD requirements are applied independent of a facility's individual case-mix, meaning the expected costs to a facility are based solely on the cost of facilities adding additional staff to meet these requirements, regardless of the facility's case-mix. Finally, we calculated the requirements' expected cost to the industry by subtracting the industry's current nurse staff cost from the estimated nurse staff cost for all facilities to meet the minimum requirements (Nurse Staff Cost for All Facilities to Meet Minimum Requirement—All Facilities' Current Nurse Staff Cost).

To measure the current nurse staffing cost to the industry, we estimated the total number of nurse staff currently employed in LTC facilities and their loaded respective labor wages. This study used the *2021 SNF—Medicare Cost Report* dataset to find the total of facilities, the total number of reported LTC specific nurse-type staff and their loaded mean annual salaries, defined as salary and fringe benefits. Using this dataset, we were able to estimate the aggregate total nurse staffing salary costs and the cost per facility, including the cost for contract staff.

To estimate the nurse staffing cost by staff type, that is, RNs, LPNs/LVNs, NAs, per resident census we used the October 2021 *Care Compare* data set that calculates average hours per resident day (HPRD) for each nurse type using the PBJ System data from 2021 Q2. Hours per resident day was defined as the average hours of care that each resident in the facility receives from that nurse type. For example, a facility that had an average HPRD of 0.5 for RNs would provide, on average, 0.5 hours (30 minutes) of RN care for each resident. We linked this dataset using the facility unique ID variable with the *2021 SNF—Medicare Cost Report* data set to create a complete dataset. Using this combined dataset, we were also able to view the impact by staff type per resident census as well as the impact by LTC facility characteristics such as facility ownership, bed size, Five-Star Quality Rating System staffing ratings, payer mix, and location. This complete dataset helped provide an understanding of which types of LTC facilities would bear the largest cost burden of a new Federal minimum staffing requirement.

Using the above dataset, we estimated each facility's current total annual salary costs for each nurse type (RN, LPN/LVN, NA) as follows: [facility specific nurse type] loaded hourly wage × [facility specific nurse type] reported HPRD × facility-level average daily facility resident census × 365. For example, if a facility reported an average loaded hourly wage of $44 for its RNs, an average of 0.4 RN HPRD, and an average daily resident census of 100, its estimated annual salary costs for RNs would be calculated as: $44 × 0.4 × 100 × 365 = $642,400. Taking this example further, if this same facility reported a loaded average hourly wage of $21 for its NAs, an average of 2.1 NA HPRD, and an average daily resident census of 100, its estimated annual salary costs for NAs would be calculated as: $21 × 2.1 × 100 × 365 = $1,609,650. If this facility only employed RNs and NAs as part of its total nurse staff, then the facility's current total nurse staff cost would be $2,252,050 ($642,400 + $1,609,650 = $2,252,050). To estimate the aggregate current nurse staff cost across all facilities, the next step was to sum all facilities' current total (RN, LPN/LVN, and NA) nurse staff cost for an overall industry nurse staff cost of $43.4 billion.

c. 3.48 Total Nurse Staffing Requirement

To estimate the cost of the 3.48 total nurse staffing HPRD requirement, we subtracted the total current nurse staffing cost per facility from the total nurse staffing cost per facility with the 3.48 total nurse staffing HPRD standard. For the purpose of the cost estimates, we continue the assumption stated in the proposed rule that facilities would hire NAs to meet the total nurse staffing requirement. The formula applied to calculate each facility's cost of meeting of meeting the requirement was: [[3.48 total nurse staffing HPRD] − [facility specific reported total nurse staffing HPRD]] × facility specific NA hourly wage × facility level average daily resident census × 365. Using the same LTC facility example from the paragraph above where the facility had an average of 0.4 RN HPRD and 2.1 NA HPRD, this LTC facility would have a total of 2.5 (0.4 + 2.1 = 2.5) total nurse staffing HPRD. To comply with the requirement, it would need to increase its NA HPRD from 2.1 to 3.08 adding an additional 0.98 (3.48 − 2.5 = 0.98) HPRD. The cost for this requirement on this facility would thus be $751,170 ([3.48 − 2.5] × $21 × 100 × 365) = $751,170).

When LTC facilities hire RNs to meet the 24/7 RN requirement, which goes into effect the same year as the 3.48 total nurse staffing HPRD requirement, the hours these RNs work will also count toward the 3.48 total nurse staffing HPRD requirement. To avoid overestimating the number of nurse staff that LTC facilities will need to hire to meet the 3.48 total nurse staffing requirement and the cost to hire them, if a LTC facility has less than 3.48 total nurse staff HPRD, we subtracted any staff hours that the facility will need to meet the 24/7 RN requirement up to the point where the LTC facility will meet the 3.48 total nurse staff HPRD requirement.

After accounting for any increase in RN hours per resident day to meet the 24/7 RN requirement, we then calculated the total number of additional hours per resident day of nurse care that LTC facilities would need to provide to meet the 3.48 HPRD total nurse staff requirement. We did this calculation by subtracting the total nurse staff hours (RN, LVN/LPN, and NA) provided from 3.48 using the following formula: [3.48 − (RN HPRD + LVN/LPN HPRD + NA HPRD)]. For any facilities that were below the 3.48 total nurse staff HPRD requirement, we assumed that they would hire NAs to fulfill any remaining hours.

Once we apply this formula to each facility in our dataset, we summed each facility's total cost to obtain the requirement cost to the industry of approximately $1.37 billion. To factor in the 2.31 percent increase in real increase in wage rates and the different timeline for rural and urban facilities to meet these requirements, in table 20 we provide the estimated cost annually and over 10 years. Overall, we estimate that the requirement will cost an average of approximately $1.36 billion annually and $13.64 billion over 10 years.

Table 20: Annual and 10 Year Cost of 3.48 Total Nurse Staff HPRD Requirement

Year	Rural Facilities	Urban Facilities	All Facilities
Year 1	$0	$0	$0
Year 2	$0	$1,157,240,099	$1,157,240,099
Year 3	$253,983,202	$1,183,972,345	$1,437,955,547
Year 4	$259,850,214	$1,211,322,106	$1,471,172,320
Year 5	$265,852,754	$1,239,303,647	$1,505,156,401
Year 6	$271,993,953	$1,267,931,561	$1,539,925,514
Year 7	$278,277,013	$1,297,220,780	$1,575,497,793
Year 8	$284,705,212	$1,327,186,580	$1,611,891,792
Year 9	$291,281,902	$1,357,844,590	$1,649,126,493
Year 10	$298,010,514	$1,389,210,800	$1,687,221,314
10 Year Total Cost	$2,203,954,765	$11,431,232,508	$13,635,187,273

c. Minimum Nurse Staffing Requirement of 0.55 RN and 2.45 NA HPRD

When LTC facilities hire RNs to meet the 24/7 RN requirement, which goes into effect before the 0.55 RN HPRD requirement, the hours these RNs work will also count toward the 0.55 RN HPRD requirement. To avoid overestimating the number of RNs that LTC facilities will need to hire and the cost to hire them, if a LTC facility meets the 0.55 RN HPRD requirement with current staff including RNs hired for the 24/7 RN requirement, we estimate that its cost is $0. For facilities that still need to hire RNs to meet the 0.55 RN HPRD requirement we calculate costs using the following formula: [[0.55 RN HPRD] − [facility specific RN HPRD + facility specific RN HPRD resulting from 24/7 RN requirement]] × facility specific RN hourly wage × facility level average daily resident census × 365. Similarly, When LTC facilities hire NAs to meet the 3.48 total nurse staff HPRD requirement, which goes into effect before the 2.45 NA HPRD requirement, the hours these NAs work will also count toward the 2.45 NA HPRD requirement. To avoid overestimating the number of NAs that LTC facilities will need to hire and the cost to hire them, if a LTC facility meets the 2.45 NA HPRD requirement when including NAs hired to meet the 3.48 total nurse staff HPRD requirement, we estimate that its cost is $0. For facilities that still need to hire NAs to meet the 2.45 NA HPRD requirement we calculate costs using the following formula: [[2.45 NA HPRD] − [facility specific NA HPRD + facility specific NA HPRD resulting from 3.48 total nurse staff requirement]] × facility specific NA hourly wage × facility level average daily resident census × 365.

In table 21, we provide the estimated cost annually and over 10 years for the 0.55 RN and 2.45 NA HPRD requirements. These requirements have a total cost of approximately $2.54 billion annually and $25.38 billion over 10 years.

Table 21: Annual and 10 Year Cost of 0.55 RN and 2.45 NA HPRD Requirements

Year	Rural Facilities	Urban Facilities	All Facilities
Year 1	$0	$0	$0
Year 2	$0	$0	$0
Year 3	$0	$2,524,018,922	$2,524,018,922
Year 4	$0	$2,582,323,759	$2,582,323,759
Year 5	$546,905,194	$2,641,975,437	$3,188,880,632
Year 6	$559,538,704	$2,703,005,070	$3,262,543,774
Year 7	$572,464,048	$2,765,444,487	$3,337,908,535
Year 8	$585,687,968	$2,829,326,255	$3,415,014,222
Year 9	$599,217,360	$2,894,683,691	$3,493,901,051
Year 10	$613,059,281	$2,961,550,885	$3,574,610,165
10 Year Total Cost	$3,476,872,554	$21,902,328,505	$25,379,201,060

Table 22 summarizes the estimated total cost for the comprehensive minimum nurse staffing requirement which includes any associated collection of information costs as described in section IV., Collection of Information Requirements, but not the regulatory review costs which we discuss in more detail later in this section. To account for real growth in RN and NA wages over time, for each requirement we continue to assume that real wages for nurse staff, as well as collection of information costs, will increase at 2.31 percent annually. Since rural and urban LTC facilities have different phase-in periods to meet the 24/7 RN and 3.48 total nurse staff HPRD requirement (2 years for facilities in urban areas and 3 years for facilities in rural areas) and the 0.55 RN and 2.45 NA HPRD requirements (3 years for facilities in urban areas and 5 years for facilities in rural areas) we provided separate cost estimates for facilities located in each area. Over a 10-year period, we anticipate an average annual cost of approximately $4.3 billion.

We would note that the estimated $21.9 billion cost for the 0.55 RN and 2.45 NA HPRD requirements over 10 years differs from the estimated cost of $36.9 billion in the proposed rule. The reason for this difference is that with the 3.48 HPRD total nurse staff requirement, NAs hired to meet the requirement will also count toward the 2.45 NA HPRD requirement. As such, a large part of this cost difference is reflected in the calculated costs for the 3.48 total nurse staffing requirement.

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Table 22: Annual Cost for the Comprehensive Minimum Nurse Staffing Requirement

Year	Collection of Information Costs for 24/7 RN (§483.35 Nursing services)	Collection of Information Costs for Facility Assessment (§483.71 Facility assessment)	24/7 RN Requirement (Urban Facilities)	24/7 RN Requirement (Rural Facilities)	3.48 Total Nurse Staffing Requirement (Urban Facilities)	3.48 Total Nurse Staffing Requirement (Rural Facilities)	0.55 RN and 2.45 NA HPRD Requirements (Urban Facilities)	0.55 RN and 2.45 NA HPRD Requirements (Rural Facilities)	Total Cost
Year 1	$24,440,832	$28,494,720	$0	$0	$0	$0	$0	$0	$52,935,552
Year 2	$25,005,415	$29,152,948	$213,764,107	$0	$1,157,240,099	$0	$0	$0	$1,425,162,569
Year 3	$25,583,040	$29,826,381	$218,702,058	$146,603,030	$1,183,972,345	$253,983,202	$2,524,018,922	$0	$4,382,688,978
Year 4	$26,174,009	$30,515,371	$223,754,076	$149,989,560	$1,211,322,106	$259,850,214	$2,582,323,759	$0	$4,483,929,093
Year 5	$26,778,628	$31,220,276	$228,922,795	$153,454,319	$1,239,303,647	$265,852,754	$2,641,975,437	$546,905,194	$5,134,413,050
Year 6	$27,397,214	$31,941,464	$234,210,912	$156,999,113	$1,267,931,561	$271,993,953	$2,703,005,070	$559,538,704	$5,253,017,991
Year 7	$28,030,090	$32,679,312	$239,621,184	$160,625,793	$1,297,220,780	$278,277,013	$2,765,444,487	$572,464,048	$5,374,362,707
Year 8	$28,677,585	$33,434,204	$245,156,433	$164,336,249	$1,327,186,580	$284,705,212	$2,829,326,255	$585,687,968	$5,498,510,485
Year 9	$29,340,037	$34,206,534	$250,819,547	$168,132,416	$1,357,844,590	$291,281,902	$2,894,683,691	$599,217,360	$5,625,526,077
Year 10	$30,017,792	$34,996,705	$256,613,478	$172,016,275	$1,389,210,800	$298,010,514	$2,961,550,885	$613,059,281	$5,755,475,730
10 Year Total Cost	$271,444,644	$316,467,914	$2,111,564,589	$1,272,156,753	$11,431,232,508	$2,203,954,765	$21,902,328,505	$3,476,872,554	$42,986,022,233

This final rule does not include any provisions requiring Medicare, Medicaid, or other non-Medicare/Medicaid payors to increase payment

rates to providers to meet any or all the expected costs of these finalized requirements. Below, however, we provide estimates of how much of the estimated cost is due to residents whose care is covered by three payor groups: Medicaid, Medicare, and other non-Medicare/Medicaid payors.

Table 23 provides annual estimates and a 10-year total estimate for the share of facilities' increased staffing costs that is due to residents utilizing Medicaid. These estimates exclude all collection of information costs. Over a 10-year period, the average annual cost for facilities' due to residents whose stay is paid for by Medicaid is approximately $2.82 billion. If Medicaid were to fully cover these costs (although there is no expectation that it will), then States would pay approximately $1.17 billion, and the Federal Government would pay $1.65 billion.

To build these estimates, we used a scenario where each facility's increased cost to meet the new minimum staffing and 24/7 RN requirements for residents utilizing Medicaid is equal to share of residents in the facility using Medicaid. More formally, we first calculated each facility's increased staffing cost for residents utilizing Medicaid for each of the four requirements (24/7 RN, 3.48 total nurse staff, 0.55 RN HPRD, and 2.45 NA HPRD) using the following formula: Increased Facility Cost for Medicaid Residents = Individual requirement cost × % facility residents covered by Medicaid. We then summed all facilities' increased costs that is due to residents utilizing Medicaid and took into account the different timeline for each of the requirements to obtain a total estimated cost for Medicaid of $28.17 billion over 10 years.

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Table 23: Impact of Comprehensive Minimum Nurse Staffing Requirement on Medicaid Spending

Year	24/7 RN State Medicaid Costs (Rural Areas)	24/7 RN State Medicaid Costs (Urban Areas)	24/7 RN Federal Medicaid Costs (Rural Areas)	24/7 RN Federal Medicaid Costs (Urban Areas)	3.48 Total Nurse HPRD Requirement State Medicaid Costs (Rural Areas)	3.48 Total Nurse HPRD Requirement State Medicaid Costs (Urban Areas)	3.48 Total Nurse HPRD Requirement Federal Medicaid Costs (Rural Areas)	3.48 Total Nurse HPRD Requirement Federal Medicaid Costs (Urban Areas)	0.55 RN and 2.45 NA HPRD Requirements State Medicaid Costs (Rural Areas)	0.55 RN and 2.45 NA HPRD Requirements State Medicaid Costs (Urban Areas)	0.55 RN and 2.45 NA HPRD Requirements Federal Medicaid Costs (Rural Areas)	0.55 RN and 2.45 NA HPRD Requirements Federal Medicaid Costs (Urban Areas)	Total State Medicaid Costs	Total Federal Medicaid Costs
1	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
2	$0	$53,154,964	$0	$81,910,452	$0	$351,968,339	$0	$462,098,986	$0	$0	$0	$0	$405,123,303	$544,009,439
3	$35,749,826	$54,382,844	$60,811,000	$83,802,584	$67,959,241	$360,098,808	$104,952,272	$472,773,473	$0	$682,438,857	$0	$943,625,739	$1,200,629,576	$1,665,965,068
4	$36,575,647	$55,639,088	$62,215,734	$85,738,424	$69,529,099	$368,417,090	$107,376,669	$483,694,540	$0	$698,203,195	$0	$965,423,494	$1,228,364,119	$1,704,448,861
5	$37,420,545	$56,924,350	$63,652,917	$87,718,981	$71,135,222	$376,927,525	$109,857,070	$494,867,884	$136,832,797	$714,331,688	$231,945,474	$987,724,777	$1,393,572,127	$1,975,767,103
6	$38,284,959	$58,239,303	$65,123,300	$89,745,290	$72,778,445	$385,634,551	$112,394,769	$506,299,332	$139,993,635	$730,832,750	$237,303,414	$1,010,541,219	$1,425,763,644	$2,021,407,324
7	$39,169,342	$59,584,631	$66,627,648	$91,818,406	$74,459,627	$394,542,709	$114,991,088	$517,994,847	$143,227,488	$747,714,987	$242,785,123	$1,033,884,721	$1,458,698,784	$2,068,101,833
8	$40,074,154	$60,961,036	$68,166,747	$93,939,411	$76,179,645	$403,656,645	$117,647,382	$529,960,528	$146,536,043	$764,987,203	$248,393,459	$1,057,767,458	$1,492,394,726	$2,115,874,985
9	$40,999,867	$62,369,236	$69,741,399	$96,109,411	$77,939,395	$412,981,114	$120,365,037	$542,202,616	$149,921,026	$782,658,408	$254,131,348	$1,082,201,887	$1,526,869,044	$2,164,751,697
10	$41,946,963	$63,809,965	$71,352,425	$98,329,539	$79,739,795	$422,520,978	$123,145,469	$554,727,496	$153,384,201	$800,737,817	$260,001,782	$1,107,200,750	$1,562,139,719	$2,214,757,461
10 Year Total Cost	$310,221,303	$525,065,417	$527,691,169	$809,112,498	$589,720,469	$3,476,747,758	$910,729,756	$4,564,619,703	$869,895,190	$5,921,904,905	$1,474,560,601	$8,188,370,045	$11,693,555,041	$16,475,083,771

Table 24 provides annual estimates and a 10-year estimate for the share of facilities' increased staffing costs that is due to residents whose care is covered by Medicare and other non-Medicare/Medicaid payors. These estimates

continue to exclude all collection of information costs. Over a 10-year period, facilities' average annual cost to meet the proposed requirements will be approximately $471 million for residents utilizing Medicare and $921 million for residents utilizing other non-Medicare/Medicaid payors.

To build these estimates, we used a scenario where the cost each facility will incur to meet the new minimum staffing and 24/7 RN requirements for residents utilizing Medicare is equal to the share of residents covered by Medicare and non-Medicare/Medicaid payors in each facility. More formally, we first calculated each facility's increased staffing cost for residents utilizing Medicare and other non-Medicare/Medicaid payors for each of the four requirements (24/7 RN, 3.48 total nurse staff, 0.55 RN HPRD, and 2.45 NA HPRD) using the following formula: Increased Facility Cost for Medicare Residents = Individual requirement cost × % facility residents covered by Medicare. We then summed all facilities' increased costs that is due to residents utilizing Medicare and took into account the different timeline for each of the requirements to obtain a total estimated cost to facilities for Medicare-covered SNF stays of $4.71 billion over 10 years.

To obtain the total cost due to residents utilizing other non-Medicare/Medicaid payors, we first calculated each facility's increased staffing cost for residents utilizing other non-Medicare/Medicaid payors for each of the four requirements (24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD) using the following formula: Increased Facility Cost for Non-Medicare/Medicaid Payors = Individual requirement cost × % facility residents covered by non-Medicare/Medicaid Payors. We then summed all facilities' increased costs that is due to residents utilizing other Non-Medicare/Medicaid payors and took into account the different timeline for each of the requirements to obtain a total estimated cost of $9.21 billion over 10 years.

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Table 24: Cost of Comprehensive Minimum Nurse Staffing Requirement due to Residents whose Stay is Covered by Medicare and Other non-Medicare/Medicaid Payors

Year	24/7 RN Medicare Costs (Rural Facilities)	24/7 RN Medicare Costs (Urban Facilities)	3.48 Total Nurse HPRD Requirement Medicare Costs (Rural Facilities)	3.48 Total Nurse HPRD Requirement Medicare Costs (Urban Facilities)	0.55 RN and 2.45 NA HPRD Requirements Medicare Costs (Rural Facilities)	0.55 RN and 2.45 NA HPRD Requirements Medicare Costs (Urban Facilities)	24/7 RN Other Non-Medicare / Medicaid Payors' Costs (Rural Facilities)	24/7 RN Other Non-Medicare / or Medicaid Payors' Costs (Urban Facilities)	Other Non-Medicare/Medicaid Payors' 3.48 Total Nurse HPRD Requirement Costs (Rural Facilities)	Other Non-Medicare/Medicaid Payors' 3.48 Total Nurse HPRD Requirement Costs (Urban Facilities)	Non-Medicare or Medicaid Payors' 0.55 RN and 2.45 NA HPRD Requirements Costs (Rural Facilities)	Non-Medicare or Medicaid Payors' 0.55 RN and 2.45 NA HPRD Requirements Costs (Urban Facilities)	Total Costs Due to Residents whose Stay is Covered by Medicare	Total Costs Due to Residents whose Stay is Covered by Other non-Medicare/ Medicaid Payors
1	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
2	$0	$25,668,903	$0	$110,056,337	$0	$0	$0	$48,465,732	$0	$226,153,246	$0	$0	$135,725,241	$274,618,978
3	$12,537,908	$26,261,855	$25,809,665	$112,598,639	$0	$305,704,601	$34,221,940	$49,585,290	$54,428,846	$231,377,386	$0	$575,820,709	$482,912,667	$945,434,172
4	$12,827,533	$26,868,504	$26,405,868	$115,199,667	$0	$312,766,377	$35,012,467	$50,730,710	$55,686,153	$236,722,204	$0	$589,122,168	$494,067,949	$967,273,702
5	$13,123,849	$27,489,166	$27,015,843	$117,860,779	$60,626,534	$319,991,280	$35,821,255	$51,902,590	$56,972,503	$242,190,486	$114,509,544	$602,730,890	$566,107,453	$1,104,127,268
6	$13,427,010	$28,124,166	$27,639,909	$120,583,363	$62,027,007	$327,383,079	$36,648,726	$53,101,540	$58,288,568	$247,785,087	$117,154,714	$616,653,973	$579,184,535	$1,129,632,608
7	$13,737,174	$28,773,834	$28,278,391	$123,368,839	$63,459,831	$334,945,628	$37,495,312	$54,328,185	$59,635,033	$253,508,922	$119,860,988	$630,898,680	$592,563,698	$1,155,727,121
8	$14,054,503	$29,438,510	$28,931,622	$126,218,659	$64,925,753	$342,682,872	$38,361,453	$55,583,166	$61,012,603	$259,364,978	$122,629,777	$645,472,440	$606,251,919	$1,182,424,417
9	$14,379,162	$30,118,540	$29,599,943	$129,134,310	$66,425,538	$350,598,846	$39,247,603	$56,867,138	$62,421,994	$265,356,309	$125,462,525	$660,382,853	$620,256,339	$1,209,738,421
10	$14,711,321	$30,814,278	$30,283,701	$132,117,313	$67,959,968	$358,697,680	$40,154,223	$58,180,768	$63,863,942	$271,486,040	$128,360,709	$675,637,697	$634,584,260	$1,237,683,379
Total 10 Year Cost	$108,798,460	$253,557,757	$223,964,943	$1,087,137,907	$385,424,630	$2,652,770,364	$296,962,980	$478,745,120	$472,309,641	$2,233,944,658	$727,978,257	$4,996,719,410	$4,711,654,062	$9,206,660,066

Sources of uncertainty about the cost estimate for the 24/7 RN, 3.48 Total Nurse Staffing HPRD, 0.55 RN and 2.45 NA HPRD requirements include:

The cost estimates assumed that LTC facilities needing RNs and/or NAs to meet these requirements will hire them without laying off other direct care or support staff. Some research,[115] [116] however, has found that when States implemented minimum hour per day requirements for direct care staff (RNs, LPNs, and NAs), LTC facilities responded by reducing indirect care staff, such as housekeeping, food service, and activities staff. If LTC facilities respond to the 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements in similar ways, then a facility's total cost for the requirements could decline significantly relative to what was presented above (see earlier discussion about appropriate accounting of costs depending on consistency between benefit and cost analytic approaches). The intent of this rule, however, is that facilities will maintain levels of indirect care staff necessary to meet their residents' needs, while also scaling up direct care staff if needed to meet the minimums.

The cost estimates assumed that real wages for RNs and NAs will grow at a real annual rate of 2.31 percent due to increasing demand for these direct care staff. Differences in demand for RNs and NAs across geographical areas, however, could lead to wages in different areas to increase at different rates, altering the cost for LTC facilities.

The cost estimates assumed that the nursing home resident population will remain stable over the next 10 years. There is some evidence, however, that the resident population is declining. CMS *Care Compare* data shows that between February 2017 and February 2024, the average number of residents in nursing homes per day declined from 1,346,712 residents to 1,207,726.[117] If the resident population continues to decrease, then the costs could be lower than what we have estimated. Similarly, if the pattern changes and the nursing home resident population increases, costs could be higher than what we have estimated.

[115] Thomas, Kali S., Kathryn Hyer, Ross Andel, and Robert Weech-Maldonado. The Unintended Consequences of Staffing Mandates in Florida Nursing Homes: Impacts on Indirect-Care Staff, 2010, Medicare Care Research and Review, Volume 67, Issue 5, Pages 555–573.

[116] Bowblis, John R., and Kathryn Hyer. Nursing Home Staffing Requirements and Input Substitution: Effects on Housekeeping, Food Service, and Activities Staff, 2013, Health Services Research, Volume 48, Issue 4, Pages: 1539–1550.

[117] CMS. (2024). Nursing homes including rehab services archived data snapshots. Accessed March 19, 2024. Available at: *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

The 24/7 RN cost estimate assumed that RNs hired to meet the requirement will make the loaded average hourly rate for RNs in the facility. If, however, LTC facilities need to hire RNs to work overnight shifts, which typically command a higher hourly rate, the costs for LTC facilities to meet this requirement could increase.

The cost estimate for the 3.48 total nurse staff requirement assumes that facilities will hire NAs to fill the necessary hours. If, however, they hire LPNs/LVNs, then the cost could increase since LPNs/LVNs command a higher hourly wage than NAs.

The cost estimate assumed that no LTC facilities will obtain exemptions from the 24/7 RN requirement, the 3.48 total nurse staffing HPRD requirement, or the 0.55 RN and 2.45 NA HPRD requirements, although some facilities could obtain exemptions. Depending on the number of facilities that obtain exemptions from the requirements and their expected cost to meet the requirements, the total cost of the rule for LTC facilities could be lower than what is estimated.

In addition to uncertainty about the magnitude of costs, there is uncertainty about whether LTC facilities or other payors would bear the cost of meeting the minimum staffing and 24/7 RN requirements. As we highlighted earlier in this RIA, we expect that LTC facilities would generally have 3 possible approaches to addressing the increased costs associated with the higher staffing levels: (1) reduce their margin or profit; (2) reduce other operational costs; and (3) increase prices charged to payors. LTC facilities may use some combination of these approaches, and those approaches could vary by facility and over time. These decisions could depend on a number of factors, including: the current margin levels of a facility; the cost increase due to the staffing requirements relative to current costs and revenues; the current level of operational costs; and the ability to negotiate prices with payors. If payors did increase payment rates to meet some or all the rule's cost, the cost for LTC facilities could be lower relative to what is estimated above.

(4). Impact of 3.48 Total Nurse Staff, 0.55 RN, and 2.45 NA HPRD Requirements on States

To provide a more in-depth understanding of the financial and staffing effects of the 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD minimum staffing requirements, we examined their impact on different groups of LTC facilities in each State, as well as Washington, DC, and Puerto Rico. We first assessed how many full-time employees LTC facilities will need to hire to meet the finalized requirements. In this analysis, we defined a full-time employee as an employee who worked 1,950 hours per year. This definition was based on a full-time employee working 5 days per week, 8 hours per day, with a 30-minute break (37.5 hours/week × 52 weeks/year).

We continued to assume that no facilities will obtain exemptions from these minimum staffing requirements. For the 3.48 total nurse staff HPRD requirement, we continued to subtract any costs that facilities will incur and employees they will need to meet the 24/7 RN requirement since RNs that facilities hire to meet the 24/7 RN requirement will also count toward the 3.48 total nurse staff HPRD requirement. For the 0.55 RN HPRD requirement, we continue to subtract any costs that facilities will incur and employees they will need to hire to meet the 24/7 RN requirements since RNs that facilities hire for the 24/7 RN requirement will also count toward the 0.55 RN HPRD requirement. Finally, for the 2.45 NA HPRD requirement, we continue to subtract any NAs hired to meet the 3.48 total nurse staff requirement since NAs that facilities hire for the 3.48 total nurse staff requirement will also count toward the 2.45 NA HPRD requirement. All calculations used the October 2021 *Care Compare* data set that provided each LTC facility's average daily resident census and average HPRD for RNs, LPNs/LVNs and NAs using the PBJ System data from 2021 Q2.For each facility, we first calculated the total number of full-time RNs, LPN/LVNs, and NAs working in a facility using the following formula: (facility specific care type HPRD × Average daily resident census × 365)/1,950. For example, if a facility has 10 residents and provides an average of 0.1 RN HPRD, then during the year, it will provide a total of 365 hours of RN care (0.1 RN HPRD × 10 residents × 365 days) yearly and have 0.187 full-time RNs. We then calculated the number of additional RNs needed by subtracting the current average hours per resident day for RNs from the minimum required RN hours per resident day. Continuing with our example in this section and assuming the facility did not need to hire any RNs to meet the 24/7 RN requirement, the LTC facility would need to provide 1,642.5 additional RN hours per year ([0.55 RN HPRD − 0.1 HPRD] × 10 residents × 365 days = 1642.5 hours) and hire 0.84 additional full-time RNs.

To calculate the total number of additional NAs needed to meet the 3.48

total nurse staff requirement, we subtracted the current average hours per resident day for all nurse staff (RNs, LPNs/LVNs, and NAs) from the minimum required hours per resident day. For example, if the same facility as previously mentioned with 10 residents provided an average of 2.2 NA HPRD, 0.187 RN HPRD, and no LPN/LVN HPRD, then to meet the 3.48 HPRD requirement it would need to provide 3,989.5 additional NA hours per year ([3.48 Total Nurse Staff HPRD − 2.2 NA HPRD − .187 RN HPRD] × 10 residents × 365 days = 3,989.5 hours) and hire 2.05 (3,989.5 hours needed/1,950 hours yearly per full-time employee) full-time NAs. This equals an average increase of 1.09 NA HPRD (3,989.5/10 residents/365 days = 1.09 HPRD). We note, however, that facilities may also wish to use other types of staff such as LPNs/LVNs to meet the total staffing standard.

Finally, to calculate the total number of additional NAs needed to meet the 2.45 NA HPRD requirement, we added together the current average hours per resident day for NAs and the average additional hours per resident day that NAs will work to meet the 3.48 total nurse staff requirement. We then subtracted this new total NA HPRD from the 2.45 NA HPRD minimum required hours per resident day. For example, the same facility that we discussed above would provide a total of 3.29 NA HPRD (2.2 HPRD from current average NA HPRD + 1.09 HPRD from the 3.48 total nurse staff requirement = 3.29 NA HPRD). Therefore, it would have already met the 2.45 NA HPRD requirement and would incur no additional costs and would not need to hire any NAs to meet the 2.45 NA HPRD requirement.

Table 25 shows the total number of RNs and NAs employed by LTC facilities in each State's urban areas, the number of full-time RNs and NAs that LTC facilities will need to hire to meet each requirement, and the percent increase in RNs and NAs that LTC facilities in each State will need to meet the proposed minimum staffing standards. Table 26 provides the same information for LTC facilities located in each State's rural areas.

Louisiana will need the largest increase in RNs in percentage terms. The number of full-time RNs in urban LTC facilities will need to increase by nearly 96 percent, while rural LTCs will need to increase the number of RNs by more than 73 percent to meet minimum standard. Facilities in Texas will need to hire the most overall RNs with the State needing 1,615 additional full-time RNs in urban areas and more than 311 RNs in rural areas. Across the United States, however, the number of RNs that facilities will need to hire varies widely, with several States, including Delaware and Hawaii, not needing to hire any RNs to meet the requirement.

Illinois will need the largest percentage increase for NAs in urban areas to meet the 3.48 total nurse staff requirement. The State will need to add 4,350 full-time NAs and increase the overall number of NAs working in LTC facilities by more than 31 percent. Similar to RNs, however, there is wide variation in the percentage increase in NAs needed for the 3.48 total nurse staff requirement across States. For example, Alaska, North Dakota, the District of Columbia, Delaware, Florida, Hawaii, Idaho, Florida, Maine, and Vermont, will need to increase the size of their NA labor force in urban LTC facilities by less than 1 percent to meet the requirement.

Delaware will need the largest percentage increase for NA in urban areas to meet the 2.45 NA HPRD requirement, increasing the number of NAs by 18.3 percent. For rural areas, Georgia will need the largest percentage increase at 19.5 percent. Across States, however, the number of NAs that facilities will need to hire continues to vary widely.

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Table 25: Current and Additional Full-Time RNs and NAs Needed per State To Meet 3.48 Total Nurse Staff, 0.55 RN, and 2.45 NA HPRD Staffing Requirements for Urban LTC Facilities

State	Existing Full-Time RNs	Additional RNs Needed for 0.55 RN HPRD Requirement	% Increase in RNs for 0.55 RN HPRD Requirement	Existing Full-Time CNAs	Additional NAs Needed for 3.48 Total Nurse Staff HPRD Requirement	% Increase in NAs for 3.48 Total Nurse Staff Requirement	Additional NAs Needed for 2.45 NA HPRD Requirement	% Increase in NAs for 2.45 NA HPRD Requirement
Alabama	1,416	129	9.1	5,011	378	7.5	545	10.9
Alaska	108	0	0.0	216	0	0.0	3	1.2
Arizona	1,247	101	8.1	4,036	137	3.4	514	12.7
Arkansas	559	220	39.3	3,775	51	1.3	151	4.0
California	9,461	1,390	14.7	40,659	580	1.4	1,221	3.0
Colorado	2,026	9	0.5	4,687	219	4.7	502	10.7
Connecticut	2,145	122	5.7	6,735	446	6.6	693	10.3
Delaware	648	0	0.0	1,376	7	0.5	252	18.3
District of Columbia	468	0	0.0	923	0	0.0	45	4.9
Florida	8,208	390	4.8	29,310	143	0.5	278	0.9
Georgia	1,469	443	30.1	6,446	921	14.3	1,085	16.8
Hawaii	743	0	0.0	1,289	3	0.2	26	2.0
Idaho	437	1	0.2	1,176	6	0.6	99	8.4
Illinois	5,965	551	9.2	13,944	4,350	31.2	1,852	13.3
Indiana	2,611	261	10.0	8,917	878	9.8	1,226	13.8
Iowa	1,254	28	2.2	4,010	228	5.7	154	3.8
Kansas	1,054	51	4.8	3,652	212	5.8	175	4.8
Kentucky	1,249	100	8.0	3,997	252	6.3	535	13.4
Louisiana	762	730	95.9	6,306	560	8.9	676	10.7
Maine	576	3	0.5	1,499	2	0.2	34	2.3
Maryland	2,939	47	1.6	7,572	346	4.6	1,242	16.4
Massachusetts	3,973	191	4.8	12,156	413	3.4	1,772	14.6
Michigan	3,050	235	7.7	8,862	734	8.3	1,538	17.4
Minnesota	2,968	3	0.1	6,267	187	3.0	404	6.4
Mississippi	509	68	13.3	1,955	103	5.3	219	11.2

State	Existing Full-Time RNs	Additional RNs Needed for 0.55 RN HPRD Requirement	% Increase in RNs for 0.55 RN HPRD Requirement	Existing Full-Time CNAs	Additional NAs Needed for 3.48 Total Nurse Staff HPRD Requirement	% Increase in NAs for 3.48 Total Nurse Staff Requirement	Additional NAs Needed for 2.45 NA HPRD Requirement	% Increase in NAs for 2.45 NA HPRD Requirement
Missouri	1,707	442	25.9	7,786	1,314	16.9	353	4.5
Montana	163	4	2.2	487	60	12.3	34	7.0
Nebraska	743	17	2.3	2,313	87	3.8	64	2.8
Nevada	667	45	6.7	1,796	86	4.8	247	13.7
New Hampshire	388	13	3.4	1,256	48	3.8	126	10.1
New Jersey	4,756	335	7.0	13,412	1,087	8.1	1,800	13.4
New Mexico	324	27	8.2	1,184	107	9.1	90	7.6
New York	10,277	745	7.2	32,047	3,406	10.6	2,726	8.5
North Carolina	2,381	376	15.8	9,175	825	9.0	988	10.8
North Dakota	313	1	0.4	1,176	5	0.4	7	0.6
Ohio	5,169	521	10.1	16,844	1,965	11.7	2,628	15.6
Oklahoma	568	203	35.7	3,725	108	2.9	232	6.2
Oregon	762	17	2.3	3,170	5	0.2	9	0.3
Pennsylvania	7,575	242	3.2	20,086	1,669	8.3	3,255	16.2
Puerto Rico	29	0	0.0	0	0	--	26	--
Rhode Island	947	14	1.5	2,752	133	4.8	156	5.7
South Carolina	1,325	163	12.3	4,793	236	4.9	558	11.6
South Dakota	240	0	0.0	618	39	6.2	51	8.3
Tennessee	1,693	230	13.6	6,047	431	7.1	1,068	17.7
Texas	4,451	1,615	36.3	21,663	2,661	12.3	3,460	16.0
Utah	926	2	0.2	2,012	87	4.3	115	5.7
Vermont	72	4	5.0	239	0	0.0	24	10.1
Virginia	1,951	344	17.6	6,838	1,082	15.8	1,082	15.8
Washington	1,967	22	1.1	5,257	47	0.9	264	5.0
West Virginia	682	22	3.2	1,987	117	5.9	313	15.8
Wisconsin	2,214	16	0.7	5,220	257	4.9	363	7.0
Wyoming	85	3	3.4	212	24	11.3	27	12.6
United States	108,220	10,495	9.7	356,871	27,042	7.6	35,306	9.9

Table 26: Current and Additional Full-Time RNs and NAs Needed per State To Meet 3.48 Total Nurse Staff, 0.55 RN, and 2.45 NA HPRD Staffing Requirements for Rural LTC Facilities

State	Existing Full-Time RNs	Additional RNs Needed for 0.55 RN HPRD Requirement	% Increase in RNs for 0.55 RN HPRD Requirement	Existing Full-Time CNAs	Additional NAs Needed for 3.48 Total Nurse Staff HPRD Requirement	% Increase in NAs for 3.48 Total Nurse Staff Requirement	Additional NAs Needed for 2.45 NA HPRD Requirement	% Increase in NAs for 2.45 NA HPRD Requirement
Alabama	721	69	9.5	2,884	135	4.7	148	5.1
Alaska	108	0	0.0	256	0	0.0	0	0.0
Arizona	60	4	6.4	169	29	17.1	31	18.2
Arkansas	487	115	23.6	2,930	22	0.8	137	4.7
California	150	37	24.5	847	7	0.8	25	3.0
Colorado	374	6	1.5	1,080	34	3.1	59	5.5
Connecticut	118	6	4.6	379	16	4.3	52	13.8
Delaware	0	0	--	0	0	--	0	--
District of Columbia	0	0	--	0	0	--	0	--
Florida	286	51	17.9	1,501	5	0.4	18	1.2
Georgia	732	177	24.2	3,147	341	10.8	614	19.5
Hawaii	177	0	0.0	393	5	1.3	28	7.2
Idaho	163	1	0.6	542	4	0.8	16	3.0
Illinois	1,049	85	8.1	3,519	688	19.6	308	8.8
Indiana	1,147	51	4.5	3,510	274	7.8	472	13.5
Iowa	1,458	29	2.0	4,789	318	6.6	236	4.9
Kansas	862	10	1.1	3,224	59	1.8	77	2.4
Kentucky	1,212	70	5.8	4,011	191	4.8	358	8.9
Louisiana	262	192	73.4	2,166	65	3.0	218	10.1
Maine	403	0	0.0	1,151	0	0.0	5	0.4
Maryland	125	0	0.0	353	15	4.2	29	8.3
Massachusetts	12	0	0.0	40	0	0.0	0	0.0
Michigan	1,299	19	1.5	3,624	105	2.9	169	4.7
Minnesota	1,218	1	0.1	3,417	14	0.4	99	2.9
Mississippi	982	70	7.1	3,544	108	3.0	408	11.5
Missouri	823	133	16.2	3,959	541	13.7	175	4.4
Montana	356	5	1.5	996	85	8.5	43	4.3
Nebraska	630	13	2.1	2,380	43	1.8	86	3.6
Nevada	61	0	0.0	189	14	7.6	8	4.5
New Hampshire	349	8	2.4	1,206	57	4.7	78	6.5

State	Existing Full-Time RNs	Additional RNs Needed for 0.55 RN HPRD Requirement	% Increase in RNs for 0.55 RN HPRD Requirement	Existing Full-Time CNAs	Additional NAs Needed for 3.48 Total Nurse Staff HPRD Requirement	% Increase in NAs for 3.48 Total Nurse Staff Requirement	Additional NAs Needed for 2.45 NA HPRD Requirement	% Increase in NAs for 2.45 NA HPRD Requirement
New Jersey	0	0	--	0	0	--	0	--
New Mexico	256	7	2.5	796	40	5.0	56	7.0
New York	827	37	4.5	2,609	433	16.6	392	15.0
North Carolina	800	92	11.5	2,945	267	9.1	298	10.1
North Dakota	386	6	1.7	1,331	46	3.4	19	1.4
Ohio	1,681	109	6.5	5,264	580	11.0	824	15.7
Oklahoma	437	94	21.4	3,040	81	2.7	124	4.1
Oregon	158	2	1.1	528	0	0.0	0	0.0
Pennsylvania	1,026	50	4.9	3,152	211	6.7	547	17.3
Puerto Rico	0	0	--	0	0	--	0	--
Rhode Island	0	0	--	0	0	--	0	--
South Carolina	279	62	22.4	1,121	88	7.9	163	14.5
South Dakota	488	2	0.5	1,382	109	7.9	55	4.0
Tennessee	683	78	11.4	2,515	123	4.9	480	19.1
Texas	1,138	311	27.3	6,143	699	11.4	1,067	17.4
Utah	122	0	0.0	269	11	4.2	19	7.1
Vermont	250	2	0.8	734	10	1.4	80	10.9
Virginia	574	99	17.3	1,990	311	15.6	340	17.1
Washington	193	5	2.5	535	37	7.0	46	8.6
West Virginia	399	32	8.0	1,464	86	5.9	137	9.3
Wisconsin	1,142	4	0.3	2,835	155	5.5	187	6.6
Wyoming	245	0	0.0	626	8	1.2	57	9.1
United States	26,708	2,144	8.0	95,485	6,476	6.8	8,787	9.2

We then assessed the financial cost for facilities to implement the 3.48 total nurse staff, 0.55 RN, and 2.45 NA HPRD minimum staffing requirements. To estimate the yearly cost per State, we used the formulas described in section

VI.C.1.(a) to first estimate each facility's yearly cost to meet each requirement. We also assumed that LTC facilities exceeding the minimum requirements for total nurse staff, RNs and/or NAs will not reduce staff to the minimum required level or lay off other staff to reduce costs. We then calculated the average cost per resident day by summing the total cost of meeting each requirement for all facilities in the State and dividing it by the total number of resident days for all facilities in the state needing to hire staff to meet the requirements. We estimated the average cost per resident day only for facilities needing staff to provide a more complete picture of the burden that the rule will impose on these facilities.

Table 27 provides the yearly Statewide cost to implement the 3.48 total nurse staff, 2.45 NA, and 0.55 RN HPRD requirements, as well as the average cost per resident day for facilities in rural and urban areas that will need to hire staff to meet the requirements. Facilities in Illinois that are not meeting the minimum staffing standards will need to spend the most with an average cost of $21.01 per resident day. The highest overall cost occurs in New York where facilities will need to collectively spend nearly $421 million to meet the minimum staffing requirements. The cost also varies across urban and rural areas. In Illinois, LTC facilities in urban areas that need staff will need to spend an average of $22.34 per resident day to meet the requirement, while in Florida, they will need to spend than $5.25 per resident day. Virginia had the highest average cost for rural LTC facilities at $17.65 per resident day.

Table 27: LTC Facilities in Each State Needing Staff and Average Cost per Resident Day by Rural and Urban Location

State	Statewide Hiring Cost ($ Million)	Average Cost per Resident Day (Statewide)	Urban LTC Facilities Needing Staff	Average Cost per Resident Day (Urban Areas)	Rural LTC Facilities Needing Staff	Average Cost per Resident Day (Rural Areas)
Alabama	57.7	$10.06	120	$10.60	57	$8.83
Alaska	0.1	$7.50	1	$7.50	0	$0.00
Arizona	35.8	$12.07	99	$12.06	8	$12.17
Arkansas	34.0	$7.42	103	$8.00	80	$6.58
California	225.6	$9.68	724	$9.71	26	$8.48
Colorado	37.7	$10.24	122	$10.32	26	$9.65
Connecticut	63.5	$12.07	140	$12.28	12	$9.14
Delaware	12.0	$11.18	36	$11.18	0	$0.00
District of Columbia	1.9	$6.33	7	$6.33	0	$0.00
Florida	54.6	$5.35	271	$5.25	22	$6.48
Georgia	154.5	$16.30	201	$17.10	125	$14.69
Hawaii	2.7	$9.61	5	$8.38	3	$10.84
Idaho	5.3	$6.95	29	$7.38	11	$5.32
Illinois	364.0	$21.01	412	$22.34	155	$14.94
Indiana	151.2	$14.05	307	$14.77	151	$12.15
Iowa	42.4	$9.27	97	$9.52	174	$9.10
Kansas	25.9	$9.40	89	$10.72	58	$6.55
Kentucky	67.7	$11.11	111	$13.22	110	$8.73
Louisiana	118.2	$15.60	175	$16.76	70	$12.10
Maine	2.4	$5.89	12	$7.17	4	$2.02
Maryland	77.5	$12.02	167	$12.15	10	$8.64
Massachusetts	125.5	$12.59	306	$12.59	0	$0.00
Michigan	128.9	$14.82	250	$15.80	68	$9.55
Minnesota	34.4	$10.33	109	$11.13	49	$7.58
Mississippi	38.4	$9.49	54	$10.95	103	$8.62
Missouri	125.4	$13.68	233	$15.15	144	$10.48
Montana	10.8	$14.31	13	$15.02	27	$13.80
Nebraska	13.4	$8.81	26	$10.39	58	$7.63
Nevada	18.5	$14.06	34	$13.96	4	$15.92
New Hampshire	19.1	$14.06	27	$13.38	19	$15.04
New Jersey	164.7	$14.87	285	$14.87	0	$0.00
New Mexico	15.6	$11.02	29	$11.47	22	$10.04
New York	421.0	$15.09	430	$15.03	72	$15.65

Table 28 shows the average cost per resident day for facilities in each State that need additional staff, dividing facilities based on their size into three groups: less than 50 beds, 50 to 100 beds, and more than 100 beds. Within

State	Statewide Hiring Cost ($ Million)	Average Cost per Resident Day (Statewide)	Urban LTC Facilities Needing Staff	Average Cost per Resident Day (Urban Areas)	Rural LTC Facilities Needing Staff	Average Cost per Resident Day (Rural Areas)
North Carolina	128.3	$13.15	256	$13.50	87	$12.03
North Dakota	4.5	$12.40	5	$7.81	15	$13.98
Ohio	289.7	$14.79	577	$15.30	227	$13.16
Oklahoma	41.1	$9.26	108	$10.70	96	$7.17
Oregon	2.8	$4.91	26	$4.76	1	$8.28
Pennsylvania	298.2	$14.98	470	$15.21	101	$13.56
Puerto Rico	0.0	$0.0	3	$0.0	0	$0.0
Rhode Island	16.3	$9.99	53	$9.99	0	$0.00
South Carolina	59.4	$12.63	113	$12.40	35	$13.41
South Dakota	11.2	$10.15	21	$10.03	44	$10.22
Tennessee	101.9	$13.12	181	$13.71	100	$11.77
Texas	408.7	$15.40	773	$15.96	303	$13.47
Utah	7.6	$6.50	49	$6.50	8	$6.52
Vermont	6.3	$10.75	4	$12.28	16	$10.28
Virginia	156.8	$19.30	179	$19.81	63	$17.65
Washington	23.4	$10.28	78	$9.40	15	$15.54
West Virginia	30.1	$10.88	59	$11.00	44	$10.68
Wisconsin	41.3	$11.26	114	$11.82	75	$10.31
Wyoming	6.2	$13.06	6	$14.37	13	$12.02
United States	4,284.2	$13.83	8,096	$13.86	2,911	$11.59

each group of LTC facilities, the cost varied widely by the number of beds and State. In Oklahoma, the average cost per resident day for facilities that have fewer than 50 beds and need additional nurse will be $1.84, while in Illinois, the average cost per resident day for facilities with more than 100 beds will be $22.78.

Table 28: Number of LTC Facilities in Each State Needing to Hire Nursing Staff and Average Cost per Resident Day by Facility Size

State	LTC Facilities Needing Staff	Statewide Hiring Cost ($ Million)	Average Cost per Resident Day (Statewide)	Cost — <50 Beds	Cost — 50 to 100 Beds	Cost — >100 Beds
Alabama	177	57.7	$10.06	$5.60	$8.70	$10.52
Alaska	1	0.1	$7.50	$0.00	$7.50	$0.00
Arizona	107	35.8	$12.07	$11.89	$7.44	$13.24
Arkansas	183	34.0	$7.42	$0.00	$7.42	$7.42
California	750	225.6	$9.68	$5.33	$9.23	$10.25
Colorado	148	37.7	$10.24	$10.94	$9.34	$10.76
Connecticut	152	63.5	$12.07	$19.07	$10.35	$12.38
Delaware	36	12.0	$11.18	$7.15	$7.38	$11.94
District of Columbia	7	1.9	$6.33	$3.88	$18.10	$4.45
Florida	293	54.6	$5.35	$7.69	$5.79	$5.25
Georgia	326	154.5	$16.30	$10.12	$14.78	$17.23
Hawaii	8	2.7	$9.61	$8.73	$14.83	$8.42
Idaho	40	5.3	$6.95	$5.52	$7.80	$6.43
Illinois	567	364.0	$21.01	$8.86	$14.86	$22.78
Indiana	458	151.2	$14.05	$14.24	$12.93	$14.85
Iowa	271	42.4	$9.27	$8.91	$9.09	$10.15
Kansas	147	25.9	$9.40	$8.70	$8.67	$11.26
Kentucky	221	67.7	$11.11	$9.16	$11.13	$11.16
Louisiana	245	118.2	$15.60	$4.91	$10.11	$16.54
Maine	16	2.4	$5.89	$0.00	$6.38	$4.78
Maryland	177	77.5	$12.02	$6.97	$9.83	$12.44
Massachusetts	306	125.5	$12.59	$11.71	$11.40	$12.84
Michigan	318	128.9	$14.82	$12.36	$12.54	$16.00
Minnesota	158	34.4	$10.33	$10.30	$10.33	$10.34
Mississippi	157	38.4	$9.49	$12.76	$7.99	$10.45
Missouri	377	125.4	$13.68	$6.62	$10.08	$15.68
Montana	40	10.8	$14.31	$16.03	$17.84	$10.77

State	LTC Facilities Needing Staff	Statewide Hiring Cost ($ Million)	Average Cost per Resident Day (Statewide)	Cost — <50 Beds	Cost — 50 to 100 Beds	Cost — >100 Beds
Nebraska	84	13.4	$8.81	$8.13	$7.39	$11.48
Nevada	38	18.5	$14.06	$6.79	$9.47	$15.33
New Hampshire	46	19.1	$14.06	$4.31	$13.58	$14.62
New Jersey	285	164.7	$14.87	$10.34	$11.22	$15.13
New Mexico	51	15.6	$11.02	$10.24	$11.04	$11.03
New York	502	421.0	$15.09	$9.47	$17.42	$14.95
North Carolina	343	128.3	$13.15	$11.27	$11.72	$13.99
North Dakota	20	4.5	$12.40	$9.93	$5.47	$19.27
Ohio	804	289.7	$14.79	$11.28	$13.80	$16.37
Oklahoma	204	41.1	$9.26	$1.84	$5.59	$11.21
Oregon	27	2.8	$4.91	$8.68	$3.79	$5.94
Pennsylvania	571	298.2	$14.98	$12.93	$12.77	$15.46
Puerto Rico	3	--	--	--	--	--
Rhode Island	53	16.3	$9.99	$10.23	$9.29	$10.29
South Carolina	148	59.4	$12.63	$8.79	$12.50	$12.82
South Dakota	65	11.2	$10.15	$9.37	$9.79	$13.07
Tennessee	281	101.9	$13.12	$7.40	$11.86	$13.69
Texas	1076	408.7	$15.40	$10.03	$12.80	$16.41
Utah	57	7.6	$6.50	$9.95	$6.88	$5.73
Vermont	20	6.3	$10.75	$5.46	$15.05	$9.59
Virginia	242	156.8	$19.30	$6.73	$16.15	$20.36
Washington	93	23.4	$10.28	$10.68	$8.44	$11.48
West Virginia	103	30.1	$10.88	$9.03	$9.86	$11.90
Wisconsin	189	41.3	$11.26	$7.93	$10.52	$12.56
Wyoming	19	6.2	$13.06	$0.00	$8.37	$14.84
United States	11,010	4,284.2	$13.83	$9.68	$14.36	$11.42

In table 29, we calculated the average cost by State for facilities needing staff to meet the minimum staffing requirements based on whether the facility accepted patients with Medicare, Medicaid, or both Medicare and Medicaid. The highest per resident day cost will be for 14 Medicaid-only facilities in North Dakota that will need to spend an average of $42.48 per resident day to meet the staffing requirements. The lowest per resident day cost for facilities needing staff will be for two Medicare-only facilities in West Virginia that will need to spend $0.59 per resident day to meet the requirements.

Table 29: Number of LTC Facilities in State Needing to Hire Staff and the Average Cost per Resident Day by Medicare, Medicaid, and Dual Acceptance Status

State	Medicare Only Facilities	Medicare Only Facilities Cost per Resident Day	Medicaid Only Facilities	Medicaid Only Facilities Cost per Resident Day	Medicare and Medicaid Facilities	Medicare and Medicaid Facilities Cost Cost per Resident Day
Alabama	4	$5.87	1	$12.92	171	$10.09
Alaska	0	$0.00	0	$0.00	1	$7.50
Arizona	13	$7.84	0	$0.00	92	$12.54
Arkansas	0	$0.00	2	$2.18	180	$7.53
California	7	$3.51	19	$28.85	721	$9.09
Colorado	9	$5.85	3	$28.34	135	$10.19
Connecticut	0	$0.00	0	$0.00	151	$12.05
Delaware	3	$6.47	2	$10.37	31	$11.36
District of Columbia	0	$0.00	0	$0.00	7	$6.33
Florida	6	$9.96	0	$0.00	285	$5.34
Georgia	4	$5.94	0	$0.00	322	$16.40
Hawaii	0	$0.00	0	$0.00	8	$9.61
Idaho	0	$0.00	0	$0.00	40	$6.95
Illinois	9	$5.58	14	$42.48	542	$20.62
Indiana	7	$17.82	5	$11.21	444	$14.06
Iowa	2	$3.09	5	$11.49	261	$9.28
Kansas	1	$12.98	9	$22.98	136	$8.82
Kentucky	5	$9.72	0	$0.00	214	$11.13
Louisiana	6	$4.27	0	$0.00	232	$15.34
Maine	0	$0.00	0	$0.00	16	$5.89
Maryland	2	$10.02	0	$0.00	174	$12.06
Massachusetts	4	$14.14	0	$0.00	296	$12.59
Michigan	1	$6.28	1	$2.71	314	$14.75
Minnesota	4	$5.84	6	$32.60	146	$9.20
Mississippi	3	$19.62	12	$9.74	142	$9.41
Missouri	5	$9.63	6	$17.31	365	$13.68
Montana	0	$0.00	0	$0.00	40	$14.31
Nebraska	0	$0.00	3	$7.53	77	$8.86
Nevada	3	$6.74	1	$26.14	34	$13.79
New Hampshire	0	$0.00	1	$6.60	45	$14.27
New Jersey	5	$8.83	0	$0.00	278	$14.71
New Mexico	0	$0.00	1	$8.08	50	$11.04
New York	0	$0.00	0	$0.00	500	$15.12
North Carolina	7	$11.76	1	$17.82	332	$13.17
North Dakota	1	$31.33	0	$0.00	18	$12.66
Ohio	5	$8.84	0	$0.00	792	$14.81
Oklahoma	2	$6.39	2	$6.92	200	$9.31
Oregon	0	$0.00	2	$7.52	23	$4.60
Pennsylvania	33	$9.70	1	$3.98	535	$15.15
Puerto Rico	3	$0.00	0	$0.00	0	$0.00
Rhode Island	0	$0.00	0	$0.00	53	$9.99
South Carolina	10	$6.87	0	$0.00	137	$12.82
South Dakota	0	$0.00	6	$7.01	58	$10.46
Tennessee	18	$9.05	4	$8.30	259	$13.36

State	Medicare Only Facilities	Medicare Only Facilities Cost per Resident Day	Medicaid Only Facilities	Medicaid Only Facilities Cost per Resident Day	Medicare and Medicaid Facilities	Medicare and Medicaid Facilities Cost Cost per Resident Day
Texas	23	$8.53	6	$10.40	1,039	$15.56
Utah	4	$9.15	4	$13.36	49	$6.09
Vermont	0	$0.00	0	$0.00	20	$10.75
Virginia	9	$3.26	5	$15.09	226	$19.68
Washington	0	$0.00	0	$0.00	93	$10.28
West Virginia	2	$0.59	1	$8.01	98	$10.81
Wisconsin	2	$1.40	1	$5.13	184	$11.35
Wyoming	0	$0.00	0	$0.00	19	$13.06
United States	222	$8.04	124	$21.13	10,585	$13.38

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b. Benefits of LTC Minimum Staff Requirement

Evidence in the literature suggests that higher staffing is associated with better quality of patient care and patient health outcomes.[118] [119] [120] While many of these benefits are difficult to quantify, research suggests a positive correlation between higher RN HPRD and more community discharges, as well as fewer hospitalizations and emergency department visits that result in significant savings for Medicare. An example of such evidence comes from the 2022 Nursing Home Staffing Study that analyzes the Medicare savings that are likely to result from different case-mix adjusted RN hours per resident day (HPRD) requirements.

The study first used the PBJ system, which contains data on daily hours worked by RNs, and data from the Minimum Data Set (MDS) on resident acuity and the number of residents in the facility, to calculate the acuity-adjusted RN HPRD for 14,140 LTC facilities based on data from 2022 Q2.[121] We would note, as discussed above, that while the benefits described in this section were calculated on the basis of acuity-adjusted data, the minimum staffing requirements being finalized in this rule will be applied independent of an individual facility's case-mix. We understand that this may impact the comparability of the benefits described in this section to those which may occur with the finalization of these requirements, but we also believe that the acuity adjusted data more accurately reflect that which is publicly reported through Care Compare and the PBJ System. Registered nurses included RNs, RNs with administrative duties, and RN directors of nursing. The 2022 Study then used Nurse Home Compare Data from 2021 Q2 to 2022 Q1 to examine the impact of different RN staffing levels on five claims-based measures: short-stay hospital readmission, short-stay emergency department (ED) visits, long-stay hospitalizations per 1,000 long-stay resident days, long-stay ED visits per 1,000 long-stay resident days, and the rate of successful return to home or community. More specifically, the study ran a multivariate regression model that used the 1st and 2nd RN staffing decile as the reference group and included the 3rd through the 10th deciles of RN staffing as covariates in the model. The model also includes several additional covariates that take into account LTC facility specific characteristics that include: (1) facility size (number of certified beds), (2) ownership type (for-profit, non-profit or government owned), (3) whether the facility is located in a rural area, (4) the facility's Medicaid population quartile, (5) whether the facility is hospital-based, (6) the facility's status in the Special Focus Facility Program, and (7) whether the facility is part of a continuing care retirement community. The study then used the model coefficients to identify the mean outcomes that were associated with each staffing level above the 1st and 2nd RN staffing deciles.

After identifying the mean outcome rate for each of the five measures that was associated with each staffing level, they compared it to the adjusted mean outcome rate for each facility to the rate the facility would have if it met the minimum required RN staffing level. For those facilities above the minimum RN staffing level, the study assumed that facilities would maintain their current RN staffing level. Based on the facility's number of short-stay residents, as well as long-stay resident days, the study then estimated the total savings at the facility level. To measure costs savings for Medicare, the study used an average estimated cost of $20,400 per hospitalization, $2,500 per ED visit, and for community and home discharge, the reduction in the number of Medicare-covered SNF days multiplied by the average daily payment amount. Using these criteria, the study estimates that a minimum RN requirement of between 0.52 and 0.60 HPRD would result in $318,259,715 in annual Medicare savings.[122]

Given that our final RN HPRD level is 0.55 we consider this amount to be our best estimate of the rule's financial benefits. There are also likely to be cost savings for Medicaid due to fewer hospitalizations and emergency department visits, although the 2022 Nursing Home Staffing Study did not quantify them. Additionally, while the savings estimate above reflects an acuity-adjusted standard, given variability in acuity across facilities, we believe that these savings estimates

[118] Cai, S., Yan, D., & Intrator, O. (2021). COVID–19 cases and death in nursing homes: The role of racial and ethnic composition of facilities and their communities. Journal of the American Medical Directors Association, 22(7), 1345–1351.

[119] Harris, J.A., Engberg, J., & Castle, N.G. (2020). Organizational and geographic nursing home characteristics associated with increasing prevalence of resident obesity in the United States. *Journal of Applied Gerontology, 39*(9), 991–999. *https://doi.org/10.1177/07464819843045 https://doi.org/10.1177/07464819843045.*

[120] Min, A., & Hong, H.C. (2019). Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A cross-sectional study using the U.S. Nursing Home Compare database. *Geriatric Nursing, 40*(2), 160–165. *https://doi.org/10.1016/j.g.*

[121] In the study, appendix E, section E.1.1 provides details on the criteria used for the acuity adjustment.

[122] Abt Associates. (2022). Nursing Home Staffing Study Comprehensive report. Page 110. Report prepared for the Centers for Medicare & Medicaid Services. *https://edit.cms.gov/files/document/nursing-home-staffing-study-final-report-appendix-june-2023.pdf.*

provide guidance on the impact of applying the minimum staffing requirements independent of a facility's case-mix.

Table 30 provides the estimated quantifiable benefits annually and over 10 years. Since the 0.55 RN HPRD requirement will not go into effect until Year 3, we estimate no reduction in Emergency Department visits and hospitalizations, as well as increase in discharges to home or the community for the first 2 years. Over 10 years, we estimate a total of approximately $2.55 billion in Medicare cost savings.

Table 30: 0.55 RN Minimum Staffing Requirement and Medicare Cost Savings

Year	Medicare Cost Savings
1	$0
2	$0
3	$318,259,715
4	$318,259,715
5	$318,259,715
6	$318,259,715
7	$318,259,715
8	$318,259,715
9	$318,259,715
10	$318,259,715
Total 10 Year Savings	$2,546,077,720

We expect that the 24/7 RN, 3.48 total nurse staff, and 2.45 NA HPRD requirements will also bring substantial benefits for residents, staff and LTC facilities. As we noted in the statement of need for this regulatory impact analysis, there is a positive association between the number of hours of care that a resident receives each day and resident health and safety.[123] [124] [125] The higher staffing standards we are finalizing and the resultant improvements in quality and safety will also provide greater assurance to residents' families—an important, but difficult to quantify, measure.

Research also suggests that there is a positive relationship between inadequate staffing and nursing staff burnout, which can lead to high employee turnover, and conversely, higher nurse staffing levels is associated with lower nurse staff turnover rates, suggesting that higher staffing levels will benefit employees by providing a better work environment.[126] [127] LTC facilities are likely to benefit from the higher staffing levels in the long-term with a reduction in the number of new staff they will need to hire and train, and lowered dependence on temporary workers, who often command higher hourly wages.

Lower turnover rates will also benefit residents and LTC facility operators. Higher turnover rates are associated with a variety of problems in LTC facilities including lower quality of resident care, worse performance on claims-based quality measures, a greater likelihood of LTC facilities receiving an infection control deficiency citation, and more overall survey deficiency citations, while higher long-term licensed nurse (RN and LPN) retention rates are correlated with lower 30-day rehospitalization rates and higher nursing assistant (NA) retention rates are associated with fewer overall deficiency citations, quality of care deficiency citations, and deficiencies that pose an immediate jeopardy to resident health or safety.[128] [129] [130] [131] [132] [133] [134]

Sources of uncertainty about the benefits of the 24/7 RN, 3.48 total nurse staff, 0.55 RN, and 2.45 NA HPRD requirements parallel the cost uncertainty discussed earlier but with some differences:

The benefits estimate assumed that LTC facilities needing RNs and/or NAs to meet these requirements will hire the necessary staff. It does not, however,

[123] Ochieng, N., Chidambaram, P., Musumeci, M. Nursing Facility Staffing Shortages During the COVID–19 Pandemic. Apr 04, 2022. Kaiser Family Foundation. Accessed at *https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staffing-shortages-during-the-covid-19-pandemic/.*

[124] Harrington, C., Carrillo, H., Garfield, R., Squires, E. Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016. Apr 03, 2018. Kaiser Family Foundation. Accessed at *https://www.kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2016-staffing-levels/.*

[125] Min A., Hong, H.C., Effect of nurse staffing on rehospitalizations and emergency department visits among short-stay nursing home residents: A Cross-sectional study using the U.S. Nursing Home Compare database. Geriatr Nurs. 2019 Mar–Apr;40(2):160–165. *doi: 10.1016/j.gerinurse.2018.09.010. Epub. 2018 Oct. 4. PMID: 30292528.*

[126] Kelly, L.A., Gee, P.M., Butler, R.J. Impact of nurse burnout on organizational and position turnover. Nurs. Outlook. 2021 Jan–Feb;69(1):96–102. *doi: 10.1016/j.outlook.2020.06.008.* Epub. 2020 Oct 4. PMID: 33023759; PMCID: PMC7532952.

[127] Donoghue, C. (2010). Nursing Home Staff Turnover and Retention: An Analysis of National Level Data. Journal of Applied Gerontology, 29(1), 89–106. *https://doi.org/10.1177/0733464809334899.*

[128] Harrington, C., Swan, J.H. Nursing home staffing, turnover, and case mix. Med. Care Res. Rev. 2003;60(3):366–92; discussion 393–9. *DOI: 10.1177/1077558703254692.*

[129] Castle, N.G., Engberg, J. Staff Turnover and Quality of Care in Nursing Homes. Medical Care 2005;43(6):616–626.

[130] Zheng, Q., Williams, C.S., Shulman, E.T., White, A.J. Association between staff turnover and nursing home quality—evidence from payroll-based journal data. J. Am. Geriatr. Soc. 2022;70(9):2508–2516. *DOI: 10.1111/jgs.17843.*

[131] Loomer, L., Grabowski, D.C., Yu, H., Gandhi, A. Association between nursing home staff turnover and infection control citations. Health Serv. Res. 2022;57(2):322–332. *DOI: 10.1111/1475–6773.13877.*

[132] Lerner, N.B., Johantgen, M., Trinkoff, A.M., Storr, C.L., Han, K. Are nursing home survey deficiencies higher in facilities with greater staff turnover. J. Am. Med. Dir. Assoc. 2014;15(2):102–7. *DOI: 10.1016/j.jamda.2013.09.003.*

[133] Thomas, K.S., Mor, V., Tyler, D.A., Hyer, K. The relationships among licensed nurse turnover, retention, and rehospitalization of nursing home residents. Gerontologist 2013;53(2):211–21. *DOI: 10.1093/geront/gns082.*

[134] Castle, N.G., Hyer, K., Harris, J.A., Engberg, J. Nurse Aide Retention in Nursing Homes. Gerontologist 2020;60(5):885–895. *DOI: 10.1093/geront/gnz168.*

take into account how changes in the number of hours per resident day of other direct care or support staff that occur in response to the finalized requirements might affect the impact that increasing the RN HPRD will have on Medicare cost savings. Some research, however, has found that when States implemented minimum hour per day requirements for direct care staff (RNs, LPNs, and NAs), LTC facilities responded by reducing indirect care staff, such as housekeeping, food service, and activities staff.[135] [136] If LTC facilities respond to the 24/7 RN, 3.48 total nurse staff HPRD, the 0.55 RN HPRD, and the 2.45 NA HPRD requirement in similar ways, then benefits of the requirements would be lower than what is presented above (see earlier discussion about appropriate accounting depending on the consistency between benefit and cost analytic approaches).

The benefits estimate assumed that LTC facilities that exceed the 24/7 RN, 3.48 total nurse staff, 0.55 RN HPRD, and 2.45 NA HPRD requirements would maintain RN, NA, and total staffing at their current levels. Research examining how LTC facilities have responded to State level staffing mandates provides mixed evidence for this assumption, with some research finding no evidence that LTC facilities exceeding minimum requirements reduce staffing, while other research suggests that they do.[137] If LTC facilities reduced RN, NA, and total nurse staffing levels to a level that is closer to the minimum requirement, then benefits would be lower than what is estimated above.

The benefits estimate assumed no real growth in the financial value of reduced Emergency Department visits and hospitalizations, as well as increase in discharges to home or the community. If, however, the cost of Emergency Department visits and hospitalizations grows faster than the rate of inflation, then value of these benefits will be higher than what we have estimated here.

The benefit estimates assumed that the nursing home resident population will remain stable over the next 10 years. There is some evidence, however, that the resident population is declining. CMS *Care Compare* data shows that between February 2017 and February 2024, the average number of residents in nursing homes per day declined from 1,346,712 residents to 1,207,726.[138] If the resident population continues to decrease, then the benefits could be lower than what we have estimated. Similarly, if the pattern changes and the nursing home resident population increases, the benefits could be higher than what we have estimated.

The benefits estimate assumed that no LTC facilities would obtain exemptions from the 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements, although some facilities could obtain such an exemption. Based only on being located in an area with a nurse staffing shortage, a preliminary analysis of the data suggests that more than 29 percent of facilities would be eligible for an 8-hour exemption from the 24/7 RN requirement and the 0.55 RN HPRD requirement, 23 percent of facilities would be eligible for an exemption from the 2.45 NA HPRD requirement, and 22 percent of facilities would be eligible for an exemption from the 3.48 HPRD total nurse staff requirement. Since facilities would also need to meet all other requirements to obtain an exemption, however, these numbers are not reflective of the number of facilities estimated to fully qualify for the exemptions as they only describe the number of facilities that would satisfy the workforce availability criterion. Depending on the number of facilities that obtain an exemption, the total benefits of the rule could be lower than what is presented above.

States could vary in how they respond to the increased staffing requirement, including whether they pay at least some of the additional nursing staffing costs with Medicaid funds. Benefits consequences are contingent upon such choices. For example, if overall Medicaid spending does not increase, but funds are shifted from other uses to increased LTC facility staffing, there would be negative health benefits for the patients experiencing reduced Medicaid coverage.

d. Transfers Associated With the 24/7 RN and 0.55 RN and 2.45 NA HPRD Minimum Staffing Requirements

We do not estimate transfers associated with the 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and the 2.45 NA HPRD minimum staffing portion of this rule since there are no requirements that Medicare, Medicaid, and other non-Medicare/Medicaid payors increase payment rates in response to these requirements.

(5) Medicaid Institutional Payment Transparency Reporting Provision Impacts

Under our authority at sections 1902(a)(6) and (a)(30) of the Act with regard to fee-for-service delivery systems, and sections 1902(a)(4) and 1932(c) of the Act with regard to managed care delivery systems, we are finalizing new reporting requirements at § 442.43(b) and (c) for States to report annually by facility on the percent of payments for Medicaid-covered services delivered by nursing facilities and ICFs/IID that are spent on compensation for direct care workers and support staff.

As finalized, States are required to report annually to CMSs on the percent of payments for nursing facility and ICF/IID services that are spent on compensation for direct care workers and support staff. We are finalizing that States are required to post all reported data on a State-maintained website (or link to such information on an MCO's or PIHP's website, as applicable), which States must ensure is reviewed quarterly to verify the accurate function of the website and that the information remains accurate and up to date. We believe that gathering and sharing data about the amount of Medicaid dollars that are going to the compensation of workers is a critical step in the larger effort to understand the ways we can enact policies that support the institutional care workforce and thereby help advance access to high quality care for Medicaid beneficiaries.

a. Costs of Medicaid Institutional Payment Transparency Reporting

The following discussion is based on costs to States, the Federal Government, and providers that were summarized in table 24 and described in detail in the Collection of Information (section V. of this final rule). As outlined in section V., we estimate one-time implementation costs of $838,475 for States to come into compliance with the reporting requirements finalized at § 442.43(b) and (c). As discussed in section V., the Federal Government, through Federal Financial Participation,

[135] Thomas, Kali S., Kathryn Hyer, Ross Andel, and Robert Weech-Maldonado. The Unintended Consequences of Staffing Mandates in Florida Nursing Homes: Impacts on Indirect-Care Staff, 2010, Medicare Care Research and Review, Volume 67, Issue 5, Pages 555–573.

[136] Bowblis, John R., and Kathryn Hyer. Nursing Home Staffing Requirements and Input Substitution: Effects on Housekeeping, Food Service, and Activities Staff, 2013, Health Services Research, Volume 48, Issue 4, Pages: 1539–1550.

[137] Chen, Min M., and David C. Grabowski. Intended and Unintended Consequences of Minimum Staffing Standards for Nursing Homes, 2015, Volume 24, Pages 822–839.

[138] CMS. (2024). Nursing homes including rehab services archived data snapshots. Accessed March 19, 2024. Available at: *https://data.cms.gov/provider-data/archived-data/nursing-homes.*

has a share in Medicaid expenditures, which for the purposes of these burden estimates is 50 percent of Medicaid expenditures. Thus, we estimate the one-time costs of the reporting requirement finalized at § 442.43(b) and (c) as $419,237 for States and $419,237 for the Federal Government. We estimate an annual total cost of $97,470 once the reporting requirement goes into effect; again, as the costs will be split between States and the Federal Government, we estimate the annual ongoing costs as $48,735 for States and $48,735 for the Federal Government. A breakdown of these figures may be found in tables 18 and 19 in the Collection of Information (section V. of this final rule.)

Additionally, under finalized § 442.43(d), States are required to make this information available on a public website; as outlined in the Collection of Information (section V. of this rule), we estimate a one-time implementation costs of $239,333 for States to come into compliance with this requirement; as the costs will be split between States and the Federal Government, we estimate the one-time cost for States as $119,667 and $119,667 for the Federal Government. We estimate an ongoing annual cost of $295,527 once reporting starts; as the costs will be split between States and the Federal Government, we estimate the one-time cost as $147,764 for States and $147,764 for the Federal Government. A breakdown of these figures may be found in tables 22 and 23 in section V.

The total State and Federal costs for both the reporting and website requirements are thus estimated at $1,077,808 for implementation costs ($838,475 + $239,333) and $392,997 ongoing annual costs once the reporting starts ($97,470 + $295,527).

As discussed in the Collection of Information (section V. of this rule), we estimate that the total cost to providers to prepare for compliance with the reporting requirement finalized at § 442.43(b) and (c) will be $36,560,002, and an annual total cost to providers of $17,912,717. A breakdown of these figures may be found in tables 30 and 31 in section V.

We do not estimate a cost to providers for the website posting requirement finalized at § 442.43(d). We also do not anticipate costs to beneficiaries associated with these requirements.

Table 31 provides a detailed summary of the estimated costs of each of the requirements for States, the Federal Government, and providers. Table 32 summarizes the estimated costs of the requirements in § 442.43 for States, the Federal Government, and providers (Nursing Care Facilities (NAICS 623110) and Residential Intellectual and Developmental Disabilities Facilities (NAICS 623210)), over 10 years. Aside from regulatory review costs (discussed in the next section) this comprises the entirety of anticipated quantifiable costs associated with the finalized changes to part 442, subpart B. The implementation costs associated with the finalized reporting and website posting requirements are split evenly over the years leading up to the finalized effective date, which is 4 years from this final rule's publication. For States and the Federal Government, this means that the implementation costs are represented as $107,736 per year for 4 years ($430,942 estimated implementation costs/4 years). For providers, the implementation costs are represented as $9,140,000 per year for 4 years ($36,560,002 estimated implementation costs/4 years). We also anticipate that once the rule goes into effect in Year 5, the ongoing annual costs will be relatively stable. We have shown the recurring annual estimate for Years 5 to 10 in table 32. The estimates below do not account for higher costs associated with medical care; the costs calculated here are related exclusively to reporting and website posting costs. Per OMB guidelines, the projected estimates for future years are reported in real (inflation-indexed) dollars.

As discussed in the Collection of Information (section V. of this rule), costs were based on: (1) the number of States (including Washington, DC, and certain territories) that currently operate Medicaid programs that cover nursing facility or ICF/IID services; (2) the number of States that deliver long-term services and supports through a managed care delivery system; and (3) the total number of freestanding Medicaid-certified nursing facility and ICF/IID facilities in all States. We do not anticipate the number of entities changing significantly over the 10 years included in the cost calculations.

Table 31: Implementation and Annual Costs Detailed

	Cost to States ($)	Cost to Federal ($)	Costs to Providers ($)	Implementation Burden Overall Total ($)	Ongoing Annual Burden Overall Total ($)
Reporting – Implementation	419,237	419,237	36,560,002	37,182,552	- -
Reporting – Recurring annual starting Year 5	48,735	48,735	17,912,717	- -	18,010,187
Website – Implementation	119,667	119,667	- -	239,333	- -
Website – Recurring annual starting Year 5	147,763	147,763	-	- -	295,526
Total	735,402	735,402	54,472,719	- 37,637,809	18,305,713

Table 32: Projected Distribution of Costs for Proposed Updates to 42 CFR Part 442, Subpart B

Year	State Costs	Federal Costs	Provider Costs	Total Costs associated with § 442.43
1	183,851	183,851	9,140,000	9,507,702
2	183,851	183,851	9,140,000	9,507,702
3	183,851	183,851	9,140,000	9,507,702
4	183,851	183,851	9,140,000	9,507,702
5	196,498	196,498	17,912,717	18,305,713
6	196,498	196,498	17,912,717	18,305,713
7	196,498	196,498	17,912,717	18,305,713
8	196,498	196,498	17,912,717	18,305,713
9	196,498	196,498	17,912,717	18,305,713
10	196,498	196,498	17,912,717	18,305,713
10 Year Total Cost	1,914,392	1,914,392	144,036,302	147,865,086

b. Benefits of Medicaid Institutional Payment Transparency Reporting

Our finalized requirements are intended to support the sufficiency of the direct care and support staff workforce through public reporting of compensation to these workers. While we believe this finalized provision will provide benefits, we are not able to quantify these benefits at this time.

There are many factors that contribute to understaffing in institutional settings. We are constantly seeking opportunities to address these challenges through guidance, policies, and rulemaking. These finalized requirements are intended to promote transparency around compensation for direct care workers and support staff. We believe that gathering and sharing data about the amount of Medicaid payments going to the compensation of workers is a critical step in the larger effort to understand the ways we can enact future policies that support the institutional care workforce.

c. Transfers Associated With Medicaid Institutional Payment Transparency Reporting

We do not estimate transfers associated with these finalized provisions.

D. Alternative Direct Care Staff HPRD Requirement Considered

As detailed earlier in this final rule, despite the existing requirements and the efforts to improve safety, as well as residents' quality of care and quality of life through the revisions in the 2016 final rule, understaffing in LTC facilities continues to be a concern. We believe the changes we are finalizing are consistent with current standards of practice and necessary to increase resident safety and quality of care. We acknowledge, however, that there were multiple avenues for establishing a minimum nurse staffing requirement and in the proposed rule we solicited comments on alternative policy options, including a specific comment solicitation in the ''Provisions of the Proposed Regulation'' section.

In developing the final rule, we considered varying staffing models that were available and different approaches we could have adopted for the proposed minimum nurse staffing requirement. We could have adopted multiple different types of combinations of a staffing requirement such as separate requirements for RNs, LVNs/LPNs, and NAs or creating standards for NAs only. We could also have implemented individual HPRD requirements for RNs and NAs together with a 24/7 RN requirement but excluded any requirement for an overall nurse staffing HPRD level, which was a policy discussed in detail in the proposed rule. Alternatively, we could have adopted non-nurse staffing requirements such as social workers, therapists, feeding assistants and other non-nurse staffing types in the minimum staffing requirement. Alternative minimum staffing policy options could have also focused on the need to increase or decrease the number of HPRD or FTEs by nurse staff and/or type or on specifying the number of staff by shift (including day, evening, night, or weekends or over a 24-hour period).

Ultimately, we chose the comprehensive 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements in this final rule to strike a balance between ensuring resident health and safety, while preserving access to care, including discharge to community-based services. We considered a staffing standard that would maintain the 24/7 RN and 2.45 NA HPRD requirements but would have a lower RN HPRD requirement. We found, however, that even a small reduction in the RN HPRD requirement compared to baseline RN HPRD levels that are in the two lowest deciles for nursing homes nationwide would lead to a large decline in quality of care. For example, the 2022 Nursing Home Staffing Study [139] found that reducing the case-mix adjusted RN HPRD requirement to between 0.45 and 0.52 hours per resident day would lead the staffing standard to have a smaller impact on Medicare savings, reduced hospitalizations and ED visits, and fewer community discharges. More specifically, the number of reduced hospitalizations would decline from 10,445 to 5,781, the number of reduced ED visits would decline from 7,525 to 4,466, increased community discharges would decline from 5,798 to 3,930, and Medicare savings would decline by more than $130 million annually. We also considered alternative minimum staffing requirements at the same level we are finalizing but with a longer phase-in period for the 3.48 total nurse staff HPRD requirement. We ultimately decide to provide a shorter phase-in period for the 3.48 total nurse staff HPRD requirement to ensure resident health and safety.

2. Medicaid Institutional Payment Transparency Reporting

We considered, but did not finalize, a proposal to require States to report per diem FFS rate for nursing facility and ICF/IID services; we did not finalize this proposal as we believed it would duplicate other reporting requirements.

We also considered, but did not finalize, a proposal to require States to report on median hourly wage and to require that States report data by job title. We did not finalize this proposal because we expected that this would increase reporting burden for States and providers without giving us additional information necessary for determining the percent of payments that are going to the workforce.

E. Regulatory Review Costs

1. Regulatory Review Costs of 24/7 RN, 3.48 Total Nurse Staff, 0.55 RN and 2.45 NA HPRD Minimum Nurse Staffing Requirements

If the 24/7 RN and the Minimum Nurse staffing requirements impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. As discussed in the Collection of Information (section V. of this final rule), 14,688 LTC facilities will be impacted by the finalized requirements. We assume that all 14,688 LTC facilities will proactively review this final rule. (We note that the FY 2023 SNF PPS proposed rule, 87 FR 22720, had around 18,000 views, as shown at *https://www.federalregister.gov/documents/2022/04/15/2022-07906/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities.* Some of these views were likely multiple views by the same reader.) We acknowledge that this assumption may understate the costs of reviewing this rule. It is possible that there may be more than one individual reviewing the rule for some LTC facilities. It is also possible that entities other than LTC facilities, such as beneficiary advocacy groups, may review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of some final rules, or that some entities may not find it necessary to fully read each rule, and therefore for the purposes of our estimate we assume that each reviewer will read approximately 50 percent of the section of the rule discussing the 24/7 RN requirement and the 3.48 total nurse staff, 0.55 RN, and 2.45 NA HPRD requirements.

Using the wage information from the Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates, *https://www.bls.gov/oes/current/oes_nat.htm,* for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits. Assuming an average reading speed of 250 words per minute, and assuming that two-thirds (67 percent) of this final rule pertains to the 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements, with approximately 40,000 words (of which we estimate 20,000 words will be read by reviewers), we estimate that it would take 80 minutes or 1.33 hours for the staff to review all the sections of the final rule pertaining to the 24/7 RN and the 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements. For each employee that reviews the rule, the estimated cost is $163.67 (1.33 hours × $123.06). Therefore, we estimate that the total one-time cost of reviewing this regulation is $2,403,985 ($163.67 × 14,688).

2. Regulatory Review Costs of Medicaid Institutional Payment Transparency Reporting

As discussed in the Collection of Information (section IV. of the proposed rule at 88 FR 61393 and 61395), 54 State Medicaid agencies and approximately 19,907 nursing facilities and ICFs/IID would be impacted by the requirements, totaling 19,961 interested parties. We note that there was an error in the proposed rule at 88 FR 64124 that stated incorrectly that 52, rather than 54 State Medicaid agencies were affected by the rule; we have corrected that figure here.

As discussed in the proposed rule at 88 FR 64124, we estimated that 75 percent of these affected entities would proactively review the final rule. We welcomed any comments on this approach but did not receive any comments. Therefore, we are calculating the regulatory review burden associated with the provision finalized at § 442.43 using this assumption. We estimate that 14,971 entities read the rule for the purpose of reviewing the provision finalized at § 442.43 ([54 + 19,907] × 75 percent.)

Using the wage information from the Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates, *https://www.bls.gov/oes/current/oes_nat.htm,* for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits. Assuming an average reading speed of 250 words per minute, and assuming that one-third of this rule pertains to Medicaid Institutional Payment Transparency Reporting, with approximately 20,000 words (of which we estimated 10,000 words were read by reviewers), we estimated that it would take 40 minutes or 0.67 hours for the staff to review portions of the sections of the final rule pertaining to the Medicaid Institutional Payment Transparency Reporting. For each employee that reviewed the rule, the estimated cost is $82.45 (0.67 hours × $123.06). Therefore, we estimated that the total one-time cost of reviewing this regulation is $1,234,359 ($82.45 × 14,971).

Table 33 provides the total estimated regulatory review costs for the rule, which is $3,638,344.

Table 33: Regulatory Review Cost

Medicaid Institutional Payment Transparency Reporting	24/7 RN, 3.48 Total Nurse Staff and 0.55 RN and 2.45 NA HPRD Minimum Nurse Staffing Requirements	Total Cost
$1,234,359	$2,403,985	$3,638,344

F. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), we have prepared an accounting statement in table 34 showing classification of the costs and benefits associated with the provisions of this final rule. This includes the total cost for the 24/7 RN and the 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements as provided in table 22, the total cost for the Medicaid Institutional Transparency Reporting as provided in table 18, the total cost for the regulatory review as provided in table 33, and Medicare savings due to fewer hospitalizations

and emergency department visits, as well as greater return to home and community, as provided in table 30.

There are $0 in transfer estimates in the statement. This statement provides our best estimate for the Medicare and Medicaid provisions of this rule.

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Table 34: Accounting Statement: 24/7 RN Requirement, 3.48 Total Nurse Staff, 0.55 RN, and 2.45 NA HPRD Requirements, and Medicaid Institutional Payment Transparency Reporting Requirement

Category	Estimates	Units		Period Covered
		Year **Dollar**	Discount Rate	
Benefits				
Annualized Monetized ($million/year)	236	2021	7%	2024-2033
	247	2021	3%	2024-2033
Costs				
Annualized Monetized ($million/year)	3,999	2021	7%	2024-2033
	4,179	2021	3%	2024-2033

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G. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all Skilled Nursing Facilities (NAICS 6231) and Intellectual and Developmental Disabilities Facilities (NAICS 6232) are small entities, as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA)

definition of a small business (that is, having revenues of less than $9.0 million to $47.0 million in any 1 year).

We utilized the revenues of individual SNF *providers* (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards, with total revenues of $34 million or less in any 1 year. In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Therefore, approximately 95 percent of the health care entities impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of $47 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. According to the 2017 Economic Census, Skilled Nursing Facilities (NAICS 6231) and Intellectual and Development Disabilities Facilities (NAICS 6232) together earned approximately $162 billion annually, with Skilled Nursing Facilities earning nearly $119 billion and Intellectual and Development Disabilities Facilities earning approximately $44 billion. Overall, the cost is estimated to be between 2.30 and 2.42 percent of revenues.

Adjusting this amount for inflation, as measured by the Consumer Price Index, combined revenues in 2021 Dollars are approximately $179.5 billion. Overall, the cost is estimated to be between 2.23 and 2.32 percent of revenues.

Table 35: Regulatory Flexibility Act Analysis

	Annual Revenue	Estimated Average Annual Cost for Providers with 3% Discount Rate	Estimated Average Annual Cost for Providers with 7% Discount Rate	Cost as % of Revenue with 3% Discount Rate	Cost as % of Revenue with 7% Discount Rate
Skilled Nursing Facilities and Intellectual and Developmental Disabilities Facilities	$179,582,997,397	$3,999,000,000	$4,179,000,000	2.23	2.32

This rule will not have a significant impact as measured by a change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. At this time, we do not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. These proposals pertain solely to SNFs and NFs. Therefore, the Secretary has determined that these provisions will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $183 million. Based on the cost estimates discussed in this section, we have assessed the various costs and benefits of the final updates to the requirements for participation for LTC facilities. These final updates will not impose new requirements for State, local, or Tribal governments. For the private sector facilities, the regulatory impact section, together with the remainder of the preamble, constitutes the analysis required under UMRA.

I. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. With regard to the updates to the requirements for participation for LTC facilities, the provisions in this final rule are not intended to, and would not preempt the applicability of any State or local law providing a higher standard (in this case, a higher HPRD requirement for total nurse staff, RNs and/or NAs or an RN coverage requirement in excess of at least one RN on site 24-hours per day, 7 days a week) than we are requiring in this final rule. To the extent Federal standards exceed State and local law minimum staffing standards, no Federal pre-emption is implicated because facilities complying with Federal law would also be in compliance with State law. We are not aware of any State or local law providing for a maximum staffing level. This final rule, however, is intended to and would preempt the applicability of any State or local law providing for a maximum staffing level, to the extent that such a State or local maximum staffing level would prohibit a Medicare, Medicaid, or dually certified LTC facility from meeting the minimum HPRD requirements and RN coverage levels finalized in this rule or from meeting higher staffing levels required based on the facility assessment provisions finalized in this rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for

Medicare & Medicaid Services, approved this document on April 10, 2024.

List of Subjects

42 CFR Part 438

Administrative practice and procedure, Grant programs—health, Health professions, Medicaid, Older adults, People with disabilities, Reporting and recordkeeping requirements.

42 CFR Part 442

Administrative practice and procedure, Grant programs—health, Health professions, Medicaid, Older adults, People with disabilities, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) *Nursing facility services and services delivered in intermediate care facilities for individuals with intellectual disabilities (ICFs/IID).* The State must comply with the requirements in § 442.43 for nursing facility and ICF/IID services.

(b) [Reserved]

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

■ 3. The authority citation for part 442 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 442.43 is added to subpart B to read as follows:

§ 442.43 Payment transparency reporting.

(a) *Definitions.* (1) *Compensation* means, with respect to direct care workers and support staff delivering services authorized under this part:

(i) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(ii) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(iii) The employer share of payroll taxes.

(2) *Direct care worker* means one of the following individuals who provides services to Medicaid-eligible individuals receiving services under this part, who may be employed by or contracted or subcontracted with a Medicaid provider or State or local government agency:

(i) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(ii) A certified nurse aide who provides services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(iii) A licensed physical therapist, occupational therapist, speech-language pathologist, or respiratory therapist;

(iv) A certified physical therapy assistant, occupational therapy assistant, speech-language therapy assistant, or respiratory therapy assistant or technician;

(v) A social worker;

(vi) A direct support professional;

(vii) A personal care aide;

(viii) A medication assistant, aide, or technician;

(ix) A feeding assistant;

(x) Activities staff; or

(xi) Any other individual who is paid to provide clinical services, behavioral supports, active treatment (as defined at § 483.440 of this chapter) or address activities of daily living (such as those described in § 483.24(b) of this chapter) for Medicaid-eligible individuals receiving Medicaid services under this part, including nurses and other staff providing clinical supervision.

(3) *Support staff* means an individual who is not a direct care worker and who maintains the physical environment of the care facility or supports other services for residents. Support staff may be employed by or contracted or subcontracted with a Medicaid provider or State or local government agency. They include any of the following individuals:

(i) A housekeeper;

(ii) A janitor or environmental services worker;

(iii) A groundskeeper;

(iv) A food service or dietary worker;

(v) A driver responsible for transporting residents;

(vi) A security guard; or

(vii) Any other individual who is not a direct care worker and who maintains the physical environment of the care facility or supports other services for Medicaid-eligible individuals receiving Medicaid services under this part.

(4) *Excluded costs* means costs reasonably associated with delivering Medicaid-covered nursing facility or ICF/IID services that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers and support staff. Such costs are limited to:

(i) Costs of required trainings for direct care workers and support staff (such as costs for qualified trainers and training materials);

(ii) Travel costs for direct care workers and support staff (such as mileage reimbursement or public transportation subsidies); and

(iii) Costs of personal protective equipment for facility staff.

(b) *Reporting requirements.* The State must report to CMS annually, by facility, the percentage of Medicaid payments (not including excluded costs) for services specified in paragraph (b)(1) of this section, that is spent on compensation for direct care workers and on compensation for support staff, at the time and in the form and manner specified by CMS. For the purposes of this part, Medicaid payment for fee-for-service (FFS) includes base and supplemental payments as defined in section 1903(bb)(2) of the Social Security Act, and for payments from a managed care organization (MCO) or prepaid inpatient health plan (PIHP) (as these entities are defined in § 438.2 of this chapter) includes the MCO's or PIHP's contractually negotiated rate, State directed payments as defined in § 438.6(c) of this chapter, pass-through payments as defined in § 438.6(a) of this chapter for nursing facilities, and any other payments from the MCO or PIHP.

(1) *Services.* Except as provided in paragraphs (b)(2) and (3) of this section, reporting must be based on all Medicaid payments (including but not limited to FFS base and supplemental payments, and payments from an MCO or PIHP, as applicable) made to nursing facility and ICF/IID providers for Medicaid-covered services, with the exception of services provided in swing bed hospitals as defined in § 440.40(a)(1)(ii)(B) of this chapter.

(2) *Exclusion of specified payments.* The State must exclude from its reporting to CMS payments claimed by the State for Federal financial participation under this part for which Medicaid is not the primary payer.

(3) *Exclusion of data from the Indian Health Service and Tribal health programs.* States must exclude data from the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (b) of this section.

(c) *Report contents and methodology*—(1) *Contents.* Reporting must provide information necessary to identify, at the facility level, the percent of Medicaid payments spent on compensation to:

(i) Direct care workers at each nursing facility;

(ii) Support staff at each nursing facility;

(iii) Direct care workers at each ICF/IID; and

(iv) Support staff at each ICF/IID.

(2) *Methodology.* The State must provide information according to the methodology, form, and manner of reporting stipulated by CMS.

(d) *Availability and accessibility requirements.* The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified in paragraphs (b) and (c) of this section. In the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and/or 1115(a) of the Act and that includes nursing facility and/or ICF/IID services in their MCO or PIHP contracts, the State may meet this requirement by linking to individual MCO's or PIHP's websites. The State must:

(1) Include clear and easy to understand labels on documents and links;

(2) Verify no less than quarterly, the accurate function of the website and the current accuracy of the information and links; and

(3) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(e) *Information reported by States.* CMS must report on its website the results of the reporting requirements specified in paragraphs (b) and (c) of this section that the State reports to CMS.

(f) *Applicability date.* States must comply with the requirements in this section beginning 4 years after June 21, 2024; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes nursing facility services or ICF/IID services, the first rating period for contracts with the MCO or PIHP beginning on or after 4 years after June 21, 2024.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 5. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 6. Section 483.5 is amended by adding the definitions of ''Hours per resident day'' and ''Representative of direct care employees'' in alphabetical order to read as follows:

§ 483.5 Definitions.

* * * * *

Hours per resident day. Staffing hours per resident per day is the total number of hours worked by each type of staff divided by the total number of residents as calculated by CMS.

* * * * *

Representative of direct care employees. A representative of direct care employees is an employee of the facility or a third party authorized by direct care employees at the facility to provide expertise and input on behalf of the employees for the purposes of informing a facility assessment.

* * * * *

■ 7. Section 483.10 is amended by revising paragraph (h)(3)(i) to read as follows:

§ 483.10 Resident rights.

* * * * *

(h) * * *

(3) * * *

(i) The resident has the right to refuse the release of personal and medical records except as provided at § 483.70(h)(2) or other applicable Federal or State laws.

* * * * *

■ 8. Section 483.15 is amended by revising paragraph (c)(8) to read as follows:

§ 483.15 Admission, transfer, and discharge rights.

* * * * *

(c) * * *

(8) *Notice in advance of facility closure.* In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(k).

* * * * *

■ 9. Section 483.35 is revised to read as follows:

§ 483.35 Nursing services.

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity, and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.71.

(a) *Sufficient staff.* (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) Except when waived under paragraph (f) of this section, licensed nurses; and

(ii) Other nursing personnel, including but not limited to nurse aides.

(2) Except when waived under paragraph (f) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(3) The facility must ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(4) Providing care includes but is not limited to assessing, evaluating, planning, and implementing resident care plans and responding to resident's needs.

(b) *Total nurse staffing (licensed nurses and nurse aides).* (1) The facility must meet or exceed a minimum of 3.48 hours per resident day for total nurse staffing including but not limited to—

(i) A minimum of 0.55 hours per resident day for registered nurses; and

(ii) A minimum of 2.45 hours per resident day for nurse aides.

(2) One or more of the hours per resident day requirements at paragraph (b)(1) of this section may be exempted for facilities found non-compliant and who meet the eligibility criteria defined at paragraph (h) of this section as determined by the Secretary.

(3) Compliance with minimum total nurse staffing hours per resident day as

set forth in one or more of the hours per resident day requirements of paragraph (b)(1) of this section should not be construed as approval for a facility to staff only to these numerical standards. Facilities must ensure there are a sufficient number of staff with the appropriate competencies and skills sets necessary to assure resident safety and to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments, acuity and diagnoses of the facility's resident population in accordance with the facility assessment at § 483.71.

(c) *Registered nurse.* (1) Except when waived or exempted under paragraph (f), (g), or (h) of this section, the facility must have a registered nurse (RN) onsite 24 hours per day, for 7 days a week that is available to provide direct resident care.

(2) For any periods when the onsite RN requirements in paragraph (c)(1) of this section are exempted under paragraph (h) of this section, facilities must have a registered nurse, nurse practitioner, physician assistant, or physician available to respond immediately to telephone calls from the facility.

(3) Except when waived under paragraph (f) or (g) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

(4) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

(d) *Proficiency of nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(e) *Requirements for facility hiring and use of nursing aides*—(1) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless—

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151 through 483.154; or

(B) That individual has been deemed or determined competent as provided in § 483.150(a) and (b).

(2) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(1)(i) and (ii) of this section.

(3) *Minimum competency.* A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in § 483.150(a) and (b).

(4) *Registry verification.* Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(5) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under section 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

(6) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(7) *Regular in-service education.* The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. In-service training must comply with the requirements of § 483.95(g).

(f) *Nursing facilities: Waiver of requirement to provide licensed nurses and a registered nurse on a 24-hour basis.* To the extent that a facility is unable to meet the requirements of paragraphs (a)(1), (b)(1)(i), and (c)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in this paragraph (f) is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

(g) *SNFs: Waiver of the requirement to provide services of a registered nurse for at least 112 hours a week.* (1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (c) of this section, if the Secretary finds that—

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either—

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of

a registered nurse or a physician for a 48-hours period; or

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental disorders; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (g)(1) of this section is subject to annual renewal by the Secretary.

(h) *Hardship exemptions from the minimum hours per resident day and registered nurse onsite 24 hours per day, for 7 days a week requirements.* A facility may be exempted by the Secretary from one or more of the requirements of paragraphs (b)(1) and (c)(1) of this section if a verifiable hardship exists that prohibits the facility from achieving or maintaining compliance. The facility must meet the four following criteria to qualify for and receive a hardship exemption:

(1) *Location.* The facility is located in an area where the supply of applicable healthcare staff (RN, nurse aide (NA), or total nurse staffing, as indicated in paragraphs (h)(1)(i), (ii), and/or (iii) of this section) is not sufficient to meet area needs as evidenced by a provider to population ratio for nursing workforce that is a minimum of 20 percent below the national average, as calculated by CMS, by using data from the Bureau of Labor Statistics and Census Bureau.

(i) The facility may receive an exemption from the total nurse staffing requirement of 3.48 hours per resident day at paragraph (b)(1) of this section if the combined licensed nurse, which includes both RNs and licensed vocational nurses (LVN)/licensed practical nurses (LPNs) and nurse aide to population ratio in its area is a minimum of 20 percent below the national average.

(ii) The facility may receive an exemption from the 0.55 registered nurse hours per resident day requirement at paragraph (b)(1)(i) of this section and an exemption of 8 hours a day from the registered nurse on site 24 hours per day, for 7 days a week requirement at paragraph (c)(1) of this section if the registered nurse to population ratio in its area is a minimum of 20 percent below the national average.

(iii) The facility may receive an exemption from the 2.45 nurse aide hours per resident day requirement at paragraph (b)(1)(ii) of this section if the nurse aide to population ratio in its area is a minimum of 20 percent below the national average.

(2) *Good faith efforts to hire.* The facility demonstrates that it has been unable, despite diligent efforts, including offering at least prevailing wages, to recruit and retain appropriate personnel. The information is verified through:

(i) Job listings in commonly used recruitment forums found online at American Job Centers (coordinated by the U.S. Department of Labor's Employment and Training Administration), and other forums as appropriate;

(ii) Documented job vacancies including the number and duration of the vacancies and documentation of offers made, including that they were made at least at prevailing wages;

(iii) Data on the average wages in the Metropolitan Statistical Area in which the facility is located and vacancies by industry as reported by the Bureau of Labor Statistics or by the State's Department of Labor; and

(iv) The facility's staffing plan in accordance with § 483.71(b)(4); and

(3) *Demonstrated financial commitment.* The facility demonstrates through documentation the amount of financial resources that the facility expends on nurse staffing relative to revenue.

(4) *Disclosure of exemption status.* The facility:

(i) Posts, in a prominent location in the facility, and in a form and manner accessible and understandable to residents, and resident representatives, a notice of the facility's exemption status, the extent to which the facility does not meet the minimum staffing requirements, and the timeframe during which the exemption applies; and

(ii) Provides to each resident or resident representative, and to each prospective resident or resident representative, a notice of the facility's exemption status, including the extent to which the facility does not meet the staffing requirements, the timeframe during which the exemption applies, and a statement reminding residents of their rights to contact advocacy and oversight entities, as provided in the notice provided to them under § 483.10(g)(4); and

(iii) Sends a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

(5) *Exclusions.* Facilities must not:

(i) Be a Special Focus Facility, pursuant to the Special Focus Facility Program established under sections 1819(f)(8) and 1919(f)(10) of the Act; or

(ii) Have been cited for having widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm, or cited at the immediate jeopardy level of severity with respect to insufficient staffing as determined by CMS, within the 12 months preceding the survey during which the facility's non-compliance is identified; or

(iii) Have failed to submit Payroll Based Journal data in accordance with § 483.70(p).

(6) *Determination of eligibility.* The Secretary, through CMS or the State, will determine eligibility for an exemption based on the criteria in paragraphs (h)(1) through (5) of this section. The facility must provide supporting documentation when requested.

(7) *Timeframe.* The term for a hardship exemption is from grant of exemption until the next standard recertification survey, unless the facility becomes a Special Focus Facility, is cited for widespread insufficient staffing with resultant resident actual harm or a pattern of insufficient staffing with resultant resident actual harm, or is cited at the immediate jeopardy level of severity with respect to insufficient staffing as determined by CMS, or fails to submit Payroll Based Journal data in accordance with § 483.70(p). A hardship exemption may be extended on each standard recertification survey, after the initial period, if the facility continues to meet the exemption criteria in paragraphs (h)(1) through (5) of this section, as determined by the Secretary.

(i) *Nurse staffing information*—(1) *Data requirements.* The facility must post the following information on a daily basis:

(i) Facility name.

(ii) The current date.

(iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:

(A) Registered nurses.

(B) Licensed practical nurses or licensed vocational nurses (as defined under State law).

(C) Certified nurse aides.

(iv) Resident census.

(2) *Posting requirements.* (i) The facility must post the nurse staffing data specified in paragraph (i)(1) of this section on a daily basis at the beginning of each shift.

(ii) Data must be posted as follows:

(A) Clear and readable format.

(B) In a prominent place readily accessible to residents, staff, and visitors.

(3) *Public access to posted nurse staffing data.* The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

(4) *Facility data retention requirements.* The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

■ 10. Section 483.40 is amended by revising paragraphs (a) introductory text, (a)(1), and (c)(2) to read as follows:

§ 483.40 Behavioral health services.

* * * * *

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with § 483.71. These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to § 483.71; and

* * * * *

(c) * * *

(2) Obtain the required services from an outside resource (in accordance with § 483.70(f)) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

* * * * *

■ 11. Section 483.45 is amended by revising the introductory text to read as follows:

§ 483.45 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(f). The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

* * * * *

■ 12. Section 483.55 is amended by revising paragraphs (a) introductory text, (a)(1), (b) introductory text, and (b)(1) introductory text to read as follows:

§ 483.55 Dental services.

* * * * *

(a) *Skilled nursing facilities.* A facility:

(1) Must provide or obtain from an outside resource, in accordance with § 483.70(f), routine and emergency dental services to meet the needs of each resident;

* * * * *

(b) *Nursing facilities.* The facility:

(1) Must provide or obtain from an outside resource, in accordance with § 483.70(f), the following dental services to meet the needs of each resident:

* * * * *

■ 13. Section 483.60 is amended by revising paragraph (a) introductory text to read as follows:

§ 483.60 Food and nutrition services.

* * * * *

(a) *Staffing.* The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.71. This includes:

* * * * *

■ 14. Section 483.65 is amended by revising paragraph (a)(2) to read as follows:

§ 483.65 Specialized rehabilitative services.

(a) * * *

(2) In accordance with § 483.70(f), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any Federal or State health care programs pursuant to section 1128 and 1156 of the Act.

* * * * *

§ 483.70 [Amended]

■ 15. Section 483.70 is amended by—

■ a. Removing paragraph (e); and

■ b. Redesignating paragraphs (f) through (q) as paragraphs (e) through (p), respectively.

■ 16. Add § 483.71 to subpart B to read as follows:

§ 483.71 Facility assessment.

The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations (including nights and weekends) and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment.

(a) The facility assessment must address or include the following:

(1) The facility's resident population, including, but not limited to:

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population, using evidence-based, data-driven methods that consider the types of diseases, conditions, physical and behavioral health needs, cognitive disabilities, overall acuity, and other pertinent facts that are present within that population, consistent with and informed by individual resident assessments as required under § 483.20;

(iii) The staff competencies and skill sets that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to the following:

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, behavioral health, and specific rehabilitation therapies;

(iv) All personnel, including managers, nursing and other direct care staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach as required in § 483.73(a)(1).

(b) In conducting the facility assessment, the facility must ensure:

(1) Active involvement of the following participants in the process:

(i) Nursing home leadership and management, including but not limited to, a member of the governing body, the medical director, an administrator, and the director of nursing; and

(ii) Direct care staff, including but not limited to, RNs, LPNs/LVNs, NAs, and representatives of the direct care staff, if applicable.

(iii) The facility must also solicit and consider input received from residents, resident representatives, and family members.

(2) [Reserved]

(c) The facility must use this facility assessment to:

(1) Inform staffing decisions to ensure that there are a sufficient number of staff with the appropriate competencies and skill sets necessary to care for its residents' needs as identified through resident assessments and plans of care as required in § 483.35(a)(3).

(2) Consider specific staffing needs for each resident unit in the facility and adjust as necessary based on changes to its resident population.

(3) Consider specific staffing needs for each shift, such as day, evening, night, and adjust as necessary based on any changes to its resident population.

(4) Develop and maintain a plan to maximize recruitment and retention of direct care staff.

(5) Inform contingency planning for events that do not require activation of the facility's emergency plan, but do have the potential to affect resident care, such as, but not limited to, the availability of direct care nurse staffing or other resources needed for resident care.

■ 17. Section 483.75 is amended by revising paragraphs (c)(2) and (e)(3) to read as follows:

§ 483.75 Quality assurance and performance improvement.

* * * * *

(c) * * *

(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at § 483.71 and including how such information will be used to develop and monitor performance indicators.

* * * * *

(e) * * *

(3) As a part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at § 483.71. Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

* * * * *

■ 18. Section 483.80 is amended by revising paragraph (a)(1) to read as follows:

§ 483.80 Infection control.

* * * * *

(a) * * *

(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to § 483.71 and following accepted national standards.

* * * * *

■ 19. Section 483.95 is amended by revising the introductory text to read as follows:

§ 483.95 Training requirements.

A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.71. Training topics must include but are not limited to—

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–08273 Filed 4–22–24; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 438, and 457

Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 438, and 457

[CMS–2439–F]

RIN 0938–AU99

Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will advance CMS's efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and Children's Health Insurance Program (CHIP) managed care enrollees. The final rule addresses standards for timely access to care and States' monitoring and enforcement efforts, reduces State burdens for implementing some State directed payments (SDPs) and certain quality reporting requirements, adds new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and that specify the scope and nature of ILOSs, specifies medical loss ratio (MLR) requirements, and establishes a quality rating system for Medicaid and CHIP managed care plans.

DATES:

Effective Dates: These regulations are effective on July 9, 2024.

Applicability Dates: In the **SUPPLEMENTAL INFORMATION** section of this final rule, we provide a table (Table 1), which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT:

Rebecca Burch Mack, (303) 844–7355, Medicaid Managed Care.

Laura Snyder, (410) 786–3198, Medicaid Managed Care State Directed Payments.

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Jamie Rollin, (410) 786–0978, Medicaid Managed Care Program Integrity.

Rachel Chappell, (410) 786–3100, and Emily Shockley, (410) 786–3100, Contract Requirements for Overpayments.

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Amanda Paige Burns, (410) 786–8030, Medicaid Quality Rating System.

Joshua Bougie, (410) 786–8117, and Chanelle Parkar, (667) 290–8798, CHIP.

SUPPLEMENTARY INFORMATION:

Applicability and Compliance Timeframes

States are required to comply by the effective date of the final rule or as otherwise specified in regulation text.

States will not be held out of compliance with the changes adopted in this final rule until the applicability date indicated in regulation text for each provision so long as they comply with the corresponding standard(s) in 42 CFR parts 438 and 457 contained in the 42 CFR, parts 430 to 481, effective as of October 1, 2023. The following is a summary of the applicability dates in this final rule:

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TABLE 1: Applicability Dates

Regulation Text	Applicability Date
§§ 438.6(c)(2)(iii); 438.6(c)(2)(vi)(B); 438.6(c)(2)(vi)(C)(*1*) and (*2*)	Applicable for the first rating period beginning on or after July 9, 2024.
§§ 438.3(e)(2)(v); 438.7(b)(6); 438.16; 457.1201(c) and (e)	Applicable for the first rating period beginning on or after September 9, 2024.
§§ 438.340(c)(1) and (c)(3); 438.340(c)(2)(ii); 457.1240(e)	Applicable no later than July 9, 2025.
§§ 438.3(i)(3) and (4); 438.207(d)(3); 438.608(a)(2) and (d)(3); 438.608(e); 457.1201(h); 457.1285	Applicable for the first rating period beginning on or after July 9, 2025.
§§ 457.1207; 457.1230(b)	Applicable no later than July 9, 2026.
§§ 438.6(c)(2)(vi)(C)(*3*) and (*4*); 438.6(c)(2)(viii); 438.6(c)(5)(i) through (iv); 438.10(c)(3); 438.68(d)(1)(iii); 438.68(d)(2); 438.207(b)(3) and (d)(2); 438.602(g)(5)-(13); 457.1207 (transparency provisions); 457.1218 (network adequacy standards); 457.1230(b); 457.1285 (transparency).	Applicable for the first rating period beginning on or afterJuly 9, 2026.
§§ 438.6(c)(2)(ii)(D); 438.6(c)(2)(ii)(F); 438.6(c)(2)(iv); 438.6(c)(2)(v); 438.6(c)(2)(vii); 438.6(c)(6); 438.6(c)(7); 438.10(d)(2); 438.66(b)(4), 438.66(c)(5); 438.66(e)(2)(vii); 438.68(b)(1); 438.68(e); 438.68(g); 438.206(c)(1)(i); 457.1207 (secret shopper surveys criteria); 457.1218 (qualitative standard, appointment wait time standards, and publication of network adequacy standards provisions); 457.1230(a).	Applicable for the first rating period beginning on or after July 9, 2027.
§§ 438.6(c)(5)(v); 438.7(c)(6); 438.10(h)(3)(iii); 438.68(f); 438.207(e) and (f); 457.1207 (information from secret shopper surveys on provider directories); 457.1218 (secret shopper surveys); 457.1230(b).	Applicable for the first rating period beginning on or after July 10, 2028
§§ 438.10(h)(1); 438.10(h)(1)(ix); 457.1207 (electronic provider directories)	Applicable on July 1, 2025.
§§ 438.358(a)(3); 438.358(b)(1); 438.364(c)(2)(iii); 457.1250(a) (EQR archiving requirement)	Applicable on December 31, 2025.
§§ 438.364(a)(2)(iii); 457.1250(a) (EQR information)	Applicable no later than 1 year after the issuance of the associated protocol.
§ 438.6(c)(4)	Applicable by the first rating period beginning on or after the release of reporting instructions.

Regulation Text	Applicability Date
§§ 438.505(a)(1); 457.1240(d)	Applicable by the end of the fourth calendar year following [inset the effective date of the final rule].
§§ 438.520(a)(6); 457.1240(d) (QRS website display)	Applicable by a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in §§ 438.520(a)(6); 457.1240(d) (QRS website display).
§ 438.6(c)(2)(ii)(H)	Applicable by the first rating period beginning on or after January 1, 2028.
§ 457.1200(d)	See applicability dates at 438.3(v), 438.10(j), 438.16(f), 438.68(h), 438.206(d), 438.207(g), 438.310(d), 438.505(a)(2), 438.602(j), and 438.608(f).

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I. Medicaid and CHIP Managed Care

A. Background

As of September 2023, the Medicaid program provided essential health care coverage to more than 88 million [1] individuals, and, in 2021, had annual outlays of more than $805 billion. In 2021, the Medicaid program accounted for 18 percent of national health expenditures.[2] The program covers a broad array of health benefits and services critical to underserved populations, including low- income adults, children, parents, pregnant individuals, the elderly, and people with disabilities. For example, Medicaid pays for approximately 42 percent of all births in the U.S.[3] and is the largest payer of long-term services and supports (LTSS),[4] services to treat substance use disorder, and services to prevent and treat the Human Immunodeficiency Virus.[5] Ensuring beneficiaries can access covered services is a crucial element of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems; for example, fee-for-service (FFS) and managed care, including through demonstrations and waiver programs. In 2021, 74.6 percent [6] of Medicaid beneficiaries were enrolled in comprehensive managed care plans; the remaining individuals received all or some services through FFS.

With a program as large and complex as Medicaid, to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements, access regulations need to be multi-factorial. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to high-quality services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In early 2022, we released a request for information (RFI) [7] to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and CHIP payments are sufficient to enlist enough providers. Some of the most common feedback we received through the RFI related to promoting cultural competency in access to and the quality of services for beneficiaries across all dimensions of health care and using payment rates as a driver to increase provider participation in Medicaid and CHIP programs. Commenters were also interested in opportunities to align approaches for payment regulation and compliance across Medicaid and CHIP delivery systems and services.

As noted above, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary knows if they are or may be eligible for Medicaid, is aware of Medicaid coverage options, and is able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Marketplace coverage, or Medicare, when they are no longer eligible for Medicaid coverage. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and*

[1] September 2023 Medicaid and CHIP Enrollment Snapshot. Accessed at *http://www.medicaid.gov/sites/default/files/2023-10/september-2023-medicaid-chip-enrollment-trend-snapshot.pdf.*

[2] CMS National Health Expenditure Fact Sheet. Accessed at *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

[3] National Center for Health Statistics. Key Birth Statistics (2020 Data. Final 2022 Data forthcoming). Accessed at *https://www.cdc.gov/nchs/nvss/births.htm.*

[4] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated June 15, 2022. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343.*

[5] Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at*https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/.*

[6] *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html.*

[7] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

Renewal Processes (87 FR 54760; hereinafter the ''Streamlining Eligibility & Enrollment proposed rule'') to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, or the Basic Health Program (BHP).[8] This rule was finalized on March 27, 2024.[9]

The third dimension is access to services and supports and was addressed in a proposed rule published on May 3, 2023 (88 FR 28092); we are finalizing it in this final rule. This final rule is focused on addressing additional critical elements of access: (1) potential access (for example, provider availability and network adequacy); (2) beneficiary utilization (the use of health care and health services); and (3) beneficiaries' perceptions and experiences with the care they did or did not receive. These terms and definitions build upon our previous efforts to examine how best to monitor access.[10]

In addition to the three above referenced rulemakings (the Streamlining Eligibility & Enrollment proposed rule, this final rule on managed care, and the Ensuring Access to Medicaid Services proposed rule), we are also engaged in non-regulatory activities to improve access to health care services across Medicaid delivery systems. Examples of these activities include best practices toolkits and other resources for States, such as the ''Increasing Access, Quality, and Equity in Postpartum Care in Medicaid and CHIP'' Toolkit [11] and direct technical assistance to States through learning collaboratives, affinity groups and individual coaching to implement best practices, including the Infant Well-Child Learning Collaborative [12] and the Foster Care Learning Collaborative.[13] As noted earlier, the Streamlining Eligibility & Enrollment proposed rule addresses the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through that proposed rule, we sought to streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals. Through the Ensuring Access to Medicaid Services final rule, and this final rule involving managed care, we outline additional steps to address the third dimension of the health care access continuum: access to services. This rule also addresses quality and financing of services in the managed care context. We sought to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all its delivery systems.

The volume of Medicaid beneficiaries enrolled in a managed care program in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021, with 74.6 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations in 2021.[14] We note that States may implement a Medicaid managed care delivery system using four Federal authorities—sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act); each is described briefly below.

Under section 1915(a) of the Act, States can implement a voluntary managed care program by executing a contract with organizations that the State has procured using a competitive procurement process. To require beneficiaries to enroll in a managed care program to receive services, a State must obtain approval from CMS under two primary authorities:

- Through a State plan amendment (SPA) that meets standards set forth in section 1932(a) of the Act, States can implement a mandatory managed care delivery system. This authority does not allow States to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible beneficiaries), American Indians/Alaska Natives (except as permitted in section 1932 (a)(2)(C) of the Act), or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the State.
- We may grant a waiver under section 1915(b) of the Act, permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a State may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2- (or 5-) year period.

We may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that include waivers permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, States may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such demonstrations are approvable only if it is determined that the demonstration would promote the objectives of the Medicaid statute and the demonstration is subject to evaluation.

The above authorities all permit States to operate their Medicaid managed care programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- *Statewideness* (section 1902(a)(1) of the Act): States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole State;
- *Comparability of Services* (section 1902(a)(10)(B) of the Act): States may provide different benefits to people enrolled in a managed care delivery system; and
- *Freedom of Choice* (section 1902(a)(23)(A) of the Act): States may generally require people to receive their Medicaid services only from a managed care plan's network of providers or primary care provider.

States that elect to operate a separate CHIP may employ a managed care delivery system as long as such coverage meets the requirements of section 2103 of the Act. Specific statutory references to managed care programs are set out at sections 2103(f)(3) and 2107(e)(1)(N) and (R) of the Act, which apply specific provisions of sections 1903 and 1932 of the Act related to Medicaid managed care to separate CHIPs. States that elect Medicaid expansion CHIPs that operate within a managed care delivery system

[8] We finalized several provisions from the proposed rule in a September 2023 **Federal Register** publication entitled *Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment.* See 88 FR 65230.

[9] *https://www.federalregister.gov/public-inspection/2024–06566/medicaid-program-streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health.*

[10] Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. ''Proposed Medicaid Access Measurement and Monitoring Plan.'' Washington, DC: The Urban Institute. August 2016. Accessed at *https://www.medicaid.gov/sites/default/files/2019-12/monitoring-plan.pdf.*

[11] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/postpartum-care/index.html.*

[12] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/well-child-care/index.html.*

[13] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/foster-care-learning-collaborative/index.html.*

[14] *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html.*

are subject to requirements under section 1932 of the Act.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (hereinafter referred to as ''the 2016 final rule'') that modernized the Medicaid and CHIP managed care regulations to reflect changes in the use of managed care delivery systems. The 2016 final rule aligned many of the rules governing Medicaid and CHIP managed care with those of other major sources of coverage; implemented applicable statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of managed care program rates; strengthened efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries; and enhanced policies related to program integrity. The 2016 final rule applied many of the Medicaid managed care rules to separate CHIP, particularly in the areas of access, finance, and quality through cross-references to 42 CFR part 438.

On July 29, 2016, we published the CMCS Informational Bulletin (CIB) concerning ''The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems.'' [15] In the January 18, 2017 **Federal Register** (82 FR 5415), we published the ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' final rule (hereinafter referred to as ''the 2017 final rule''). In the 2017 final rule, we finalized changes to the transition periods for pass-through payments. Pass-through payments are defined at § 438.6(a) as any amount required by the State (and considered in calculating the actuarially sound capitation rate) to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to hospitals, physicians, or nursing facilities that is not for the following purposes: a specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under § 438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; graduate medical education (GME) payments; or Federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. The 2017 final rule codified the information in the CIB and gave States the option to eliminate physician and nursing facility payments immediately or phase down these pass-through payments over the 5-year transition period if they prefer and specified the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). That final rule prevented increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established in the 2016 final rule.

In the November 13, 2020 **Federal Register** (85 FR 72754), we published the ''Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care'' final rule (hereinafter referred to as the ''2020 final rule'') which streamlined the Medicaid and CHIP managed care regulatory framework to relieve regulatory burdens; support State flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The rule was intended to ensure that the regulatory framework was efficient and feasible for States to implement in a cost-effective manner and ensure that States can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

Since publication of the 2020 final rule, the COVID–19 public health emergency (PHE) challenged States' ability to ensure beneficiaries' access to high-quality care, ensure adequate provider payment during extreme workforce challenges, and provide adequate program monitoring and oversight. On January 28, 2021, Executive Order (E.O.) 14009, *Strengthening Medicaid and the Affordable Care Act,* was signed establishing the policy objective to protect and strengthen Medicaid and the Affordable Care Act (ACA) and to make high-quality health care accessible and affordable for every American. It directed executive departments and agencies to review existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this policy. On April 25, 2022, Executive Order 14070, *Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,* was signed directing agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. This final rule aims to fulfill Executive Orders 14009 and 14070 by helping States to use lessons learned from the PHE and build stronger managed care programs to better meet the needs of the Medicaid and CHIP populations by improving access to and quality of care provided.

This rule finalizes new standards to help States improve their monitoring of access to care by requiring the establishment of new standards for appointment wait times, use of secret shopper surveys, use of enrollee experience surveys, and requiring States to submit a managed care plan analysis of payments made by plans to providers for specific services, to monitor plans' network adequacy more closely. It finalizes standards that will apply when States use in lieu of services and settings to promote effective utilization and that specify the scope and nature of these services and settings. It also finalizes provisions that reduce burden for States that choose to direct MCOs, PIHPs, or PAHPs in certain ways to use their capitation payments to pay specified providers specified amounts (known as State directed payments), enhance quality, fiscal and program integrity of State directed payments, address impermissible redistribution arrangements related to State directed payments, and add clarity to the requirements related to medical loss ratio calculations. To improve transparency and provide valuable information to enrollees, providers, and CMS, this rule finalizes State website requirements for content and ease of use. Lastly, this final rule will make quality reporting more transparent and meaningful for driving quality improvement, reduce burden of certain quality reporting requirements, and establish State requirements for implementing a Medicaid and CHIP quality rating system aimed at ensuring monitoring of performance by Medicaid and CHIP managed care plans and empowering beneficiary choice in managed care.

Finally, we believe it is important to acknowledge the role of health equity within this final rule. Medicaid and CHIP provided coverage for nearly 55 million people from racial and ethnic minority backgrounds in 2020. In 2020, Medicaid enrollees were also more likely to live in a rural community and over ten percent of enrollees spoke a

[15] *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib072916.pdf.*

primary language other than English, while approximately eleven percent qualified for benefits based on disability status.[16] Consistent with Executive Order 13985 [17] *Advancing Racial Equity and Support* for *Underserved Communities Through the Federal Government,* we are working to advance health equity across CMS programs consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022–2032 [18] and the HHS Equity Action Plan.[19] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable care and coverage.

A key part of our approach will be to work with States to improve measurement of health disparities through the stratification of State reporting on certain measures to identify potential differences in access, quality, and outcomes based on demographic factors like race, ethnicity, age, rural/urban status, disability, language, sex, sexual orientation, and gender identity, as well as social determinants of health (SDOH).

The ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' final rule (hereinafter referred to as the ''Mandatory Medicaid and CHIP Core Set Reporting final rule'') was published in the August 31, 2023 **Federal Register** (88 FR 60278). In that rule, we finalized that the Secretary would specify, through annual subregulatory guidance, which measures in the Medicaid and CHIP Child Core Set, the behavioral health measures of the Medicaid Adult Core Set, and the Health Home Core Sets, States will be required to stratify, and by which factors, such as race, ethnicity, sex, age, rural/urban status, disability, language or other factors specified by the Secretary. CMS also finalized a phased-in timeline for stratification of measures in these Core Sets. In the Medicaid Program; Ensuring Access to Medicaid Services final rule, published elsewhere in the **Federal Register**, we also finalized a similar phased-in timeline and process for mandatory reporting and stratification of the home and community-based services (HCBS) Quality Measure Set.

Measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of our approach to advancing health equity and aligning with the CMS Strategic Priorities.[20] In this final rule, we establish our intent to align with the stratification factors required for Core Set measure reporting, which we believe will minimize State and managed care plan burden to report stratified measures. To further reduce burden on States, we will permit States to report using the same measurement and stratification methodologies and classifications as those in the Mandatory Medicaid and CHIP Core Set Reporting final rule and the Ensuring Access to Medicaid Services final rule. We believe these measures and methodologies are appropriate to include in States' Managed Care Program Annual Report (MCPAR) because § 438.66(e)(2) requires information on and an assessment of the operation of each managed care program, including an evaluation of managed care plan performance on quality measures. Reporting these measures in the MCPAR would minimize State and provider burden while allowing more robust CMS monitoring and oversight of the quality of the health care provided at a managed care plan and program level. We anticipate publishing additional subregulatory guidance and adding specific fields in MCPAR to accommodate this measure and data stratification reporting to simplify the process for States.

Finally, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

[16] CMS Releases Data Briefs That Provide Key Medicaid Demographic Data for the First Time, *https://www.cms.gov/blog/cms-releases-data-briefs-provide-key-medicaid-demographic-data-first-time.*

[17] Executive Order 13985, *https://www.whitehouse.gov/briefing-room/presidential actions/2021/01/20/executive-order-advancing racial-equity-and-support-or-underserved communities-through-the-federal-government/.*

[18] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cmsframework-health-equity.pdf.*

[19] HHS Equity Action Plan, *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf.*

[20] CMS Strategic Plan 2022, *https://www.cms.gov/cms-strategic-plan.*

B. Summary of the Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

For convenience, throughout this document, the term ''PAHP'' is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services, which is a subset of what is ordinarily included under the term PAHP. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it is specifically identified as a ''Non-Emergency Medical Transportation (NEMT) PAHP.'' Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) (as defined above) and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or PCCM entities.

For CHIP, the preamble uses ''CHIP'' when referring collectively to separate child health programs and title XXI Medicaid expansion programs. We use ''separate CHIP'' specifically in reference to separate child health programs and also in reference to any proposed changes in subpart L of part 457, which are only applicable to separate child health programs operating in a managed care delivery system. In this final rule, all proposed changes to Medicaid managed care regulations are equally applicable to title XXI Medicaid expansion managed care programs as described at § 457.1200(c).

We received a total of 415 timely comments from State Medicaid and CHIP agencies, advocacy groups, health care providers and associations, health insurers, managed care plans, health care associations, and the general public. The following sections, arranged by subject area, include a summary of the comments we received and our responses to those comments. In response to the May 3, 2023 proposed rule, some commenters chose to raise issues that were beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments.

1. Access (42 CFR 438.2, 438.10, 438.66, 438.68, 438.206, 438.207, 438.214, 438.602, 457.1207, 457.1218, 457.1230, 457.1250, and 457.1285)

a. Enrollee Experience Surveys (§§ 438.66(b), 438.66(c), 457.1230(b) and 457.1207)

In the 2016 final rule, we renamed and expanded § 438.66 *State Monitoring Requirements* to ensure that States had robust systems to monitor their managed care programs, utilize the monitoring results to make program improvements, and report to CMS annually the results of their monitoring activities. Existing regulations at § 438.66(c)(5) require States to use the data collected from their monitoring activities to improve the performance of their managed care programs, including results from any enrollee or provider satisfaction surveys conducted by the State or managed care plan. Some States currently use surveys to gather direct input from their managed care enrollees, which we believe is a valuable source of information on enrollees' actual and perceived access to services. As a general matter, disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Surveys can focus on matters that are important to enrollees and for which they are the best and, sometimes, only source of information. Patient experience surveys can also focus on how patients experienced or perceived key aspects of their care, not just on how satisfied they were with their care. For example, experience surveys can focus on asking patients whether or how often they accessed health care, barriers they encountered in accessing health care, and their experience including communication with their doctors, understanding their medication instructions, and the coordination of their health care needs. Some States already use enrollee experience surveys and report that the data are an asset in their efforts to assess whether the managed care program is meeting its enrollees' needs.

One of the most commonly used enrollee experience survey in the health care industry, including for Medicare Advantage (MA) organizations, is the Consumer Assessment of Healthcare Providers and Systems (CAHPS®).[21] CAHPS experience surveys are available for health plans, dental plans, and HCBS programs, as well as for patient experience with providers such as home health, condition specific care such as behavioral health, or facility-based care such as in a hospital. Surveys specially designed to measure the impact of LTSS on the quality of life and outcomes of enrollees are the National Core Indicators-Aging and Disabilities (NCI–AD®) Adult Consumer Survey™ [22] and the National Core Indicators®—Intellectual and Developmental Disabilities (NCI–I/DD). Whichever survey is chosen by a State, it should complement data gathered from other network adequacy and access monitoring activities to provide the State with a more complete assessment of their managed care programs' success at meeting their enrollees' needs. To ensure that States' managed care program monitoring systems, required at § 438.66(a), appropriately capture the enrollee experience, we proposed to revise § 438.66(b)(4) to explicitly include ''enrollee experience'' as something that must be addressed under a State's managed care monitoring system. Section 438.66(c)(5) currently requires States to use the results from any enrollee or provider satisfaction surveys they choose to conduct to improve the performance of its managed care program. To ensure that States have the data from an enrollee experience survey to include in their monitoring activities and improve the performance of their managed care programs, we proposed to revise § 438.66(c)(5) to require that States conduct an annual enrollee experience survey. To reflect this, we proposed to revise § 438.66(c)(5) to add ''an annual'' before ''enrollee'' and add ''experience survey conducted by the State'' after ''enrollee.'' We also proposed to replace ''or'' with ''and'' to be explicit that use of provider survey results alone would not be sufficient to comply with § 438.66(c)(5). While we encourage States and managed care plans to utilize provider surveys, we did not propose to mandate them at this time. We believe other proposals in the proposed rule, such as enrollee surveys and secret shopper surveys, may yield information that will inform our decision on the use of provider surveys in the future. We invited comment on whether we should mandate the use of a specific enrollee experience survey, define characteristics of acceptable survey instruments, and the operational considerations of enrollee experience surveys States use currently.

To reflect these proposals in MCPAR requirements at § 438.66(e), we proposed conforming edits in § 438.66(e)(2)(vii). We proposed to include the results of an enrollee experience survey to the list of items that States must evaluate in their report and add ''provider'' before ''surveys'' to distinguish them from enrollee experience surveys. Additionally, consistent with the transparency proposals described in section I.B.1.g. of this final rule, we proposed to revise § 438.66(e)(3)(i) to require that States post the report required in § 438.66(e)(1) on their website within 30 calendar days of submitting it to CMS. Currently § 438.66(e)(3)(i) only requires that the report be posted on the State's website but does not specify a timeframe; we believe that adding further specificity about the timing of when the report should be posted will be helpful to interested parties and bring consistency to this existing requirement. This proposal is authorized by section 1902(a)(6) of the Act, which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

For an enrollee experience survey to yield robust, usable results, it should be easy to understand, simple to complete, and readily accessible for all enrollees that receive it; therefore, we believe they should meet the interpretation, translation, and tagline criteria in § 438.10(d)(2). Therefore, we proposed to add enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2). This will ensure that enrollees that receive a State's enrollee experience survey will be fully notified that oral interpretation in any language and written translation in the State's prevalent languages will be readily available, and how to request auxiliary aids and services, if needed.

These proposals are authorized by section 1932(b)(5) of the Act which requires each managed care organization to demonstrate adequate capacity and services by providing assurances to the State and CMS that they have the capacity to serve the expected enrollment in their service area, including assurances that they offer an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and maintain a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) through

[21] The acronym ''CAHPS'' is a registered trademark of the Agency for Healthcare Research and Quality.

[22] NCI–AD Adult Consumer Survey™ is a copyrighted tool.

regulations based on our authority under section 1902(a)(4) of the Act. Because enrollee experience survey results will provide direct and candid input from enrollees, States and managed care plans could use the results to determine if their networks offer an appropriate range of services and access as well as if they provide a sufficient number, mix, and geographic distribution of providers to meet their enrollees' needs. Enrollee experience survey data will enable managed care plans to assess whether their networks are providing sufficient capacity as experienced by their enrollees and that assessment will inform the assurances that the plan is required to provide to the State and CMS. These proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes: standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Data from enrollee experience surveys will enable States to use the results to evaluate whether their plans' networks are providing access to covered services within reasonable timeframes and in a manner that ensures continuity of care. These data will also inform the development and maintenance of States' quality assessment and improvement strategies and will be critical to States' monitoring and evaluation of the quality and appropriateness of care and services provided to enrollees.

We remind States that in addition to the mandatory external quality review (EQR) activities under § 438.358(b), there is an existing optional EQR activity under § 438.358(c)(2) for the administration or validation of consumer or provider surveys of quality of care. States that contract with MCOs and use external quality review organizations (EQROs) to administer or validate the proposed enrollee experience surveys may be eligible to receive up to a 75 percent enhanced Federal match, pursuant to § 438.370, to reduce the financial burden of conducting or validating the proposed enrollee survey(s).

We requested comment on the cost and feasibility of implementing enrollee experience surveys for each managed care program as well as the extent to which States already use enrollee experience surveys for their managed care programs.

We proposed that States would have to comply with § 438.66(b) and (c) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We proposed this applicability date in § 438.66(f).

Since we did not adopt MCPAR for separate CHIPs, we do not plan to adopt the new Medicaid enrollee experience survey requirements proposed at § 438.66(b) and (c) for separate CHIPs. However, States currently collect enrollee experience data for CHIP through annual CAHPS surveys as required at section 2108(e)(4) of the Act. Currently, there are no requirements for States to use these data to evaluate their separate CHIP managed care plans network adequacy or to make these survey results available to beneficiaries to assist in selecting a managed care plan. We believed that enrollee experience data can provide an invaluable window into the performance of managed care plans and assist States in their annual review and certification of network adequacy for separate CHIP MCOs, PIHPs, and PAHPs. For this reason, we proposed to amend § 457.1230(b) to require States to evaluate annual CAHPS survey results as part of the State's annual analysis of network adequacy as described in § 438.207(d). Since States already collect CAHPS survey data for CHIP and will likely not need the same timeframe to implement as needed for implementing the proposed Medicaid enrollee experience surveys requirement, we proposed for the provision at § 457.1230(b) to be applicable 60 days after the effective date of the final rule. However, we are open to a later applicability date such as 1, 2, or 3 years after the effective date of the final rule. We invited comment on the appropriate applicability date for this provision.

We also believe that access to enrollee experience data is critical in affording separate CHIP beneficiaries the opportunity to make informed decisions when selecting their managed care plan(s). To this end, we proposed at § 457.1207 to require States to post comparative summary results of CAHPS surveys by managed care plan annually on State websites as described at § 438.10(c)(3). The posted summary results must be updated annually and allow for easy comparison between the managed care plans available to separate CHIP beneficiaries. We sought public comment on other approaches to including CHIP CAHPS survey data for the dual purposes of improving access to managed care services and enabling beneficiaries to have useful information when selecting a managed care plan.

We summarize and respond to public comments received on Enrollee experience surveys (§§ 438.66(b) and (c), and 457.1230(b)) below.

Comment: We received many supportive comments on our proposal for States to conduct an annual enrollee experience survey. Commenters agreed that enrollees are often the best source of information about their care and best able to provide insights about how to improve the quality of the care they receive. Many commenters were particularly supportive of requiring written survey materials to comply with the interpretation, translation, and tagline criteria in § 438.10(d)(2) so that surveys are fully accessible and easy to read and understand. Many commenters also supported reporting the results in the MCPAR and requiring States to post them on their website within 30 days of submission.

Response: We appreciate the comments in support of our proposal for annual enrollee surveys and the applicability of § 438.10(d)(2) to facilitate participation by enrollees that require reasonable accommodations and interpretation or translation. We believe this will be critical to helping enrollees respond to the surveys and produce more robust and actionable results. We also appreciate the confirmation that including the survey results in the MCPAR and posting them on the State's website timely is the best option to make the results consistently presented and available.

Comment: A few commenters encouraged CMS to require States to include a representative sample of enrollees who are dually eligible for Medicaid and Medicare, in marginalized populations, or had chronic conditions in the experience surveys and require that results be disaggregated by population and other key demographics. Several commenters recommended that we ensure that surveys are not too long, the questions are not too complex, and that the survey is distributed and available in multiple ways (mailing, phone, or email).

Response: We thank commenters for these thoughtful suggestions and encourage States to utilize them to improve the comprehensiveness and utility of the survey results. We may consider some of these suggestions in future rulemaking.

Comment: Some commenters stated that the proposed annual enrollee

experience survey would be duplicative of other surveys currently done by States and would contribute to enrollee survey fatigue. Commenters offered several suggestions, including not requiring an annual survey and letting States choose the cadence, as well as aligning Medicare and Medicaid surveys particularly for aligned plans. One commenter suggested that States be permitted to use surveys administered by their managed care plans while another recommended that States use independent survey vendors.

Response: We understand commenters' concerns about survey fatigue for enrollees and the downward impact that could have on response rates. After considering the comments, we are finalizing § 438.66(c)(5) with an exemption for Medicaid managed care plans in which all enrollees are enrolled in a Medicare Advantage (MA) dual eligible special needs plan (D–SNP) subject to the condition in § 422.107(e)(1)(i). In such circumstances, we already require annual CAHPS surveys for enrollees in D–SNPs, and all enrollees sampled for the CAHPS survey would be dually eligible individuals within the same State. Where States choose not to conduct an experience survey based on this exemption, the requirement still applies at § 438.66(c) that States use data to improve the performance of their Medicaid managed care programs, but when all enrollees are enrolled in a D–SNP subject to the condition in § 422.107(e)(1)(i), the data on enrollee experiences would come from the D–SNP's CAHPS results. States can require through the State Medicaid agency contract at § 422.107 that D–SNPs share CAHPS results with the State.

Allowing States to utilize existing annual experience surveys will reduce the risk of survey fatigue and enable the collection of annual experience surveys without placing an unreasonable demand on enrollees.

Comment: Some commenters encouraged CMS to also require States to survey providers as part of their annual surveying process to provide accurate information on root-cause analyses for issues with access. Commenters suggested the creation and administration of a family caregiver experience survey, the inclusion of questions directly related to mental health access or preferences for in-person services vs. telehealth services, and population specific surveys. A commenter recommended that CMS specify that the survey instrument must assess MCO performance for customer service, provider access, availability of benefits, any out-of-pocket cost burden, and the availability of language services and disability accommodations.

Response: We thank commenters for these suggestions and encourage States to consider including these in their monitoring and oversight strategy. Provider surveys, while not required at this time, can be a rich source of information on managed care plan performance on topics that enrollees cannot provide. We encourage States to use robust provider surveys as a complement to enrollee surveys to capture a comprehensive view of the operations of their managed care programs. We believe the additional topic areas or surveys suggested by commenters would enable States to collect new types of information to better inform their monitoring and oversight activities.

Comment: Some commenters recommended that CMS mandate a specific survey instrument such as CAHPS® while some other commenters stated that CMS should not specify a survey instrument and give States the flexibility to use surveys that capture the topic areas most relevant to their programs. Others recommended requiring CAHPS to reduce burden and improve comparability, although some commenters noted increasing concerns with low response rates to CAHPS surveys. Some commenters noted that many States have been doing experience surveys for years and have refined their questions over time to gather the most valuable and needed data. A few commenters suggested that, at a minimum, CMS should define characteristics of an acceptable survey or develop evidence-based questions that States can use in their surveys. A few commenters stated that given the prevalent and successful adoption of National Core Indicators®—Intellectual and Developmental Disabilities (NCI–I/DD) and National Core Indicators—Aging and Disabilities (NCI–AD™), CMS should align expectations for the experience of care surveys for managed care with the approved HCBS measure set, including NCI. One commenter requested that CMS provide technical guidance on the sample methodology, targets for the consumer satisfaction index, and the baseline template for an enrollee experience survey.

Response: While we understand the concern about comparability among States, we believe that States capturing information that is specific to their programs and populations is critical for these surveys to inform the development and execution of effective monitoring and oversight activities. We expect that enrollee survey responses that are detailed and specific will be more likely to be utilized by States to make program improvements as required in § 438.66(c). Standardized surveys such as CAHPS, NCI–I/DD, and NCI–AD may be sufficient for monitoring, oversight, and quality improvement activities of some programs, but not others, such as those with a narrow set of populations or benefits. As such, we believe we should allow States to select the enrollee experience survey that will best aid in their monitoring, oversight, and quality improvement activities. At this time, we do not believe we should define minimum survey characteristics or satisfaction index, develop evidence-based questions, or provide a template. Rather, we will monitor implementation of this requirement and may propose to revise § 438.66 to include this type of detail in future rulemaking. Furthermore, the MAC QRS as specified in § 438.510, is requiring the full CAHPS Health Plan survey (both Adult and Child Surveys) in the initial mandatory measure set for the plans included in the MAC QRS. (See section I.B.6.e.) The CAHPS survey in the MAC QRS is a standardized instrument through which beneficiaries provide information about their experience with their managed care plan. The MAC QRS itself will, once it is implemented by all States that contract with an applicable managed care plan, provide standardized information and quality performance data to support users in comparing enrollee experience data for Medicaid (and/or CHIP) managed care plans available within a State and in making comparisons among plans with similar benefits across States.

Comment: One commenter recommended that States be required to collect enrollees' preferred languages during the Medicaid enrollment process and share it with plans so that enrollee surveys may be administered in the relevant language.

Response: We acknowledge that collecting preferred languages is ideally done at the time of eligibility determination or enrollment. However, applicants are not legally required to provide that information. As such, States and managed care plans should attempt to collect the information whenever they are in contact with an enrollee and store the information in their system so that any information provided to enrollees, including experience surveys, is in their preferred language.

Comment: One commenter requested that States with small percentages of enrollees in managed care be exempted from conducting an enrollee experience survey.

Response: We do not agree that States with small managed care programs should be exempted from conducting an enrollee experience survey. Regardless of the number of enrollees in a program, their direct input is valuable to States and managed care plans to ensure that they are meeting the needs of their covered populations.

Comment: One commenter suggested that States share information gathered from enrollee experience surveys with managed care plans to support continuous improvement in enrollee experiences across all plans.

Response: We agree and, although summary results will be provided by States in their annual MCPARs (which are published on their websites as required in 42 CFR 438.66(e)(3)(i)), we encourage States to share the detailed response data with their plans as soon as they are available. Improving managed care programs and enrollees' experience is a shared responsibility between CMS, the State, and its managed care plans and that is best fulfilled through collaboration and shared goals.

Comment: One commenter suggested that States be permitted to use surveys administered by their managed care plans while another recommended that States use independent survey vendors.

Response: States may elect to use an independent survey vendor; however, we decline to finalize that requirement in this rule to avoid additional burden on States. We will evaluate the results of the enrollee experience surveys and may use that information to inform future policy. We are finalizing § 438.66(c)(5) as a State obligation to facilitate consistency in administration within managed care programs. However, we will evaluate survey results and may revisit this policy in future rulemaking.

Comment: One commenter recommended that enhanced FFP be made available to cover the cost of administering the secret shopper surveys.

Response: We do not have the authority to provide enhanced FFP as the level of FFP available for Medicaid expenditures is specified in statute.

Comment: One commenter supported requiring States to include their most recent CHIP CAHPS survey results in their annual analysis of network adequacy and to post comparative summary results of CAHPS surveys by managed care plan annually on State websites to be applicable 60 days after the effective date of the final rule.

Response: We appreciate the support for our applicability date proposal.

Comment: Many commenters recommended that CMS delay the requirements to post CHIP CAHPS survey results and evaluate network adequacy requirements as described in §§ 457.1207 and 457.1230(b), respectively. The commenters stated concerns about State administrative burden (that is, staff training) and the additional time needed for States to disaggregate Medicaid and CHIP data. Commenters recommended a range of implementation timelines, from 1 to 2 years following the effective date of the final rule. Another commenter noted that they do not believe they will be able to meet the proposed deadline for posting CHIP CAHPS survey results without technical assistance from CMS.

Response: We appreciate the commenters' suggestion to extend the implementation deadline for these provisions and recognize the administrative burden these proposals may put on States. After consideration of the public comments we received, we are finalizing an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. We believe extending the implementation date to 2 years following the effective date of the final rule will provide States with adequate time to conduct the network adequacy analysis. As always, we are available to provide technical assistance if needed.

Comment: Many commenters supported our proposal to post CHIP CAHPS survey data. Specifically, one commenter noted MCOs serving Medicaid populations already participate in the CHIP CAHPS survey to capture feedback from enrollees. The commenter noted that they believe that leveraging the CAHPS survey would improve comparability across plans while minimizing the administrative burden on plans to implement a new survey.

Response: We appreciate the robust number of comments in support of our proposal to require posting of comparative CHIP enrollee survey experience information by MCO. We agree that capturing information that is specific to each State's programs and populations is critical to inform the development and execution of effective monitoring and oversight activities.

Comment: One commenter had concerns about the administrative burden of collecting and reporting CHIP enrollee information in CHIP CAHPS surveys because low enrollment may make it challenging for States to collect statistically representative data at the subgroup level. The commenter recommended that States sample a sufficient number of beneficiaries to ensure survey results are representative while weighing considerations related to cost-effectiveness.

Response: We understand the commenter's concern and acknowledge the administrative burden of collecting and reporting this information. We note that our minimum enrollment threshold policy at 438.515(a)(1)(i) for Medicaid, incorporated into separate CHIP regulations through a cross-reference at § 457.1240(d), requires States to collect data from contracted managed care plans that have 500 or more enrollees. We will provide guidance on when quality ratings should be suppressed due to lower enrollment in the technical resource manual. We believe CHIP CAHPS surveys are an important tool that States, and managed care plans can use to ensure they are meeting the needs of their covered populations regardless of program size.

After consideration of the public comments we received, we are finalizing §§ 438.66(b), and (f), and 457.1230(b) as proposed, except that we are finalizing an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. We are also finalizing § 438.66(c)(5) to permit States to use a CAHPS survey as required for Medicare Advantage D–SNPs.

b. Appointment Wait Time Standards (§§ 438.68(e) and 457.1218)

In the 2020 final rule, we revised § 438.68(b)(1) and (2) by replacing the requirement for States to set time and distance standards with a more flexible requirement that States set a quantitative network adequacy standard for specified provider types. We noted that quantitative network adequacy standards that States may elect to use included minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We encouraged States to use the quantitative standards in combination—not separately—to ensure that there are not gaps in access to, and availability of, services for enrollees. (85 FR 72802)

Ensuring that it provides timely access to high-quality services in a manner that is equitable and consistent is central to an effective Medicaid and CHIP program. States and managed care plans have sometimes been challenged

to ensure that networks can provide all covered services in a timely manner.[23] During the PHE, managed care plans faced many new challenges ensuring access to covered services and those challenges shed light on opportunities for improvement in monitoring timely access. These challenges include workforce shortages, changes in providers' workflows and operating practices, providers relocating leaving shortages in certain areas, and shifts in enrollee utilization such as delaying or forgoing preventive care. Some of these challenges have changed the delivery of health care services, requiring States and managed care plans to adjust their monitoring, evaluation, and planning strategies to ensure equitable access to all covered services.

On February 17, 2022, we issued a request for information [24] (RFI) soliciting public input on improving access in Medicaid and CHIP, including ways to promote equitable and timely access to providers and services. Barriers to accessing care represented a significant portion of comments received, with common themes related to providers not accepting Medicaid and recommendations calling for us to set specific quantitative access standards. Many commenters urged us to consider developing a Federal standard for timely access to providers and services but giving State Medicaid and CHIP agencies the flexibility to impose more stringent requirements. A recently published study [25] examined the extent to which Medicaid managed care plan networks may overstate the availability of physicians in Medicaid and evaluated the implications of discrepancies in the ''listed'' and ''true'' networks for beneficiary access. The authors concluded that findings suggest that current network adequacy standards might not reflect actual access and that new methods are needed that account for physicians' willingness to serve Medicaid patients. Another review of 34 audit studies demonstrated that Medicaid is associated with a 1.6-fold lower likelihood in successfully scheduling a primary care appointment and a 3.3-fold lower likelihood in successfully scheduling a specialty appointment when compared with private insurance.[26]

Based on the RFI comments received, research, engagement with interested parties, and our experience in monitoring State managed care programs, we are persuaded about the need for increased oversight of network adequacy and overall access to care and proposed a new quantitative network adequacy standard. Specifically, we proposed to redesignate existing § 438.68(e) regarding publication of network adequacy standards to § 438.68(g) and create a new § 438.68(e) titled ''Appointment wait time standards.''

At § 438.68(e)(1)(i) through (iv), we proposed that States develop and enforce wait time standards for routine appointments for four types of services: outpatient mental health and substance use disorder (SUD)—adult and pediatric, primary care—adult and pediatric, obstetrics and gynecology (OB/GYN), and an additional type of service determined by the State (in addition to the three listed) in an evidence-based manner for Medicaid. We included ''If covered in the MCO's, PIHP's, or PAHP's contract'' before the first three service types (paragraphs (e)(1)(i) through (iii)) to be clear that standards only need to be developed and enforced if the service is covered by the managed care plan's contract, but the fourth service (paragraph (e)(1)(iv)) must be one that is covered by the plan's contract. For example, we understand that primary care and OB/GYN services are likely not covered by a behavioral health PIHP; therefore, a State will not be required to set appointment wait time standards for primary care and OB/GYN providers for the behavioral health PIHP and will only have to set appointment wait time standards for mental health and SUD providers, as well as one State-selected provider type. To ensure that our proposal to have States set appointment wait time standards for mental health and SUD, as well as one State-selected provider type for behavioral PIHPs and PAHPs is feasible, we requested comment on whether behavioral health PIHPs and PAHPs include provider types other than mental health and SUD in their networks. Although we believe behavioral health PIHPs and PAHPs may include other provider types, we wanted to validate our understanding. We proposed to adopt the proposed wait time standards for separate CHIP through an existing cross-reference at § 457.1218. We proposed primary care, OB/GYN, and mental health and SUD because they are indicators of core population health; therefore, we believe requiring States to set appointment wait time standards for them will have the most impact on access to care for Medicaid and CHIP managed care enrollees.

At § 438.68(e)(1)(iv), we proposed that States select a provider type in an evidence-based manner to give States the opportunity to use an appointment wait time standard to address an access challenge in their local market. We did not propose to specify the type of evidence to be used; rather, we defer to States to consider multiple sources, such as encounter data, appeals and grievances, and provider complaints, as well as to consult with their managed care plans to select a provider type. We believe proposing that States select one of the provider types subject to an appointment wait time standard will encourage States and managed care plans to analyze network gaps effectively and then innovate new ways to address the challenges that impede timely access. States will identify the provider type(s) they choose in existing reporting in MCPAR, per § 438.66(e), and the Network Adequacy and Access Assurances Report (NAAAR), per § 438.207(d).

To be clear that the appointment wait time standards proposed in § 438.68(e) cannot be the quantitative network adequacy standard required in § 438.68(b)(1), we proposed to add ''. . . , other than for appointment wait times . . .'' in § 438.68(b)(1). We did not propose to define routine appointments in this rule; rather, we defer to States to define it as they deem appropriate. We encouraged States to work with their managed care plans and their network providers to develop a definition of ''routine'' that will reflect usual patterns of care and current clinical standards. We acknowledged that defining ''urgent'' and ''emergent'' for appointment wait time standards could be much more complex given the standards of practice by specialty and the patient-specific considerations necessary to determine those situations. We invited comments on defining these terms should we undertake additional rulemaking in the future. We clarified that setting appointment wait time standards for routine appointments as proposed at § 438.68(e)(1) will be a minimum; States are encouraged to set additional appointment wait time standards for other types of

[23] *https://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf; https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf.*

[24] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[25] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747.*

[26] W. Hsiang, A. Lukasiewicz, and M. Gentry, ''Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis,'' SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118.*

appointments. For example, States may consider setting appointment wait time standards for emergent or urgent appointments as well.

To provide States with flexibility to develop appointment wait time standards that reflect the needs of their Medicaid and CHIP managed care populations and local provider availability while still setting a level of consistency, we proposed maximum appointment wait times at § 438.68(e)(1): State developed appointment wait times must be no longer than 10 business days for routine outpatient mental health and substance use disorder appointments at § 438.68(e)(1)(i) and no longer than 15 business days for routine primary care at § 438.68(e)(1)(ii) and OB/GYN appointments at § 438.68(e)(1)(iii). We did not propose a maximum appointment wait time standard for the State-selected provider type. These proposed maximum timeframes were informed by standards for individual health insurance coverage offered through Federally-Facilitated Marketplaces (FFMs) established under the Affordable Care Act that will begin in 2025 of 10 business days for behavioral health and 15 business days for primary care services; we noted that we elected not to adopt the FFMs' appointment wait time standard of 30 business days for non-urgent specialist appointments as we believe focusing on primary care, OB/GYN, and mental health and SUD is the most appropriate starting place for Medicaid and CHIP managed care standards. These proposed timeframes were also informed by engagement with interested parties, including comments in response to the RFI. We proposed to require appointment wait times for routine appointments only in this rule as we believe that providers utilize more complex condition and patient-specific protocols and clinical standards of care to determine scheduling for urgent and emergent care. We may address standards for other types of appointments in future rulemaking and hope that information from the use of appointment wait time standards for routine appointments will inform future proposals.

In developing this proposal, we considered appointment wait time standards between 30 calendar days and 45 calendar days. Some interested parties stated that these standards would be more appropriate for routine appointments and would more accurately reflect current appointment availability for most specialties. However, we believe 30 calendar days and 45 calendar days as the maximum wait time may be too long as a standard; we understand it may be a realistic timeframe currently for some specialist appointments, but we were not convinced that they should be the standard for outpatient mental health and SUD, primary care, and OB/GYN appointments. We invited comment on aligning with FFM standards at 10 and 15 business days, or whether wait time standards should differ, and if so, what standards will be the most appropriate.

To make the appointment wait time standards as effective as possible, we deferred to States on whether and how to vary appointment wait time standards for the same provider type; for example, by adult versus pediatric, telehealth versus in-person, geography, service type, or other ways. However, we proposed that wait time standards must, at a minimum, reflect the timing proposed in § 438.68(e)(1). We encouraged States to consider the unique access needs of certain enrollees when setting their appointment wait time standards to facilitate obtaining meaningful results when assessing managed care plan compliance with the standards.

As a general principle, we sought to align across Medicaid managed care, CHIP managed care, the FFMs, and Medicare Advantage (MA) when reasonable to build consistency for individuals who may change coverage over time and to enable more effective and standardized comparison and monitoring across programs. Proposing 90 percent compliance with a 10- and 15-business day maximum appointment wait time standards will be consistent with standards set for qualified health plans (QHPs) on the FFMs for plan year 2025.[27] However, we note that for MA, CMS expects MA plans to set reasonable standards for primary care services for urgently needed services or emergencies immediately; services that are not emergency or urgently needed, but in need of medical attention within one week; and routine and preventive care within 30 days.[28]

To ensure that managed care plans' contracts reflect their obligation to comply with the appointment wait time standards, we proposed to revise § 438.206(c)(1)(i) to include appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1230(a). We believe this was necessary since our proposal at § 438.68(e)(1) to develop and enforce appointment wait time standards is a State responsibility; this revision to § 438.206(c)(1)(i) will specify the corresponding managed care plan responsibility.

We proposed to revise the existing applicability date in § 438.206(d) for Medicaid, which is applicable for separate CHIPs through an existing cross-reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d), to reflect that States will have to comply with § 438.206(c)(1)(i) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

Current requirements at § 438.68(c)(1) and (2) for Medicaid, and through a cross-reference at § 457.1218 for separate CHIP, direct States to consider 12 elements when developing their network adequacy standards. We reminded States that § 438.68(c)(1)(ix) includes the availability and use of telemedicine, e-visits, and/or other evolving and innovative technological solutions as an element that States must consider when developing their network adequacy standards. Services delivered via telehealth seek to improve a patient's health through two-way, real time interactive communication between the patient and the provider. Services delivered in this manner can, for example, be used for assessment, diagnosis, intervention, consultation, and supervision across distances. Services can be delivered via telehealth across all populations served in Medicaid including, but not limited to children, individuals with disabilities, and older adults. States have broad flexibility to cover telehealth through Medicaid and CHIP, including the methods of communication (such as telephonic or video technology commonly available on smart phones and other devices) to use.[29] States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68 that accurately reflect the practical use of both types of care in their State. Therefore, States should review encounter data to gauge telehealth use by enrollees over time and the availability of telehealth appointments by providers and account for that information when developing

[27] 45 CFR 156.230(a)(2)(i)(B); Draft 2025 Letter to Issuers in the Federally-facilitated Exchanges, chapter 2, section 3.iii.b, available at *https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf.*

[28] MCM Chapter 4 (*www.cms.gov*).

[29] *https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf.*

their appointment wait time standards. We also reminded States that they have broad flexibility for covering services provided via telehealth and may wish to include quantitative network adequacy standards or specific appointment wait time standards for telehealth *in addition* to in-person appointment standards, as appropriate based on current practices and the extent to which network providers offer telehealth services. Although States have broad flexibility in this area, we reminded States of their responsibility under section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act to ensure effective communications for patients with disabilities for any telehealth services that are offered and to provide auxiliary aids and services at no cost to the individual to ensure that individuals with disabilities are able to access and utilize services provided via telehealth; we also reminded States of their responsibilities under Title VI of the Civil Rights Act of 1964, including the obligation to take reasonable steps to ensure meaningful language access for persons with limited English proficiency when providing telehealth services.[30]

Current Medicaid regulations at § 438.68(e), and through a cross-reference at § 457.1218 for separate CHIP, require States to publish the network adequacy standards required by § 438.68(b)(1) and (2) on their websites and to make the standards available upon request at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. To ensure transparency and inclusion of the new proposed appointment wait time standards in this provision, we proposed several revisions: to redesignate § 438.68(e) to § 438.68(g); to replace ''and'' with a comma after ''(b)(1);'' add ''(b)'' before ''(2)'' for clarity; and add a reference to (e) after ''(b)(2).'' We believe these changes make the sentence clearer and easier to read. Lastly, § 438.68(e) currently includes ''. . . the website required by § 438.10.'' For additional clarity in redesignated § 438.68(g), we proposed to replace ''438.10'' with ''§ 438.10(c)(3)'' to help readers more easily locate the requirements for State websites. These proposed changes apply equally to separate CHIP managed care through existing cross-references at §§ 457.1218 and 457.1207.

At § 438.68(e)(2), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we proposed that managed care plans will be deemed compliant with the standards established in paragraph (e)(1) when secret shopper results, described in section I.B.1.c. of this final rule, reflect a rate of appointment availability that meets State established standards at least 90 percent of the time. By proposing a minimum compliance rate for appointment wait time standards, we will provide States with leverage to hold their managed care plans accountable for ensuring that their network providers offer timely appointments. Further, ensuring timely appointment access 90 percent of the time will be an important step toward helping States ensure that the needs of their Medicaid and CHIP populations are being met timely. As with any provision of part 438 and subpart L of part 457, we may require States to take corrective action to address noncompliance.

To ensure that appointment wait time standards will be an effective measure of network adequacy, we believe we needed some flexibility to add provider types to address new access or capacity issues at the national level. Therefore, at § 438.68(e)(3), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we proposed that CMS may select additional types of appointments to be added to § 438.68(e)(1) after consulting with States and other interested parties and providing public notice and opportunity to comment. From our experience with the COVID–19 PHE, as well as multiple natural disasters in recent years, we believe it prudent to explicitly state that we may utilize this flexibility as we deem appropriate in the future.

We recognized that situations may arise when an MCO, PIHP, or PAHP may need an exception to the State established provider network standards, including appointment wait times. Prior to this final rule, § 438.68(d) provided that, to the extent a State permitted an exception to any of the provider-specific network standards, the standard by which an exception will be evaluated and approved must be specified in the MCO, PIHP, or PAHP contract and must be based, at a minimum, on the number of providers in that specialty practicing in the MCO's, PIHP's, or PAHP's service area. We proposed to make minor grammatical revisions to § 438.68(d)(1) by deleting ''be'' before the colon and inserting ''be'' as the first word of § 438.68(d)(1)(i) and (ii), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218. We also proposed to add a new standard at § 438.68(d)(1)(iii) for Medicaid, and through an existing cross-reference at § 457.1218 for separate CHIP, for reviews of exception requests, which will require States to consider the payment rates offered by the MCO, PIHP, or PAHP to providers included in the provider group subject to the exception. Managed care plans sometimes have difficulty building networks that meet network adequacy standards due to low payment rates. We believe that States should consider whether this component is a contributing factor to a plan's inability to meet the standards required by § 438.68(b)(1) and (2) and (e), when determining whether a managed care plan should be granted an exception. We reminded States of their obligation at § 438.68(d)(2) to monitor enrollee access on an ongoing basis to the provider types in managed care networks that operate under an exception and report their findings as part of the annual Medicaid MCPAR required at § 438.66(e).

Our proposal for States to develop and enforce appointment wait time standards proposed at § 438.68(e) and the accompanying secret shopper surveys of plan's compliance with them (described in section I.B.1.c. of this final rule) proposed at § 438.68(f) are authorized by section 1932(b)(5) of the Act, and is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act, and authorized for CHIP through section 2103(f)(3) of the Act. We believed that secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards and these data will aid managed care plans as they assess their networks, under § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area and that it offers appropriate access to preventive and primary care services for their enrollees. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act and required

[30] U.S. Department of Justice, Civil Rights Division and Department of Health and Human Services, Office for Civil Rights, ''Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons,'' July 29, 2022, available online at *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html.*

for CHIP through section 2103(f)(3) of the Act.

Section 1932(d)(5) of the Act requires that, no later than July 1, 2018, contracts with MCOs and PCCMs, as applicable, must include a provision that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any network. Although States have had to comply with this provision for several years, we believe we should reference this important provision in 42 CFR part 438, as well as use our authority under section 1902(a)(4) of the Act to apply it to PIHPs and PAHPs. To do this, we proposed a new § 438.214(d)(2) to reflect that States must ensure through their MCO, PIHP, and PAHP contracts that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any Medicaid managed care plan network.

We proposed that States comply with § 438.68(b)(1), (e), and (g) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We proposed that States comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule. We proposed that States comply with § 438.68(d)(1)(iii) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 2 years after the effective date of the final rule. We have proposed these applicability dates in § 438.68(h) for Medicaid, and for separate CHIPs through an existing cross-reference at § 457.1218 and a proposed cross-reference at § 457.1200(d).

We summarize and respond to public comments received on appointment wait time standards (§§ 438.68(e) and 457.1218) below.

Comment: Many commenters supported our proposals related to appointment wait time standards in § 438.68(e) for Medicaid, and through cross-reference at § 457.1218 for separate CHIPs, and affirmed that development and enforcement of appointment wait times would contribute to improved access to enrollees.

Response: We appreciate the support for our proposals and believe that appointment wait time standards will complement the quantitative network adequacy standards already implemented and enrich the data available to States for monitoring access to care.

Comment: Many commenters supported requiring appointment wait time standards but suggested that 10- and 15-business days may not be the appropriate standards. Most commenters that offered alternatives recommended either 30 business days—which is consistent with Medicare Advantage for routine appointments—or 30- and 45-days. A few recommended other maximum timeframes as high as 90 days. Some commenters stated that although aligning Medicaid managed care wait time standards with those of the FFMs seems a reasonable approach given the churn between the programs, the FFMs have not yet implemented the 10- and 15-business day standards so there is no data to verify whether they are realistic. A few commenters noted that they believe that Medicaid standards should not be significantly shorter than the average wait time for physician services in the United States generally. One commenter recommended that CMS collect data to calculate a baseline over a multi-year period and then use that to inform the development of a benchmark for improved access that is both feasible and meaningful.

Response: We appreciate the many comments on our 10- and 15-business day appointment wait time proposal. In developing this proposal, we considered other appointment wait time standards including 30 business days and 45 business days. However, we believe 30 business days and 45 business days as the maximum wait time may be too long as a standard; we understand it may be a realistic timeframe currently for other types of appointments but we were not convinced that they should be the standard for outpatient mental health and SUD, primary care, and OB/GYN appointments as these appointment types are the most commonly used, are indicators of core population health, and very often prevent the need for urgent or emergent care. We acknowledge that we do not yet have compliance data from the FFMs to substantiate that 10- and 15-business day appointment wait time standards are achieveable or appropriate for Medicaid and CHIP managed care programs. However, we believe that any alignment with the FFMs strengthens managed care plan and provider performance due to the high overlap between the programs. Many issuers offering QHPs also offer Medicaid and CHIP managed care plans and may be able to find efficiencies in their policies and practices. Similarly, payers that have QHPs and Medicaid and CHIP managed care plans often have many of the same providers in both networks, and having similar standards eases administrative burden on the providers. We agree that monitoring data over time is important and will help us assess whether the 10- and 15-business day standards need revision or if other systemic efforts are needed to improve appointment wait times, such as national initiatives to increase the provider supply. However, we believe we should finalize the new requirements and collect data concurrently to generate the most useful results.

Comment: Some commenters recommended that CMS define ''routine'' for appointment wait time standards for consistency in implementation and results while others supported letting States define it to be reflective of their local markets.

Response: We understand commenters' concerns regarding consistency in implementation and interpreting the results of secret shopper surveys for compliance with appointment wait times. Currently, Medicaid, CHIP, Medicare, and the FFMs do not have a codified definition for a ''routine'' appointment. We believe that providers use many factors, including current specialty-specific clinical standards to assess appointment requests. We encourage States to work with their managed care plans and their network providers and even other States to develop a definition of ''routine'' appointment to ensure consistency within and across their managed care programs. At a minimum, we expect any definition of a ''routine'' appointment to include appointments for services such as well-child visits, annual gynecological exams, and medication management. We decline to adopt a definition of ''routine'' that States would be required to use in this final rule but will review data from the secret shopper surveys and may consider adding a definition in future guidance or rulemaking.

Comment: Some commenters recommended that CMS define ''urgent'' and ''emergent'' and include these types of appointments in the appointment wait time standards as well. A few commenters suggested that CMS refine the appointment wait time standards by specifying existing patient appointments separately from new patient appointments given that new patients often need an extended initial visit which is often not available within 10- or 15-business days.

Response: We decline to define ''urgent'' and ''emergent'' as we are not implementing appointment wait time standards in § 438.68(e) and through cross-reference at § 457.1218 for urgent or emergent appointments. We did not propose appointment wait time standards for urgent or emergent appointments given the potential for serious harm when there is a need for such care. We believe it is prudent to start with less time-sensitive appointments and use secret shopper data to inform any potential future rulemaking on urgent or emergent wait time standards. However, we remind States and managed care plans that ''emergency medical condition'' is defined in §§ 438.114(a) and 457.10 as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following: (i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (ii) Serious impairment to bodily functions; or (iii) Serious dysfunction of any bodily organ or part. As noted in the prior response, we will review data from the secret shopper surveys to determine if adding additional definitions could improve appointment wait time compliance or measurement.

We appreciate commenters' suggestion to add specificity to appointment availability by separately measuring for new and existing patients. However, we do not want to make developing and implementing appointment wait time standards unnecessarily complicated, particularly since this will be a new way of assessing access for some States. States are welcome to add this level of detail to their appointment wait time standards, but we decline to require it in this final rule. States that set appointment wait time standards separately for new and existing patients must ensure that both standards comply with the maximum wait times in § 438.68(e).

Comment: A few commenters recommended that States obtain input from interested parties to aide in choosing the fourth appointment type.

Response: We agree with commenters and encourage States to consult with a wide range of interested parties—including their Medicaid and CHIP managed care plans, other plan types, providers, enrollees, and local advocacy organizations—when determining which provider or specialty to select to comply with §§ 438.68(e)(1)(iv) and 457.1218.

Comment: One commenter questioned how appointment wait time standards apply to dual eligible special needs plans (D–SNPs) and how they intersect with existing Medicare requirements. The commenter noted concern that, without clarification, there could be confusion on secret shopper surveys and enforcement of wait time standards.

Response: We appreciate the comment and the opportunity to clarify. The appointment wait time standards finalized in § 438.68(e) apply to routine appointments with certain types of Medicaid and CHIP managed care network providers. For Medicaid managed care plans that are also D–SNPs in Medicare Advantage, States are only required by § 438.68(e)(1)(i) through (iii) to apply appointment wait time standards if the MCO, PIHP or PAHP is the primary payer. Any requirements on D–SNPs for services under the D–SNP contract with CMS are addressed in Medicare Advantage regulations.

Comment: A few commenters suggested that instead of measuring compliance with appointment wait time standards linked to remedy plans, CMS should provide incentives to providers that meet certain wait time standards. These commenters noted this would be far more effective than approaching it from a punitive perspective. Commenters also recommended that managed care plans look at other policies and practices that impact provider contracting and appointment availability such as timely credentialing, accurate and timely claims payment, and inefficient and redundant prior authorization processes.

Response: We agree that managed care plans offering incentives to providers that meet appointment wait time standards is a very useful suggestion and encourage managed care plans to consider it as part of developing a more comprehensive approach to appointment availability. There are many processes used by managed care plans that influence a provider's willingness to be part of a network and managed care plans should continually monitor processes that may jeopardize their networks' stability and take action to address them. However, we do not agree that the results from secret shopper surveys should be used for incentives alone. We believe that remedy plans will help States and managed care plans address identified access concerns and secret shopper survey results will provide timely data to inform the development of robust and effective remedy plans. We acknowledge that remedy plans should not be the only tool used by states and managed care plans and support the use of multifaceted approaches to improve access.

Comment: Some commenters recommended that CMS require managed care plans to include a hold harmless provision in their network provider contracts so that network providers cannot be held responsible for the managed care plan's compliance with appointment wait time standards. Commenters stated concern that some managed care plans may impose some type of penalty on network providers that do not offer appointments that comply with the appointment wait time standards and that these actions could have the unintended consequence of worsening enrollees' access to care as physician practices are forced to see fewer Medicaid patients or opt out of being network providers.

Response: We appreciate commenters raising this concern and while it is not immediately clear to us why managed care plans would believe punitive action on network providers would be an effective way to encourage providers to offer more timely appointments, we defer to States and managed care plans to determine the appropriateness of a hold harmless provision in network contracts. As we note in the prior comment, strengthening managed care plan networks through timely credentialing, accurate and timely claims payment, and efficient prior authorization processes would seem a far more productive way to support providers to improve or expand access. States and managed care plans should collaborate to bolster relationships with providers and focus on the shared goal of improving access.

Comment: One commenter suggested that we revise § 438.68(e) to use ''services'' instead of ''provider types'' to allow PCPs that do gynecological services to be counted towards compliance for primary care, as well as OB/GYN.

Response: We appreciate this comment and agree that ''services'' instead of ''provider types'' in § 438.68(e)(1) would be clearer and more consistent with §§ 438.68(a) and 438.206. Using ''services'' would also be more consistent with managed care plan contracts' specification of ''covered services.'' Our intent in proposing and finalizing appointment wait time standards is assessing access to care, not to limit the types of providers that could offer the services in paragraphs (e)(1)(i) through (iii). Understanding the scope of services subject to appointment wait time standards can be useful when

incorporated into the secret shopper survey by producing more detailed results and a truer view of access as experienced by enrollees. We accordingly are adopting the commenter's suggestion to use ''services'' instead of ''provider types'' in the final version of § 438.68(e)(1) and, for consistency, (e)(3).

To ensure consistency in § 438.68(d) with the adoption of ''services, we are finalizing minor wording revisions. In paragraph (d)(1), we are removing ''provider-specific'' to be more inclusive of all network standards in § 438.68; in (d)(1)(iii), we are adding ''or for the service type;'' and in paragraph (d)(2), we are adding ''or service'' after ''provider type'' for consistency with § 438.68(e)(1).

Comment: We received numerous suggestions for variations on our proposed wait time standards. One commenter recommended setting appointment wait time standards for obstetrical services based on trimesters, such as appointments within 14 calendar days in the first trimester, 7 calendar days in second trimester, and 3 calendar days in the third trimester. Another commenter recommended that CMS permit States to define an appointment wait time standard for additional behavioral health specialists, facility types, or service types, either inpatient or outpatient, as long as the specialist, facility, or service type identified in the State-defined standard is distinct from the broader group of outpatient mental health and SUD providers subject to the 10-business day standard.

Response: States have the flexibility to develop appointment wait time standards by using more detailed criteria as long as the additional level of detail does not create a standard that exceeds the maximum timeframes in § 438.68(e). For example, requiring obstetrical appointments within 14, 7, and 3 calendar days is acceptable as none of them exceed the 15- calendar day limit in § 438.68(e)(1)(iii). Additionally, States can also include additional wait time standards for other services beyond the requirement in (e)(1)(iv) for a State-selected type, but they cannot replace or supplant the services in § 438.68(e)(1)(i)–(iii).

Comment: A few commenters recommended that the appointment wait time standards in § 438.68(e)(1) use ''calendar days'' instead of ''business days'' for ease of application and monitoring. One commenter recommended adding appointment wait time standards for HCBS, which is rendered 24/7 thus making ''calendar days'' more appropriate.

Response: We decline to accept the commenters' suggestion as we believe that requiring appointment wait time standards only for routine appointments in this final rule makes ''business days'' appropriate. Additionally, using ''business'' days is consistent with standards for the FFMs and Medicare Advantage, which reduces burden on States, managed care plans, and providers. Should we consider revising § 438.68(e) in future rulemaking to address HCBS, we will consider the impact of using a calendar day standard.

Comment: Some commenters recommended that there be an exception process for rural areas or health professional shortage areas (HPSAs), as they will present some very large challenges for managed care plans to meet the appointment wait time standards due to provider shortages. One commenter recommended that CMS add more specificity to § 438.68(d) so that States use exceptions consistently.

Response: We understand that provider shortages, particularly prevalent in rural areas and HPSAs, present challenges to ensuring timely access. This is why we believe requiring the use of appointment wait time standards and measuring compliance with them is important and should produce valuable information that can help States and managed care plans develop effective solutions. However, we acknowledge that implementing standards, analyzing results, and developing solutions to access issues that need improvement will take time and in the interim, States may want a mechanism to identify known access challenges. Existing regulations at § 438.68(d) permit States to use an exception process for any of the provider-specific network standards required in § 438.68. The flexibility to permit States to decide if and/or when to use an exception process was codified in the 2016 final rule. States have been using exception processes that meet the needs of their programs and may find this provision useful as areas for improvement are identified and remedy plans are implemented.

Comment: Some commenters did not support requiring appointment wait time standards; they stated that one of the most common reasons for access issues is a shortage of providers in an area or a specialty and that appointment wait time standards cannot address provider supply. Commeters stated particular concerns for mental health and SUD, rural areas, and HPSAs. These commenters stated that appointment wait time standards will generate a significant amount of burden for States, plans, and providers with little, if any, improvement in access. Some commenters raised concerns that appointment wait time standards will increase pressure on providers and lead to burn out, expand patient panels to unmanageable levels, and potentially drive providers out of Medicaid. One commenter stated that national standards without consideration for regional variances, market makeup, or workforce constraints, are overly rigid and, despite States' and plans' best efforts, may simply prove unachievable. Another stated that States must have the autonomy to design and implement their own standards to account for State-specific conditions. Commenters recommended that CMS partner with other agencies such as the Health Resources and Services Administration to promote growth of the provider supply nationally.

Response: We acknowledge that States developing and enforcing appointment wait time standards will not solve all access issues. However, we believe they can be effective for the majority of the routine appointments for services that we are finalizing. While some States already enforce appointment wait time standards, we know that it will be new and impose some new burden initially for other States. We believe the effort will have a positive impact on access once the standards are implemented and the State, managed care plans, and providers are taking a coordinated approach towards the same goal. We also believe that there are opportunities for managed care plans to ease provider burden to enable them to provide timely appointments such as by ensuring timely, efficient credentialing processes, ensuring that prior authorization is used effectively and meaningfully, and by ensuring timely and accurate claims payment. We believe we provide States the ability to account for regional variances, State-specific conditions, market makeup, or workforce constraints in two ways: by only providing the maximum appointment wait time with States setting the exact standard within that parameter for three types of services and by allowing States to set the wait time standard for an additional State-selected service. We reflect these in § 438.68(e) with ''[. . .]State-established timeframes but no longer than[. . .]'' and § 438.68(e)(1)(iv) with ''[. . .]State-established timeframes.'' We intentionally drafted § 438.68(e) to provide parameters for appointment wait time standards while also giving States the ability to customize the

standards for their specific markets, populations, and programs. Lastly, broader efforts are underway to address access nationally. For example, on July 25, 2023, the Department of Agriculture announced USDA's Emergency Rural Health Care Grants [31] to help strengthen rural America's health care infrastructure. Additionally, we released a proposed rule on September 1, 2023 proposing minimum staffing standards for long-term care facilities and Medicaid institutional payment transparency reporting.[32]

Comment: Many commenters suggested revising the compliance date for appointment wait time standards from the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule. We received comments suggesting an applicability date as soon as 1 year after the final rule's effective date and a few for applicability dates in excess of 5 years.

Response: We appreciate the comments on our proposed applicability date. We considered all of the access provisions in the final rule and have chosen applicability dates that balance the needs of enrollees with the level of effort necessary to effectively implement each provision. We believe finalizing the applicability date of the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule is appropriate for appointment wait time standards in § 438.68(e).

Comment: We received a few comments in response to our request in the preamble on whether behavioral health PIHPs and PAHPs include other services that would enable States to select another service to fulfill § 438.68(e)(1)(iv). Commenters clarified that most behavioral health PIHPs and PAHPs do not include other covered services, and therefore, States would be unable to comply with § 438.68(e)(1)(iv).

Response: We appreciate commenters clarifying this for us as we want to ensure that the regulation text is accurate. To reflect this, we will finalize a revision to § 438.68(e)(1)(iv) to add ''and covered in the MCO's, PIHP's, or PAHP's contract'' after ''[. . .]other than those listed in paragraphs (e)(1)(i) through (iii) of this section.'' This will clarify that States do not need to develop appointment wait time standards or perform secret shopper surveys for services other than mental health and SUD for PIHPs and PAHPs that cover mental health and SUD services only.

Comment: One commenter stated that CMS does not have the authority to set national appointment wait time standards because section 1932(c)(1)(A)(i) of the Act authorizes States to develop standards for access to care, not the Secretary.

Response: We clarify for the commenter that the text at § 438.68(e) requires States to develop appointment wait time standards and that § 438.68(e)(i) through (iii) only establish the maximum times within which States must set their standards.

Comment: We received several comments supportive of including appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts in § 438.206(c)(1)(i).

Response: We thank commenters for their support. We note a drafting error in the proposed rule for the applicability date for § 438.206(c)(1)(i) as specified in § 438.206(d). We proposed an applicability date in § 438.206(d) of the first rating period that begins on or after 4 years after July 9, 2024; however; to align with the requirement for States to develop and enforce appointment wait time standards at § 438.68(b), managed care plan contracts need to reflect the appointment wait time standards on the same timeframe. Because § 438.68(b) was proposed and is being finalized as the first rating period beginning on or after 3 years after July 9, 2024, so should § 438.206(c)(1)(i) as specified in § 438.206(d). Therefore, in this final rule, § 438.206(d) is being finalized as applicable on the first rating period beginning on or after 3 years after July 9, 2024.

Comment: One commenter suggested that CMS strengthen Federal requirements to ensure children enrolled in CHIP managed care plans have timely access to all covered services, when available, and encouraged CMS to further define specialists as being pediatric specialists. The commenter noted that they believe pediatric specialists are often not included in CHIP MCO networks if the State or Federal standard does not specifically require them. Therefore, CHIP MCOs may be able to satisfy network adequacy requirements by including adult specialists, despite their inability to adequately care for the specialized needs of pediatric patients.

Response: We appreciate the commenters' concern for strengthening requirements to ensure children enrolled in managed care plans have timely access to all covered services, when available. We currently define pediatric specialist in Medicaid at § 438.68(b)(iv), which is incorporated into CHIP regulations through cross-reference at § 457.1218. We remind States that the standards described in Medicaid at § 438.68(b)(iv) and in CHIP through cross-reference at § 457.1218 are the minimum standards that a State must meet to comply with their annual quality review. If a State has identified deficiencies in pediatric specialist availability, States have the option to develop higher standards than the Federal minimum.

After reviewing the public comments, we are finalizing § 438.68(e) as proposed except for a revision to use ''services'' instead of ''provider types'' in § 438.68(e)(1) and (e)(3) and to add ''and covered in the MCO's, PIHP's, or PAHP's contract'' to § 438.68(e)(1)(iv). We are also finalizing minor conforming changes in § 438.68(d)(1) and (2). We are finalizing § 438.206(d), which is applicable for separate CHIPs through an existing cross-reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d), as ''. . . the first rating period that begins on or after 3 years after July 9, 2024 . . .'' We are finalizing §§ 438.68(h), 438.206(c) and 457.1218 as proposed.

c. Secret Shopper Surveys (§§ 438.68(f), 457.1207 and 457.1218)

We recognized that in some States and for some services, Medicaid beneficiaries face significant gaps in access to care. Evidence suggested that in some localities and for some services, it takes Medicaid beneficiaries longer to access medical appointments compared to individuals with other types of health coverage.[33] This may be exacerbated by difficulties in accessing accurate information about managed care plans' provider networks; although Medicaid and CHIP managed care plans are required to make regular updates to their online provider directories in accordance with §§ 438.10(h)(3) and 457.1207 respectively, analyses of these directories suggest that a significant share of provider listings include inaccurate information on, for example, how to contact the provider, the provider's network participation, and whether the provider is accepting new

[31] *https://www.usda.gov/media/press-releases/2023/07/25/biden-harris-administration-helps-expand-access-rural-health-care.*

[32] *https://www.federalregister.gov/public-inspection/2023-18781/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid.*

[33] W. Hsiang, A. Lukasiewicz, and M. Gentry, ''Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis,'' SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118.*

patients.[34] Relatedly, analyses have shown that the vast majority of services delivered to Medicaid beneficiaries are provided by a small subset of health providers listed in managed care plan provider directories, with a substantial share of listed providers delivering little or no care for Medicaid beneficiaries.[35] Some measures of network adequacy may not be as meaningful as intended if providers are ''network providers'' because they have a contract with a managed care plan, but in practice are not actually accepting new Medicaid enrollees or impose a cap on the number of Medicaid enrollees they will see.

To add a greater level of validity and accuracy to States' efforts to measure network adequacy and access, we proposed to require States to use secret shopper surveys as part of their monitoring activities. Secret shopper surveys are a form of research that can provide high-quality data and actionable feedback to States and managed care plans and can be performed either as ''secret'' meaning the caller does not identify who they are performing the survey for or ''revealed'' meaning the caller identifies the entity for which they are performing the survey. While both types of surveys can produce useful results, we believe the best results are obtained when the survey is done as a secret shopper and the caller pretends to be an enrollee (or their representative) trying to schedule an appointment. Results from these surveys should be unbiased, credible, and reflect what it is truly like to be an enrollee trying to schedule an appointment, which is a perspective not usually provided by, for example, time and distance measures or provider-to-enrollee ratios. Many States and managed care plans currently use some type of survey to monitor access; however, we believe there should be some consistency to their use for Medicaid managed care programs to enable comparability.

To ensure consistency, we proposed a new § 438.68(f) to require that States use independent entities to conduct annual secret shopper surveys of managed care plan compliance with appointment wait time standards proposed at § 438.68(e) and the accuracy of certain data in all managed care plans' electronic provider directories required at § 438.10(h)(1). These proposed changes apply equally to separate CHIPs through existing cross-references at §§ 457.1218 and 457.1207. We believe that the entity that conducts these surveys must be independent of the State Medicaid or CHIP agency and its managed care plans subject to the survey to ensure unbiased results. Therefore, at § 438.68(f)(3)(i), we proposed to consider an entity to be independent of the State if it is not part of the State Medicaid agency and, at § 438.68(f)(3)(ii), to consider an entity independent of a managed care plan subject to a secret shopper survey if the entity is not an MCO, PIHP, or PAHP; is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys; and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. Given the valuable data the proposed secret shopper surveys could provide States, we believe requiring the use of an independent entity to conduct the surveys is critical to ensure unbiased results.

We also proposed to require States to use secret shopper surveys to determine the accuracy of certain provider directory information in MCOs', PIHPs', and PAHPs' most current electronic provider directories at § 438.68(f)(1)(i). Since we believe that paper directory usage is dwindling due to the ever-increasing use of electronic devices and because electronic directory files are usually used to produce paper directories, we are not requiring secret shopper validation of paper directories. Rather, we proposed in § 438.68(f)(1)(i)(A) through (C) to require surveys of electronic provider directory data for primary care providers, OB/GYN providers, and outpatient mental health and SUD providers, if they are included in the managed care plan's provider directories. We proposed these provider types because they are the provider types with the highest utilization in many Medicaid managed care programs.

To ensure that a secret shopper survey can be used to validate directory data for every managed care plan, we proposed in § 438.68(f)(1)(i)(D) to require secret shopper surveys for provider directory data for the provider type selected by the State for its appointment wait time standards in § 438.68(e)(1)(iv). We acknowledged that the State-chosen provider type may vary across managed care plan types and thus, States may have to select multiple provider types to accommodate all their managed care programs. For example, a State may select a provider type from their MCOs' directories that is not a provider type included in their mental health PIHP's directories; just as the State may select a provider type from their behavioral health PIHPs' directories that is not a provider type included in their dental PAHPs' directories. We noted that the State-chosen provider type cannot vary among plans of the same type within the same managed care program. Although this degree of variation between States will limit comparability, we believe that the value of validating provider directory data outweighs this limitation and that having results for provider types that will be important to State-specific access issues will be a rich source of data for States to evaluate managed care plan performance and require the impacted plan to implement timely remediation, if needed.

At § 438.68(f)(1)(ii)(A) through (D), we proposed to require that States use independent entities to conduct annual secret shopper surveys to verify the accuracy of four pieces of data in each MCO, PIHP, or PAHP electronic provider directory required at § 438.10(h)(1): the active network status with the MCO, PIHP, or PAHP; the street address as required at § 438.10(h)(1)(ii); the telephone number as required at § 438.10(h)(1)(iii); and whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi). We believe these are the most critical pieces of information that enrollees rely on when seeking network provider information. Inaccuracies in this information can have a tremendously detrimental effect on enrollees' ability to access care since finding providers that are not in the managed care plan's network, have inaccurate addresses and phone numbers, or finding providers that are not accepting new patients listed in a plan's directory can delay their ability to contact a network provider and ultimately, receive care.

To maximize the value of using secret shopper surveys to validate provider directory data, identified errors must be corrected as quickly as possible. Therefore, at § 438.68(f)(1)(iii) and (iv) respectively, we proposed that States must receive information on all provider directory data errors identified in secret shopper surveys no later than 3 business days from identification by the entity conducting the secret shopper survey and that States must then send that data to the applicable managed care plan within 3 business days of receipt. We also proposed in § 438.68(f)(1)(iii) that

[34] A. Burman and S. Haeder, ''Directory Accuracy and Timely Access in Maryland's Medicaid Managed Care Program,'' Journal of Health Care for the Poor and Underserved, available at *https://pubmed.ncbi.nlm.nih.gov/35574863/* A. Bauman and S. Haeder, ''Potemkin Protections: Assessing Provider Directory Accuracy and Timely Access for Four Specialties in California,'' Journal of Health Politics, Policy and Law, 2022, available at *https://pubmed.ncbi.nlm.nih.gov/34847230/*.

[35] A. Ludomirsky, et. al., ''In Medicaid Managed Care Networks, Care is Highly Concentrated Among a Small Percentage of Physicians,'' Health Affairs, May 2022, available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747*.

the information sent to the State must be ''sufficient to facilitate correction'' to ensure that enough detail is provided to enable the managed care plans to quickly investigate the accuracy of the data and make necessary corrections. We note that States could delegate the function of forwarding the information to the managed care plans to the entity conducting the secret shopper surveys so that the State and managed care plans receive the information at the same time. This will hasten plans' receipt of the information, as well as alleviate State burden. To ensure that managed care plans use the data to update their electronic directories, we proposed at § 438.10(h)(3)(iii) to require MCOs, PIHPs, and PAHPs to use the information from secret shopper surveys required at § 438.68(f)(1) to obtain corrected information and update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii), and included in separate CHIP regulations through an existing cross-reference at § 457.1207. While updating provider directory data after it has been counted as an error in secret shopper survey results will not change a managed care plan's compliance rate, it will improve provider directory accuracy more quickly and thus, improve access to care for enrollees.

To implement section 5123 of the Consolidated Appropriations Act, 2023,[36] which requires that managed care plans' and PCCM entities' (if applicable) provider directories be searchable and include specific information about providers, we proposed to revise § 438.10(h)(1) by adding ''searchable'' before ''electronic form'' to require that managed care plans' and PCCM entities' (if applicable) electronic provider directories be searchable. We also proposed to add paragraph (ix) to § 438.10(h)(1) to require that managed care plans' and PCCM entities' (if applicable) provider directories include information on whether each provider offers covered services via telehealth. These proposals will align the text in § 438.10(h) with section 1932(a)(5) of the Act, as amended by section 5123 of the Consolidated Appropriations Act, 2023. Section 5123 of the Consolidated Appropriations Act, 2023 specifies that the amendments to section 1932(a)(5) of the Act will take effect on July 1, 2025; therefore, we proposed that States comply with the revisions to § 438.10(h)(1) and new (h)(1)(ix) by July 1, 2025.

[36] *https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf.*

Our proposals for a secret shopper survey of provider directory data proposed at § 438.68(f)(1) are authorized by section 1932(a)(5)(B)(i) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, which require each Medicaid MCO to make available the identity, locations, qualifications, and availability of health care providers that participate in their network. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We proposed that secret shopper surveys include verification of certain providers' active network status, street address, telephone number, and whether the provider is accepting new enrollees; these directory elements reflect the identity, location, and availability, as required for Medicaid in section 1932(a)(5)(B)(i) of the Act and required for CHIP through section 2103(f)(3) of the Act. Although the statute does not explicitly include ''accurate'' to describe ''the identity, locations, qualifications, and availability of health care providers,'' we believe it is the intent of the text and therefore, utilizing secret shopper surveys to identify errors in provider directories will help managed care plans ensure the accuracy of the information in their directories. Further, our proposal at § 438.10(h)(3)(iii) for managed care plans to use the data from secret shopper surveys to make timely corrections to their directories will also be consistent with statutory intent to reflect accurate identity, locations, qualifications, and availability information. Secret shopper survey results will provide vital information to help managed care plans fulfill their obligations to make the identity, locations, qualifications, and availability of health care providers that participate in the network available to enrollees and potential enrollees.

We believe using secret shopper surveys could also be a valuable tool to help States meet their enforcement obligations of appointment wait time standards, required in § 438.68(e). Secret shopper surveys are perhaps the most commonly used tool to assess health care appointment availability and can produce unbiased, actionable results. At § 438.68(f)(2), we proposed to require States to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards proposed in § 438.68(e)(1). We also proposed in § 438.68(f)(2)(i) that, after consulting with States and other interested parties and providing public notice and opportunity to comment, we may select additional provider types to be added to secret shopper surveys of appointment wait time standards. We believe that after reviewing States' assurances of compliance and accompanying analyses of secret shopper survey results as proposed at § 438.207(d), and through an existing cross-reference at § 457.1230(b) for separate CHIP, we may propose additional provider types be subject to secret shopper surveys in future rulemaking.

In section I.B.1.b. of this final rule above, we noted that States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68(e) that accurately reflect the practical use of telehealth and in-person appointments in their State. To ensure that States reflect this, in § 438.68(f)(2)(ii) we proposed that appointments offered via telehealth only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments and that telehealth visits offered during the secret shopper survey be separately identified in the survey results. We believe it is appropriate to prohibit managed care plans from meeting appointment wait time standards with telehealth appointments alone and by separately identifying telehealth visits in the results because this will help States determine if the type of appointments being offered by providers is consistent with expectations and enrollees' needs. We note that this proposal differs from the draft requirement for QHPs in the FFMs beginning in 2025, which does not take telehealth appointments into account for purposes of satisfying the appointment wait time standards.[37] Managed care encounter data in Transformed Medicaid Statistical Information system (T–MSIS) reflect that most care is still provided in-person and that use of telehealth has quickly returned to near pre-pandemic levels. We believe by explicitly proposing to limit the counting of telehealth visits to meet appointment wait time standards, as well as the segregation of telehealth and in-person appointment data, secret shopper survey results will produce a more accurate reflection of what enrollees' experience when attempting to access care. We considered aligning appointment wait times and telehealth visits with the process used by MA for

[37] 45 CFR 156.230; 2025 Draft Letter to Issuers in the Federally facilitated Exchanges, available at *https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf.*

demonstrating overall network adequacy, which permits MA organizations to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits. See § 422.116. However, we believe our proposed methodology will provide States and CMS with more definitive data to assess the use of telehealth and enrollee preferences and will be the more appropriate method to use at this time. We requested comment on this proposal.

Secret shopper surveys of plans' compliance with appointment wait time standards proposed at § 438.68(f)(2) is authorized by section 1932(b)(5) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, because secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards. This data should aid managed care plans as they assess their networks, pursuant to § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act for Medicaid and section 2103(f)(3) of the Act for CHIP.

It is critical that secret shopper survey results be obtained in an unbiased manner using professional techniques that ensure objectivity. To reflect this, we proposed at § 438.68(f)(3) that any entity that conducts secret shopper surveys must be independent of the State Medicaid agency and its managed care plans subject to a secret shopper survey. In § 438.68(f)(3)(i) and (ii), we proposed the criteria for an entity to be considered independent: Section 438.68(f)(3)(i) proposes that an entity cannot be a part of any State governmental agency to be independent of a State Medicaid agency and § 438.68(f)(3)(ii) proposes that to be independent of the managed care plans subject to the survey, an entity will not be an MCO, PIHP, or PAHP, will not be owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and will not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. We proposed to define ''independent'' by using criteria that is similar, but not as restrictive, as the criteria used for independence of enrollment brokers and specified at § 438.810(b)(1). We believe this consistency in criteria will make it easier for States to evaluate the suitability of potential survey entities. We reminded States that the optional EQR activity at § 438.358(c)(5) could be used to conduct the secret shopper surveys proposed at § 438.68(f) and for secret shopper surveys conducted for MCOs, States may be able to receive enhanced Federal financial participation (FFP), pursuant to § 438.370.

Secret shopper surveys can be conducted in many ways, using varying levels of complexity and gathering a wide range of information. We wanted to give States flexibility to design their secret shopper surveys to produce results that not only validate managed care plans' compliance with provider directory data accuracy as proposed at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2), but also provide States the opportunity to collect other information that will assist them in their program monitoring activities and help them achieve programmatic goals. To provide this flexibility, we proposed a limited number of methodological standards for the required secret shopper surveys. In § 438.68(f)(4), we proposed that secret shopper surveys use a random sample and include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract. We believe these are the most basic standards that all secret shopper surveys must meet to produce useful results that enable comparability between plans and among States. We proposed in § 438.68(f)(4)(iii) that secret shopper surveys to determine plan compliance with appointment wait time standards will have to be completed for a statistically valid sample of providers to be clear that a secret shopper surveys must be administered to the number of providers identified as statistically valid for each plan. To ensure consistency, equity, and context to the final compliance rate for each plan, we believe it is important that inaccurate provider directory data not reduce the number of surveys administered. Therefore, as a practical matter, if the initial data provided by a State to the entity performing the survey does not permit surveys to be completed for a statistically valid sample, the State must provide additional data to enable completion of the survey for an entity statistically valid sample. We did not believe this provision needed to apply to secret shopper surveys of provider directory data proposed in paragraph (f)(1) since the identification of incorrect directory data is the intent of those surveys and should be reflected in a plan's compliance rate.

Because we believe secret shopper survey results can produce valuable data for States, managed care plans, enrollees, and other interested parties, we proposed at § 438.68(f)(5), that the results of these surveys be reported to CMS and posted on the State's website. Specifically, at § 438.68(f)(5)(i), we proposed that the results of the secret shopper surveys of provider directory data validation at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2) must be reported to CMS annually using the content, form, and submission times proposed in § 438.207(d). At § 438.68(f)(5)(ii), we proposed that States post the results on the State's website required at § 438.10(c)(3) within 30 calendar days of the State submitting them to CMS. We believe using the existing report required at § 438.207(d) will lessen burden on States, particularly since we published the NAAAR template [38] in July 2022 and are also developing an electronic reporting portal to facilitate States' submissions. We anticipate revising the data fields in the NAAAR [39] to include specific fields for secret shopper results, including the provider type chosen by the State as required in § 438.68(e)(1)(iv) and (f)(1)(i)(D). This proposal is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

We recognize that implementing secret shopper surveys will be a significant undertaking, especially for States not already using them; but we believe that the data produced by successful implementation of them will be a valuable addition to States' and CMS's oversight efforts. As always, technical assistance will be available to help States effectively implement and utilize secret shopper surveys. We invited comment on the type of technical assistance that will be most useful for States, as well as States' best practices and lessons learned from using secret shopper surveys.

We also proposed in § 438.68(h) that States would have to comply with

[38] *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx.*

[39] *https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#NETWORK:~:text=Report.%20%C2%A0The%20current-,excel%20template,-(XLSX%2C%20218.99%20KB.*

§ 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule.

We summarize and respond to public comments received on Secret shopper surveys (§§ 438.68(f), 457.1207, 457.1218) below.

Comment: Many commenters supported requiring States to use secret shopper surveys to validate compliance with appointment wait time standards and to verify the accuracy of certain provider directory data. Commenters stated that these surveys would provide valuable information on the access provided by plan networks and provide a mechanism to drive improvements in accuracy and specificity of provider directories. Another commenter stated that the results of secret shopper surveys would provide accurate and transparent plan information that is vital to ensuring Medicaid managed care populations have access to the care they need. A few commenters stated the proposed requirements would bring much-needed consistency to the way these surveys are conducted which should lead to uniform identification and quick correction of inaccurate information.

Response: We thank commenters for their support to require secret shopper surveys as proposed in § 438.68(f). We believe that all interested parties will benefit from an independent evaluation of the degree to which managed care plans' networks provide timely appointments and the accuracy of provider directory data. The results, particularly for provider directory data, will enable timely corrections that will improve access.

Comment: Many commenters supported the use of independent entities to perform the secret shopper surveys. Commenters stated that this would ensure that surveys were conducted in an impartial manner and would produce more reliable results. One commenter recommended that we also include ''any direct or indirect relationship'' to our definition of ''independence,'' consistent with § 438.810(b)(2)(i).

Response: We appreciate the supportive comments; our intent in including an independence requirement for the surveyors was to improve the validity of the results and to assure interested parties that the results presented an objective assessment of routine appointment availability for their managed care plan and its network providers. We decline to modify the definition of ''independence'' in this final rule. We acknowledge a more robust definition is appropriate in § 438.810(b)(2) for enrollment brokers, but do not believe the same level is warranted for secret shopper surveys. Enrollment brokers are responsible for providing information to enrollees to assist them in making informed decisions when selecting a managed care plan. Because enrollees are often limited to changing their managed care plans annually and because managed care plans receive a capitation payment for each enrollee enrolled in their plan, ensuring that enrollment brokers are independent of the managed care plans from which enrollees can choose is critical to ensure that enrollees receive information and assistance in an unbiased manner and that the enrollees' best interest is prioritized. We do not believe the same level of risk exists with secret shopper surveys. Additionally, we have been made aware that States are sometimes challenged to find entities that meet the requirements in § 438.810 to fulfill the functions of an enrollment broker and we did not want to impose those same challenges on States when procuring secret shopper survey vendors. We believe the functions of an enrollment broker and a secret shopper survey vendor are sufficiently different to warrant a different level of requirements for independence.

Comment: One commenter recommended using revealed shopper surveys instead of secret shopper surveys. Another commenter recommended that CMS produce standardized definitions, methodologies, and templates for use in conducting secret shopper surveys.

Response: We appreciate the comments but decline to adopt them in this final rule. We believe that secret shopper surveys capture information that is unbiased, credible, and reflect what enrollees experience when trying to schedule an appointment. This is not possible with a revealed survey and, therefore, is less likely to fulfill our goal of assessing appointment availability or encountering incorrect provider directory data as enrollees do. To the suggestion that we publish definitions, methodologies, and templates, we do not believe that is necessary as we believe States have sufficient experience in using secret shopper surveys or can rely on the expertise of outside entities. Further, while we are finalizing a minimum set of methodological standards for secret shopper surveys in § 438.68(f)(4), we believe States should have some latitude to customize their surveys beyond the minimum requirements to capture information and details that impact their programs and populations. We believe that being overly prescriptive may lessen the surveys' utility.

Comment: A few commenters recommended requiring implementation sooner than the rating period for contracts with MCOs, PIHPs, and PAHPs that begins on or after 4 years after the effective date, while other commenters recommended extending implementation beyond 4 years. A few commenters stated that a shorter timeframe was reasonable because some States already use secret shopper surveys for certain aspects of their program.

Response: We appreciate the range of comments on the applicability date. Because secret shopper surveys will be used to measure compliance with appointment wait time standards and provider directory accuracy, we intentionally proposed an applicability date that was 1 year after the applicability date for appointment wait time standards. We clarify that States can comply with § 438.68(f) sooner than the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after the effective date of the rule and we encourage them to do so, particularly for surveys of provider directory data accuracy. We considered all of the access provisions in the final rule and have chosen applicability dates for each provision that balance the needs of enrollees with the level of effort necessary to effectively implement each one. We believe finalizing the applicability date as the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after the effective date of the final rule is appropriate for § 438.68(f).

Comment: A few commenters stated that dually eligible individuals must navigate multiple provider networks and directories with Medicare serving as the primary payer of most services for which the secret shopper survey will evaluate appointment availability. These commenters recommended that secret shopper surveys for integrated D–SNPs should account for Medicare as a primary payer for many of the services evaluated in the survey and the challenges due to misalignment of provider networks.

Response: We clarify that network adequacy standards and any associated secret shopper surveys only apply for services for which the Medicaid managed care plan is the primary payer. Section 438.68(e) and (f) do not apply for services for which Traditional Medicare, a D–SNP, or another Medicare Advantage plan has primary responsibility for dually eligible Medicaid managed care plan enrollees.

Comment: A few commenters stated that many States already do some form of secret shopper surveys and requested CMS to clarify if existing secret shopper surveys will meet the requirements of § 438.68(f).

Response: It is possible that States' existing secret shopper surveys may satisfy the requirements of § 438.68(f); however, that is an assessment that each State would have to make by evaluating each existing survey's content and methodology to ensure that it complies with all requirements in § 438.68(f).

Comment: Some commenters recommended that CMS prohibit duplicative or multiple provider surveys. If CMS finalizes the requirement for States to utilize secret shopper surveys to determine timely access compliance, these commenters believe potential duplication must be addressed to prevent over burdening providers' staff and detracting from the time they have available to take actual patients' phone calls.

Response: We understand the commenters' concern and agree that States should make every effort to supply provider data to their survey entities that does not generate repeated calls to the same provider for multiple managed care plans. We acknowledge this may not always be possible in small geographic areas or areas with few providers. However, as § 438.68(f)(4)(iii) only requires a statistically valid sample of providers be included in each survey, we believe that the level of repeat calls to the same provider will be minimal.

Comment: We received many comments on our proposal that managed care plans must meet a 90 percent compliance threshold. Some commenters noted that they believe that 90 percent will likely prove exceedingly difficult to attain, particularly given the national shortages of providers of certain services and in certain geographic areas. These commenters recommended that CMS adopt a lower percentage in initial years and then adjust it as plans and providers acclimate to the new standards; suggestions included compliance rates from 50 percent to 75 percent. Other commenters supported a 90 percent compliance rate believing that it was appropriate for access to the services proposed. Some commenters also stated that aligning with FFM standards was effective and efficient given the high overlap of managed care plans between Medicaid and the FFMs.

Response: We acknowledge that achieving a 90 percent compliance rate is a high standard, but we believe that as we are finalizing appointment wait time standards for only four types of services (primary care, OB/GYN, mental health and SUD, and a State chosen one), three of which are the most commonly used on a frequent and repetitive basis, we believe it is critically important that managed care plans have robust networks for these services with sufficient capacity to provide timely appointments to meet the needs of the plan's enrollees. Additionally, as commenters noted, there is a high overlap of managed care plans between Medicaid and the FFMs, so efficiencies are likely achievable that will aid in meeting requirements for both products. Additionally, we intentionally proposed an applicability date for secret shopper surveys in § 438.68(f)(2) that was 1 year after the applicability date for appointment wait time standards in § 438.68(e)(1) to give managed care plans time to ensure that their networks are able to meet established standards. Given the importance for enrollees to be able to access routine appointments for the required services in a timely manner, we are finalizing a 90 percent compliance rate in § 438.68(e)(2).

Comment: A few commenters recommended a range of revisions to § 438.68(f) including adding additional services or all plan covered services to the secret shopper survey requirement. Other commenters suggested additional fields for surveys of provider directory data. One commenter recommended that CMS allow State-derived studies to continue which focus on key areas based on State needs instead of specifying provider types and directory fields.

Response: We believe that it is important to consistently focus the requirements for appointment wait time standards and secret shopper on the same provider and service types. This will enable coordinated and focused approaches and strategies. We believe it prudent to start with a core set of the most used services and let States and managed care plans evaluate and refine their network management activities to ensure appropriate access rather than be overly broad and dilute the impact of their efforts. After reviewing secret shopper survey data, we may include additional services in § 438.68(e)(1) in future rulemaking.

Comment: A few commenters stated that conducting annual studies of appointment availability for the same services does not allow initiatives based on the previous year's results to be implemented and assessed for effectiveness before the next study is done. A few commenters also stated that requiring an annual secret shopper survey does not consider seasonality.

Response: We acknowledge that not all areas for improvement identified in a secret shopper survey can be remedied within a year, as we reflected in § 438.207(f)(2). However, there are some that can be and conducting an annual secret shopper survey enables timely reporting of the results of managed care plans' successful efforts to improve access. To the comment on the impact of seasonality on secret shopper results, we acknowledge that some provider types are more impacted by seasonal fluctuations in appointment requests than others. We believe States can take that into consideration when they schedule their secret shopper surveys and, if done consistently from year to year, the impact should be consistent and not disproportionate.

Comment: A few commenters recommended that CMS make clear to States that the secret shopper surveys are to be used to collect the information proposed in this rule only and not use them to collect and make public any information about reproductive health care services.

Response: We confirm that the secret shopper surveys required at § 438.68(f) are to be used to collect information within the scope and intent of this final rule and not used to collect any other information or make public information beyond information on the performance of MCOs, PIHPs, and PAHPs in meeting wait time standards.

Comment: Some commenters recommended that CMS clarify whether the secret shopper survey requires that appointments be offered by a specific provider or by any provider in the practice that is in the managed care plan's network. For example, if a patient wants an appointment and a specific provider does not have availability but other comparable providers in the practice do, an appointment with another provider should be counted as meeting the appointment wait time standard. One commenter contended that secret shopper surveys are not the best tool to identify providers that do not see Medicaid enrollees (despite being in a plan's directory) or see only a minimal number. This commenter recommended using what the commenter believes were more productive approaches such as claims data analysis to identify providers in directories that do not bill Medicaid, analysis of hours authorized in a treatment plan versus hours of services delivered and analyzing direct feedback from members.

Response: We appreciate commenters raising this issue and giving us the opportunity to clarify our intent. We did not specify that the appointment wait

time standard had to be met by the specific provider in the directory, but rather that a routine appointment for primary care services, OB/GYN services, mental health and SUD services, and the State-chosen service type must be offered within established timeframes. We understand that while a specific provider may be listed in the directory, that provider may not have availability when an appointment is requested. Our goal with the initial implementation of the appointment wait time standards and secret shopper surveys is to determine if enrollees can access care when they request it. As such, we believe that being offered an appointment by any provider in a practice is sufficient for determining compliance with appointment wait time standards.

However, we want to clarify that when verifying the accuracy of provider directory data, secret shopper surveys must verify the published information. Meaning, if the provider directory lists Dr. X, then the active network status, address, phone number, and open panel status for Dr. X must be verified; a directory reflecting accurate information for other providers in the same practice is not sufficient for Dr. X's data to be considered ''accurate'' for compliance with § 438.68(f)(1)(ii). In the proposed rule preamble, we acknowledged the issue of providers being listed in managed care plan directories but delivering little or no care for Medicaid enrollees (88 FR 28101). This issue could be addressed in secret shopper surveys of appointment wait times and we encourage States to build their surveys to include this level of detail. However, we did not specifically require this in § 438.68(f) as we believe secret shopper surveys that verify provider directory data will capture this information. We believe there are efficiencies that can be utilized between the appointment wait time and provider directory data surveys, such as by requesting an appointment and verifying the information in 438.68(f)(ii) in the same call to a provider, that will reflect a more robust and accurate picture of access to providers listed in managed care plans' provider directories. We agree with the commenter's suggestions for other methods that can be used to validate network providers' availability and utilization to ensure that they are ''active'' network providers. However, we believe the commenters' suggestions should be used in addition to the secret shopper surveys to further refine and contextualize the secret shopper results.

Comment: Some commenters recommended that CMS require the entity conducting the secret shopper surveys and States to send the applicable information on provider directory data errors on a schedule other than the proposed 3-business days. Suggestions ranged from 6 days to monthly. One commenter recommended that CMS consider an approach that allows States to receive and report managed care plan errors in an aggregate or summarized form on a quarterly basis in addition to an individual 6-day communication to managed care plans. One commenter recommended that States be permitted to select their own timeframe for when data would be sent to managed care plans. One commenter suggested that managed care plans should be given a seven-day grace period to correct directory data errors before it is counted against their final accuracy rate.

Response: We appreciate the range of comments on our proposals in § 438.68(f)(1)(iii) and (iv) on the timeframes for directory data identified in secret shopper surveys to be sent to States and managed care plans. As we stated in the proposed rule preamble, inaccuracies in the information subject to a secret shopper survey can have a tremendously detrimental effect on enrollees' ability to access care since finding providers that are not in the managed care plan's network, have inaccurate addresses and phone numbers, or finding providers that are not accepting new patients listed in a plan's directory can delay their ability to contact a network provider that can provide care (88 FR 28102). We acknowledge that 3 business days is a fast turnaround time but we believe it's reasonable given that: (1) the information from the survey vendor will be transmitted electronically; (2) we explicitly stated that States could delegate the function of forwarding the information to the managed care plans to the entity conducting the secret shopper surveys so that the State and managed care plans receive the information at the same time; and (3) given that the applicability date for secret shopper surveys is the first rating period for MCOs, PIHPs, or PAHPs that begins on or after 4 years after the effective date of the rule, States and managed care plans have ample time to establish processes for this data exchange. We do not agree with the commenter that managed care plans should have a grace period in which to make corrections before the error is counted. The point of using secret shopper surveys is to assess enrollees' experience when they utilize a plan's provider directory; therefore, not calculating an accurate error rate undermines the goal of the survey.

Comment: A few commenters stated that 3 business days was not sufficient time for managed care plans to make corrections to inaccurate directory data.

Response: We appreciate commenters raising this concern as it seems the preamble may have been unclear on this issue to some readers. Section 438.68(f)(1)(iii) specifies that States must receive information on errors in directory data identified in secret shopper surveys no later than 3 business days from the day the error is identified. Section 438.68(f)(1)(iv) requires States to send that information to the applicable managed care plan no later than 3 business days from receipt. As such, the 3 business day timeframes are for data transmission, not correction of the erroneous data. Section 438.10(h)(3)(iii) specifies that managed care plans must use the information received from the State to update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii) and included in separate CHIP regulations through an existing cross-reference at § 457.1207.

Comment: Some commenters opposed requiring secret shopper surveys and stated that utilizing secret shopper surveys requires significant State resources to contract with third party survey organizations, provide limited accuracy, and ultimately are not a meaningful way of advancing the goal of directory accuracy. A few commenters stated that secret shopper surveys are not effective for addressing the root causes of access issues and cause provider burden and dissatisfaction. One commenter believed that the burden would be particularly apparent for behavioral health providers, who often operate small businesses independently without staffing support. One commenter recommended just collecting attestations from plans, consistent with the approach in the 2024 Notice of Benefit and Payment Parameters final rule for QHPs on the FFMs.

Response: We understand commenters' concerns. However, despite existing regulations on network adequacy and access in §§ 438.68 and 438.206 and monitoring and reporting requirements in §§ 438.66 and 438.207, we continue to hear from enrollees and other interested parties that managed care plan networks do not provide access to covered services that meets the needs of covered populations. As we noted in the proposed rule preamble, external studies document findings that suggest that current network adequacy standards might not reflect actual access

and that new methods are needed that account for physicians' willingness to serve Medicaid patients. Additionally, 34 audit studies demonstrated that Medicaid is associated with a 1.6-fold lower likelihood in successfully scheduling a primary care appointment (88 FR 28098). We believe that proactive steps are necessary to address areas that need improvement, and we believe provisions in this final rule, including requirements for secret shopper surveys to assess the accuracy of provider directory data and compliance with appointment wait time standards, are an important first step. The use of secret shopper surveys is consistent with the proposed requirements for QHPs on the FFMs as specified in the 2025 Draft Letter to Issuers in the Federally-facilitated Exchanges.[40]

Comment: We received a wide range of comments and suggestions on the methodology for secret shopper surveys including: entities conducting secret shopper surveys need to be equipped with the same information that a Medicaid enrollee would have including Medicaid program name, plan name, member ID number, and date of birth; much of the value of a secret shopper survey depends on how a question is worded and requested; familiarity of office scheduling staff with secret shopper surveys-particularly when surveyors are unable to provide necessary information indicating they are real patients; and survey questions may need to account for factors such as providers that generally rely on electronic rather than telephone appointments.

Response: We appreciate the many comments that shared valuable input on secret shopper survey methodologies. We encourage States to consider these and collaborate with the survey entity when designing their surveys. We encourage States to consider providing sufficient details to their survey entity such as a verifiable Medicaid ID number to enable them to respond to requests for such information.

Comment: One commenter noted that given the mandatory nature of EQRO provider data validation activities § 438.358(b)(1)(iv), it is unclear how the proposed secret shopper survey will add any value to the existing policy framework or is not duplicative of existing processes. The commenter recommended that CMS require States to administer the CAHPS® survey which includes questions focused on appointment availability and access to care to prevent secret shopper surveys outside of CAHPS® inadvertently negatively impacting CAHPS® results due to duplicative data collection, different survey methodologies, and inconsistent results across different surveys measuring appointment availability.

Response: We do not agree that secret shopper surveys would be duplicative of provider data validation activities in § 438.358(b)(1)(iv). As stated in the CMS EQR Protocols published in February 2023,[41] the activities in protocol 4 include validating the data and methods used by managed care plans to assess network adequacy, validating the results and generating a validation rating, and reporting the validation findings in the annual EQR technical report. These activities are different than the secret shopper surveys finalized in § 438.68(f) which will verify appointment access and the accuracy of directory data directly with a provider's office. We are unclear why the commenter noted their belief that secret shopper surveys outside of CAHPS® could inadvertently negatively impact CAHPS® results due to duplicative data collection, different survey methodologies, and inconsistent results. We acknowledge that no single tool to measure access is perfect, which is why the managed care regulations in 42 CFR part 438 require multiple tools that will provide a more comprehensive and contextualized view of access for each program.

Comment: Many commenters supported posting the results of secret shopper surveys on States' websites and noted it will help individual patients and patient advocates better understand if there are individual or systemic issues. Some commenters appreciated our requiring that the results of secret shopper surveys be included in the NAAAR as that will make it easier to locate and provide context for the other network adequacy information in the report. A few commenters suggested that States' NAAARs also be posted on *Medicaid.gov.*

Response: We believe that reporting secret shopper survey results in the NAAAR is a logical and low burden option for States and will provide a consistent place for interested parties to locate them. We appreciate the suggestion to also include States' NAAARs on *Medicaid.gov.* Currently, there are challenges with producing the MCPAR and NAAAR as documents that are compliant with sections 504 and 508 of the Rehabilitation Act; thus, they cannot currently be posted on *Medicaid.gov.* Efforts are underway to resolve these issues for MCPARs which are collected through the web-based portal, and we expect that when we are collecting NAAARs through a web-based portal, we will be able to resolve the current formatting challenges to produce compliant documents that can be posted.

Comment: A few commenters recommended that CMS not implement secret shopper surveys pending further decisions on development of a National Directory of Healthcare Providers and Services, the subject of a CMS request for information released in October 2022. These commenters stated that using a national directory to validate provider data would greatly reduce duplicative calls to providers that participate in multiple managed care plans and lessen burden on providers.

Response: We acknowledge that work on the National Directory of Healthcare Providers and Services is ongoing. We agree that if or when a national directory is available, there likely will be efficiencies that can be leveraged to lessen burden on providers and States. However, we believe that inaccurate directory data has been an issue for too long and has a great impact on access; as such, we do not agree that delaying the secret shopper requirement in § 438.68(f)(1) is appropriate.

Comment: One commenter requested clarification on how the proposed wait time standards interact with services that States ''carve out'' of managed care plan contracts (that is, services delivered in FFS) and requested that CMS issue guidance to ensure secret shopper surveys only assess compliance with appointment wait times for covered services.

Response: As specified in § 438.68(e)(1)(i) through (iii), appointment wait time standards must be established for routine appointments if the required services are covered by the managed care plan's contract. To make this clear, we explicitly include ''If covered in the MCO's, PIHP's, or PAHP's contract,[. . .]'' in paragraphs (e)(1)(i) through (iii). Therefore, secret shopper surveys must not include services that are not covered in a managed care plan's contract.

Comment: Some commenters supported our proposal to only count telehealth appointments toward wait time standards if the provider also offered in-person appointments. One commenter noted that telehealth should not replace in-person care, as there are some significant equity concerns and telehealth is not a one-size-fits-all solution. Many other commenters stated that all telehealth appointments should

[40] *https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf.*

[41] *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care/quality-of-care-external-quality-review/index.html.*

be counted towards a plan's compliance rate and that this is especially important for mental health and SUD appointments. Other commenters recommended that CMS adopt the ten percent credit toward a plan's compliance rate as is used by Medicare Advantage. A few commenters recommended that States be permitted to determine how much telehealth appointments should be counted toward a plan's compliance score.

Response: We thank commenters for their comments on this important aspect of secret shopper surveys. As we stated in the preamble, we acknowledge the importance of telehealth, particularly for mental health and SUD services. However, we do not believe that managed care plans should be able to provide services via telehealth only. Managed care encounter data in T–MSIS reflects that most care is still provided in-person and that use of telehealth has quickly returned to near pre-pandemic levels. We believe limiting the counting of telehealth visits to meet appointment wait time standards, as well as the segregation of telehealth and in-person appointment data, is the correct approach to use. While increased reliance on telehealth can and should be part of the solution to address access deficiencies and used to address a network adequacy or access issue for a limited time, it should be used in concert with other efforts and strategies to address the underlying access issue. We do not believe that relying solely on telehealth is an appropriate way to meet all enrollees' care needs in the long term. We will monitor information over time, such as encounter data, secret shopper survey results, MCPAR submissions, and NAAAR submissions to inform potential future revisions to § 438.68(f)(2)(ii). We do not believe adopting Medicare Advantage's ten-percentage point credit methodology would be appropriate as it is designed to apply to time and distance standards—which are substantially different than appointment wait time standards.

Comment: One commenter recommended that CMS require that appointment wait time data evaluations be disaggregated by key social, demographic, and geographic variables to identify and address any access discrepancies for specific subpopulations.

Response: We decline to add these additional requirements on secret shopper survey results in this final rule; however, we believe data disaggregated as suggested by the commenter could provide States with valuable information about their programs. We encourage States to consider these suggestions as they develop their surveys.

After reviewing the public comments, we are finalizing §§ 438.68(f), 457.1207, and 457.1218 as proposed.

d. Assurances of Adequate Capacity and Services—Provider Payment Analysis (§§ 438.207(b) and 457.1230(b))

We believe there needs to be greater transparency in Medicaid and CHIP provider payment rates for States and CMS to monitor and mitigate payment-related access barriers. There is considerable evidence that Medicaid payment rates, on average, are lower than Medicare and commercial rates for the same services and that provider payment influences access, with low rates of payment limiting the network of providers willing to accept Medicaid patients, capacity of those providers who do participate in Medicaid, and investments in emerging technology among providers that serve large numbers of Medicaid beneficiaries. However, there is no standardized, comprehensive, cross-State comparative data source available to assess Medicaid and CHIP payment rates across clinical specialties, managed care plans, and States. Given that a critical component of building a managed care plan network is payment, low payment rates can harm access to care for Medicaid and CHIP enrollees in multiple ways. Evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.[42] [43] Relatedly, researchers have found that increases in the Medicaid payment rates are directly associated with increases in provider acceptance of new Medicaid patients. In short, two key drivers of access—provider network size and capacity—are inextricably linked with Medicaid provider payment levels and acceptance of new Medicaid patients.[44] [45] While many factors affect provider participation, given the important role that payment rates play in assuring access, greater transparency is needed to understand when and to what extent provider payment may influence access in State Medicaid and CHIP programs to specific provider types or for Medicaid and CHIP beneficiaries enrolled in specific plans.

We also believe that greater transparency and oversight is warranted as managed care payments have grown significantly as a share of total Medicaid payments; in FY 2021, the Federal government spent nearly $250 billion on payments to managed care plans.[46] With this growth, we seek to develop, use, and facilitate State use of data to generate insights into important, provider rate related indicators of access. Unlike FFS Medicaid and CHIP programs, managed care plans generally have the ability to negotiate unique reimbursment rates for individual providers. Generally, unless imposed by States through a State-directed payment or mandated by statute (such as Federally qualified health center (FQHC) payment requirements established under section 1902(bb) of the Act), there are no Federal regulatory or statutory minimum or maximum limits on the payment rates a managed care plan can negotiate with a network provider. As such, there can be tremendous variation among plans' payment rates, and we often do not have sufficient visibility into those rates to perform analyses that will promote a better understanding of how these rates are impacting access. Section 438.242(c)(3) for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP, requires managed care plans to submit to the State all enrollee encounter data, including allowed amounts and paid amounts, that the State is required to report to us. States are then required to submit those data to T–MSIS as required in § 438.818 for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP. However, variation in the quantity and quality of T–MSIS data, particularly for data on paid amounts, remains. We believe that provider payment rates in managed care are inextricably linked with provider network sufficiency and capacity and proposed a process through which managed care plans must report, and States must review and analyze, managed care payment rates to

[42] Holgash K, Heberlein M. Physician acceptance of new Medicaid patients. Washington (DC): Medicaid and CHIP Payment and Access Commission; 2019 Jan 24. Available from *https://www.macpac.gov/wp-content/uploads/2019/01/Physician-Acceptance-of-New-Medicaid-Patients.pdf.*

[43] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:*10.1377/hlthaff.2020.00611.*

[44] National Bureau of Economic Research, ''Increased Medicaid Reimbursement Rates Expand Access to Care,'' October 2019, available at *https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care.*

[45] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:*10.1377/hlthaff.2020.00611.*

[46] Congressional Budget Office, ''Baseline Projections—Medicaid,'' May 2022, available at *https://www.cbo.gov/system/files/2022-05/51301-2022-05-medicaid.pdf.*

providers as a component of States' responsibility to ensure network adequacy and enrollee access consistent with State and Federal standards. Linking payment levels to quality of care is consistent with a strategy that we endorsed in our August 22, 2022 CIB [47] urging States to link Medicaid payments to quality measures to improve the safety and quality of care.

To ensure comparability in managed care plans' payment analyses, in our May 3, 2023 proposed rule, we proposed to require a payment analysis that managed care plans would submit to States per § 438.207(b)(3) and States would be required to review and include in the assurance and analysis to CMS per § 438.207(d). Specifically, we proposed to replace the periods at the end of § 438.207(b)(1) and (2) with semi-colons and add ''and'' after § 438.207(b)(2) to make clear that (b)(1) through (3) will all be required for Medicaid managed care, and for separate CHIP through an existing cross-reference at § 457.1230(b).

At § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we proposed to require that MCOs, PIHPs, and PAHPs submit annual documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract. We proposed that the analysis use paid claims data from the immediate prior rating period to ensure that all payments are captured, including those that are negotiated differently than a plan's usual fee schedule. We also believe that using claims data ensures that utilization is considered to prevent extremely high or low payments from inappropriately skewing the results. We acknowledged that paid claims data will likely not be complete within 180 days of the end of a rating period, which is when this analyis is proposed to be reported by the State in § 438.207(d)(3)(ii). However, we believe that the data are sufficiently robust to produce a reasonable percentage that reflects an appropriate weighting to each payment based on actual utilization and could be provided to the State far enough in advance of the State submitting its reporting to CMS to be incorporated. We believe this analysis of payments provides States and CMS with vital information to assess the adequacy of payments to providers in managed care programs, particularly when network deficiencies or quality of care issues are identified or grievances are filed by enrollees regarding access or quality.

In § 438.207(b)(3)(i) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we proposed to require each MCO, PIHP, and PAHP to use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management current procedural terminology (CPT) codes for primary care, OB/GYN, mental health, and SUD services. Due to the unique payment requirements in section 1902(bb) of the Act for FQHCs and rural health clinics (RHCs), we proposed in § 438.207(b)(3)(iv) to exclude these provider types from the analysis. We further proposed that this analysis provide the percentage that results from dividing the total amount the managed care plan paid by the published Medicare payment rate for the same codes on the same claims. Meaning, the payment analysis will reflect the comparison of how much the managed care plan paid for the evaluation and managment CPT codes to the published Medicare payment rates including claim-specific factors such as provider type, geographic location where the service was rendered, and the site of service. In § 438.207(b)(3)(i)(A) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we also proposed that the plans will include in the analysis separate total amounts paid and separate comparison percentages to Medicare for primary care, OB/GYN, mental health, and substance use disorder services for ease of analysis and clarity. Lastly in § 438.207(b)(3)(i)(B) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we proposed that the percentages be reported separately if they differ between adult and pediatric services. We believe the proposals in § 438.207(b)(3)(i)(A) and (B) would ensure sufficient detail in the data to enable more granular analysis across plans and States, as well as to prevent some data from obscuring issues with other data. For example, if payments for adult primary care are significantly lower than pediatric primary care, providing separate totals and comparison percentages will prevent the pediatric data from artificially inflating the adult totals and percentages. We believe this level of detail will be necessary to prevent misinterpretation of the data.

We proposed in § 438.207(b)(3)(ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to require that the payment analysis provide the total amounts paid for homemaker services, home health aide services, and personal care services and the percentages that results from dividing the total amount paid by the amount the State's Medicaid or CHIP FFS program would have paid for the same claims. We proposed two differences between this analysis and the analysis in § 438.207(b)(3)(i): first, this analysis will use all codes for the services as there are no evaluation and management CPT codes for these LTSS; and second, we proposed the comparison be to Medicaid or CHIP FFS payment rates, as applicable, due to the lack of comparable Medicare rates for these services. We proposed these three services as we believe these have high impact to help keep enrollees safely in the community and avoid institutionalization. Again, we believe this analysis of payment rates will be important to provide States and CMS with information to assess the adequacy of payments to providers in managed care programs, particularly when enrollees have grievances with services approved in their care plans not being delivered or not delivered in the authorized quantity. We requested comment on whether in-home habilitation services provided to enrollees with I/DD should be added to this analysis.

We believe that managed care plans could perform the analyses in § 438.207(b)(3)(i) and (ii) by: (1) Identifying paid claims in the prior rating period for each required service type; (2) identifying the appropriate codes and aggregating the payment amounts for the required service types; and (3) calculating the total amount that will be paid for the same codes on the claims at 100 percent of the appropriate published Medicare rate, or Medicaid/CHIP FFS rate for the analysis in § 438.207(b)(3)(ii), applicable on the date of service. For the aggregate percentage, divide the total amount paid (from (2) above) by the amount for the same claims at 100 percent of the appropriate published Medicare rate or Medicaid/CHIP FFS, as appropriate (from (3) above). We believe this analysis would require a manageable number of calculations using data readily available to managed care plans.

To ensure that the payment analysis proposed in § 438.207(b)(3) is appropriate and meaningful, we proposed at paragraph (b)(3)(iii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to exclude payments for claims for the services in paragraph (b)(3)(i) for which the managed care

[47] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib08222022.pdf.*

plan is not the primary payer. A comparison to payment for cost sharing only or payment for a claim for which another payer paid a portion will provide little, if any, useful information.

The payment analysis proposed at § 438.207(b)(3) is authorized by sections 1932(c)(1)(A)(ii) and 2103(f)(3) of the Act, which requires States' quality strategies to include an examination of other aspects of care and service directly related to the improvement of quality of care. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Because the proposed payment analysis will generate data on each managed care plan's payment levels for certain provider types as a percent of Medicare or Medicaid FFS rates, States could use the analysis in their examination of other aspects of care and service directly related to the improvement of quality of care, particularly access. Further, sections 1932(c)(1)(A)(iii) and 2103(f)(3) of the Act authorize the proposals in this section of this final rule as enabling States to compare payment data among managed care plans in their program, which could provide useful data to fulfill their obligations for monitoring and evaluating quality and appropriateness of care.

We also proposed to revise § 438.207(g) to reflect that managed care plans will have to comply with § 438.207(b)(3) no later than the first rating period that begins on or after 2 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance.

We summarize and respond to public comments received on Assurances of adequate capacity and services—Provider payment analysis (§§ 438.207(b) and 457.1230(b)) below.

Comment: Many commenters supported our proposal for a managed care plan payment analysis in § 438.207(b)(3). Commenters noted they believe it will provide greater insight into how Medicaid provider payment levels affect access to care. One commenter stated that it was abundantly clear that low provider payment rates harm Medicaid beneficiaries, as they limit provider participation. Some commenters stated the payment analysis can contribute to identifying and redressing gaps in access. One commenter stated that Medicaid FFS and Medicare rates are a matter of public knowledge and the rates paid by managed care plans should be as well.

Response: We agree that managed care programs should have comparable transparency on provider payment to Medicaid and CHIP FFS programs and the analysis finalized at § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b) is an important step. We acknowledge an oversight in the wording of § 438.207(b)(3)(i) in the proposed regulation text. The preamble noted how the necessary calculations could be produced and included ''For the aggregate percentage, divide the total amount paid (from 2. above) by the amount for the same claims at 100 percent of the appropriate published Medicare rate or Medicaid/CHIP FFS, as appropriate (from 3. Above).'' (88 FR 28105) Unfortunately, ''amount paid by the'' was erroneously omitted in (b)(3)(i) so that the sentence did not reflect the two components needed to produce a percentage. To correct this, we are finalizing § 438.207(b)(3)(i) to state that the payment analysis must provide the total amount paid for evaluation and management CPT codes in the paid claims data from the prior rating period for primary care, OB/GYN, mental health, and substance use disorder services, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services.

Comment: Many commenters did not support our proposal for a managed care plan payment analysis in § 438.207(b)(3). A few commenters stated that CMS should rely on States to work with their contracted managed care plans in evaluating which factors they believe are most relevant to access in their specific areas, and in determining what types of comparative data (whether it is payment information or other metrics) would be most useful and cost effective for such evaluations. Some commenters were concerned that the comparison CMS is requesting will be misleading, statistically invalid, present an incomplete narrative on provider payment, and will dissuade participation by providers in the Medicaid program which is contrary to CMS's stated goals. Commenters believe that comparing payment on a per code level is likely to result in a volume of information that is overwhelming for a member of the general public and unlikely to yield information that is beneficial.

Response: We understand why States would prefer to be able to select which factors they believe are most relevant to access in their specific areas for evaluation and determine which types of comparative data would be most useful. However, we believe for these analyses to be useful, there must be consistency, and permitting each State to conduct a unique analysis would not achieve that. We do not agree with commenters that state that the analysis will be misleading, statistically invalid, or produce too much information for most interested parties as we intentionally kept the scope of service types and results required to be produced very limited. For example, § 438.207(b)(3)(i)(A) and (B) requires a separate total and percentage for primary care, obstetrics and gynecology, mental health, and substance use disorder services, with a potential breakout of these percentages by adult and pediatric services. If a managed care plan's calculations do not produce a different percentage for pediatric services for a service type, then the managed care plan would only need to produce four totals and four percentages—one total and one percentage for primary care, obstetrics and gynecology, mental health, and substance use disorder services. If a managed care plan's calculations produce a different percentage for pediatric services, then the managed care plan would need to produce two percentages for each type of service. We do not believe that producing this few results will be misleading, invalid, or overwhelming for most interested parties. We also do not believe that the results of these analyses will dissuade providers from joining managed care plans' networks. We are confident that providers will be able to interpret the data appropriately and are familiar enough with managed care plan contracting practices to base their network participation decisions on specific information provided to them as part of network contract exploration and negotiation.

Comment: We received numerous comments on the proposed applicability date of the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after the effective date of the rule. Some commenters recommended that CMS finalize an applicability date at least 2 years following the release of any relevant subregulatory guidance. Other commenters recommended an applicability date sooner than 2 years after the effective date of the rule. Some commenters recommended that CMS pilot the payment analysis with a small subset of evaluation and management (E/M) codes, stating that this would allow CMS to address key implementation challenges before requiring national reporting on the broader subset of codes.

Response: We appreciate the input on our applicability date proposal. Given that almost all managed care plans evaluate their provider payment rates

annually when the Medicare payment rates are published, we do not believe that managed care plans will have an inordinate amount of burden performing the analysis finalized in § 438.207(b)(3). While we may publish guidance on performing the analysis in the future, it is not immediately planned and so we cannot predicate the applicability date on it. To the comments suggesting that we finalize a sooner applicability date, we do not believe that would be prudent given the other requirements being finalized in this rule that will impact managed care plans. We encourage managed care plans to use the time between the final rule and the first rating period that begins on or after 2 years after the effective date to develop the necessary calculations and data extracts. As always, we are available to provide technical assistance if needed.

Comment: Many commenters suggested ways to revise the payment analysis to produce different or more detailed results including: requiring the analysis for all payments to all provider types and for all services for which there is a network adequacy requirement; adding psychotherapy codes, psychological testing, and neuropsychological testing; showing the different payment rates between physicians and nurse practitioners; capturing average payment rates broken out by geographic and population areas; comparing Medicaid payment rates to commercial insurance rates; and publishing the average payment rate per service.

Response: We appreciate these suggestions and encourage States to include them in addition to the analysis required in § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). Expanding the required analysis to include some or all of these layers of detail could prove very helpful to States and managed care plans in their network adequacy and access monitoring and improvement activities. To give managed care plans time to develop their analyses to comply with the final rule, we decline to add any of the suggested revisions to § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), at this time, but may consider them in future rulemaking.

Comment: Several commenters stated concern about proprietary and confidential data being released in the payment analysis and noted that CMS must ensure that data are protected from inappropriate disclosure. One commenter stated that any claims of the purported proprietary or confidential nature of these provider payment rates should be summarily dismissed, particularly given that the contractors are using public funds. This commenter further contended that concerns that rate transparency is inflationary have not been seen with increasing transparency for commercial insurance provider payments; to the extent this does occur in Medicaid, it is needed. Another commenter stated concern that a requirement to publicly post the report of the results would make this information readily available to anyone in the State, including interested parties that are hostile to Medicaid and/or access to specific types of services and could expose some services and/or provider types to politically motivated attempts to decrease their payment rates.

Response: We appreciate commenters raising these issues. The provider payment analysis as finalized in this rule at § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), will produce only aggregate results without revealing specific payments or specific providers. As specified in § 438.207(b)(3)(i) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), the analysis would produce the total amount paid for E/M codes in the paid claims data from the prior rating period, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services. Although the resulting totals and percentages must be categorized as primary care, OB/GYN, mental health, or substance use disorder, no additional identifying data are required.

Comment: Many commenters questioned how non-FFS payments that often include non-E/M services should be accommodated in the analysis and recommended that CMS provide detailed guidance as to address capitated providers, value-based payment (VBP) arrangements, bundled payments, or alternative payment types. These commenters stated that excluding these types of payments would undermine and devalue the shift to alternative payment models and quality-based payment incentives and believe specific guidance is needed so that managed care plans can consistently and accurately reflect alternative payment models in their payment analyses. A few commenters recommended that such payments be excluded from the provider payment analysis to avoid results being skewed by Medicaid managed care plans' assumption-driven allocations of non-service specific payments to individual services and to ensure comparability of analyses across multiple Medicaid managed care programs. Some commenters stated concern that this data collection effort will not factor in complex hospital, specialty hospital, and multi-functional inter-disciplinary health care delivery system arrangements which are negotiated in the context of the delivery of multiple services instead of on a one-off basis. One commenter recommended that the analysis allow managed care plans to incorporate a proportional allocation of incentive, bonus, or other payments made to a provider outside of the adjudication of claims to ensure that the analysis accurately reflects all payments, including those based on value or quality achievements.

Response: We agree that capitation (to providers), VBP arrangements, bundled payments, and other unique payment arrangements that reward and support quality over quantity are important, and it was not our intention to appear to discourage them or minimize their value. However, given the wide-ranging designs of such payments, we elected to not propose a specific way to address them in this iteration of the analyses. We believe that finding a consistent way to include these arrangements in these analyses is critical and want to use the analyses submitted to inform our determination of how best to do this. Further, as we are finalizing that only E/M codes be included in the analysis, we want to better understand the scope of services included in these types of arrangements. We decline to adopt the commenter's suggestion to permit a proportional allocation of incentive, bonus, or other payments to be incorporated into the totals or percentages required in § 438.207(b)(3)(i) and (ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). However, to collect information on these arrangements and their impact on provider payment for primary care, OB/GYN, mental health, and SUD services, we will permit managed care plans to include data in their submissions required in § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b) that reflect the value of these non-FFS payment arrangements and their impact on the totals and percentages (to the degree possible given the inclusion of other services) required in § 438.207(b)(3)(i) and (ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). As States are required to utilize the data submitted by their plans as required at

§ 438.207(b) to produce the analysis and assurance required at § 438.207(d), we will include fields in the NAAAR that will enable States to include this additional information. We encourage managed care plans and States to provide specific and detailed information on capitation (to providers), VBP arrangements, bundled payments, and other unique payment arrangements to enable us to determine the most appropriate way to collect this information in potential future revisions to § 438.207(b)(3).

Comment: One commenter contended that they believe the analysis will produce an inaccurate picture of the impact of Medicaid payments on access given the significant portion of Medicaid payments flowing through FQHCs and rural health clinics, which are excluded per § 438.207(b)(3)(iv).

Response: We intentionally excluded FQHCs and RHCs given their statutorily required payment structure. We acknowledge that FQHCs and RHCs provide a high volume of primary care, OB/GYN, mental health, and SUD services, but they are paid a bundled rate. As addressed in the prior response, bundled payments are challenging to disaggregate and we believe it best to not include them in the payment analysis at this time.

Comment: One commenter recommended that CMS require the data required in § 438.207(b)(3) to be submitted by plans to the State within 90 days of the end of the rating period for annual NAAAR submissions that must be submitted to CMS within 180 days of the end of a rating period.

Response: We decline to specify that managed care plans must submit the data required at § 438.207(b) to the State within 90 days of the end of the rating period. We defer to States to determine the timeframe for plan submission given that States must submit annual NAAARs within 180 days of the end of a rating period. We encourage States to specify the submission timeframe in their managed care plan contracts for clarity.

Comment: One commenter recommended that CMS require the payment analysis required at § 438.207(b)(3) to be certified by the managed care plan's CEO.

Response: Section 438.606(a) specifies that managed care plans' Chief Executive Officer; Chief Financial Officer; or an individual who has delegated authority to sign for the Chief Executive Officer or Chief Financial Officer must certify ''. . . data, documentation, or information specified in § 438.604. . . .'' As all information provided by managed care plans consistent with § 438.207(b) must be posted on the State's website per § 438.604(a)(5), existing § 438.606(a) will apply the certification requirement to the data provided by the managed care plans for § 438.207(b)(3).

Comment: One commenter suggested that CMS publish a national report of these payment analyses to provide a nationwide picture of Medicaid payment.

Response: We appreciate the suggestion and may consider doing so in the future.

Comment: A few commenters recommended that the States should be required to make publicly available the results of the provider payment analyses.

Response: We point out the requirement in § 438.602(g)(2) that through cross reference to § 438.604(a)(5) requires documentation described in § 438.207(b), on which the State bases its certification that the managed care plan has complied with its requirements for availability and accessibility of services, be posted on the State's website as required at § 438.10(c)(3).

Comment: A few commenters contended that the payment analysis in § 438.207(b)(3) should not be required annually and suggested that triennially would be less burdensome on the State agencies.

Response: We appreciate commenters' suggestion but believe the payment analysis should be completed annually given that managed care plan contracts and capitation rates are developed and approved on an annual basis. We note a typographical error in § 438.207(b)(3) that we have corrected in this final rule. In the preamble (88 FR 28104), we wrote ''At § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose to require that MCOs, PIHPs, and PAHPs submit *annual* documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract.'' Unfortunately, we failed to include ''annual'' in § 438.207(b)(3). We did not receive comments questioning this discrepancy and, as reflected in this and other comments, commenters understood our intent that the anlyses be conducted and submitted annually. As such, we are finalizing § 438.207(b)(3) as ''Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO's, PIHP's, or PAHP's contract, provides an annual payment analysis using paid claims data from the immediate prior rating period. . . .''

Comment: A few commenters stated that the payment analysis at § 438.207(b)(3) would create a significant new burden for Medicaid agencies who would become responsible for conducting the complex analysis of payments for each managed care plan and across managed care plans for their market. One commenter stated that an actuarial services contractor would be needed to evaluate past encounter data to define which CPT or Healthcare Common Procedure Coding System (HCPCS) codes need to be included for each managed care plan.

Response: We appreciate the opportunity to provide clarity on managed care plan and State responsibilities as these comments are not consistent with the proposed requirements. The payment analysis is specified in § 438.207(b)(3) for Medicaid managed care, and through a cross-reference at § 457.1230(b) for separate CHIP and is required to be conducted by each managed care plan, not the State. The States' only calculation is specified in § 438.207(d)(2)(ii) for Medicaid, and through a cross-reference at § 457.1230(b) for separate CHIP and requires States to produce a State-level payment percentage for each service type by using the number of member months for the applicable rating period to weight each managed care plan's reported percentages. To the comment that an actuarial services contractor would need to define which CPT/HCPCS codes need to be included for each managed care plan, the analysis in § 438.207(b)(3) for Medicaid, and through a cross-reference at § 457.1230(b) for separate CHIP requires the use of paid claims data from the immediate prior rating period. Managed care plans have all of their claims data and can isolate the E/M codes and paid amounts. We are unclear why an actuary would be needed for that or why a State would assume this task for its managed care plans.

Comment: One commenter recommended that CMS reconsider the timelines for conducting and reporting provider rates due to the delayed approvals of State plans, waivers, and rate certifications of actuarially sound capitation rates that can impact the actual or planned managed care plan payments to providers. For example, if a State plan is approved within 90 days but the capitation rates the State will pay its managed care plans are not approved for several months after, States who are risk averse may postpone all reprocessing until all necessary CMS approvals have been received which

may extend beyond the deadline for reporting.

Response: We are unclear on the commenter's recommendation regarding the impact of State plans, waivers, and rate certification approvals on the payment analysis of provider payment. We are also unclear on the reference to ''reprocessing.'' Regardless, we clarify that the timing of authority documents or managed care plan contracts and rates should not impact the provider payment analysis as it utilizes actual paid claims data for a single rating period; reprocessing of claims after the close of a rating period would be captured in the following year's analysis.

Comment: One commenter noted that in developing the statutory requirements for Medicaid managed care programs, Congress required States contracting with Medicaid managed care entities to ''develop and implement a quality assessment and improvement strategy'' that includes ''[s]tandards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity.'' The commenter contended that the payment analysis and disclosure requirements being proposed by CMS are unsupported by this statutory language, which concerns itself with beneficiary access to care, not with comparative payment analyses.

Response: We disagree with the commenter as we believe there is a strong link between access to care and provider payment and the payment analysis finalized at § 438.207(b)(3) for Medicaid managed care, and through a cross-reference at § 457.1230(b) for separate CHIP, and the associated required review and analysis of the documentation submitted by its managed care plans at § 438.207(d) facilitates States' inclusion of payment information in a consistent way to enable States to develop effective ''[s]tandards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity.'' As we noted in the preamble (88 FR 28104), evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.[48] [49] Researchers also found that increases in the Medicaid payment rates are directly associated with increases in provider acceptance of new Medicaid patients. In short, two key drivers of access—provider network size and capacity—are inextricably linked with Medicaid provider payment levels and acceptance of new Medicaid patients.[50] [51]

Comment: Some commenters stated that given the differences between the Medicaid population and the Medicare population, any payment analysis required to compare payment rates to providers in managed care should use Medicaid FFS as a benchmark as it is more appropriate and relevant than Medicare FFS. Some commenters question the validity of comparing Medicaid payment rates to Medicare, especially for OB/GYN, neonatal, and pediatric services given that Medicaid pays for far more of these services than Medicare. A few commenters recommended that CMS clarify that using Medicare is only a mechanism for evaluating payment adequacy in a standardized way and that CMS is not suggesting that Medicare payment rates are the appropriate benchmark to ensure Medicaid beneficiaries have access to care. One commenter stated that Medicare rates fall short of covering the cost to deliver care for most providers. A few commenters suggested that the payment analysis should use commercial plans' rates as the comparison.

Response: We appreciate the range of comments on our proposal to use Medicare FFS rates the payment analysis at § 438.207(b)(3) and through a cross-reference at § 457.1230(b) for separate CHIP. To the suggestion to use Medicaid or CHIP FFS rates, we do not believe that is appropriate given that each State sets their own rates and therefore, would provide no level of consistency or comparability among the analyses. We acknowledge that Medicare does not pay for a large volume of OB/GYN, neonatal, and pediatric services, but it still provides a consistent benchmark with rates developed in a standardized and vetted manner. (88 FR 28104) However, we believe that limiting the analysis to E/M codes and requiring all managed care plans to conduct their analysis using published Medicare rates will mitigate the impact. Further, we clarify that our intent is not to make a statement on the appropriate benchmark to ensure Medicaid and CHIP beneficiaries have access to care. We selected Medicare FFS rates for the payment analysis for several reasons: they are consistently and rigorously developed and vetted, most managed care plans routinely evaluate their payment rates against Medicare FFS rates as a standard business practice, they are the only complete and reliable set of rates published annually, and they are easily accessible. We do not believe that using commercial rates would be feasible given that none of the reasons listed above are true for commercial rates.

Comment: We received several comments in support of including habilitation services in the payment analysis. These commenters stated that habilitation services are critical for enrollees, particularly those in the I/DD population, who commonly receive personal care services as part of their habilitation services. As such, since personal care services are included in the payment analysis, so too should habilitation services. These commenters also clarified that while habilitation services are most frequently covered for enrollees in the I/DD population and provided in their home, it could be covered for other enrollees in other settings. The commenters assert that limiting the payment analysis to habilitation services for just one population and setting adds unnecessary complexity and that using claims data for all habilitation services would reduce burden on managed care plans and make the results more comprehensive.

Response: We appreciate the comments and agree that adding habilitation services, irrespective of population or setting, to the payment analysis would provide States with valuable information for monitoring access to vital services for certain enrollees. This revision also makes the payment analysis for habilitation services consistent with the analysis for homemaker services, home health aide services, and personal care services—which has no limitations based on population or setting. We very much appreciate the information on reducing burden by eliminating an unnecessary limitation on the data based on population and setting and have revised § 438.207(b)(3)(ii) accordingly. To

[48] Holgash K, Heberlein M. Physician acceptance of new Medicaid patients. Washington (DC): Medicaid and CHIP Payment and Access Commission; 2019 Jan 24. Available from *https://www.macpac.gov/wp-content/uploads/2019/01/Physician-Acceptance-of-New-Medicaid-Patients.pdf.*

[49] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:*10.1377/hlthaff.2020.00611.*

[50] National Bureau of Economic Research, ''Increased Medicaid Reimbursement Rates Expand Access to Care,'' October 2019, available at *https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care.*

[51] Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood).* 2021;40(2). doi:*10.1377/hlthaff.2020.00611.*

reflect this, we are finalizing § 438.207(b)(3)(ii) by moving ''personal care'' before ''and'' and adding ''habilitation services'' after ''and.''

Comment: A few commenters stated that some States do not maintain separate Medicaid FFS fee schedules for most I/DD services while others noted that some States that use managed long-term services and supports (MLTSS) exclusively do not maintain Medicaid FFS rates. These commenters pointed out that not having Medicaid FFS rates in these circumstances makes part of the payment analysis in § 438.207(b)(3)(ii) impossible. A few commenters suggested that CMS consider requiring States to report an average unit cost instead of a Medicaid FFS comparison as this would enable States that do not have a Medicaid FFS rate or have not made updates to Medicaid FFS rates to still produce a valuable analysis. One commenter suggested using other sources when a State's Medicaid FFS fee schedule is unavailable such as comparison to regional payment data or other States' rates.

Response: States can utilize a managed care delivery system for home health services, homemaker services, personal care services, and habilitation services but they must still identify payment methodologies in their State plans for all services authorized in their State plan. Thus, while a State may not be actively paying Medicaid FFS claims for the services identified in § 438.207(b)(3)(ii), they should be able to produce payment rates consistent with the methodology approved in their State plan. We also clarify that rates approved in 1915(c) waivers are considered CMS-approved FFS payment rates and can be used for the payment analysis in § 438.207(b)(3)(ii). We appreciate the suggestion of producing an average unit cost; however, that would be inconsistent with the rest of the analysis and would be overly impacted by outlier payment rates.

Comment: A few commenters stated that in the ''Medicaid Program; Ensuring Access to Medicaid Services'' proposed rule,[52] CMS proposed to publish the E/M codes to be used for the payment rate analysis in subregulatory guidance along with the final rule and questioned if CMS would do that for the payment analysis in § 438.207(b)(3).

Response: We did not intend to publish a specific list of E/M codes for the managed care plan payment analysis in § 438.207(b)(3). We believe that using paid claims data to derive the E/M codes is more appropriate as paid claims provide the codes used by managed care plan providers and limits the codes in plans' analysis to those that are relevant. Further, we believe the varied scope of covered services among managed care plans makes using only E/M codes used by providers on their claims most appropriate and simplifies extracting the relevant data from a plan's paid claims data. For example, a PIHP that covers only mental health and SUD will have far fewer E/M codes in their claims data than an MCO that covers primary care and OB/GYN services. In the interest of efficiency and relevance, we decline to publish a list of E/M codes for the managed care plan payment analysis in § 438.207(b)(3) in this rule.

Comment: A few commenters noted that final provider payments can include a variety of adjustments and that CMS should work with State Medicaid programs to develop an analysis method that accounts for these differences to ensure that comparisons accurately reflect differences in base provider payment rates. Another commenter stated concern that the results of this type of analysis could be biased by differences in the mix of services provided by different managed care plans and suggested that instead of each plan using its own utilization mix, States provide statewide utilization that would be used by all plans in their provider payment analysis.

Response: We understand that there are adjustments made to contractually negotiated provider rates when claims are adjudicated, and we believe it is appropriate to include these in the analysis to accurately reflect the amount paid to the provider types in the analysis as compared to the published Medicare payment rate. Regardless of the mix of services provided by different managed care plans, the analysis required at § 438.207(b)(3) only includes E/M codes for primary care, OB/GYN, mental health, and SUD; as such, we are unclear why the commenter believes that the results will be biased. Lastly, we do not agree with the commenter's suggestion that each managed care plan should use statewide utilization instead of its own data that reflects the plan's unique utilization mix. We believe this would render the analysis meaningless as the analysis is intended to produce customized results that reflect each plan's expenditures.

Comment: One commenter requested clarification on whether States that report managed care plan payment rate analyses will report in the aggregate or by named managed care plan.

Response: The documentation provided by each managed care plan that will include the payment analysis finalized in § 438.207(b)(3) for Medicaid and, included in separate CHIP regulations through an existing cross-reference at § 457.1230(b), will be reviewed by States and reported in the NAAAR, per § 438.207(d). The fields in the NAAAR for reporting of the payment analysis will be by managed care plan consistent with § 438.207(d)(2)(i). States will report the data from its plans' reported payment analysis percentages in the NAAAR as well as percentages weighted using the member months for the applicable rating period.

Comment: A few commenters requested clarification on the exact scope of LTSS included in the categories of homemaker, home health aide, and personal care services, and whether they should be included regardless of where they are provided or under what delivery model. One commenter suggested that CMS provide guidance clarifying whether payments for homemaker and home health aide services provided to dually eligible enrollees for intermittent skilled care or for other purposes would be excluded from the analysis.

Response: We thank commenters for raising these questions so that we can provide additional clarity. The payment analysis required at § 438.207(b)(3)(ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), includes all codes for homemaker services, home health aide services, personal care services, and habilitation services as these services do not generally utilize E/M CPT codes. (88 FR 28105) We did not specify limitations on where the services are provided and only services covered in a managed care delivery system can be included as the analysis must utilize managed care plan paid claims data. Regarding whether payments for homemaker and home health aide services provided to dually eligible enrollees are included in the analysis, § 438.207(b)(3)(iii) was proposed and finalized to specify that payments for which the managed care plan is not the primary payer are excluded from the analysis. Therefore, homemaker and home health aide services will be included in the managed care plan's analysis if Medicaid was the primary payer for the claim.

Comment: One commenter stated that section 1932 of the Social Security Act does not address ''comparability'' of reimbursement rates or with transparency, leaving the proposed

[52] Published in the May 3, 2023 **Federal Register** (88 FR 27960 through 28089); *https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08959.pdf.*

payment analysis without any clear statutory basis.

Response: We believe that 1932(c)(1)(A)(ii) and (iii) of the Act provide CMS the authority for the payment analysis at § 438.207(b)(3). As we stated in the proposed rule, 1932(c)(1)(A)(ii) requires States' quality strategies to include an examination of other aspects of care and service directly related to the improvement of quality of care and procedures for monitoring and evaluating the quality and appropriateness of care and services. The payment analysis required at § 438.207(b)(3) will generate data on each managed care plan's payment levels for certain provider types which States should use in their examination of other aspects related to the improvement of quality of care, particularly access. Further, the data from the payment analysis will provide consistent, comparable data that can contribute an important perspective to States' activities to monitor and evaluate quality and appropriateness of care given the well-established link between payment levels and provider participation.

After reviewing the public comments, we are finalizing §§ 438.207(b)(3) and (g), and 457.1230(b) as proposed, except for a minor wording correction in § 438.207(b)(3)(i) and to add habilitation in § 438.207(b)(3)(ii).

e. Assurances of Adequate Capacity and Services Reporting (§§ 438.207(d) and 457.1230(b))

Section § 438.207(d) requires States to review the documentation submitted by their managed care plans, as required at § 438.207(b), and then submit to CMS an assurance of their managed care plans' compliance with §§ 438.68 and 438.206. To make States' assurances and analyses more comprehensive, we proposed to revise § 438.207(d) to explicitly require States to include the results from the secret shopper surveys proposed in § 438.68(f) (see section I.B.1.c. of this final rule) and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We also proposed to require States to include the payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this final rule) to their assurance and analyses reporting. Additionally, on July 6, 2022, we published a CIB [53] that provided a reporting template *Network Adequacy and Access Assurances Report* [54] for the reporting required at § 438.207(d). To be clear that States will have to use the published template, we proposed to explicitly require that States submit their assurance of compliance and analyses required in § 438.207(d) in the ''format prescribed by CMS.'' The published template will fulfill this requirement as will future versions including any potential electronic formats. We believe the revision proposed in § 438.207(d) is necessary to ensure consistent reporting to CMS and enable effective analysis and oversight. Lastly, because we proposed new requirements related to the inclusion of the payment analysis and the timing of the submission of this reporting to CMS, we proposed to redesignate the last sentence in paragraph (d) of § 438.207 as paragraph (d)(1) and create new paragraphs (d)(2) and (3).

In § 438.207(d)(2) for Medicaid and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b), we proposed that the States' analysis required in § 438.207(d)(1) must include the payment analysis required of plans in § 438.207(b)(3) and provide the elements specified in paragraphs (d)(2)(i) and (ii). Specifically, § 438.207(d)(2)(i) proposed to require States to include the data submitted by each plan and § 438.207(d)(2)(ii) proposed to require States to use the data from its plans' reported payment analysis percentages and weight them using the member months associated with the applicable rating period to produce a Statewide payment percentage for each service type. We believe these data elements will provide valuable new data to support States' assurances of network adequacy and access and we will revise the NAAAR template published in July 2022 to add fields for States to easily report these data. We reminded States that § 438.66(a) and (b) require States to have a monitoring system for all of their managed care programs and include all aspects, including the performance of their managed care plans in the areas of availability and accessibility of services, medical management, provider network management, and appeals and grievances. Accordingly, States should have ample data from their existing monitoring activities and which will be supplemented by the proposed requirements in this rule, to improve the performance of their managed care programs for all covered services, as required in § 438.66(c). Because concerns around access to primary care, mental health, and SUD services have been raised nationally, we expect States to review and analyze their plans' data holistically to provide a robust, comprehensive analysis of the adequacy of each plan's network and level of realistic access and take timely action to address deficiencies.

Section 438.207(d) was codified in 2002 (67 FR 41010) as part of the implementing regulations for section 1932(b)(5) of the Act ''Demonstration of Adequate Capacity and Services.'' In the 2016 final rule, we made minor revisions to the language but did not address the timing of States' submission of their assurance and analysis. Given the July 2022 release of the NAAAR template for the assurance and analysis, we believe it would be appropriate to clarify this important aspect of the reporting requirement. To simplify the submission process and enable States and CMS to allot resources most efficiently, we proposed to establish submission times in § 438.207(d)(3)(i) through (iii) that correspond to the times for managed care plans to submit documentation to the State in § 438.207(c)(1) through (3). Specifically for Medicaid, we proposed that States submit their assurance and analysis at § 438.207(d)(3): (1) at the time they submit a completed readiness review, as specified at § 438.66(d)(1)(iii); (2) on an annual basis and no later than 180 calendar days after the end of each contract year; and (3) any time there has been a significant change as specified in § 438.207(c)(3) and with the submission of the associated contract. We also proposed in § 438.207(d)(3) that States must post the report required in § 438.207(d) on their website within 30 calendar days of submission to CMS. We believe the information in this report will be important information for interested parties to have access to on a timely basis and 30 calendar days seems adequate for States to post the report after submitting.

Since we did not adopt the MCPAR requirements for separate CHIP managed care in the 2016 final rule, we are also not adopting the proposed submission timeframe at § 438.207(d)(3)(i). However, we proposed for separate CHIPs to align with Medicaid for the proposed network adequacy analysis submission timeframes at § 438.207(d)(3)(ii) and (iii) through the existing cross-reference at § 457.1230(b).

In § 438.207(e), we proposed a conforming revision to add a reference to the secret shopper evaluations proposed at § 438.68(f) as part of the documentation that States must make available to CMS, upon request, and included in separate CHIP regulations through an existing cross-reference at

[53] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib07062022.pdf.*

[54] *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx.*

§ 457.1230(b). We believe this was necessary as the text of § 438.207(e) only addressed the documentation provided by the managed care plans.

Sections 1932(b)(5) and 2103(f)(3) of the Act require Medicaid and CHIP MCOs to demonstrate adequate capacity and services by providing assurances to the State and CMS, as specified by the Secretary, that they have the capacity to serve the expected enrollment in its service area, including assurances that they offer an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and maintains a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Our proposals to require States to include the secret shopper surveys proposed in § 438.68(f), as well as the payment analysis proposed in § 438.207(b)(3) in their assurance and analyses reporting proposed at § 438.207(d) are authorized by section 1932(b)(5) of the Act for Medicaid and authorized for CHIP through section 2103(f)(3) of the Act because the States' reports reflect the documentation and assurances provided by their managed care plans of adequate capacity, an appropriate range of services, and access to a sufficient number, mix, and geographic distribution of network providers. Sections 1932(b)(5) and 2103(f)(3) of the Act also require that the required assurances be submitted to CMS in a time and manner determined by the Secretary; that information is proposed in § 438.207(d)(3)(i) through (iii) and corresponds to the requirements for submission of documenation from managed care plans in § 438.207(c)(3).

We also proposed to revise § 438.207(g) to reflect that States will have to comply with paragraph (d)(2) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and paragraph (d)(3) no later than the first managed care plan rating period that begins on or after 1 year after the effective date of the final rule. We proposed that States will not be held out of compliance with the requirements of paragraphs (e) of this section prior to the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule, so long as they comply with the corresponding standard(s) codified in paragraph (e) contained in the 42 CFR parts 430 to 481, most recently published before the final rule. We proposed that States must comply with paragraph (f) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these are reasonable timeframes for compliance given the level of new burden imposed by each.

We summarize and respond to public comments received on Assurances of adequate capacity and services reporting (§§ 438.207(d) and 457.1230(b)) below.

Comment: Many commenters supported our proposal to have States incorporate their review and analysis of their managed care plan provider payment analysis required in § 438.207(b)(3) into their NAAARs. These commenters stated this will provide much needed transparency in a consistent manner across all managed care programs.

Response: We thank commenters for their support for our proposal. We believe incorporating the payment analyses into a State's NAAAR is the least burdensome approach and will make the data easy to locate and understand.

Comment: One commenter suggested that in addition to requiring that the payment analysis in § 438.207(b) be included in States' NAAARs, which are posted on their website, that CMS also require States to submit their reports to their interested parties' advisory groups.

Response: We appreciate the suggestion that States share their NAAARs with their interested parties' advisory groups. We decline to adopt an additional requirement in this final rule but encourage States to consider incorporating distribution of their NAAARs into their advisory group processes.

Comment: A few commenters supported the specificity on the timing of submission of the NAAAR in § 438.207(d)(3), as it would improve consistency among States. One commenter pointed out that it seemed duplicative to submit the NAAAR for new managed care plans at the same time as the readiness review information (as proposed in § 438.207(d)(3)(i)) and suggested giving States more time to submit the NAAAR for newly contracted plans.

Response: We believe adding requirements for the submission times of the NAAAR will not only improve consistency but help States recognize some efficiencies as the submission times in § 438.207(d)(3) align with other existing report submissions. We appreciate commenters pointing out that our proposal in § 438.207(d)(3)(i) for States to submit the readiness review results and the NAAAR at the same time would not yield the most effective information. To address this, we will finalize § 438.207(d)(3)(i) to require the submission of the NAAAR in advance of contract approval. This will provide managed care plans time to continue working to address any deficiencies identified in the readiness review and enable States to report the most current network adequacy and access information to inform our final determination regarding contract approval. We believe this revision in the submission timeframe will benefit the newly contracted managed care plan, the State, and CMS.

After reviewing the public comments, we are finalizing §§ 438.207(d) and 457.1230(b) as proposed except for a revision to § 438.207(d)(3)(i) to revise the submission time to enable contract approval.

f. Remedy Plans To Improve Access (§ 438.207(f))

For FFS programs, we rely on § 447.203(b)(8) to require States to submit corrective action plans when access to care issues are identified. Because of the numerous proposals in this rule that will strengthen States' monitoring and enforcement of access requirements and the importance of timely remediation of access issues, we believe we should have a similar process set forth in part 438 for managed care programs. In § 438.68(e), we proposed a process that will require States to carefully develop and enforce their managed care plans' use of appointment wait time standards to ensure access to care for Medicaid managed care enrollees. As proposed in a new § 438.207(f), when the State, MCO, PIHP, PAHP, or CMS identifies any access issues, including any access issues with the standards specified in §§ 438.68 and 438.206, the State will be required to submit a plan to remedy the access issues consistent with this proposal. If we determine that an access issue revealed under monitoring and enforcement rises to the level of a violation of access requirements under section 1932(c)(1)(A)(i) of the Act, as incorporated in section 1903(m)(2)(A)(xii) of the Act, we have the authority to disallow FFP for the payments made under the State's managed care contract for failure to ensure adequate access to care. We intend to closely monitor any State remedy plans that will be needed to ensure that both CMS and States will adequately and appropriately address emerging access issues in Medicaid managed care programs.

Using § 447.203(b)(8) as a foundation, we proposed to redesignate existing § 438.207(f) as § 438.207(g) and

proposed a new requirement for States to submit remedy plans in new § 438.207(f), titled Remedy plans to improve access. In § 438.207(f)(1), we proposed that when the State, MCO, PIHP, PAHP, or CMS identifies an issue with a managed care plan's performance regarding any State standard for access to care under this part, including the standards at §§ 438.68 and 438.206, States will follow the steps set forth in paragraphs (i) through (iv). First, in paragraph (1)(i), States will have to submit to CMS for approval a remedy plan no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue. We believe 90 calendar days is sufficient time for States to effectively assess the degree and impact of the issue and develop an effective set of steps including timelines for implementation and completion, as well as responsible parties. In § 438.207(f)(1)(ii), we proposed that the State must develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties. We believe 12 months to be a reasonable amount of time for States and their managed care plans to implement actions to address the access issue and improve access to services by enrollees of the MCO, PIHP, or PAHP. We did not propose to specify that the remedy plan will be implemented by the managed care plans or the State; rather, we proposed that the remedy plan identify the responsible party required to make the access improvements at issue, which will often include actions by both States and their managed care plans. Additionally, we believe this proposal acknowledged that certain steps that may be needed to address provider shortages can only be implemented by States. For example, changing scope of practice laws to enable more providers to fill gaps in access or joining interstate compacts to enable providers to practice geographically due to the opportunity to hold one multistate license valid for practice in all compact States, streamlined licensure requirements, reduced expenses associated with obtaining multiple single-State licenses, and the creation of systems that enable electronic license application processes. Lastly, in § 438.207(f)(1)(ii), we proposed some approaches that States could consider using to address the access issue, such as increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization.

We proposed in § 438.207(f)(1)(iii) to require States to ensure that improvements in access are measurable and sustainable. We believe it is critical that remedy plans produce measurable results to monitor progress and ultimately, bring about the desired improvements in access under the managed care plan. We also proposed that the improvements in access achieved by the actions be sustainable so that enrollees can continue receiving the improved access to care and managed care plans continue to ensure its provision. In paragraph (f)(1)(iv) of this section, we proposed that States submit quarterly progress updates to CMS on implementation of the remedy plan so that we will be able to determine if the State was making reasonable progress toward completion and that the actions in the plan are effective. Not properly monitoring progress of the remedy plan could significantly lessen the effectiveness of it and allow missed opportunities to make timely revisions and corrections.

Lastly, in paragraph (f)(2) of this section, we proposed that if the remedy plan required in paragraph (f)(1) of this section does not address the managed care plan's access issue within 12 months, we may require the State to continue to take steps to address the issue for another 12 months and may require revision to the remedy plan. We believe proposing that we be able to extend the duration of actions to improve access and/or require the State to make revision to the remedy plan will be critical to ensuring that the State's and managed care plans' efforts are effective at addressing the identified access issue.

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan as we believe States taking timely action to address identified access issues is fundamental and necessary to the operation of an effective and efficient Medicaid program. The proposal for States to submit quarterly progress reports is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Lastly, we believe these proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes (and extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act): standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Implementing timely actions to address managed care plan access issues will be an integral operational component of a State's quality assessment and improvement strategy.

We summarize and respond to public comments received on Remedy plans to improve access (§ 438.207(f)) below.

Comment: Many commenters stated support for requiring States to submit remedy plans to address access areas in need of improvement in § 438.207(f). Commenters noted that when combined with CMS's ability to disallow FFP for payments made under managed care contracts when the State fails to ensure access to care, requiring remedy plans would significantly advance the goal of ensuring that enrollees have access to the services they need. Many commenters supported requiring remedy plans to include specific steps and timelines and encouraged CMS to go further to include payment adequacy information. These commenters stated this requirement would impose much-needed transparency and accountability.

Response: We believe that the use of remedy plans will improve how States and managed care plans collaborate to develop robust, productive solutions to address access areas in need of improvement. We expect remedy plans to reflect how multiple factors were considered, including information on provider payment rates, State workforce initiatives, telehealth policies, and broad delivery system reforms. We decline to specifically require the inclusion of payment adequacy information in remedy plans in this final rule given the payment analysis requirement in § 438.207(b) and the associated reporting requirement in § 438.207(d); however, we encourage States to consider incorporating those analyses, as relevant, since they will be a readily available resource.

Comment: Some commenters recommended that remedy plans include input from a wide array of interested parties. These commenters stated that allowing community-

interested parties to understand how the State and its managed care plans intend to work together to correct the access issue(s) can not only help enrollees make informed enrollment choices, but also help ensure that all options for addressing the issues are considered and that steps in remedy plans are feasible for the assigned parties. A few commenters recommended requiring remedy plans to consider claim denial rates, prior authorization requests, and other sources of administrative burden which, in addition to payment rates, is another top reason physicians cite for not participating in managed care plans.

Response: We agree that remedy plans should include input from multiple sources to the extent feasible. We acknowledge that this may be challenging within the 90-calendar day timeframe for developing and submitting a plan. However, we believe States can gather input on ways to address access issues at any time and utilize it when a remedy plan is needed. We encourage States to consider how improvements in claim denial rates, timely and accurate prior authorization requests, and other sources of administrative burden can be used in remedy plans to encourage increased provider participation.

Comment: Many commenters stated concerns about the administrative burden of meeting the 90-day deadline for remedy plan submission and the diversion of limited State resources to comply with this mandate. Several commenters also stated that, depending on the number of potential remedies plans due at one time, 90 days may not be sufficient to collect data and complete the analysis needed to develop a useful remedy plan. These commenters recommended a longer timeframe between collecting reports from the plans and submission to CMS. Several commenters recommended revising the 90-day submission time to 180 days, given the anticipated volume of information reported.

Response: We understand commenters' concerns but do not believe extending the 90-calendar day development and submission timeframe for remedy plans is appropriate as States have experience using formal plans to address program areas in need of improvement. Further, States have been required to have a monitoring and oversight system that addresses all aspects of their managed care program and use the data collected from its monitoring activities to improve the performance of its managed care program since § 438.66(a) through (c) was issued in the 2016 final rule. We see the remedy plans finalized at § 438.207(f) to add structure (that is, specific steps, timelines, and responsible parties) to the requirement in § 438.66(c) to use data collected from a State's monitoring activities to improve the performance of its managed care program. As such, we do not believe that 90 calendar days is an unreasonable timeframe for submission.

Comment: Many commenters stated that 12 months to remediate many of the issues that will be included in remedy plans is not feasible particularly for those that include initiatives like changing State scope of practice laws. Some commenters noted that the most effective workforce recruitment and retention efforts may take more than 12 months to yield full results and result in sustainable improvements. Another commenter stated that it is unclear what meaningful change could be enacted and what systemic barriers could be solved within 12 months. However, other commenters stated that with as many issues of access to care as are already known, allowing for up to 2 years to remedy a specifically identified problem with multiple progress report opportunities would be too long for enrollees to wait to see the benefits. One commenter recommended that unless an extreme scenario occurs, CMS should employ a 12-month timeframe with no 12-month extension.

Response: We appreciate the wide range of comments on the duration of remedy plans.

We acknowledge that there are network adequacy and access issues that will be identified during secret shopper surveys that will require a range of effort, solutions, and time to produce improvement. Some issues will be able to be resolved with short, quickly implemented activities. While others, such as workforce expansion or changing scope of practice laws to permit enrollment of new provider types, will take more robust, multi-pronged, collaborative solutions over an extended period. Regardless, we believe that remedy plans serve a critical function in addressing identified deficiencies by focusing States', managed care plans', and other interested parties' efforts on the development and implementation of definitive steps to address areas for improvement, including both short-term and long-term strategies to address access to care issues. We also believe that including timeframes and responsible parties for each planned action provide structure and accountability, as well as facilitates effective implementation and monitoring.

As we state in § 438.207(f)(1)(ii), States' and managed care plans' actions may include a variety of approaches, including increasing payment rates to providers, improving outreach to and problem resolution with providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization. We encourage States to collaborate with their managed care plans as soon as feasible to evaluate plan performance for improvement opportunities and ensure that process improvements related to credentialing, accurate claims processing, and prior authorization processing are implemented effectively and timely. Given that § 438.207(f) will not be applicable until the first rating period that begins on or after 4 years after the effective date of the final rule, we believe States have ample time to use existing data from monitoring activities to identify existing access issues and begin formulating and implementing steps to remediate them in advance of a State's first remedy plan submission. We encourage States to proactively take steps to address identified access issues to minimize the number of issues that remain four years after the effective date of the final rule. We decline the suggestion to not finalize our ability to extend remedy plans for an additional 12 months. We believe that the ability to extend the remedy plans an additional 12 months is an important flexibility that will be necessary for issues that require a longer timeframe to produce measurable improvement. We also believe extending some remedy plans an additional 12 months enables ongoing monitoring and progress reporting to ensure adequate resolution and sustainability.

Comment: Many commenters requested that CMS provide additional detail on what access issues would rise to the level of needing a remedy plan. Commenters stated the text ''could be improved'' is vague and does not give clear criteria for States to know when remedy plans will be required. One commenter stated that the rule seems to give CMS a lot of discretion as to how heavy-handed it wants to be, on a case-by-case basis, without providing expectations that States can rely on. Several commenters stated that States need some level of assurance from CMS as to when they will need to produce remedy plans.

Response: We acknowledge that some commenters believe that the regulation text at § 438.207(f)(1) is vague. However,

we do not agree and believe that it is appropriate for us to have the ability to require remedy plans when an area in which a managed care plan's access to care under the access standards could be improved is identified and we should not be restricted to a finite list of criteria. Further, we clarify that § 438.207(f)(1) includes ''under the access standards in this part'' which provides many of the criteria upon which we will base our requests for remedy plans, such as the quantitative network adequacy and appointment wait time standards in § 438.68 and payment analysis reporting in § 438.207(d).

Comment: Some commenters were opposed to CMS requiring remedy plans. A few commenters stated that remedy plans were not needed as States already employ a variety of strategies, including corrective action plans, monetary damages, and other forms of intermediate sanctions, to ensure plan compliance with contractual standards regarding network adequacy and access to care. Some commenters stated concerns that this provision may not successfully address underlying challenges with access. A few commenters stated that it is inappropriate for CMS to insert itself into the contractor management process in the manner envisioned by the rule. A few commenters noted that withholding FFP in this case is a highly disproportionate and unreasonable consequence when States and managed care plans cannot make more providers exist in the State and can only have a limited impact on whether existing providers choose to enroll as Medicaid providers. A few commenters suggested that CMS give States the autonomy to create and enforce their own corrective action plans for access issues at State discretion. Some commenters recommended that CMS should first consider how it can play a role (perhaps by working closely with the Health Resources and Services Administration and the U.S. Department of Education), providing upside incentives to States to enact policies to help grow and retain the healthcare workforce and that the creation of remedy plans will be a distraction from what should be CMS's primary focus of growing the healthcare workforce.

Response: We understand that some commenters believe that remedy plans are not necessary. Prior to this final rule, the managed care regulations in 42 CFR, part 438 have not contained a specific provision for formal plans to address areas of program weakness. We have typically relied on technical assistance and periodic meetings to monitor States' progress to strengthen program performance. Unfortunately, we find that these methods do not always yield consistent, documented results and we believe that access concerns in managed care programs warrant a more organized, traceable process. Additionally, we do not intend to use remedy plans to usurp authority from States or intervene inappropriately in their contractual relationships. To the contrary, we believe remedy plans will help CMS, States, and managed care plans work collaboratively and coalesce around blueprints for improvement of specific access issues that can be shared and enhanced over time. Lastly, as oversight bodies and interested parties continue to audit, submit Freedom of Information Act requests, and analyze performance of the Medicaid program, we believe establishing a consistent process for addressing access issues in managed care is necessary and CMS, States, and managed care plans will all benefit from having documentation to substantiate improvement efforts. To the comment that we also need to take steps to work with our Federal partners, HHS and the entire Biden-Harris Administration continues to undertake efforts to improve access. For example, funding was recently awarded to improve health care facilities in rural towns across the nation. See *https://www.usda.gov/media/press-releases/2023/07/25/biden-harris-administration-helps-expand-access-rural-health-care*. On August 10, 2023, the Health Resources and Services Administration announced awards of more than $100 million to train more nurses and grow the nursing workforce. See *https://www.hhs.gov/about/news/2023/08/10/biden-harris-administration-announces-100-million-grow-nursing-workforce.html*.

Comment: One commenter requested that CMS consider permitting integrated plans for dually eligible individuals to substitute compliance with Medicare network requirements for participation in the proposed remedy plans.

Response: We appreciate that integrated plans must comply with Medicare and Medicaid requirements for network adequacy and access. However, we believe that when an access issue is identified that warrants a remedy plan, all the State's impacted Medicaid managed care plans need to contribute to the successful execution of it. This is particularly relevant given the vulnerable populations covered by plans that cover both Medicare and Medicaid services for dually eligible enrollees.

Comment: A few commenters recommended that the remedy plans, once approved, be posted on the State's website and that the State agency be required to share them with interested parties' advisory groups.

Response: We appreciate the suggestion for States to post their approved remedy plans on their website; however, we decline to include that in this final rule. We encourage States to consider posting their approved remedy plans on their websites and sharing them with their interested parties' advisory groups so that interested parties can support States and plans as they work to execute their remedy plans.

Comment: Some commenters recommended delaying the applicability date until the first rating period for managed care plan contracts that begins on or after 6 years after the effective date of the final rule. Another commenter suggested an applicability date that is at least 1 year after the secret shopper survey is required.

Response: We believe it is important to align the use of remedy plans with States receiving secret shopper survey results. As such, we decline to extend the applicability date.

After reviewing the public comments, we are finalizing § 438.207(f) as proposed.

g. Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285)

In the 2016 final rule, we finalized § 438.10(c)(3) for Medicaid, which is included in separate CHIP regulations through cross-reference at § 457.1207, which required States to operate a website that provides specific information, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites. A State's website may be the single most important resource for information about its Medicaid program and there are multiple requirements for information to be posted on a State's website throughout 42 CFR part 438. Regulations at § 438.10(c)(6)(ii) required certain information to be ''prominent and readily accessible'' and § 438.10(a) defined ''readily accessible'' as ''electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.'' Despite these requirements, we have received input from numerous and varied interested parties since the 2016 final rule about how challenging it can be to locate regulatorily required information on some States' websites.

There is variation in how ''user-friendly'' States' websites are, with some States making navigation on their website fairly easy and providing information and links that are readily available and presenting required information on one page. However, we have not found this to be the case for most States. Some States have the required information scattered on multiple pages that requires users to click on many links to locate the information they seek. While such websites may meet the current minimum standards in part 438, they do not meet our intent of providing one place for interested parties to look for all required information. Therefore, we determined that revisions were necessary to ensure that all States' websites required by § 438.10(c)(3) provide a consistent and easy user experience. We acknowledged that building websites is a complex and costly endeavor that requires consideration of many factors, but we believe that States and managed care plans share an obligation to build websites that quickly and easily meet the needs of interested parties without undue obstacles. We noted that State and managed care plan websites must be compliant with all laws, including the Americans with Disabilities Act (ADA), section 504 and 508 of the Rehabilitation Act, Title VI of the Civil Rights Act of 1964, and section 1557 of the Affordable Care Act. In implementing this proposed rule, we believe there are several qualities that all websites should include, such as being able to:

- Function quickly and as expected by the user;
- Produce accurate results;
- Use minimal, logical navigation steps;
- Use words and labels that users are familiar with for searches;
- Allow access, when possible, without conditions such as establishment of a user account or password;
- Provide reasonably comparable performance on computers and mobile devices;
- Provide easy access to assistance via chat; and
- Provide multilingual content for individuals with LEP.

We also believe that States and managed care plans should utilize web analytics to track website utilization and inform design changes. States should create a dashboard to regularly quantify website traffic, reach, engagement, sticking points, and audience characteristics. Given the critical role that websites fill in providing necessary and desired program information, we believe proposing additional requirements on States' websites was appropriate.

We acknowledge that States and managed care plans may have information accessible through their websites that is not public facing; for example, enrollee specific protected health information. Proper security mechanisms should continue to be utilized to prevent unauthorized access to non-public facing information, such as the establishment of a user account and password or entry of other credentials. Data security must always be a priority for States and managed care plans and the proposals in § 438.10(c)(3) in no way diminish that obligation for States.

To increase the effectiveness of States' websites and add some consistency to website users' experience, we proposed in § 438.10(c)(3) to revise ''websites'' to ''web pages'' in the reference to managed care plans. We proposed this change to clarify that if States provide required content on their website by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, the link on the State's site will have to be to the specific page that includes the requested information. We believe this prevents States from showing links to a landing page for the managed care plan that then leaves the user to start searching for the specific information needed. Next, we proposed to add ''States must:'' to paragraph (c)(3) before the items specified in new paragraphs (c)(3)(i) through (iv). In § 438.10(c)(3)(i), we proposed to require that all information, or links to the information, required in this part to be posted on the State's website, be available from one page. We believe that when website users have to do repeated searches or click through multiple pages to find information, they are more likely to give up trying to locate it. As such, we carefully chose the information that is required in 42 CFR part 438 to be posted on States' websites to ensure effective communication of information and believe it represented an important step toward eliminating common obstacles for States' website users.

At § 438.10(c)(3)(ii), we proposed to require that States' websites use clear and easy to understand labels on documents and links so that users can easily identify the information contained in them. We believe that using terminology and the reading grade level consistent with that used in other enrollee materials, such as handbooks and notices, will make the website more familiar and easy to read for enrollees and potential enrollees. Similar to having all information on one page, using clear labeling will reduce the likelihood of users having to make unnecessary clicks as they search for specific information.

In § 438.10(c)(3)(iii), we proposed that States check their websites at least quarterly to verify that they are functioning as expected and that the information is the most currently available. Malfunctioning websites or broken links can often render a website completely ineffective, so monitoring a website's performance and content is paramount. While we proposed that a State's website be checked for functionality and information timeliness no less than quarterly, we believe this to be a minimum standard and that States should implement continual monitoring processes to ensure the accuracy of their website's performance and content.

Lastly, in § 438.10(c)(3)(iv), to enable maximum effectiveness of States' websites, we proposed to require that States' websites explain that assistance in accessing the information is available at no cost to them, including information on the availability of oral interpretation in all languages and written translation in each prevalent non-English language, alternate formats, auxiliary aids and services, and a toll-free TTY/TDY telephone number. This proposal was consistent with existing information requirements in § 438.10(d) and section 1557 of the Affordable Care Act. Clear provision of this information will help to ensure that all users have access to States' websites and can obtain assistance when needed.

The Medicaid managed care website transparency revisions proposed at § 438.10(c)(3)(i) through (iv) will apply to separate CHIP through the existing cross-reference at § 457.1207.

To help States monitor their website for required content, we proposed to revise § 438.602(g) to contain a more complete list of information. While we believe the list proposed in § 438.602(g) will help States verify their website's compliance, we clarify that a requirement to post materials on a State's website in 42 CFR part 438 or any other Federal regulation but omitted from § 438.602(g), is still in full force and effect. Further, requirements on States to post specific information on their websites intentionally remain throughout 42 CFR part 438 and are not replaced, modified, or superceded by the items proposed in § 438.602(g)(5) through (12). Section 438.602(g) specified four types of information that States must post on their websites; we proposed to add nine more as (g)(5) through (13): (5) enrollee handbooks,

provider directories, and formularies required at § 438.10(g), (h), and (i); (6) information on rate ranges required at § 438.4(c)(2)(v)(A)(3); (7) reports required at §§ 438.66(e) and 438.207(d); (8) network adequacy standards required at § 438.68(b)(1) and (2), and (e); (9) secret shopper survey results required at § 438.68(f); (10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C); (11) links to all required Application Programming Interfaces including as specified in § 431.60(d) and (f); (12) quality related information required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i); and (13) documentation of compliance with requirements in subpart K—Parity in Mental Health and Substance Use Disorder Benefits. Although we proposed to itemize these nine types of information in § 438.602(g)(5) through (13), we note that all but the following three are currently required to be posted on States' websites: the report at § 438.207(d), secret shopper survey results at § 438.68(f), and State directed payment evaluation reports at § 438.6(c)(2)(v)(C). Lastly, in § 438.10(c)(3), we proposed to make the list of website content more complete by removing references to paragraphs (g) through (i) only and including a reference to § 438.602(g) and ''elsewhere in this part.''

We proposed to revise § 438.10(j) to reflect that States will have to comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and that States will have to comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule. Lastly, we proposed that States must comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these dates provide reasonable time for compliance given the varying levels of State and managed care plan burden.

We proposed to add § 438.602(j) to require States to comply with § 438.602(g)(5) through (13) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

For separate CHIP managed care, we currently require States to comply with the transparency requirements at § 438.602(g) through an existing cross-reference at § 457.1285. We proposed to align with Medicaid in adopting most of the consolidated requirements for posting on a State's website proposed at § 438.602(g)(5) through (13) for separate CHIP:

We proposed to adopt the provision at § 438.602(g)(5) (which specifies that States must post enrollee handbooks, provider directories, and formularies on the State's website) because requirements at § 438.10(g) through (i) are currently required for separate CHIP through an existing cross-reference at § 457.1207.

We did not propose to adopt the provision at § 438.602(g)(6) (which requires that States must post information on rate ranges on their websites) because we do not regularly review rates for separate CHIP.

We proposed to adopt the provision at § 438.602(g)(7) (which specifies that States must post their assurances of network adequacy on the State's website) since the proposed network adequacy reporting at § 438.207(d) will apply to separate CHIP through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this final rule). Since we did not adopt the managed care program annual reporting requirements at § 438.66(e) for separate CHIP, we proposed to exclude this reporting requirement at § 457.1230(b).

We proposed to adopt the provision at § 438.602(g)(8) (which requires State network adequacy standards to be posted on the State's website) for separate CHIP because we proposed to adopt the new appointment wait time reporting requirements through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this final rule), though we proposed to exclude references to LTSS as not applicable to separate CHIP.

We proposed to adopt the provision at § 438.602(g)(9) (which specifies that States must post secret shopper survey results on the State's website) for separate CHIP network access reporting to align with our proposed adoption of secret shopper reporting at § 438.68(f) through an existing cross-reference at § 457.1218 (see section I.B.1.c. of this final rule).

We did not propose to adopt the provision at § 438.602(g)(10) (which directs States to post SDP evaluation reports on the State's website) because State directed payments are not applicable to separate CHIP.

We proposed to adopt the provision at § 438.602(g)(11) (which specifies that States must post required information for Application Programming Interfaces on the State's website) given the existing requirements at § 457.1233(d).

We proposed to adopt the provision at § 438.602(g)(12) (which requires States to post quality-related information on the State's website) for separate CHIP as required through cross-references at § 457.1240(c) and (e), as well as the applicable EQR report through a cross-reference at § 457.1250(a). However, we proposed to exclude the reference to § 438.362(c) since MCO EQR exclusion is not applicable to separate CHIP.

We proposed to adopt the provision at § 438.602(g)(13) (which requires States to post documentation of compliance with parity in mental health and substance use disorder benefits on the State's website) for separate CHIP through the existing cross-reference at § 457.1285. However, we proposed to replace the reference to subpart K of part 438 with CHIP parity requirements at § 457.496 in alignment with contract requirements at § 457.1201(l).

We proposed to amend § 457.1285 to state, the State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2) and 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Our proposals for requirements for States' websites at § 438.10(c)(3) and the list proposed in § 438.602(g) are authorized by sections 1932(a)(5)(A) and 2103(f)(3) of the Act for Medicaid and which require each State, enrollment broker, or managed care entity to provide all enrollment notices and informational and instructional materials in a manner and form which may be easily understood by enrollees and potential enrollees. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We believe that our proposals will make States' websites easier to use by incorporating easily understood labels, having all information accessible from one page, verifying the accurate functioning of the site, and clearly explaining the availability of assistance- all of which will directly help States fulfill their obligation to provide informational materials in a manner and form which may be easily understood.

We summarize and respond to public comments received on Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285) below.

Comment: Many commenters supported our proposal to require that States' managed care websites contain

all required information on one page that is clear and easy to understand, that is verified at least quarterly, and that helps users. Commenters confirmed that interested parties often face difficulty navigating State websites and the proposed requirements would greatly improve the usability of States' websites.

Response: We appreciate the support for our proposals. We believe State managed care websites are critical sources of information for interested parties and efforts to improve their utility is a fundamental responsibility for States.

Comment: We received a comment recommending that we require States to post direct links to the appropriate document or information on the managed care plan's site. Another commenter questioned whether the requirements in § 438.10(c)(3) will apply to the State website and/or the managed care plans' websites.

Response: We appreciate the commenter raising this question and welcome the opportunity to provide clarification. Existing regulation text at § 438.10(c)(3) requires ''The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, ...'' This means that the link to an MCO's, PIHP's, PAHP's or PCCM entity's website must be to the required *content,* not just to a random location on the MCO's, PIHP's, PAHP's, or PCCM entity's website. Our proposal to revise ''websites'' to ''web pages'' was intended to make that clearer, not alter this existing requirement. While the requirements of § 438.10(c)(3) are applicable to State websites, States can certainly apply them to their managed care plans through their managed care plan contract. Given that States must provide assistance to website users at § 438.10(c)(3)(iv) and through existing cross-reference at § 457.1207 for separate CHIP, we encourage States to ensure that their plans' websites meet at least the same minimum standards.

Comment: A few commenters urged CMS to require States to post other documents on the State website, such as the Annual Medical Loss Ratio reports and mental health parity compliance analyses that managed care plans must submit to the State. Conversely, other commenters stated concern that some required reports are inherently technical and difficult to understand and that it would be extremely hard or impossible to render at a grade 6 reading level.

Response: We appreciate the suggestion that managed care plans' MLR reports be posted on States' managed care web page. While we did not propose that MLR reports be posted on States' managed care web page in this rule, we may consider it in future rulemaking. The posting of mental health parity analyses completed by MCOs is consistent with existing § 438.920 and we encourage States to ensure a clearly identifiable label on such analyses or links to them. However, we want to be cognizant of the amount of information that we require States to present on their managed care web pages and balance that with interested parties' use and need. The website requirement in § 438.10(c)(3) was added in the 2016 final rule to acknowledge the increasing use of electronic media by enrollees and potential enrollees for critical program information. We believe these websites would be a valuable and welcome way to address problems that Medicaid and CHIP programs have struggled with for years; for example, missed mail, incorrect mailing addresses, and excessively long or too frequent mailings. While we understand that other interested parties also use the States' web page, we want to be thoughtful about the required content, particularly given that § 438.10(c)(3)(i) and § 457.1207 for separate CHIP will require that all information be accessible from one page.

To the concern that some reports that are required to be posted on States' managed care web page are complicated and technical, we acknowledge that not all of the information is as easy to present as others. We encourage States to include approaches that may assist readers, such as providing executive summaries that contain less detail and are easier to read but still capture the most important information. This type of an aid would enable readers to determine if they want to read the longer or more complicated document.

Comment: We received several comments regarding the administrative burden and cost associated with developing a chat feature. One commenter suggested that information should be able to be automatically heard read aloud by clicking on the material for the most common languages within each State.

Response: We clarify that including a chat feature on a website was a recommended practice, but it was not proposed in § 438.10(c)(3). As we stated, we believe a chat feature to be one of the minimal qualities that all websites should include but as we did not propose it, we did not include it in our burden estimates for this provision. We appreciate the suggestion that users should be able to click on the material and it be automatically read aloud and encourage States and managed care plans to consider building this feature into their web pages.

Comment: A commenter supported our proposals at § 457.1207 to require States to operate a website that provides certain information, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites. The commenter suggested aligning transparency requirements for Medicaid MCOs proposed at § 438.602(g) with transparency requirements applicable to separate CHIP MCOs.

Response: We thank the commenter for their suggestion. We clarify that we did propose to align separate CHIP with most of the Medicaid transparency requirements at § 457.1207 through an amended cross-reference to § 438.602(g)(5) through (13), except in situations where the Medicaid requirement is not relevant for separate CHIP. We did not adopt the provision at § 438.602(g)(6), which requires that States must post information on rate ranges on their websites because we do not regularly review rates for separate CHIP. We believe finalizing the amendments at § 457.1285 will align the transparency requirements of Medicaid MCOs and separate CHIP MCOs when appropriate.

After reviewing the public comments, we are finalizing §§ 438.10(c), 438.602(g), 457.1207, and 457.1285 as proposed.

h. Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b) and 438.214(b))

Throughout 42 CFR part 438, we use ''behavioral health'' to mean mental health and SUD. However, it is an imprecise term that does not capture the full array of conditions that are intended to be included, and some in the SUD treatment community have raised concerns with its use. It is important to use clear, unambiguous terms in regulatory text. Therefore, we proposed to change ''behavioral health'' throughout 42 CFR part 438 as described here. In the definition of PCCM entity at § 438.2 and for the provider types that must be included in provider directories at § 438.10(h)(2)(iv), we proposed to replace ''behavioral health'' with ''mental health and substance use disorder;'' for the provider types for which network adequacy standards must be developed in § 438.68(b)(1)(iii), we proposed to remove ''behavioral health'' and the parentheses; and for the provider types addressed in credentialing policies at § 438.214(b), we proposed to replace ''behavioral'' with ''mental health.'' We also proposed in the definition of PCCM entity at § 438.2 to replace the slash

between ''health systems'' and ''providers'' with ''and'' for grammatical accuracy.

Similarly, we also proposed to change ''psychiatric'' to ''mental health'' in § 438.3(e)(2)(v) and § 438.6(e). We believe that ''psychiatric'' does not capture the full array of services that can be provided in an institution for mental disease (IMD).

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan, because use of clear, unambiguous terms in regulatory text is imperative for proper and efficient operation of the plan.

We summarize and respond to public comments received on Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b)) below.

Comment: We received several comments supporting our proposal to revise ''behavioral health'' throughout part 438 regulations to ''mental health'' and ''SUD'' as appropriate.

Response: We appreciate commenters' support and will finalize ''mental health'' and ''SUD'' in §§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b) to ensure that these provisions are clear and unambiguous.

After reviewing the public comments, we are finalizing §§ 438.2, 438.3(e), 438.10(h), 438.68(b), and 438.214(b) as proposed.

2. State Directed Payments (SDPs) (§§ 438.6, 438.7 and 430.3)

a. Background

Section 1903(m)(2)(A) of the Act requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound. CMS has historically used our authority under section 1902(a)(4) of the Act to apply the same requirements to contracts between States and PIHPs or PAHPs. Under risk-based managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers. Subject to certain exceptions, States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). However, there are circumstances under which requiring managed care plans to make specified payments to health care providers is an important tool in furthering the State's overall Medicaid program goals and objectives; for example, funding to ensure certain minimum payments are made to safety net providers to ensure access to care, funding to enhance access to behavioral health care providers as mandated by State legislative directives, or funding for quality payments to ensure providers are appropriately rewarded for meeting certain program goals. Balancing that this type of State direction reduces the plan's ability to effectively manage costs but can be an important tool for states. CMS, in the 2016 final rule, established specific exceptions to the general rule prohibiting States from directing the expenditures of MCOs, PIHPs and PAHPs at § 438.6(c)(1)(i) through (iii). These exceptions came to be known as State directed payments (SDPs).

The current regulations at § 438.6(c) specify the parameters for how and when States may direct the expenditures of their Medicaid managed care plans and the associated requirements and prohibitions on such arrangements. Permissible SDPs include directives that certain providers of the managed care plan participate in value-based payment (VBP) models, that certain providers participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or that the managed care plan use certain fee schedule requirements (for example, minimum fee schedules, maximum fee schedules, and uniform dollar or percentage increases). Among other requirements, § 438.6(c) requires SDPs to be based on the utilization and delivery of services under the managed care contract and are expected to advance at least one of the objectives in the State's managed care quality strategy.

All SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). Further, § 438.6(c)(2)(ii) requires that most SDPs be approved in writing prior to implementation.[55] To obtain written prior approval, States must submit a ''preprint'' form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c).[56] States must obtain written prior approval of certain SDPs in order for CMS to approve the corresponding Medicaid managed care contract(s) and rate certifications(s). States were required to comply with this prior approval requirement for SDPs no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2017.

Each SDP preprint submitted to CMS is reviewed by a Federal review team to ensure that the payments comply with the regulatory requirements in § 438.6(c) and other applicable laws. The Federal review team consists of subject matter experts from various components and groups within CMS, which regularly include those representing managed care policy and operations, quality, and actuarial science. Over time, these reviews have expanded to include subject matter experts on financing of the non-Federal share and demonstration authorities when needed. The CMS Federal review team works diligently to ensure a timely review and that standard operating procedures are followed for a consistent and thorough review of each preprint. Most preprints are reviewed on an annual basis; SDPs that are for VBP arrangements, delivery system reform, or performance improvement initiatives and that meet additional criteria in the Federal regulations are eligible for multi-year approval.

CMS has issued guidance to States regarding SDPs on multiple occasions. In November 2017, we published the initial preprint form[57] along with guidance for States on the use of SDPs.[58] In May 2020, CMS published guidance on managed care flexibilities to respond to the PHE, including how States could use SDPs in support of their COVID–19 response efforts.[59] In January 2021, we published additional guidance for States to clarify existing policy, and also issued a revised preprint form that States must use for rating periods beginning on or after July 1, 2021.[60] The revised preprint form is more comprehensive compared to the initial preprint, and it is designed to systematically collect the information that CMS identified as necessary as part

[55] State directed payments that are minimum fee schedules for network providers that provide a particular service under the contract using State plan approved rates as defined in § 438.6(a) are not subject to the written prior approval requirement at § 438.6(c)(2)(ii); however, they must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for prior written approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

[56] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[57] *https://www.medicaid.gov/sites/default/files/2020-02/438-preprint.pdf.*

[58] *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib11022017.pdf.*

[59] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051420.pdf.*

[60] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

of our review of SDPs to ensure compliance with the Federal regulatory requirements.[61] This includes identification of the estimated total dollar amount for the SDP, an analysis of provider reimbursement rates for the class(es) of providers that the SDP is targeting, and information about the sources of the non-Federal share used to finance the SDP.

Since § 438.6(c) was codified in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDP arrangements submitted by States for approval has also grown steadily and quickly. In CY 2017, we received 36 preprints from 15 States for our review and approval. In contrast, in CY 2021, we received 223 preprints from 39 States. For CY 2022, we received 298 preprints from States. In total, as of October 2023, we have reviewed nearly 1,400 SDP proposals and approved 1,244 proposals since the 2016 final rule was issued.[62]

SDPs also represent a notable amount of spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that, in 2020, CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion.[63] The U.S. Government Accountability Office (GAO) also reported that at least $20 billion in SDP expenditures has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 approved preprints[64] and in another report they estimated that SDPs totaled $38.5 billion in 2022 according to their analysis of CMS approved SDP preprints approved through August 2022 while acknowledging the total estimated SDP spending was likely higher.[65] Our internal analysis of all SDPs approved from the time that § 438.6(c) was issued in the 2016 final rule through the end of fiscal year 2022 estimates that the total spending for all SDPs approved for the most recent rating period for States is nearly $52 billion annually[66] (Federal and State) and at least half of that amount is for provider payments States require plans to pay in addition to the rates negotiated between the plans and providers.

In its December 2023 report, the GAO acknowledged that CMS has taken steps to enhance its process for approving SDPs and recommended that CMS enhance fiscal guardrails for SDPs. Specifically, the GAO recommended that CMS improve these guardrails by establishing a definition of, and standards for, assessing whether SDPs result in payment rates that are reasonable and appropriate, and communicating those to States; determining whether additional fiscal limits are needed; and requiring States to submit data on actual spending amounts at the SDP preprint renewal.[67] The GAO also recommended that CMS consider interim evaluation results or other performance information from States at the SDP preprint renewal, and recommended increased transparency of SDP approvals. As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives as part of our review process, as well as ensuring that SDPs are developed and implemented with appropriate fiscal and program integrity guardrails. The proposed changes in this rule are intended, individually and taken together, to ensure the following policy goals:

(1) Medicaid managed care enrollees receive access to high-quality care under SDP arrangements.

(2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDP payment arrangements; and

(3) CMS and States have the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and transparency of SDP payment arrangements.

We are issuing the requirements in this final rule based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound and our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan, and is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. As noted in the 2016 final rule, regulation of SDPs is necessary to ensure that Medicaid managed care plans have sufficient discretion to manage the risk of covering the benefits outlined in their contracts, which is integral to ensuring that capitation rates are actuarially sound as defined in § 438.4 (81 FR 27582). Where a proposal is also based on interpreting and implementing other authority, we note that in the applicable explanation of the proposed policy.

We did not adopt the Medicaid managed care SDP requirements described at § 438.6 in the 2016 final rule for separate CHIPs because there was no statutory requirement to do so, and we wished to limit the scope of new regulations and administrative burden on separate CHIP managed care plans. For similar reasons, we did not propose to adopt the new Medicaid managed care SDP requirements proposed at §§ 438.6 and 438.7 for separate CHIPs.

We proposed to define State directed payments as a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section. We proposed this definition as it is currently used by States and CMS in standard interactions, as well as in published guidance to describe these contract requirements. Defining this term also improves the readability of the related regulations. We have also proposed to rename the header for paragraph (c) of § 438.6 to ''*State Directed Payments under MCO, PIHP, or PAHP contracts*'' to reflect this term.

In addition, we proposed several revisions to § 438.6 to further specify and add to the existing requirements

[61] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[62] The number of proposals includes initial preprints, renewals and amendments. An individual SDP program could represent multiple SDP proposals as described here (that is, an initial application, 1 renewal, and 3 amendments).

[63] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.* Projected payment amounts are for the most recent rating period, which may differ from calendar year or fiscal year 2020.

[64] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

[65] U.S. Government Accountability Office, ''Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency.'' December 14, 2023, available at *https://www.gao.gov/assets/d24106202.pdf.*

[66] This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through the end of fiscal year 2022, under CMS's standard review process. Rating periods differ by State; some States operate their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of the end of fiscal year 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

[67] U.S. Government Accountability Office, ''Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency.'' December 14, 2023, available at *https://www.gao.gov/assets/d24106202.pdf.*

and standards for SDPs. First, we proposed revisions, including: codifying administrative requirements included in recent guidance;[68] exempting SDPs that establish payment rate minimums at 100 percent of the total published Medicare payment rate from the written prior approval requirement; incorporating SDPs for non-network providers in certain circumstances; setting new procedures and timeframes for the submission of SDPs and related documentation; codifying and further specifying standards and documentation requirements on total payment rates; further specifying and strengthening existing requirements related to financing, as well as the connection to the utilization and delivery of services; updating and providing flexibilities for States to pursue VBP through managed care; strengthening evaluation requirements and other areas; and addressing how SDPs are incorporated into capitation rates or reflected in separate payment terms. The proposed regulatory provisions include both new substantive standards and new documentation and contract term requirements. In addition, we proposed a new appeal process for States that are dissatisfied with CMS's determination related to a specific SDP preprint and new oversight and monitoring standards. In recognition of the scope of changes we proposed, some of which will require significant time for States to implement, we proposed a series of applicability dates over a roughly 5-year period for compliance. These applicability dates are discussed in section I.B.2.p. of this final rule.

We reiterate here our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Although the changes in this rule are intended to work harmoniously to achieve a set of goals and further specific policies, they are not so interdependent that they will not work as intended even if a provision is held invalid. The SDP provisions may operate independently of each other. For example, the financing provisions finalized as § 438.6(c)(2)(ii)(G) and (H) are separate, distinct, and severable from all the other standards enumerated in § 438.6(c). Most of the SDP parameters and conditions in the regulation govern the development of the actual SDP arrangement, operational processes associated with documentation and CMS review and approval, as well as the SDP evaluation. If the financing provisions § 438.6(c)(2)(ii)(G) and/or (H) or even the payment limit established in § 438.6(c)(2)(iii) were to change, all the other standards around SDPs would continue to remain enforceable because the other provisions do not impact either of the financing provisions or the payment limit. Similarly, the operational and evaluation standards adopted in this rule could be implemented separately if necessary.

An outline of the remaining parts of this section of this final rule is provided below:

b. Contract Requirements Considered to be SDPs (Grey Area Payments) (§ 438.6(c)(1))
c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), (c)(2) and (c)(5)(iii)(A)(*5*))
d. Non-Network Providers (§ 438.6(c)(1)(iii))
e. SDP Submission Timeframes (§§ 438.6(c)(2)(viii) and 438.6(c)(2)(ix))
f. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for Certain SDPs and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I) and (c)(2)(iii))
g. Financing (§ 438.6(c)(2)(ii)(G) and (c)(2)(ii)(H))
h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))
i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))
j. Quality and Evaluation (§ 438.6(c)(2)(ii)(C), (c)(2)(ii)(D), (c)(2)(ii)(F), (c)(2)(iv), (c)(2)(v) and (c)(7))
k. Contract Term Requirements (§ 438.6(c)(5) and and 438.7(c)(6))
l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J) and (c)(6), and 438.7(f))
m. SDPs included through Adjustments to Base Capitation Rates (§§ 438.6(c)(6), and § 438.7(c)(4) through (c)(6))
n. Appeals (§ 430.3(e))
o. Reporting Requirements to Support Oversight and Inclusion of SDPs in MLR Reporting (§§ 438.6(c)(4), and 438.8(e)(2)(iii)(C) and (f)((2)(vii))
p. Applicability Dates (§§ 438.6(c)(4) and 438.6(c)(8), and 438.7(f))

We summarize and respond to public comments received on State Directed Payments (§§ 438.6, 438.7, 430.3) below.

We received comments related to the definitions of ''academic medical center,'' ''qualified practitioner services at an academic medical center,'' ''inpatient hospital services,'' outpatient hospital services,'' ''performance measure'' and ''total published Medicare payment rate''; see sections I.B.2.f., I.B.2.j., and I.B.2.c. respectively of this final rule for our responses.

We did not receive comments on the remaining proposed definitions.

We are finalizing the following definitions in § 438.6(a) as proposed: ''Academic medical center,'' ''Average commercial rate,'' ''Final State directed payment cost percentage,'' ''Inpatient hospital services,'' ''Maximum fee schedule,'' ''Minimum fee schedule,'' ''Outpatient hospital services,'' ''Nursing facility services,'' ''Performance measure,'' ''Population-based payment,'' ''Qualified practitioner services at an academic medical center,'' ''Total payment rate,'' ''Total published Medicare payment rate,'' and ''Uniform increase.'' We are not finalizing a definition for the term ''separate payment term'' or the provisions regarding separate payment terms (see section I.B.2.l. of this final rule for discussion).

The definition for the term ''State directed payment'' is finalized as proposed but has been moved from § 438.6(a) to § 438.2 because it is used in multiple provisions in part 438. We are also finalizing revisions throughout §§ 438.6 and 438.7 to use the term ''State directed payment'' in place of ''contract arrangement'' or similar terms that are used in the current regulations to refer to State directed payments.

The definition for ''Condition-based payment'' is finalized with the phrase ''covered under the contract'' at the end to specify that such prospective payment must be for services delivered to Medicaid managed care enrollees covered under the managed care contract.

b. Contract Requirements Considered to be SDPs (Grey Area Payments) (§ 438.6(c)(1))

Under § 438.6(c) (currently and as amended in this rule), States are not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan unless it is an SDP that complies with § 438.6(c), is permissible in a specific provision under Title XIX, is permissible through an implementing regulation of a Title XIX provision related to payments to providers, or is a permissible pass-through payment that meets requirements in § 438.6(d). States are also not permitted to make payments directly to providers for services covered under the contract between the State and a managed care plan as specified in § 438.60.

In our November 2017 CIB entitled ''Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts,'' we noted instances

[68] *https://www.medicaid.gov/sites/default/files/2021-12/smd21001.pdf.*

where States may include general contract requirements for provider payments that will not be subject to approval under § 438.6(c) if the State was not mandating a specific payment methodology or amounts under the contract.[69] We also noted that these types of contract requirements will not be pass-through payments subject to the requirements under § 438.6(d), as we believe they maintained a link between payment and the delivery of services. One scenario in the CIB described contract language generally requiring managed care plans to make 20 percent of their provider payments as VBP or alternative payment arrangements when the State does not mandate a specific payment methodology and the managed care plan retains the discretion to negotiate with network providers the specific terms for the amount, timing, and mechanism of such VBP or alternative payment arrangements. We continue to believe that this scenario does not meet the criteria for an SDP nor a pass-through payment. However, we believe that the aforementioned VBP scenario represents the State imposing a quality metric on the managed care plans rather than the providers. We believe that this specific type of contractual condition and measure of plan accountability is permissible, so long as it meets the requirements for an incentive arrangement under § 438.6(b)(2), or a withhold arrangement under § 438.6(b)(3).

The other scenario described in the November 2017 CIB relates to instances where the State contractually implements a general requirement for Medicaid managed care plans to increase provider payment for covered services provided to Medicaid enrollees covered under the contract, where the State did not mandate a specific payment methodology or amount(s) and managed care plans retain the discretion for the amount, timing, and mechanism for making such provider payments. At the time, we believed that these areas of flexibility for the plan would be sufficient to exclude the State's contract requirement from the scope of § 438.6(c). However, as we have continued to review managed care contracts and rate certifications since November 2017, we have grown increasingly concerned that excluding this type of vague contractual requirement for increased provider payment from the requirements of § 438.6(c) created an unintended loophole in regulatory oversight, presenting a significant program integrity risk. For example, some States include general contract requirements for significant increases to provider payments that require the State to add money to the capitation rates paid to the managed care plans as part of rate development for a specific service (for example, hospital services) but without any further accountability to ensure that the additional funding included in the capitation payments is paid to providers for a specific service or benefit provided to a specific enrollee covered under the contract. While this is similar to the definition of pass-through payment in § 438.6(a), these contractual requirements do not meet all of the other requirements in § 438.6(d) to be permissible pass-through payments. We commonly refer to these types of contractual arrangements as ''grey area payments'' as they do not completely comply with § 438.6(c) nor § 438.6(d).

Based on our experience since the 2017 CIB, we concluded that general contractual requirements to increase provider payment rates circumvent the intent of the 2016 final rule and the subsequent 2017 Pass-Through Payment Final Rule to improve the fiscal integrity of the program and ensure the actuarial soundness of all capitation rates.[70] As we stated in the preamble of the 2016 final rule ''[w]e believe that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services to beneficiaries covered under the contract. . . . In our review of managed care capitation rates, we have found pass-through payments being directed to specific providers that are generally not directly linked to delivered services or the outcomes of those services. These pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services.'' (81 FR 27587) Further, ''[a]s a whole, [42 CFR] § 438.6(c) maintains the MCO's, PIHP's, or PAHP's ability to fully utilize the payment under that contract for the delivery and quality of services by limiting States' ability to require payments that are not directly associated with services delivered to enrollees covered under the contract.'' (81 FR 27589).

In January 2021, we published State Medicaid Director Letter (SMDL) #21–001,[71] through which we sought to close the unintentional loophole created in the November 2017 CIB and realign our implementation of the regulation with the original intent of the 2016 final rule and the 2017 final rule. The 2021 SMDL provides that if a State includes a general contract requirement for provider payment that provides for or adds an amount to the provider payment rates, even without directing the specific amount, timing or methodology for the payments, and the provider payments are not clearly and directly linked specifically to the utilization and delivery of a specific service or benefit provided to a specific enrollee, then CMS will require the contractual requirement to be modified to comply with § 438.6(c) or (d) beginning with rating periods that started on or after July 1, 2021. We maintain this interpretation. At this time, we further specify our stance that any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement; our proposal reflected this position. States wishing to impose quality requirements or thresholds on managed care plans, such as the requirement that a certain percentage of provider payments be provided through a VBP arrangement, must do so within the parameters of § 438.6(b). We did not believe changes were needed to the regulation text in § 438.6(c) or (d) to reflect this reinterpretation and clarification because this preamble provided an opportunity to again bring this important information to States' attention. We noted in the proposed rule that CMS would continue this narrower interpretation of § 438.6(c) and (d) and we solicited comments on whether additional clarification about these grey area payments is necessary, or if revision to the regulation text would be helpful.

We summarize and respond to public comments received on Contract Requirements Considered to be SDPs (Grey Area Payments) below.

Comment: Some commenters supported CMS's restatement of our existing policy that any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement, and that ''grey area payments'' are prohibited. One

[69] *https://www.hhs.gov/guidance/document/delivery-system-and-provider-payment-initiatives-under-medicaid-managed-care-contracts.*

[70] *https://www.federalregister.gov/documents/2017/01/18/2017-00916/medicaid-program-the-use-of-new-or-increased-pass-through-payments-in-medicaid-managed-care-delivery.*

[71] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

commenter noted that reiterating these existing requirements improves transparency.

Response: We appreciate the commenters' support and agree that restating our existing policy promotes greater transparency. We believe it aids States' planning and operational efforts for associated managed care activities. We note that guidance on this topic has been previously published at SMD #21–001 and restatement in this final rule provides consistent documentation of the policy and its scope. (see 88 FR 28113)

Comment: Some commenters opposed CMS's interpretation. These commenters encouraged CMS to revise the Federal regulatory requirements to instead indicate that broad contract requirements that direct managed care plans to move a set percent of provider payments into value-based arrangements do not trigger SDP provisions. One such commenter indicated that the continuation of ''grey area payments'' allows States necessary flexibility to support State initiatives to ensure access to medically necessary services, such as hospital services, while still operating within the financial realities of State budgets.

Response: We continue to believe that our current policy is reasonable and appropriate, and we decline to revise the regulation to allow flexibility for States to continue directing general increases to payments without using an SDP to ensure that payments are tied to utilization of service. We reject the recommendation to continue to permit ''grey area payments'' that are about general direction to increase payments. We believe the existing authorities available to States, including SDPs and incentive arrangements, can be useful tools in States' efforts to ensure access to care. After review of these comments, we recognize that our intent as outlined in the proposed rule preamble (88 FR 28113) would be clearer if we included a minor modification to § 438.6(c)(1). Therefore, we are amending § 438.6(c)(1) to add the phrase ''in any way'' after ''. . . The State may not . . .'' to make the regulation more explicit that any State direction of an MCO's, PIHP's or PAHP's expenditures is impermissible unless it meets the requirements set forth in § 438.6(c).

We are also finalizing the definition for ''State directed payment'' as proposed although we are moving it to § 438.2 in recognition of regulatory references to SDPs that are outside of § 438.6. We are making minor changes in the text of this definition to be consistent with how it is codified in § 438.2 instead of § 438.6. In addition, the final definition cites § 438.6(c) instead of paragraphs (c)(1)(i) through (iii) to reflect how paragraph (c) includes additional requirements for SDPs.

Comment: Some commenters requested clarification on whether payments to FQHCs, RHCs and Certified Community Behavioral Health Clinics (CCBHCs) under a prospective payment system (PPS) are considered SDPs since they mandate the amount of payment.

Response: We appreciate this request for clarification as an opportunity to remind commenters of existing regulation that explicitly addresses this topic. As outlined in § 438.6(c)(1), the State may not direct the MCO's, PIHP's or PAHP's expenditures under the contract, except as specified in a provision of Title XIX or in another regulation implementing a Title XIX provision related to payments to providers. Therefore, the payment of statutorily-required PPS rates to FQHCs and RHCs under Title XIX or CCBHC demonstrations under section 223 of the Protecting Access to Medicare Act of 2014 are not considered SDPs and are not prohibited by § 438.6. If States elect to adopt payment methodologies similar to those under the CCBHC demonstration but the State or facilities are not part of an approved section 223 demonstration, those payment arrangements would need to comply with SDP requirements in § 438.6(c) as the Federal statutory requirements only extend to those States and facilities participating in an approved demonstration.

After reviewing public comments, and for the reasons outlined in the proposed rule and our responses to comments, we are amending § 438.6(c)(1) to clarify that States may not in any way direct MCO, PIHP or PAHP expenditures, unless such direction is permitted under § 438.6(c)(1) and we are finalizing the definition for ''State directed payment'' in § 438.2 instead of § 438.6(a) as originally proposed.

c. Medicare Exemption, SDP Standards and Prior Approval (§§ 438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(*5*))

In § 438.6(c), States are permitted to direct managed care plans' expenditures under the contract as specified in § 438.6(c)(1)(i) through (iii), subject to written prior approval based on complying with the requirements in § 438.6(c)(2). In the preamble to the 2020 final rule, we noted our observation that a significant number of proposals submitted by States for review under § 438.6(c)(2) required managed care plans to adopt minimum fee schedules specified under an approved methodology in the Medicaid State plan. In response, we adopted several revisions to § 438.6(c) in the 2020 final rule.[72] We defined ''State plan approved rates'' in § 438.6(a) as ''amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan,'' and excluded supplemental payments that are paid in addition to State plan approved rates. We also revised § 438.6(c)(1)(iii)(A) to explicitly address SDPs that are a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates and revised § 438.6(c)(2)(ii) to exempt these specific SDP arrangements from the written prior approval requirement. However, SDPs described in paragraph § 438.6(c)(1)(iii)(A) must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for written prior approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

This piece of the 2020 final rule was, in part, intended to eliminate unnecessary and duplicative review processes to promote efficient and effective administration of the Medicaid program. This rule improved States' efforts to timely implement certain SDP arrangements that meet their local goals and objectives without drawing upon State staff time unnecessarily. We continue to believe exempting payment arrangements based on an approved State plan rate methodology from written prior approval does not increase program integrity risk or create a lack of Federal oversight. We continue to review the corresponding managed care contracts and rate certifications which include these SDPs, and TMSIS reporting requirements apply to SDPs that do not require prior approval. The State plan review and approval process ensures that Medicaid State plan approved rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area, as required under section 1902(a)(30) of the Act.

As we have reviewed and approved SDPs since the 2020 final rule, we

[72] *https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care.*

continue to believe this same rationale applies to SDPs that adopt a minimum fee schedule using Medicare established rates for providers that provide a particular service under the contract. Medicare rates are developed under Title XVIII of the Act and there are annual rulemakings associated with Medicare payment for benefits available under Parts A and B. Additionally, section 1852(a)(2) of the Act and 42 CFR 422.214 respectively provide, with some exceptions, that Medicare Advantage plans pay out-of-network providers, and those providers accept in full, at least the amount payable under FFS Medicare for benefits available under Parts A and B, taking into account cost sharing and permitted balance billing.[73] These considerations mean that Medicare Part A and B payment rates are appropriate and do not require additional review by CMS in the context of a Medicaid managed care SDP. Therefore, prior written approval by CMS is not necessary to ensure that the standards for SDPs in current § 438.6(c)(2) are met when the total published Medicare payment rate is used in the same or a close period as a minimum fee schedule.

Consistent with how we have considered State plan rates to be reasonable, appropriate, and attainable under §§ 438.4 and 438.5, Medicare established rates also would meet this same threshold. Therefore, we proposed to exempt SDPs that adopt a minimum fee schedule based on total published FFS Medicare payment rates from the written prior approval requirement as such processes will be unnecessary and duplicative. We proposed to amend § 438.6(c) to provide specifically for SDPs that require use of a minimum fee schedule using FFS Medicare payment rates and to exempt them from the written prior approval requirement.

First, we proposed to add a new definition to § 438.6(a) for ''total published Medicare payment rate'' as amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B. We proposed to redesignate the existing § 438.6(c)(1)(iii)(B) through (D) as § 438.6(c)(1)(iii)(C) through (E), respectively, and add a new § 438.6(c)(1)(iii)(B) explicitly recognizing SDP arrangements that are a minimum fee schedule using a total published Medicare payment rate that is no older than from the 3 most recent and complete years prior to the rating period as a permissible type of SDP.[74] We also proposed to revise redesignated paragraph (c)(1)(iii)(C) to take into account the proposed new category of SDPs that use one or more total published Medicare payment rates. As part of the proposals for paragraphs (c)(1)(iii)(A) through (E), we also proposed to streamline the existing regulation text to eliminate the phrase ''as defined in paragraph (a)'' as unnecessary; we expect that interested parties and others who read these regulations will read them completely and recognize when defined terms are used.

We also proposed to restructure § 438.6(c)(2) and amend its paragraph heading to *Standards for State directed payments* as discussed fully in later sections. As part of this restructuring, we proposed to redesignate part of the provision in § 438.6(c)(2)(ii) to § 438.6(c)(2)(i) to describe which SDPs require written prior approval. This revision included a conforming revision in § 438.6(c)(2)(i) to reflect the re-designation of § 438.6(c)(1)(iii)(B) through (D) as (c)(1)(iii)(C) through (E). This revision will ensure that that SDPs described in paragraph (c)(1)(iii)(B) along with the SDPs described in paragraph (c)(1)(iii)(A), are not included in the written prior approval requirement. As described in our proposed rule, States that adopt a minimum fee schedule using 100 percent of total published Medicare payment rates will still need to document these SDPs in the corresponding managed care contracts and rate certifications, and those types of SDPs must still comply with requirements for all SDPs other than prior written approval by CMS, just as minimum fee schedules tied to State plan approved rates described in paragraph (c)(1)(iii)(A) must comply. Under our proposal, SDPs described under paragraphs (c)(1)(iii)(A) and (B) would still need to comply with the standards listed in the proposed restructured § 438.6(c)(2)(ii). (See sections I.B.2.f. through I.B.2.l. of this final rule for proposed new requirements and revisions to existing requirements for all SDPs to be codified in paragraph (c)(2)(ii).)

Our proposal to exempt these Medicare payment rate SDPs from written prior approval from CMS was specific to SDPs that require the Medicaid managed care plan to use a minimum fee schedule that is equal to 100 percent of the total published Medicare payment rate. SDP arrangements that use a different percentage (whether higher or lower than 100 percent) of a total published Medicare payment rate as the minimum payment amount or that are simply based off of an incomplete total published Medicare payment rate would be included in the SDPs described in paragraph (c)(1)(iii)(C). Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable. Accordingly, we believe SDPs that proposed provider payment rates that are incomplete or either above or below 100 percent of total published Medicare payment rates may not necessarily meet these criteria and thus, should remain subject to written prior approval by CMS. Our proposal was consistent with this belief.

We also did not propose to remove the written prior approval requirement for SDPs for provider rates tied to a Medicare fee schedule in effect more than 3 years prior to the start of the rating period. This is reflected in our proposed revision to redesignated paragraph (c)(1)(iii)(C) to describe fee schedules for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in proposed new paragraph (c)(1)(iii)(B). We proposed the limit of 3 years to be consistent with how § 438.5(c)(2) requires use of base data that is at least that recent for rate development. Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable. Accordingly, we believe that SDPs that propose provider payment rates tied to a total published Medicare payment rate in effect more than 3 years prior to the start of the rating period may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

We solicited public comments on our proposal to specifically address SDPs that are for minimum fee schedules using 100 percent of the amounts in a total published Medicare payment rate for providers that provide a particular service when the total published Medicare payment rate was in effect no more than 3 years prior to the start of the rating period and on our proposal to exempt these specific types of SDP arrangements from the prior written approval requirement in § 438.6(c)(2)(ii).

We also proposed to add new § 438.6(c)(5) (with the paragraph

[73] See also 42 CFR 422.100(b) and 422.214 and guidance in the ''MA Payment Guide for Out of Network Payments'', April 15, 2015, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf*.

[74] Section 438.5 requires that States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates.

heading *Requirements for Medicaid Managed Care Contract Terms for State directed payments),* for oversight and audit purposes. Proposed new paragraph (c)(5)(iii)(A)(5) requires the managed care plan contract to include certain information about the Medicare fee schedule used in the SDP, regardless of whether the SDP was granted an exemption from written prior approval under § 438.6(c)(1)(iii)(B). That is, for SDPs which use total published Medicare payment rates, the contract would need to specify which Medicare fee schedule(s) the State directs the managed care plan to use and any relevant and material adjustments due to geography, such as rural designations, and provider type, such as Critical Access Hospital or Sole Community Hospital designation.

Under our proposal, the managed care contract must also identify the time period for which the Medicare fee schedule is in effect, as well as the rating period for which it is used for the SDP. Consistent with proposed § 438.6(c)(1)(iii)(B), the Medicare fee schedule must be in effect no more than 3 years prior to the start of the rating period for the services provided in the arrangement. This 3-year requirement is like requirements in § 438.5 for rate setting, under which data that the actuary relies on must be from the 3 most recent years that have been completed, prior to the rating period for which rates are being developed. For example, should a State seek to implement a § 438.6(c)(1)(iii)(B) fee schedule in CY 2025, the Medicare fee schedule must have been in effect for purposes of Medicare payment at least at the beginning of CY 2021.

Requiring sufficient language in the contract regarding the Medicare fee schedule would provide clarity to CMS, managed care plans, and providers regarding the explicit Medicare payment methodology being used under the contract. For broader discussion of § 438.6(c)(5), see section I.B.2.k. of this final rule.

We requested comment on other material or significant information about a Medicare fee schedule that will need to be included to ensure the managed care contract sufficiently describes this type of SDP.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We summarize and respond to public comments received on our proposals related to the SDPs that use total published Medicare payment rates, including the proposed exemption from the written prior approval and contract content requirements, § 438.6(c)(1)(iii)(B), (2), and (5)(iii)(A)(*5*) below.

Comment: Many commenters supported exempting minimum fee schedule SDPs at 100 percent of the total published Medicare payment rates specified in § 438.6(c)(1)(iii)(B) from written prior approval as Medicare payment rates have already been approved through the extensive Medicare notice-and-comment rulemaking process. As such, this exemption from written prior approval would reduce the administrative burden for State Medicaid programs and for CMS. Commenters also supported CMS's assertion that minimum fee schedules that are based on 100 percent of published Medicare payment rates pose comparatively little risk and satisfy the criteria of being reasonable, appropriate, and attainable. Further, commenters supported the proposal that the Medicare fee schedule should be in effect no more than 3 years prior to the start of the applicable rating period for the SDP.

Response: We appreciate commenters' support and agree that the exemption from written prior approval finalized in § 438.6(c)(2)(i) will eliminate an unnecessary and duplicative review process for SDPs and will facilitate more efficient and effective administration of the Medicaid program. We continue to believe that this exemption does not increase program integrity risk as Medicare payment rates are rigorously developed and vetted annually by CMS. Additionally, while the SDPs described in § 438.6(c)(1)(iii)(A) and (B) are not subject to prior approval, they are not automatically renewed, must comply with requirements and standards in part 438, and must be documented appropriately in the managed care contract and rate certification submission consistent with § 438.7. We take this opportunity to remind States that as specified in § 438.7(b)(6), rate certifications must include a description of any special contract provisions related to payment in § 438.6, including SDPs authorized under § 438.6(c)(1)(iii)(A) and (B). We also direct the commenter to section I.B.2.l. of this final rule for further details on the documentation of SDPs in rate certifications.

Comment: Several commenters supported the exemption from written prior approval for minimum fee schedule SDPs at 100 percent of the total published Medicare payment rate but suggested that we expand the scope of this exemption for additional SDPs that use Medicare fee schedules. Many of these commenters suggested a range, such as 95 to 105 percent of Medicare payment rates, or a threshold as high as 125 percent of Medicare payment rates. One commenter suggested that any minimum fee schedule SDPs using payments in the range between the State Plan rate and the Medicare payment rate should qualify for the exemption from written prior approval.

Response: We continue to believe that minimum fee schedule SDPs using 100 percent of total published Medicare payment rates are reasonable and appropriate to remove from written prior approval requirements as they are developed by CMS and finalized through rulemaking. We have concerns about expanding this exemption to SDPs that use other percentages of total published Medicare payment rates. Only Medicare payment rates as published have undergone CMS development and oversight. Deviations from these payment rates introduce variations that have not been appropriately considered and vetted in a regulatory capacity to ensure the rate is reasonable, appropriate, and attainable. However, not using the published Medicare payment rate does not trigger a presumption on CMS's part that the proposed rates are not reasonable, appropriate, and attainable. Rather, we believe that minimum fee schedule SDPs which use Medicare payment rates that are incomplete or at a percentage other than 100 percent of the total published Medicare payment rate must continue to be reviewed by CMS and receive written prior approval via a preprint.

Comment: A few commenters recommended that CMS allow other SDPs to be exempt from prior approval requirements. Some of these commenters suggested CMS exempt from the prior written approval requirement any SDP that adopts minimum fee schedules, particularly those for behavioral health services and HCBS. Another commenter suggested extending this exemption to SDPs that provide uniform increases.

Response: We disagree that additional types of SDPs should be exempted from written prior approval of preprints. SDPs that use minimum fee schedules other than State plan approved rates or 100 percent of the total published Medicare payment rate, as well as uniform increases, must continue to be reviewed by CMS and receive written approval via a preprint, to ensure the payment rates are reasonable, appropriate, and attainable, in addition to ensuring compliance with § 438.6(c). The level of scrutiny and review that applies to the total Medicare payment rate and State plan approved rates does

not apply to other minimum or maximum fee schedules used in an SDP, so there are not sufficient assurances that the payment rates are reasonable, appropriate, and attainable to justify an exemption from CMS review and approval. Our exemption from written prior approval of certain SDPs is predicated on prior CMS involvement in the rates, such as our development of the total published Medicare payment rate and our approval of Medicaid State plan rates. As such, it would not be appropriate to exempt all minimum fee schedules or uniform increases regardless of service type and payment level.

Comment: One commenter suggested that any minimum fee schedule using Medicare as a benchmark should be exempt from all SDP requirements.

Response: We decline to expand the Medicare exemption from written prior approval to an exemption from all SDP regulatory requirements entirely. There are many critical components that every SDP must meet, including requirements that it be based on utilization and delivery of services, advance quality, not condition provider participation in the SDP on a provider entering or adhering to intergovernmental transfers (IGT) arrangements, and that it be documented in managed care plan contracts and accounted for in rate development. As discussed throughout this section of the final rule, there are important policy and legal considerations furthered by these requirements for SDPs. As always, CMS will continue to seek efficiencies in our operational review processes to facilitate timely action.

Comment: Some commenters who supported the Medicare exemption also requested that the exemption be expanded based on alternative benchmarks. One commenter requested alternatives for provider types not represented in Medicare. One commenter was concerned that States should be able to look to other Medicare payment methodologies than the Medicare Physician Fee Schedule, such as the Medicare partial hospitalization program for psychiatric care.

Response: We acknowledge that the exemption from written prior approval finalized in § 438.6(c)(2)(i) will not accommodate all service and provider types, such as those not addressed in the total published Medicare payment rates. Our goal in finalizing § 438.6(c)(2)(i) is to reduce State administrative burden by exempting SDPs that are a minimum fee schedule using a total published Medicare payment rate as this total payment rate is developed by CMS. States are still able to pursue SDPs that are not tied to the State plan or Medicare payment rates, but those proposals require written prior approval. The term ''total published Medicare payment rate'' is defined in § 438.6(a) to include ''amounts calculated for payment for specific services that have been developed under Title XVIII Part A and Part B.'' Therefore, the exemption for SDPs specified in § 438.6(c)(1)(iii)(B) is not limited to the Medicare Physician Fee schedule and would encompass Medicare payment rates for other Medicare covered services under Parts A and B.

Comment: One commenter requested that CMS revise its definition of State plan approved rates to include payments that are estimated to be equivalent to what Medicare would have paid using a payment-to-charge ratio such as is permitted in the Medicaid FFS supplemental payment Upper Payment Limit demonstrations required by § 447.272.

Response: State plan approved rates are defined in § 438.6(a) as amounts calculated for services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the State plan, and this definition specifically indicates that ''Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.'' This is because Medicaid FFS supplemental payments are not calculated or paid based on the number of services rendered on behalf of an individual beneficiary, and therefore, are separate and distinct from State plan approved rates. We do not intend to revisit the definition for State plan approved rates or the associated exemption from written prior approval. Further detail on this policy is in the 2020 final rule (85 FR 72776 through 72779).

Comment: While commenters supported the administrative efficiency associated with this exemption, some commenters stated that Medicare rates are not sufficient compensation for certain services, for example for highly specialized services, and can yield extremely low payment rates for some services. One commenter urged CMS not to consider adopting a framework that suggests Medicare payment rates are the appropriate benchmark to ensure Medicaid beneficiaries have access to care and recommended clarifying that this approach is solely a mechanism for evaluating payment adequacy in a standardized way. Another commenter opposed this provision saying that exactly 100 percent of the published Medicare payment rates was an arbitrary and strict benchmark. One commenter, while supportive of CMS's goals, cautioned that CMS should not discourage States from using common service definitions, appropriate risk adjustment, and applicable payment groupings that are designed for the Medicaid population, rather than the Medicare population.

Response: The provision finalized as proposed at § 438.6(c)(2)(i)—to exempt certain SDPs described in § 438.6(c)(1)(iii)(B) from the prior written approval requirement—was intended solely to reduce administrative burden on States and CMS. As noted earlier, we are finalizing the exemption for minimum fee schedule SDPs at the total published Medicare payment rate because these rates, like Medicaid State plan rates, have already been approved by CMS. We disagree that 100 percent of total published Medicare rates is an arbitrary and overly rigid standard for the exemption from the prior written approval requirement. We also did not assert that Medicare rates were appropriate for all services, populations, and providers and do not intend this provision for certain SDPs to communicate such a position. States have the option to design SDPs based on the needs of their Medicaid population and the structure of their Medicaid managed care programs.

Comment: One commenter stated concerns that exempting these SDPs from prior approval would mean CMS would no longer receive evaluations for some minimum fee schedules that could substantially increase provider payment rates from Medicaid managed care plans.

Response: The exemption is limited to written prior approval of a preprint. As we discussed in the proposed rule, all SDPs, including those described in § 438.6(c)(1)(iii)(A) and (B), would still need to comply with the standards listed in the finalized § 438.6(c)(2)(ii) (see 88 FR 28114). As finalized, § 438.6(c)(2)(ii) reflects this policy. In addition, other requirements for SDPs adopted in the rule, such as the reporting requirements in paragraph (c)(4) and certain contract term requirements in paragraph (c)(5) will also apply to the SDPs specified in paragraph (c)(1)(iii)(A) and (B). (To the extent that certain SDP requirements are limited to specified SDPs, those are discussed in the relevant parts of section I.B.2. of this final rule.) For example, while it is true the SDP evaluation report would not need to be submitted to CMS for review at a specified time, the State is required to continue to evaluate the SDP and such evaluation must be made available to

CMS upon request. See section I.B.2.j. of this final rule for further details on SDP evaluations.

Comment: Some commenters were supportive of the proposed exemption but stated concern, urging CMS to consider requiring States and their actuaries to include detailed information describing the SDP within their rate certification documentation. These commenters stated that clear rate certification documentation that includes information about SDPs that are not subject to the CMS written prior approval process will help ensure the fiscal sustainability of the Medicaid program.

Response: We agree that SDPs being adequately described in rate certifications is an important program integrity safeguard. SDPs that are exempt from written prior approval must comply with requirements and standards in part 438 and be appropriately documented in the managed care contract and rate certification submission consistent with § 438.7. We take this opportunity to remind States that as specified in § 438.7(b)(6), rate certifications must include a description of any special contract provisions related to payment in § 438.6, including SDPs authorized under § 438.6(c)(1)(iii)(A) and (B). We also direct the commenter to section I.B.2.k. of this final rule for further details on the documentation of SDPs in rate certifications.

Comment: Another commenter recommended that CMS define ''published Medicare rates'' to be inclusive of additions and adjustments such as GME, indirect medical education, and Area Wage Index specific to each hospital to ensure the payment rates account for the acuity of the patient, the population served, and services provided in a particular geographic area of the country.

Response: The exemption from written prior approval in § 438.6(c)(2)(i) for SDPs specified in § 438.6(c)(1)(iii)(B) includes the ''total published Medicare payment rate,'' which aligns with the inpatient prospective payment system (IPPS) web pricer amount [75] and is fully inclusive of all components included in the rate developed by CMS for Medicare payment. States retain the ability to propose SDPs that use a fee schedule which is based on a Medicare payment rate but in some way revises or deviates from the underlying approved methodology or adds other types of variability. However, such SDPs are not within the scope of § 438.6(c)(1)(iii)(B) because they would not use 100 percent of the total published Medicare payment rate. These would be SDPs described in § 438.6(c)(1)(iii)(C), which are not eligible for the exemption in § 438.6(c)(2)(i) and are subject to written approval from CMS. Additionally, any SDPs that use a payment in addition to the total published Medicare rate (as calculated by the IPPS web pricer) are not within the scope of § 438.6(c)(1)(iii)(B), are not eligible for the exemption in § 438.6(c)(2)(i) and are subject to written prior approval from CMS. Any SDP that in any way adjusts the total published Medicare payment rate must receive written prior approval by CMS.

Additionally, for clarity, we restate that for all SDPs that specify a Medicare-referenced fee schedule regardless of whether it is eligible for an exemption from written prior approval, the associated managed care contract must comply with § 438.6(c)(5)(iii)(A)(5) and include information about the Medicare fee schedule(s) that is necessary to implement the SDP, identify the specific Medicare fee schedule, the time period for which the Medicare fee schedule is in effect, and any material adjustments due to geography or provider type that are applied. We also direct the commenter to section I.B.2.k. of this final rule for further details on the documentation of SDPs in managed care contracts.

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to § 438.6(a), (c)(2)(i), and (c)(5)(iii)(A)(5) as proposed for the reasons outlined here and in the proposed rule. We are further finalizing the definition of ''Total published Medicare payment rate'' at § 438.6(a) as proposed and finalizing §§ 438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(5) as proposed.

d. Non-Network Providers (§ 438.6(c)(1)(iii))

We proposed to remove the term ''network'' from the descriptions of SDP arrangements in current (and revised as proposed) § 438.6(c)(1)(iii). Existing regulations specify that for a State to require an MCO, PIHP or PAHP to implement a fee schedule under § 438.6(c)(1)(iii), the fee schedule must be limited to ''network providers.'' This limitation is not included in § 438.6(c)(1)(i) or (ii) for SDP arrangements that are VBP and multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives. In our experience working with States, limiting the descriptions of SDP arrangements subject to § 438.6(c)(iii) to those that involve only network providers has proven to be too narrow and has created an unintended barrier to States' and CMS's policy goals to ensure access to quality care for beneficiaries.

In the 2016 final rule, we finalized current § 438.6(c)(1)(iii) to include ''network'' before ''providers'' in this provision.[76] As previously noted, the regulation at § 438.6(c)(1) generally prohibits States from directing the MCO's, PIHP's or PAHP's expenditures under the contract unless it meets one of the exceptions (as provided in a specific provision in Title XIX, in another regulation implementing a Title XIX provision related to payment to providers, a SDP that complies with § 438.6(c), or a pass-through payment that complies with § 438.6(d)). Therefore, the inclusion of the word ''network'' in the SDP arrangement descriptions in the 2016 final rule has prevented States from including contract requirements to direct their Medicaid managed care plans on how to pay non-network providers.

In our work with States over the years, some States have noted concerns with the requirement that permissible SDPs only apply to (or include) payments by Medicaid managed care plans to network providers. States have noted that limiting SDPs to network providers is impractical in large and diverse States. Several States had, prior to the 2016 final rule, pre-existing contractual requirements with managed care plans that required a specific level of payment (such as the State's Medicaid FFS rates) for non-network providers. This aligns with our experience working with States as well, and we note section 1932(b)(2)(D) of the Act requires that non-network providers furnishing emergency services must accept as payment in full an amount equal to the Medicaid State plan rate for those services. Some States have historically required plans to pay non-network providers at least the Medicaid State plan approved rate or another rate established in the managed care contract. Many States with enrollees on their borders rely on providers in neighboring States to deliver specialty services, such as access to children's hospitals.

While we support States' and plans' efforts to develop strong provider networks and to focus their efforts on providers who have agreed to participate in plan networks, executing network agreements with every provider may not always be feasible for plans.

[75] *https://webpricer.cms.gov/#/.*

[76] *https://www.federalregister.gov/d/2016-09581/p-1269.*

For example, in large hospital systems, it may be impractical for every plan to obtain individual network agreements with each rounding physician delivering care to Medicaid managed care enrollees. In such instances, States may have an interest in ensuring that their Medicaid managed care plans pay non-network providers at a minimum level to avoid access to care concerns. We have also encountered situations in which States opt to transition certain benefits, which were previously carved out from managed care, from FFS into managed care. In these instances, States would like to require their managed care plans to pay out-of-network providers a minimum fee schedule in order to maintain access to care while allowing plans and providers adequate time to negotiate provider agreements and provider payment rates for the newly incorporated services. Consequently, we proposed these changes to provide States a tool to direct payment to non-network providers, as well as network providers.

Therefore, we proposed to remove the term ''network'' from the descriptions of permissible SDP arrangements in § 438.6(c)(1)(iii). Under this proposal, the permissible SDPs are described as payment arrangements or amounts ''for providers that provide a particular service under the contract'' and this will permit States to direct payments under their managed care contracts for both network and non-network providers, subject to the requirements in § 438.6(c) and other regulations in part 438. We note that, as proposed, all standards and requirements under § 438.6(c) and related regulations (such as § 438.7(c)) will still be applicable to SDPs that direct payment arrangements for non-network providers.

Finally, as pass-through payments are separate and distinct from SDPs, we are maintaining the phrase ''network provider'' in § 438.6(d)(1) and (6). Existing pass-through payments are subject to a time-limited transition period and in accordance with § 438.6(d)(3) and (5), respectively, hospital pass-through payments must be fully eliminated by no later than the rating period beginning on or after July 1, 2027 and nursing facility and physician services pass-through payments were required to have been eliminated by no later than the rating period beginning on or after July 1, 2022 with the exception of pass-through payments for States transitioning services and populations in accordance with § 438.6(d)(6). Therefore, we did not believe that it is appropriate or necessary to eliminate the word ''network'' from § 438.6(d).

We solicited public comments on our proposal. We sought comment on whether this change will result in negative unintended consequences.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We summarize and respond to public comments received on our proposal regarding SDPs for non-network providers (§ 438.6(c)(1)(iii)) below.

Comment: Many commenters supported our proposal to remove ''network'' from § 438.6(c)(1)(iii) noting that the revision would remove barriers to access to quality care for enrollees and provide more flexibility for States to direct managed care plan payment to a wider array of providers. Some commenters noted that this change would ensure alignment across all types of providers.

Response: We appreciate the support for the proposed changes to § 438.6(c)(1)(iii). We agree that these revisions will provide States with more flexibility, and could improve access to quality care, and establish parity for provider eligibility for all types of SDPs.

Comment: One commenter sought clarification as to whether CMS is proposing to require States to include non-network providers in SDPs or if States will have flexibility to elect whether an SDP is limited to network or non-network providers.

Response: We appreciate the request for clarification and clarify that the revision to § 438.6(c)(1)(iii) grants States the option to direct payment under § 438.6(c) to network and/or non-network providers. As part of the provider class definition for each SDP required in § 438.6(c)(2)(ii)(B), States should identify in the SDP preprint whether the provider class eligible for the SDP is inclusive of network and/or non-network providers. We are also finalizing § 438.6(c)(5)(ii) to require States to document both a description of the provider class eligible for the SDP and all eligibility requirements in the applicable managed care contract. We believe such description will need to include whether an SDP is applicable to network and/or non-network providers so that managed care plans can accurately implement the SDP.

Comment: One commenter noted that States should provide clear and timely guidance to managed care plans about SDP related adjustments to the capitation rates and sufficient details about the SDP for the managed care plan to be able to effectuate the SDP for non-network providers. The commenter stated that States should be required to issue a fee schedule for non-network providers to managed care plans with sufficient time, preferably 90 days, to make programming and operational changes necessary to operationalize the SDP.

Response: We agree with the commenter that States should account for SDPs in applicable rate certifications and contracts in a clear and timely manner. To ensure that managed care plans receive necessary information on the State's intent and direction for the SDP, we are finalizing provisions that establish minimum documentation requirements for all SDPs and timeframes for submission of managed care contracts and rate certifications that incorporate SDPs (see sections I.B.2.e., I.B.2.k., and I.B.2.l. of this final rule for further details). We believe these requirements will help ensure that plans have sufficient and timely information to effectuate SDPs with providers.

Comment: Several commenters stated support for removing ''network'' from § 438.6(c)(1)(iii) and requested that CMS permit SDPs that require network providers to be paid higher payment amounts than out-of-network providers. One commenter requested that CMS grant States flexibility to implement maximum fee schedules for non-network providers that are lower than the fee schedules for network providers to incentivize providers to join managed care plan networks while still allowing for flexibility in contracting.

Response: States are permitted to direct payment in any of the ways suggested by commenters, subject to all the requirements in § 438.6(c) and applicable law. Unless limited or circumscribed by a requirement for how a Medicaid managed care plan pays certain non-contracted providers, States could choose to utilize network status as the basis on which to define provider classes or subclasses for an SDP under § 438.6(c)(2)(i)(B). We encourage States to consider how best to design SDPs for network and non-network providers to achieve the goals and objectives of their managed care programs.

Comment: Several commenters opposed removing ''network'' from § 438.6(c)(1)(iii) and recommended that we continue to limit certain types of SDPs to network providers. Some of these commenters noted that this proposed change might disincentivize providers from contracting with managed care plans and undermine network adequacy or access to network providers. One commenter noted that this change would run counter to CMS's goals to improve access to managed care network providers.

Response: We disagree that permitting States to direct fee schedule or uniform

increase type SDPs specified in § 438.6(c)(1)(iii) to non-network providers will erode access to network providers or undermine network adequacy. As discussed in the proposed rule, we believe that this change may improve access to care in certain situations. For example, States have stated interest in directing plans to pay at least the Medicaid State plan rate to non-network providers in neighboring States that furnish specialty services unavailable in the State or non-network providers that render services to enrollees during inpatient stays. (88 FR 28115) We believe these examples demonstrate that permitting SDPs for non-network providers could help States fulfill their obligation to ensure timely access to all covered services. To the extent that a State decides that concerns about disincentivizing network participation should limit SDPs that direct payment to non-network providers, our regulation similarly permits that policy choice.

Comment: One commenter urged CMS to delay the applicability date from the effective date of the final rule to the first rating period beginning on or after 2 years after the effective date of the rule to allow managed care plans to prepare for network adequacy fluctuations.

Response: We decline to delay the applicability date of § 438.6(c)(1)(iii). Since the inception of SDPs in the 2016 final rule, States have been permitted to direct plan expenditures to network and non-network providers consistent with § 438.6(c)(1)(i) and (ii). To our knowledge, these SDPs have not caused any network adequacy fluctuations. The revision to § 438.6(c)(1)(iii) simply extends the option for States to include non-network providers in other types of SDPs, including minimum fee schedules, maximum fee schedules and uniform increases. Therefore, we do not believe it necessary to extend the applicability date; this amendment to § 438.6(c)(1)(iii) is applicable upon the effective date of this final rule. States may seek prospective amendments to existing SDPs or develop new SDPs consistent with this amendment to § 438.6(c)(1)(iii) without additional delay.

Comment: One commenter noted that implementing certain payment arrangements with non-network providers could prove burdensome for managed care plans to implement and track as the managed care plans do not have a formal contractual relationship with non-network providers.

Response: Managed care plans have extensive experience paying claims for non-network providers for many purposes including for certain inpatient care, emergency services, and statutorily permitted use of non-network family planning providers. Additionally, States have been permitted to adopt and CMS has approved SDPs described in existing § 438.6(c)(1)(i) and (ii) to direct managed care plans to pay non-network providers since the 2016 final rule. We encourage States and plans to utilize lessons learned to implement other types of SDPs that include non-network providers. Plans and States should work together to reduce administrative burden, including for the impacted non-network providers whenever possible, and develop SDP implementation processes to ensure timely and accurate payment.

Comment: One commenter opposed removing ''network'' from § 438.6(c)(1)(iii) stating that the provision cannot be adopted without CMS performing a regulatory impact analysis.

Response: We included a robust discussion of the most impactful SDP provisions for which we had sufficient data in the regulatory impact analysis in the proposed rule and the public had the opportunity to comment on it and provide additional information for our consideration. We acknowledge that we do not have sufficient quantitative data presently to assess the impact of all provisions, including removing ''network'' from § 438.6(c)(1)(iii). Nor did commenters provide such data.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revision to remove ''network'' from the descriptions of the SDPs in § 438.6(c)(1)(iii) as proposed.

e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (c)(2)(ix))

Since we established the ability for States to direct the expenditures of their managed care plans in the 2016 final rule, we have encouraged States to submit their requests for written prior approval 90 days in advance of the start of the rating period whenever possible. We also recommend that States seek technical assistance from CMS in advance of formally submitting the preprint for review to CMS for more complicated proposals to facilitate the review process.

Submitting 90 days in advance of the rating period provides CMS and the State time to work through the written prior approval process before the State includes the SDP in their managed care plan contracts and the associated rate certifications. If States include SDPs in managed care contracts and capitation rates before we issue written prior approval, any changes to the SDP made as a result of the review process will likely necessitate contract and rate amendments,[77] creating additional work for States, actuaries, CMS, and managed care plans. Submitting SDP preprints at least 90 days in advance of the rating period can help reduce the need for subsequent contract and rate amendments to address any inconsistencies between the contracts and rate certifications and approved SDPs. State directed payments that are not submitted 90 days in advance of the affected rating period also cause delays in the approval of managed care contracts and rates because those approvals are dependent on the written prior approval of the SDP. Since we cannot approve only a portion of a State's Medicaid managed care contract, late SDP approvals delay approval of the entire contract and the associated capitation rates.

Some States have not been successful in submitting their SDP preprints in advance of the rating period for a variety of reasons. Sometimes it is due to changes in program design, such as a new benefit linked to the SDP being added to the Medicaid managed care contract during the rating period. Other unforeseen changes, such as PHEs or natural disasters, can also create circumstances in which States need to respond to urgent concerns around access to care by implementing an SDP during the rating period. While we recognize that from time to time there may be a circumstance that necessitates a late preprint submission, we have found that some States routinely submit SDP preprints at the very end of the rating period with implementation dates retroactive to the start of the rating period. We have provided repeated technical assistance to these States, and we published additional guidance in 2021[78] to reiterate our expectation that States submit SDP preprints before the start of a rating period. This guidance also made clear that CMS will not accept SDP preprints for rating periods that are closed; however, we have not been able to correct the situation with some States.

To make our processes more responsive to States' needs while ensuring that reviews linked to SDP approvals are not unnecessarily delayed, we proposed a new § 438.6(c)(2)(viii)(A) through (C) to set the deadline for submission of SDP preprints that require written prior

[77] The term ''rate amendment'' is used to reference an amendment to the initial rate certification.

[78] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

approval from CMS under paragraph (c)(2)(i) (redesignated from § 438.6(c)(2)(ii)). In § 438.6(c)(2)(viii)(A), we proposed to require that all SDPs that require written prior approval from CMS must be submitted to CMS no later than 90 days in advance of the end of the rating period to which the SDP applies. This proposed requirement would apply if the payment arrangement for which the State is seeking written prior approval begins at least 90 days in advance of the end of the rating period. We encourage all States to submit SDPs in advance of the start of the rating period to ensure CMS has adequate time to process the State's submissions and can support the State in incorporating these payments into their Medicaid managed care contracts and rate development. We proposed to use a deadline of no later than 90 days prior to the end of the applicable rating period because we believed this minimum timeframe would balance the need for State flexibility to address unforeseen changes that occur after the managed care plan contracts and rates have been developed with the need to ensure timely processing of managed care contracts and capitation rates. When a State fails to submit all required documentation for any SDP arrangement that requires written prior approval 90 days prior to the end of the rating period to which the SDP applies, the SDP will not be eligible for written prior approval; therefore, the State will not be able to include the SDP in its Medicaid managed care contracts and rate certifications for that rating period.

In § 438.6(c)(2)(viii)(B), we proposed to address the use of shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters, by permitting States to submit all required documentation before the end of the rating period for SDP proposals that will start less than 90 days before the end of the rating period. Although CMS is not finalizing this proposal, we note that it was intended to provide flexibility to allow States effectively to use SDPs during the final quarter of the rating period to address urgent situations that affect access to and quality of care for Medicaid managed care enrollees.

There are SDPs, such as VBP and delivery system reform, that can currently be approved under § 438.6(c)(3) for up to three rating periods. For these, we proposed in § 438.6(c)(2)(viii)(C) that the same timeframes described in § 438.6(c)(2)(viii)(A) and (B) apply to the first rating period of the SDP.

To illustrate these timeframes in the proposed rule, we used the example of an SDP eligible for annual approval that a State is seeking to include in their CY 2025 rating period. In the example, under the current regulations, CMS recommended that a State seeking approval of an SDP for the calendar year (CY) 2025 rating period would ideally submit the preprint by October 3, 2024. However, under this proposal to revised § 438.6(c)(2)(viii), if the start of the SDP was on or before October 2, 2025, the State must submit the preprint no later than October 2, 2025 in order for CMS to accept it for review; if the State submitted the preprint for review after that date, CMS could not grant written prior approval of the preprint for the CY 2025 rating period under our proposal. The State could instead seek written prior approval for the CY 2026 rating period instead if the preprint could not be submitted for the CY 2025 rating period by the October 2, 2025 deadline.

We described in the proposed rule an alternative requiring all SDPs to be submitted prior to the start of the rating period for which the State was requesting written prior approval. This would be a notable shift from current practice, which requires all preprints be submitted prior to the end of the rating period. We noted in the proposed rule that States submit all preprints prior to the start of the rating period would reduce administrative burden and better align with the prospective nature of risk-based managed care. However, instituting such a deadline could potentially be too rigid for States that needed to address an unanticipated or acute concern during the rating period.

Lastly, we described in the proposed rule an alternative of requiring that States submit all SDPs in advance of the start of the payment arrangement itself. For example, a State may seek to start a payment arrangement halfway through the rating period (for example, an SDP for payments starting July 1, 2025 for States operating on a CY rating period). Under this alternative approach, the State would have to submit the preprint for prior approval before July 1, 2025 in order for it to be considered for written prior approval. This approach would provide additional flexibility for States establishing new SDPs but will limit the additional flexibility for that SDP to that initial rating period. If the State wanted to renew the SDP for the subsequent rating period (for example, CY 2026), it would have to resubmit the preprint before the start of that rating period.

As discussed in section I.B.2.p. of this final rule on Applicability Dates, we proposed that States must comply with these new submission timeframes beginning with the first rating period beginning on or after 2 years after the effective date of the final rule. In the interim, we would continue our current policy of not accepting submissions for SDPs after the rating period has ended. We solicited public comment on our proposals and these alternatives, as well as additional options that will also meet our goals for adopting time limits on when an SDP can be submitted to CMS for written prior approval.

For amendments to approved SDPs, we proposed at § 438.6(c)(2)(ix) to require all amendments to SDPs approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) to be submitted for written prior approval as well. We also proposed at § 438.6(c)(2)(ix)(A) to require that all required documentation for written prior approval of such amendments be submitted prior to the end of the rating period to which the SDP applies in order for CMS to consider the amendment. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have to submit any amendment to the preprint for that rating period before December 31, 2025. After December 31, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. The same would be true for an SDP that was approved for one rating period after the start of the rating period (for example, approval on October 1, 2025 for a CY 2025 rating period). In that instance, the State would have until December 31, 2025 to submit any amendment to the preprint for CMS review; after December 31, 2025, CMS would not accept any amendments to that SDP for that rating period.

We further proposed in § 438.6(c)(2)(ix)(B) to set timelines for the submission of amendments to SDPs approved for multiple rating periods as provided in paragraph (c)(3). Under this proposal, § 438.6(c)(2)(ix)(A) and (B) would allow an amendment window for the proposal within the first 120 days of each of the subsequent rating periods for which the SDP is approved after the initial rating period. The amendment process for the first year of the multiple rating periods would work the same way as it would for any SDP approved for one rating period and be addressed by proposed paragraph (xi)(A). However, in recognition that the SDP is approved for multiple rating periods, we proposed in § 438.6(c)(2)(ix)(B) that the State would be able to amend the approved preprint for the second (CY 2026 in our example) and third (CY 2027 in our example) rating periods

within the first 120 days of the CY 2026 rating period (for example, by May 1, 2026). The requested amendment could not make any retroactive changes to the SDP for the CY 2025 rating period because the CY 2025 rating period would be closed in this example. The State would not be permitted to amend the payment arrangement after May 1, 2026 for the CY 2026 rating period. The State will be able to do the same for the CY 2027 rating period as well—amend the SDP before the end of the first 120 days of the CY 2027 rating period, but only for the CY 2027 rating period and not for the concluded CY 2025 or CY 2026 rating periods.

As proposed, these deadlines would be mandatory for written prior approval of an SDP or any amendment of an SDP. When a State fails to submit all required documentation for any amendments within these specified timeframes, the SDP will not be eligible for written prior approval. Therefore, the State would not be able to include the amended SDP in its Medicaid managed care contracts and rate certifications for that rating period. The State could continue to include the originally approved SDP as documented in the preprint in its contracts for the rating period for which the SDP was originally approved. We note that written prior approval of an SDP does not obligate a State to implement the SDP. If a State chose not to implement an SDP for which CMS has granted prior approval, elimination of an SDP would not require any prior approval, under our current regulations or this proposal. If a State decides not to implement an approved SDP after it has been documented in the rate certification and contract the State would have to submit amendments for the rates and contract to remove the contractual obligation for the SDP and the impact of the SDP on the rates. We solicited comment on this aspect of our proposal.

We proposed regulatory changes in §§ 438.6(c)(5)(vi) and 438.7(c)(6) to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date we granted written prior approval of the SDP, whichever is later. States should submit their rate certifications prior to the start of the rating period, and § 438.7(c)(2) currently requires that any rate amendments [79] comply with Federal timely filing requirements. However, we believe given the nature of SDPs, there should be additional timing restrictions on when revised rate certifications that include SDPs can be provided for program integrity purposes. We also reminded States that these proposals do not supersede other requirements regarding submission of contract and rate certification documentation when applicable, including but not limited to those that require prior approval or approval prior to the start of the rating period such as requirements outlined in §§ 438.3(a), 438.4(c)(2), and 438.6(b)(1). These proposals are discussed in later sections: section I.B.2.k. of this final rule on Contract Term Requirements for SDPs; section I.B.2.l. of this final rule on Separate Payment Terms; and section I.B.2.m. of this final rule on SDPs included through Adjustments to Base Capitation Rates.

We proposed these regulatory changes to institute submission timeframes to ensure efficient and proper administration of the Medicaid program. We had also described an alternative of requiring that States submit all amendments to SDPs for written prior approval within either 120 days of the start of the payment arrangement or 120 days of CMS issuing written prior approval, whichever was later. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have 120 days after the start of the payment arrangement (May 1, 2025) to submit any amendment to the preprint for that rating period. After May 1, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. If, however, that SDP were approved after the start of the rating period (for example, October 1, 2025 for a CY 2025 rating period); the State will have 120 days from that written prior approval (January 29, 2026) to submit any amendment to the preprint for CMS review; after January 29, 2026, CMS will not accept any amendments to that SDP for that rating period. Requiring that States submit any amendments to the SDP preprint within 120 days of either the start of the payment arrangement or the initial approval could reduce some administrative burden by limiting the time period for amendments to SDP preprints. However, the timeframe would be specific to each preprint, which could present some challenges in ensuring compliance. Additionally, it would not preclude States from submitting amendments after the end of the rating period; in fact, it may encourage States to submit SDP preprints toward the end of the rating period to preserve the ability to amend the preprint after the end of the rating period. CMS does not believe such practices are in alignment with the prospective nature of risk-based managed care.

We solicited public comment on our proposals and these alternatives, as well as additional options that will also meet our goals for adopting time limits on when SDP preprints are submitted to CMS for approval and when amendments to SDPs can be submitted to CMS for written prior approval.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comments on these proposals.

We summarize and respond to public comments received on SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix)) below.

Comment: We received a wide range of comments on the submission timeframes that we proposed for SDP preprints and amendments in § 438.6(c)(2)(viii) and (ix), as well as alternatives that we described in the proposed rule. Some commenters supported requiring States to submit preprints to CMS at least 90 days prior to end of the rating period as this proposal would provide States the most flexibility. One commenter contended that submission 90 days before the end of the rating period makes it difficult to ensure that there is time for CMS to review the SDP and for States to adequately and accurately update the contract(s) and capitation rate(s) to reflect the approved SDP. Commenters stated concern with States waiting so late into the rating period to submit an SDP preprint for CMS approval, and noted this would very often trigger retroactive contract and capitation rate adjustments, which creates more burden and uncertainty for States, managed care plans, providers, and CMS. One commenter noted that a submission timeframe not linked to the start of a rating period would help States implement SDPs when legislatures pass budgets after the start of a rating period or when they are designed to run less than a full rating period to address urgent access issues. Many of these commenters also supported our proposal in § 438.6(c)(2)(ix)(A) for SDP preprint amendments to be submitted prior to the end of the rating period, but some did not support our proposal in § 438.6(c)(2)(ix)(B) as they noted the differing timeframes by SDP approval duration disadvantaged States using

[79] The term ''rate amendment'' is used to reference an amendment to the initial rate certification.

multi-year SDPs such as VBP arrangements. A few commenters also did not support having submission dates that varied from the initial year to subsequent years as those dates could be hard to track as SDPs changed over time. In contrast, other commenters suggested that SDP preprints be required to be submitted before the start of the rating period to ensure prospective implementation of SDPs. However, some of these commenters stated that 90 days before the rating period was too long and would often conflict with annual rate setting processes. Some commenters supported the alternative described in the proposed rule to use the start date of the payment arrangement instead of the start of the rating period because this enabled States to respond to events during a rating period such as changes to State budgets, other legislative actions, identified access issues, or natural disasters and emergencies most efficiently and in the least burdensome way. Some commenters had overall concerns with the complexity of our proposals on submission timeframes for SDP preprints and preprint amendments and stated that this could lead to States inadvertently missing submission deadlines, particularly during certain situations such as natural disasters.

Response: We appreciate the comments on our proposals in § 438.6(c)(2)(viii) and (ix), as well as on the other SDP preprint submission timeframes alternatives described in the proposed rule (88 FR 28116 and 28117). Since § 438.6(c) was codified in the 2016 final rule, we have encouraged States to submit SDP preprints at least 90 days in advance of the start of the applicable rating period for consistency with the prospective nature of managed care plan contracts and capitation rates, and because it facilitates timely contract and rate certification review and approval by CMS. However, some States have consistently struggled to submit preprints 90 days in advance of the rating period for a multitude of reasons, including State budget processes and unexpected program issues that arose during the rating period. To make our processes more responsive to States' needs while ensuring that contract and rate certification reviews dependent on SDP approvals are not unnecessarily delayed, we proposed a new § 438.6(c)(2)(viii) and (ix) that specified multiple submission timeframes based on the duration of an SDP. While we received comments in support of and in opposition to our proposals in § 438.6(c)(2)(viii) and (ix), the comments persuaded us that our proposal could inadvertently make submission timeframes overly complicated which could exacerbate rather than alleviate submission compliance and hinder States' efforts to respond to unexpected issues. We recognize the need for flexibility for States to propose or revise SDPs to address changes that occur during the rating period that are unexpected or expected but that will not be in effect until after the start of the rating period. However, we also continue to believe that it is important for States to be timely with submissions of SDPs as much as possible to align with contract and rate certification reviews, as well as to facilitate efficient implementation of SDPs by managed care plans. While we appreciate the support provided by commenters for requiring States to submit preprints 90 days before the end of the rating period, we share commenters' concern about the number of retroactive contract and rate adjustments that may be necessitated by approval of an SDP preprint after the end of a rating period. This would create more burden and uncertainty for States, plans, providers, and CMS.

After review of the comments, we reconsidered how to balance timely and accurate SDP preprint submissions with enabling States to be nimble enough to administer efficient and responsive programs. In the discussion in the proposed rule about the alternative of requiring that States submit all SDPs in advance of the start of the payment arrangement, we stated ''This would provide additional flexibility for States establishing new SDPs but would limit the additional flexibility for that SDP to that initial rating period. If the State wanted to renew the SDP the subsequent rating period . . ., it would have to resubmit the preprint before the start of that rating period.'' After reviewing the comments that emphasized the need for State flexibility, we have determined that there is no substantial risk to requiring all SDP preprints to be submitted before the start of payment arrangement and that a single submission timeframe is the most efficient and, least burdensome, and strikes the right balance between the extremes of the start and end of the rating period. As such, we are finalizing the submission timeframe for all SDPs as before the implementation of the payment arrangement as indicated by the start date for the SDP identified in the preprint. The start date specified in the preprint is the date when the managed care plans must implement the payment arrangement, and therefore, we believe a more relevant date upon which to base preprint submission than the start or end of the rating period. We encourage States to submit their preprints as far in advance of an SDP's start date as possible to facilitate approval before the start date. We also remind States that they remain at risk for a disallowance of FFP until and unless we have approved the SDP preprint, when required, as well as the managed care contracts and capitation rates that include the payment arrangement, and all other conditions and requirements for FFP have been satisfied (for example, the prior approval requirement for managed care contracts and the claims timely filing deadline).

To further simplify our regulation text and help States understand their obligations relative to SDP preprint submissions, we are also finalizing that all amendments to SDP preprints must be submitted before the start date of the SDP amendment. We believe these changes will reduce burden for States, managed care plans, and providers, facilitate efficient implementation of SDPs by managed care plans, and promote more timely and accurate processing of SDP amendments.

To reflect these changes, several revisions to the text that was proposed in § 438.6(c)(2)(viii) and (ix) are being finalized in this rule. First, § 438.6(c)(2)(viii) will be revised to specify that States must complete and submit all required documentation for each SDP for which written approval is required before the specified start date of the SDP. Required documentation includes at least the completed preprint and as applicable, the total payment rate analysis and the ACR demonstration as described in § 438.6(c)(2)(iii) and the evaluation plan as required in § 438.6(c)(2)(iv). The deadline we are finalizing means before the first payment to a provider under the SDP (not merely prior to the State's request for FFP for the State's payments to its managed care plans that incorporate the SDPs). Second, proposed § 438.6(c)(2)(viii)(A) through (C) are not being finalized. Third, proposed § 438.6(c)(2)(ix) is not being finalized.

Under § 438.6(c)(2)(viii) as finalized, if the required documentation—meaning a complete SDP preprint or complete amendment to the preprint (inclusive of at least the completed preprint and, as applicable, the total payment rate analysis, the ACR demonstration and the evaluation plan)—is not submitted before the start date specified in the preprint, the SDP or SDP amendment will not be eligible for approval. States must be diligent and ensure that an SDP preprint or

amendment is accurate and complete, as further described in CMCS Informational Bulletin ''Medicaid and CHIP Managed Care Monitoring and Oversight Tools'' published on November 7, 2023.[80] Please note that the required documentation to satisfy § 438.6(c)(2)(viii) does not include the Medicaid managed care contract amendment or rate amendment that accounts for the SDP; the timeframes for submission of contracts and rates that account for SDPs are addressed in section I.B.2.k. and section I.B.2.m. of this final rule.

Comment: A few commenters either opposed instituting a ''hard'' deadline for submission or recommended a provision be added to provide CMS and States additional flexibility to adjust timeframes if determined necessary for the benefit of the Medicaid program and its recipients at CMS's discretion.

Response: We respectfully disagree with commenters. As stated in the preamble of the proposed rule and in our responses to other comments, we believe it is critical to ensure timely processing of contracts and rates, provide transparency for plans and interested parties, align more with the prospective nature of managed care and ensure more timely payment for providers. In addition, this new requirement for when SDP preprints or amendments to preprints must be submitted to CMS for approval before the SDP starts will provide an opportunity to protect program integrity by assuring that the scope and terms of SDPs are described and documented for evaluation against the regulatory requirements before payments under the SDP begin. As noted in the earlier response, if the required documentation—meaning a complete SDP preprint or complete amendment to the preprint (inclusive of at least the completed preprint, the total payment rate analysis, the ACR demonstration and the evaluation plan as applicable) is not submitted before the start date specified in the preprint, the SDP or SDP amendment will not be eligible for approval. We also believe that the submission deadline we are finalizing will provide flexibility to allow States to respond to quickly changing conditions for the benefit of their Medicaid enrollees and programs by tying the submission of the required documentation to before the SDP begins, rather than the beginning or end of the relevant rating period.

Comment: One commenter encouraged CMS to consider an equivalent 90-day timeframe for CMS's review and approval of preprint submissions.

Response: We are committed to working with States to review SDP preprints as expeditiously as possible and encourage States to request technical assistance, particularly for new or complicated proposals, as early as possible before formally submitting preprints. We reiterate that we encourage States to submit preprints as far as possible in advance of the SDP start date to facilitate timely processing of preprints, contracts, and rate certifications.

Comment: One commenter suggested that CMS encourage States to work with their managed care plan partners and share SDP preprints after they are submitted to CMS to facilitate managed care plans' timely and accurate implementation of the SDP.

Response: We agree that while CMS is not requiring States to share SDP preprints with their managed care plans after submission, close collaboration between States and their plans and actuaries facilitates timely and accurate implementation of SDPs. In February 2023, we started publicly posting SDP approvals on Medicaid.gov to facilitate transparency. We encourage States to consider collaborating with both their managed care plans and other partners early in the SDP process.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(viii) to specify that States must complete and submit all required documentation for all SDPs and associated amendments for which written approval is required before the specified start date and are not finalizing paragraphs § 438.6(c)(2)(viii)(A) through (C) and paragraph (ix).

f. Standard for Total Payment Rates for Each SDP, Establishment of Payment Rate Limitations for Certain SDPs, and Expenditure Limit for All SDPs (§§ 438.6(c)(2)(ii)(I), 438.6(c)(2)(iii))

Standard for Total Payment Rates for Each SDP. Section 1903(m)(2)(A)(iii) of the Act requires contracts between States and managed care plans that provide for payments under a risk-based contract for services and associated administrative costs to be actuarially sound. Under section 1902(a)(4) of the Act, CMS also has authority to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan. Under CMS regulations and interpretations of section 1903(m)(2)(A)(iii) of the Act, actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the period and the population covered under the terms of the contract. In risk-based managed care, managed care plans have the responsibility to manage the financial risk of the contract, and one of the primary tools plans use is negotiating payment rates with providers. Absent Federal statutory or regulatory requirements or specific State contractual restrictions, the specific payment rates and conditions for payment between risk-bearing managed care plans and their network providers are subject to negotiations between the plans and providers, as well as overall private market conditions. As long as plans are meeting the requirements for ensuring access to care and network adequacy, States typically provide managed care plans latitude to develop a network of providers to ensure appropriate access to covered services under the contract for their enrollees and fulfill all of their contractual obligations while managing the financial risk.

As noted earlier, both the volume of SDP preprints being submitted by States for approval and the total dollars flowing through SDPs have grown steadily and quickly since § 438.6(c) was issued in the 2016 final rule. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion in 2020.[81] Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through the end of fiscal year 2022, provides that the total spending approved for each SDP for the most recent rating period for States is nearly $52 billion annually[82] with at least half of that spending representing payments that States are requiring be paid in

[80] *https://www.medicaid.gov/sites/default/files/2023-11/cib11072023.pdf.*

[81] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' *June 2022, available at https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*

[82] This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through the end of fiscal year 2022, under CMS's standard review process. Rating periods differ by State; some States operate their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of the end of fiscal year 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

addition to negotiated rates.[83] This $52 billion figure is an estimate of annual spending. As SDP spending continues to increase, we believed it is appropriate to apply additional regulatory requirements for the totality of provider payment rates under SDPs to ensure proper fiscal and programmatic oversight in Medicaid managed care programs, and we proposed several related regulatory changes as well as exploring other potential payment rate and expenditure limits.

As noted in the 2016 final rule, section 1903(m)(2)(A)(iii) of the Act requires that contracts between States and Medicaid managed care organizations for coverage of benefits use prepaid payments to the entity that are actuarially sound. By regulation based on section 1902(a)(4) of the Act, CMS extended the requirement for actuarially sound capitation rates to PIHPs and PAHPs. The regulations addressing actuarially sound capitation rates are at §§ 438.4 through 438.7.

Federal requirements at § 438.6(c)(2) specify that SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5 and generally accepted actuarial principles and practices. Under the definition in § 438.4, actuarially sound capitation rates are ''projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract . . .'' Consistent with this definition in § 438.4, we noted in the State Medicaid Director Letter #21–001 published on January 8, 2021 that CMS requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process. We proposed to codify this standard regarding the provider payment rates for each SDP more clearly in the regulation. As part of the proposed revisions in § 438.6(c)(2)(ii) to specify the standards that each SDP must meet, we proposed a new standard at § 438.6(c)(2)(ii)(I) to codify our current policy that each SDP ensure that the total payment rate for each service, and each provider class included in the SDP must be reasonable, appropriate, and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. We proposed in § 438.6(a) to define ''total payment rate'' as the aggregate for each managed care program of: (1) the average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the SDP; (2) the effect of the SDP on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; (3) the effect of any and all other SDPs on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; and (4) the effect of any and all allowable pass-through payments, as defined in § 438.6(a), paid to any and all providers in the provider class specified in the SDP for which the State is seeking written prior approval on the average rate paid to providers in the specified provider class. We noted that while the total payment rate described above is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. We assess if the total payment level across all SDPs in a managed care program is reasonable, appropriate, and attainable.

We noted that § 438.6(c)(1)(iii)(A) describes an SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service. As finalized in section I.B.2.c. of this final rule, § 438.6(c)(1)(iii)(B) describes an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate that was in effect no more than 3 years prior to the start of the applicable rating period for a particular service. An SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service does not currently require prior written approval by CMS per § 438.6(c)(2)(ii), and we proposed in § 438.6(c)(2)(i) to not require written prior approval for an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate. We also believe that both of these specific payment rates will be (and therefore meet the requirement that) reasonable, appropriate, and attainable because CMS has reviewed and determined these payment rates to be appropriate under the applicable statute and implementing regulations for Medicaid and Medicare respectively. However, for other SDP arrangements, additional analysis and consideration is necessary to ensure that the payment rates directed by the State meet the standard of reasonable, appropriate, and attainable.

The proposed standard at § 438.6(c)(2)(ii)(I) also included a requirement that upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. While we did not propose to require States to provide documentation in a specified format to demonstrate that the total payment rate is reasonable, appropriate, and attainable for all services (see section I.B.2.f. for documentation requirements for some SDPs), we intend to continue requesting information from all States for all SDPs documenting the different components of the total payment rate using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. We formalized this process in the revised preprint form [84] published in January 2021, and described it in the accompanying SMDL. We noted in the proposed rule that we will continue to review and monitor all payment rate information submitted by States for *all* SDPs as part of our oversight activities and to ensure managed care payments to providers under SDPs are reasonable, appropriate, and attainable. Based on our ongoing monitoring of payment rates, we may issue guidance further detailing documentation requirements and a specified format to demonstrate that the total payment rate is reasonable, appropriate, and attainable for all services. We solicited comments on our proposed changes.

Establishment of Payment Rate Limitations for Certain SDPs. Some entities, including MACPAC [85] and GAO,[86] have released reports focused on SDPs. Both noted concerns about the growth of SDPs and lack of a regulatory payment ceiling on the amounts paid to providers under an SDP. Our proposed standard at § 438.6(c)(2)(ii)(I) will codify our current practice of determining whether the total payment rate is

[83] As part of the revised preprint form, States are requested to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates versus limiting or replacing negotiated rates. Approximately half of the total dollars identified for the SDP actions included were identified by States for payment arrangements that required plans to pay an amount in addition to the rates negotiated between the plan and provider(s) rates.

[84] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[85] *https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicaid-and-chip/ June 2022 Report to Congress on Medicaid and CHIP, Chapter 2.*

[86] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' *June 28, 2022, available at https://www.gao.gov/assets/gao-22-105731.pdf.*

reasonable, appropriate, and attainable for each SDP. However, neither in our guidance nor in our proposed regulatory requirement at § 438.6(c)(2)(ii)(I) have we defined the terms ''reasonable, appropriate, and attainable'' as they are used for SDPs. To address this, we proposed several regulatory standards to establish when the total payment rates for certain SDPs are reasonable, appropriate, and attainable. We proposed to adopt at § 438.6(c)(2)(iii) both specific standards and the documentation requirements necessary for ensuring compliance with the specific standards for the types of SDPs described in paragraphs (c)(1)(i), (ii), and (iii)(C) through (E) where the SDP is for one or more of the following types of services: inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center.

To explain and provide context for proposed new paragraph (c)(2)(iii), we discussed the historical use of the average commercial rate (ACR) benchmark for SDPs, the proposed payment limit for inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services (including proposed definitions for these types of services) and some alternatives considered, the proposed requirement for States to demonstrate the ACR, and the proposed requirements for States to demonstrate compliance with the ACR and total payment rate comparison requirement. We have included further sub-headers to help guide the reader through this section.

1. Historical Use of the Average Commercial Rate Benchmark for SDPs

In late 2017, we received an SDP preprint to raise inpatient hospital payment rates broadly that would result in a total payment rate that exceeded 100 percent of Medicare rates in that State, but the payments would remain below the ACR for that service and provider class in that State. We had concerns about whether the payment rates were still reasonable, appropriate, and attainable for purposes of CMS approval of the SDP as being consistent with the existing regulatory requirement that all SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices. We realized that approving an SDP that exceeded 100 percent of Medicare rates would be precedent-setting for CMS. We explored using an internal total payment rate benchmark that could be applied uniformly across all SDPs to evaluate preprints for approval and to ensure that payment is reasonable, appropriate, and attainable.

Medicare is a significant payer in the health insurance market and Medicare payment is a standardized benchmark used in the industry. Medicare payment is also a benchmark used in Medicaid FFS, including the Upper Payment Limits (UPLs) that apply to classes of institutional providers, such as inpatient and outpatient hospitals, clinics, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), that are based on a reasonable estimate of the amount that Medicare would pay for the Medicaid services. The UPLs apply an aggregate payment ceiling based on an estimate of how much Medicare would have paid in total for the Medicaid services as a mechanism for determining economy and efficiency of payment for State plan services while allowing for facility-specific payments.[87] Generally for inpatient and outpatient services, these UPL requirements apply to three classes of facilities based on ownership status: State-owned, non-State government-owned, and private. Hospitals within a class can be paid different amounts and facility-specific total payment rates can vary, sometimes widely, so long as in the aggregate, the total amount that Medicaid paid across the class is no more than what Medicare would have paid to those providers for those services. When considering the Medicaid FFS UPL methodologies, we had some concerns that applying the same standards for the total payment rate under SDPs to three classes based on ownership status, would not be appropriate for implementing the SDP requirements.

Currently, § 438.6(c)(2)(ii)(B) (which requires SDPs to direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the managed care contract) provides States with broader flexibility than what is required for FFS UPLs in defining the provider class for which States can implement SDPs. This flexibility has proven important for States to target their efforts to achieve their stated policy goals tied to their managed care quality strategy. For example, CMS has approved SDPs where States proposed and implemented SDPs that applied to provider classes defined by criteria such as participation in State health information systems. In other SDPs, the eligible provider class was established by participation in learning collaboratives which were focused on health equity or social determinants of health. In both cases, the provider class under the SDP was developed irrespective of the facility's ownership status. These provider classes can be significantly wider or narrower than the provider class definitions used for Medicaid UPL demonstrations in Medicaid FFS. Therefore, the provider classes in some approved SDPs did not align with the classes used in Medicaid FFS UPL demonstrations, which are only based on ownership or operation status (that is, State government-owned or operated, non-State government-owned or operated, and privately-owned and operated facilities) and include all payments made to all facilities that fit in those ownership-defined classes. Not all providers providing a particular service in Medicaid managed care programs must be included in an SDP. Under § 438.6(c)(2)(ii)(B), States are required to direct expenditures equally, using the same terms of performance, for a *class* of providers furnishing services under the contract; however, they are not required to direct expenditures equally using the same terms of performance for *all providers* providing services under the contract.

Without alignment across provider classes, CMS could have faced challenges in applying a similar standard of the Medicaid FFS UPL to each provider class that the State specified in the SDP irrespective of how each provider class that the State specified in the SDP compared to the ownership-defined classes used in the Medicaid FFS UPL. Given the diversity in provider classes States have proposed and implemented under SDPs approved by CMS at the time (and subsequently), combined with the fact that not all providers of a service under the contract are necessarily subject to the SDP, CMS had concerns that applying the Medicaid FFS UPL to each provider class under the SDP could have resulted in situations in managed care where provider payments under SDPs would not align with Medicaid FFS policy. In some instances, payments to particular facilities could potentially be significantly higher than allowed in Medicaid FFS, and in others, facility-specific payments could potentially be significantly lower than allowed in Medicaid FFS.

We note that States have been approved to make Medicaid FFS supplemental payments up to the ACR

[87] The Upper Payment Limit regulations for FFS Medicaid are §§ 447.272 (inpatient hospital services), 447.321 (outpatient hospital services) and 447.325 (other inpatient and outpatient facility services).

for qualified practitioners affiliated with and furnishing services (for example, physicians under the physician services benefit) in academic medical centers, physician practices, and safety net hospitals.[88] CMS had previously approved SDPs that resulted in total payment rates up to the ACR for the same providers that States had approved State plan authority to make supplemental payments up to the ACR in Medicaid FFS. Additionally, while CMS does not review the provider payment rate assumptions for all services underlying Medicaid managed care rate development, we had recently approved Medicaid managed care contracts in one State where plans are paid capitation rates developed assuming the use of commercial rates paid to providers for all services covered in the contract.

For these reasons, in 2018, CMS ultimately interpreted the current § 438.6(c)(2)(i) (which we proposed to re-designate as § 438.6(c)(2)(ii)(I) and (J) along with revisions to better reflect our interpretation) to allow total payment rates in an SDP up to the ACR. The statutory and regulatory requirements for the UPL in Medicaid FFS do not apply to risk-based managed care plans; therefore, permitting States to direct MCOs, PIHPs, or PAHPs to make payments higher than the UPL does not violate any current Medicaid managed care statutory or regulatory requirements. We adopted ACR as the standard benchmark for all SDPs. This standard benchmark for all SDPs applied ACR more broadly (that is, across more services and provider types) than allowed under Medicaid FFS, due to the Medicare payment-based UPLs applicable in FFS. Our rationale in 2018 for doing so was that using the ACR allowed States more discretion than the Medicaid FFS UPL because it allows States to ensure that Medicaid managed care enrollees have access to care that is comparable to access for the broader general public. Also, we believe using the ACR presented the least disruption for States as they were transitioning existing, and often long-standing, pass-through payments[89] into SDPs, while at the same time providing a ceiling for SDPs to protect against the potential of SDPs threatening States' ability to comply with our interpretation of current § 438.6(c)(2)(i) that total provider payment rates resulting from SDPs be reasonable, appropriate, and attainable. Finally, using the ACR provided some parity with Medicaid FFS payment policy for payments for qualified practitioners affiliated with and furnishing services at academic medical centers, physician practices, and safety net hospitals where CMS has approved rates up to the ACR.[90]

Since 2018, we have used the ACR as a benchmark for total payment rates for all SDP reviews. Under this policy, States have had to document the total payment rate specific to each service type included in the SDP and specific to each provider class identified. For example, if an SDP provided a uniform increase for inpatient and outpatient hospital services with two provider classes (rural hospitals and non-rural hospitals), the State is required to provide an analysis of the total payment rate (average base rate paid by plans, the effect of the SDP, the effect of any other approved SDP(s), and the effect of any permissible pass-through payments) using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. In the example above, the State is required to demonstrate the total payment rates for inpatient services for rural hospitals, inpatient services for non-rural hospitals, outpatient services for rural hospitals and outpatient services for non-rural hospitals separately. We formalized this process in the revised preprint form[91] published in January 2021, and described it in the accompanying SMDL. While CMS has collected this information for each SDP submitted for written prior approval, we historically requested the impact not only of the SDP under review, but any other payments required by the State to be made by the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period.

When a State has not demonstrated that the total payment rate for each service and provider class included in each SDP arrangement is at or below either the Medicare or Medicaid FFS rate (when Medicare does not cover the service), CMS has requested documentation from the State to demonstrate that the total payment rates that exceed the Medicare or the Medicaid FFS rate do not exceed the ACR for the service and provider class. CMS has worked with States to collect documentation on the total payment rate, which has evolved over time. CMS has not knowingly approved an SDP where the total payment rate, inclusive of all payments made by the plan to all of the providers included in the provider class for the same rating period, was projected to exceed the ACR.

2. Proposed Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at Academic Medical Centers, and Nursing Facility Services

While CMS has not knowingly approved an SDP that included payment rates that are projected to exceed the ACR, States are increasingly submitting preprints that will push total payment rates up to the ACR. Therefore, we

[88] CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on Medicaid.gov at *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html*. Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used*. As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

[89] Pass-through payments are defined in § 438.6(a) as, ''any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for a specific service or benefit provided to a specific enrollee covered under the contract, a provider payment methodology permitted under § 438.6(c), a sub-capitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments.''

[90] CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on Medicaid.gov. Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used*. As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

[91] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf*.

proposed to move away from the use of an internal benchmark to a regulatory limit on the total payment rate, using the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services. We also considered other potential options for this limit on total payment rate for these four services.

CMS believes that using the ACR as a limit is appropriate as it is generally consistent with the need for managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to care for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services.

While Medicaid is a substantial payer for these services, it is not the most common payer for inpatient hospital, outpatient hospital and qualified practitioner services at an academic medical center. Looking at the National Health Expenditures data for 2020, private health insurance paid for 32 percent of hospital expenditures, followed by Medicare (25 percent) and Medicaid (17 percent). There is a similar breakdown for physician and clinical expenditures—private health insurance pays for 37 percent of physician and clinical expenditures, followed by Medicare (24 percent) and Medicaid (11 percent).[92] For these three services, commercial payers typically pay the highest rates, followed by Medicare, followed by Medicaid.[93] [94] [95] [96]

Based on both CMS's experience with SDPs for inpatient hospital services, outpatient hospital services and qualified practitioner services at an academic medical center as well as data from the National Health Expenditure survey and other external studies examining payment rates across Medicaid, Medicare and the commercial markets, we believe that for these three services, the ACR payment rate limit will likely be reasonable, appropriate, and attainable while allowing States the flexibility to further State policy objectives through implementation of SDPs.

We also believe that this proposed ACR payment rate limit aligns with the SDP actions submitted to CMS. Based on our internal data collected from our review of SDPs, the most common services for which States seek to raise total payment rates up to the ACR are qualified practitioner services at academic medical centers, inpatient hospital services, and outpatient hospital services. Looking at approvals since 2017 through March 2022, we have approved 145 preprint actions that were expected to yield SDPs equal to the ACR: 33 percent of these payments are for professional services at academic medical centers; 18 percent of these payments are for inpatient hospital services; 17 percent of these payments are for outpatient hospital services; 2 percent are for nursing facilities. Altogether, this means that at least two thirds of the SDP submissions intended to raise total payment rates up to the ACR were for these four provider classes. While States are pursuing SDPs for other types of services, very few States are pursuing SDPs that increase total payment rates up to the ACR for those other categories or types of covered services.

While there have not been as many SDP submissions to bring nursing facilities up to a total payment rate near the ACR, there have been a few that have resulted in notable payment increases to nursing facilities. In the same internal analysis referenced above, 2 percent of the preprints approved that were expected to yield SDPs equal to the ACR were for nursing facilities. There have also been concerns raised as part of published audit findings about a particular nursing facility SDP.[97] Therefore, we proposed to include these four services—inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services—in § 438.6(c)(2)(iii) and limit the total payment rate for each of these four services to ACR for any SDP arrangements described in paragraphs (c)(1)(i) through (iii), excluding (c)(1)(iii)(A) and (B), that are for any of these four services. States directing MCO, PIHP or PAHP expenditures in such a manner that results in a total payment rate above the ACR for any of these four types of services will not be approvable under our proposal. Such arrangements will violate the standard proposed in § 438.6(c)(2)(ii)(I) that total payment rates be reasonable, appropriate, and attainable and the standard proposed in § 438.6(c)(2)(iii) codifying specific payment level limits for certain types of SDPs. We noted that while the total payment rate is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. The proposed total payment limit will apply across all SDPs in a managed care program; States will not be able to, for example, create multiple SDPs that applied, in part or in whole, to the same provider classes and be projected to exceed the ACR. These proposals are based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound and in order to apply these requirements to PIHPs and PAHPs as well as MCOs, we rely on our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan.

For some services where Medicaid is the most common or only payer (such as HCBS,[98] mental health services,[99] substance use disorder services,[100] and

[92] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.*

[93] Congressional Budget Office, ''The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services,'' January 2022, available at *https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf.*

[94] E. Lopez, T. Neumann, ''How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature,'' Kaiser Family Foundation, April 15, 2022, available at *https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/.*

[95] Medicaid and CHIP Payment and Access Commission, ''Medicaid Hospital Payment: A Comparison across States and to Medicare,'' April 2017, available at *https://www.macpac.gov/wp-content/uploads/2017/04/Medicaid-Hospital-Payment-A-Comparison-across-States-and-to-Medicare.pdf.*

[96] C. Mann, A. Striar, ''How Differences in Medicaid, Medicare, and Commercial Health Insurance Payment Rates Impact Access, Health Equity, and Cost,'' The Commonwealth Fund, August 17, 2022, available at *https://www.commonwealthfund.org/blog/2022/how-differences-medicaid-medicare-and-commercial-health-insurance-payment-rates-impact.*

[97] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[98] The National Health Expenditures data for 2020 who that Medicaid is the primary payer for other health, residential and personal care expenditures, paying for 58 percent of such expenditures where private insurance only paid for 7 percent of such services. For home health care expenditures, Medicare paid for 34 percent of such services, followed by Medicaid at 32 percent followed by private insurance (13 percent.) *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.*

[99] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html.*

[100] *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/.*

obstetrics and gynecology services [101] [102]), interested parties have raised concerns about a number of issues surrounding these services, including quality and access to care. For some of these services States have found it difficult to determine the appropriate payment rate to allow them to further their overall Medicaid program goals and objectives. For example, one State shared data from its internal analysis of the landscape of behavioral health reimbursement in the State that showed Medicaid managed care reimbursement for behavioral health services is higher than commercial reimbursement. Further, a study [103] authorized through Oregon's Legislature outlined several disparities in behavioral health payment, including a concern that within the commercial market, behavioral health providers often receive higher payment rates when furnishing services to out-of-network patients, potentially reducing incentives for these providers to join Medicaid managed care or commercial health plan networks.

We acknowledged that some States have had difficulty with providing payment rate analyses that compare a particular payment rate to the ACR, including for services other than inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers. For example, based on our experience, some States have found it difficult to obtain data on commercial rates paid for HCBS. States have stated that commercial markets do not generally offer HCBS, making the availability of commercial rates for such services scarce or nonexistent. This same concern has been raised for other services, such as behavioral health and substance use disorder services, among others, where Medicaid is the most common payer and commercial markets do not typically provide similar levels of coverage.

Therefore, we did not propose at this time to establish in § 438.6(c)(2)(iii) payment rate ceilings for each SDP for services other than inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers that States include in SDPs. While SDPs for all other services will still need to meet the proposed standard at § 438.6(c)(2)(ii)(I) that the total payment rate for each SDP (meaning the payment rate to providers) is reasonable, appropriate, and attainable, we noted that we believe further research is needed before codifying a specific payment rate limit for these services. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities and to ensure managed care payments are reasonable, appropriate, and attainable. Depending on our future experience, we may revisit this issue as necessary.

For clarity and consistency in applying these proposed new payment limits, we proposed to define several terms in § 438.6(a), including a definition for ''inpatient hospital services'' that will be the same as specified at 42 CFR 440.10, ''outpatient hospital services'' that will be the same as specified in § 440.20(a) and ''nursing facility services'' that will be the same as specified at § 440.40(a). Relying on existing regulatory definitions will prevent confusion and provide consistency across Medicaid delivery systems.

We also proposed definitions in § 438.6(a) for both ''academic medical center'' and ''qualified practitioner services at an academic medical center'' to clearly articulate which SDP arrangements will be limited based on the proposed payment rate. We proposed to define ''academic medical center'' as a facility that includes a health professional school with an affiliated teaching hospital. We proposed to define ''qualified practitioner services at an academic medical center'' as professional services provided by physicians and non-physician practitioners affiliated with or employed by an academic medical center.

We did not propose to establish a payment rate ceiling for qualified practitioners that are not affiliated with or employed by an academic medical center. We have not seen a comparable volume or size of SDP preprints for provider types not affiliated with hospitals or academic medical centers, and we believe establishing a payment ceiling will likely be burdensome on States and could inhibit States from pursuing SDPs for providers such as primary care physicians and mental health providers; we sought comment on this issue. Depending on our future experience, we may revisit this policy choice in the future but until then, qualified practitioner services furnished at other locations or settings will be subject to the general standard we currently use that is proposed to be codified at § 438.6(c)(2)(ii)(I) that total payment rates for each service and provider class included in the SDP must be reasonable, appropriate, and attainable.

In the proposed rule, we noted our position that establishing a total payment rate limit of the ACR for these four services appropriately balances the need for additional fiscal guardrails while providing States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. In our view, utilizing the ACR in a managed care delivery system is appropriate and acknowledges the market dynamics at play to ensure that managed care plans can build provider networks that are comparable to the provider networks in commercial health insurance and ensure access to care for managed care enrollees. However, as we monitor implementation of this SDP policy, in future rulemaking we may consider establishing additional criteria for approval of SDPs at the ACR, such as meeting minimum thresholds for payment rates for primary care and behavioral health, to ensure the State and its managed care plans are providing quality care to Medicaid and CHIP enrollees and to support State efforts to further their overall program goals and objectives, such as improving access to care. These additional criteria could incorporate a transition period to mitigate any disruption to provider payment levels.

Codifying a payment rate limit of ACR for these four service types may incent States and interested parties to implement additional payment arrangements that raise total payment rates up to the ACR for other reasons beyond advancing access to care and enhancing quality of care in Medicaid managed care. Most SDPs that increase total payment rates up to the average commercial rate are primarily funded by either provider taxes, IGTs, or a combination of these two sources of the non-Federal share. These SDPs represent some of the largest SDPs in terms of total dollars that are required to be paid in addition to base managed care rates. We are concerned about incentivizing States to raise total payment rates up to the ACR based on the source of the non-Federal share, rather than based on furthering goals and objectives outlined in the State's managed care quality strategy. To mitigate this concern, which is shared

[101] *https://www.acog.org/advocacy/policy-priorities/medicaid.*

[102] *https://www.kff.org/womens-health-policy/issue-brief/medicaid-coverage-for-women/.*

[103] J. Zhu, *et al.,* ''Behavioral Health Workforce Report to the Oregon Health Authority and State Legislature,'' February 1, 2022, available at *https://www.oregon.gov/oha/ERD/SiteAssets/Pages/Government-Relations/Behavioral%20Health%20Workforce%20Wage%20Study%20Report-Final%20020122.pdf.*

not only by CMS but oversight bodies and interested parties such as MACPAC,[104] we proposed additional regulatory changes related to financing the non-Federal share; see section I.B.2.g. of the proposed rule and section I.B.2.g. of this final rule for further information.

In light of these concerns, the proposed rule described several alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. One alternative discussed was establishing the total payment rate limit at the Medicare rate; this is a standardized benchmark used in the industry and is often a standard utilized in Medicaid FFS under UPL demonstrations in 42 CFR part 447. The Medicare rate is also not based on proprietary commercial payment data, and the payment data could be verified and audited more easily than the ACR. A total payment rate limit at the Medicare rate may limit the growth in payment rates more than limiting the total payment rate to the ACR. We also considered, and solicited feedback on, establishing a total payment rate limit for all services, not limited to just these four services, for all SDP arrangements described in § 438.6(c)(1)(i), (ii), and (iii)(C) through (E) at the Medicare rate in the final rule. We invited public comments on these alternatives.

We also noted our concerns about whether Medicare is an appropriate payment rate limit for managed care payments given the concerns and limitations we noted earlier in the ''Historical Use of the Average Commercial Rate Benchmark for SDPs'' section in section I.B.2.f. of the proposed rule, such as provider class limitations. Additionally, Medicare payment rates are developed for a population that differs from the Medicaid population. For example, Medicaid covers substantially more pregnant women and children than Medicare. Although Medicaid FFS UPLs are calculated as a reasonable estimate of what Medicare would pay for Medicaid services and account for population differences across the programs, it can be a challenging exercise to do so accurately. Therefore, we sought public comment to further evaluate if Medicare will be a reasonable limit for the total provider rate for the four types of services delivered through managed care that we proposed, all services, and/or additional types of services. Beneficiaries enrolled in a Medicaid managed care plan are often more aligned with individuals in commercial health insurance (such as, adults and kids), whereas the Medicaid FFS population is generally more aligned with the Medicare population (older adults and individuals with complex health care needs). To acknowledge the challenges in calculating the differences between the Medicaid and Medicare programs, we solicited feedback on whether the total payment rate limit for each SDP for these four services should be set at some level between Medicare and the ACR, or a Medicare equivalent of the ACR in the final rule. We invited public comments on these alternatives.

In considering these potential alternatives, we solicited comment on whether robust quality goals and objectives should be a factor in setting a total payment rate limit for each SDP for these four types of services. Specifically, we described including a provision permitting a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services at the ACR, while limiting the total payment rate for any SDP arrangements described in § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. As we noted earlier, one of the benefits of establishing a total payment rate limit of the ACR for these four services is State flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. One alternative we considered in the proposed rule was an additional fiscal guardrail compared to our proposal by limiting the total payment rate for these four services to ACR for value-based initiatives only and further limiting the total payment rate for these four services to the Medicare rate for fee schedule arrangements (for example, uniform increases, minimum or maximum fee schedules). This alternative would account for the importance of robust quality outcomes and innovative payment models and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees while limiting higher payment rates used when quality outcomes or quality driven payment models are not being used. We invited public comments on whether this potential alternative should be included in the final rule.

We acknowledged that some States currently have SDPs that have total payment rates up to the ACR and that these alternative proposals could be more restrictive. Under the alternative proposals, States could need to reduce funding from current levels, which could have a negative impact on access to care and other health equity initiatives. We also sought public comment on whether CMS should consider a transition period in order to mitigate any disruption to provider payment levels if we adopt one of the alternatives for a total payment rate limit on SDP expenditures in the final rule.

We sought public comment on our proposal to establish a payment rate limit for SDP arrangements at the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services. Additionally, we solicited public comment on the alternatives we considered for a payment rate limit at the Medicare rate, a level between Medicare and the ACR, or a Medicare equivalent of the ACR for these four service types. We also solicited public comment on whether the final rule should include a provision establishing a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDP arrangements described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate.

3. Average Commercial Rate Demonstration Requirements

To ensure compliance with the proposed provision that the total payment rate for SDPs that require written prior approval from CMS for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical centers and nursing facility services do not exceed the ACR for the applicable services subject to the SDP, CMS will need certain information and documentation from the State. Therefore, we proposed in

[104] MACPAC's report noted, ''The largest directed payment arrangements are typically targeted to hospitals and financed by them. Of the 35 directed payment arrangements projected to increase payments to providers by more than $100 million a year, 30 were targeted to hospital systems and at least 27 were financed by provider taxes or IGTs. During our interviews, interested parties noted that the amount of available IGTs or provider taxes often determined the total amount of spending for these types of arrangements. Once this available pool of funding was determined, States then worked backward to calculate the percentage increase in provider rates. Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

§ 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration (which will document the average commercial rate using data in alignment with the requirements we are finalizing at § 438.6(c)(2)(iii)(A)); and (2) a total payment rate comparison to the ACR at § 438.6(c)(2)(iii)(B). We proposed the timing for these submissions in § 438.6(c)(2)(iii)(C). Under our proposal, the ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the applicability date of this section and then updated at least every 3 years, so long as the State continues to include the SDP in one or more managed care contracts. The total payment rate comparison to the ACR would be submitted with the preprint as part of the request for approval of each SDP and updated with each subsequent preprint submission (each amendment and renewal).

At § 438.6(c)(2)(iii)(A), we proposed to specify the requirements for demonstration of the ACR if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. This demonstration must use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to FQHCs, RHCs and any non-commercial payers such as Medicare; and (6) excludes any payment data for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP. We considered QHPs operating in the Marketplaces to be commercial payers for purposes of this proposed provision, and therefore, payment data from QHPs should be included when available.

At § 438.6(c)(2)(iii)(A)(*1*), States would be required to use payment data specific to the State for the analysis, as opposed to regional or national analyses, to provide more accurate information for assessment. Given the wide variation in payment for the same service from State to State, regional or national analyses could be misleading, particularly when determining the impact on capitation rates that are State-specific. Additionally, each State's Medicaid program offers different benefits and has different availability of providers. We currently request payment rate analyses for SDPs to be done at a State level for this reason and believe it will be important and appropriate to continue to do so.

At § 438.6(c)(2)(iii)(A)(*2*), we proposed to require States to use data that is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section. This will ensure that the data are reflective of the current managed care payments and market trends. It also aligns with rate development standards outlined in § 438.5. For example, for the ACR demonstration for an SDP seeking written prior approval for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services for a CY 2025 rating period, the data used must be from calendar year 2021 and later. We used a calendar year for illustrative purpose only; States must use their rating period timeframe for their analysis.

We proposed at § 438.6(c)(2)(iii)(A)(*3*) to require States to use data that is specific to the service type(s) included in the SDP, which would be a change from current operational practice. In provider payment rate analyses for SDPs currently, States are required to compare the total payment rate for each service and provider class to the corresponding service and provider class specific ACR. For example, States requiring their managed care plans to implement SDPs for inpatient hospital services for three classes of providers—rural hospitals, urban hospitals, and other hospitals—will have to produce payment rate analyses specific to inpatient hospital services in rural hospitals, inpatient hospital services in urban hospitals, and inpatient hospital services in other hospitals separately. Under our current operational practice, if the total payment rate for any of these three provider classes exceeds Medicare payment rates, CMS requests the State provide documentation demonstrating that the total payment rate does not exceed the ACR specific to both that service and that provider class. As noted later in this same section, we proposed in § 438.6(c)(2)(iii)(B), to continue to require States to produce the total payment rate comparison to the ACR at a service and provider class level. However, our proposal to codify a requirement for an ACR demonstration includes changes to our approach to determining the ACR and would require States to submit the ACR demonstration, irrespective of if the total payment rate were at or below the Medicare rate or State plan rate for all preprints seeking written prior approval for the four services.

During our reviews of SDP preprints since the 2016 final rule, it has become clear that requiring an ACR analysis that is specific both to the service and provider class can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries. For example, we have often heard from States that rural hospitals commonly earn a larger share of their revenue from the Medicaid program than they do from commercial payers. There is also evidence that rural hospitals tend to be less profitable than urban hospitals and at a greater risk of closure.[105] These hospitals often serve a critical role in providing access to services for Medicaid beneficiaries living in rural areas where alternatives to care are very limited or non-existent. If States want to target funding to increase reimbursement for hospital services to rural hospitals, limiting the ceiling for such payments to the ACR for rural hospitals only will result in a lower ceiling than if the State were to broaden the category to include hospitals with a higher commercial payer mix (for example, payment data for hospital services provided at a specialty cardiac hospital, which typically can negotiate a higher rate with commercial plans). However, in doing so, the existing regulatory requirement for SDPs at § 438.6(c)(2)(ii)(B) required that the providers in a provider class be treated the same—meaning they get the same uniform increase. In some cases, this has resulted in States not being able to use Medicaid funds to target hospitals that provide critical services to the Medicaid population, but instead using some of those Medicaid funds to provide increases to hospitals that serve a lower share of Medicaid beneficiaries.

In another example to demonstrate the potential effects of requiring an ACR analysis that is specific to both the service and provider class level, a State could seek to implement an SDP that will provide different increases for different classes of hospitals (for example, rural and urban public hospitals will receive a higher percentage increase than teaching hospitals and short-term acute care hospitals). The SDP preprint could

[105] MACPAC Issue Brief, ''Medicaid and Rural Health.'' Published April 2021 *https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf.*

provide for separate additional increases for hospitals serving a higher percentage of the Medicaid population and certain specialty services and capabilities. However, if the average base rate that the State's Medicaid managed care plans paid was already above the ACR paid for services to one of the classes (for example, rural hospitals), the State could not apply the same increases to this class as it will the other classes, even if the average base rate paid for the one class was below the ACR when calculated across all hospitals. In this example, the State will be left with the option of either eliminating the one class (for example, rural hospitals) from the payment arrangement or withdrawing the entire SDP proposed preprint even if the State still had significant concerns about access to care as it related to the one class (for example, rural hospitals). The focus on the ACR for the service at the provider class level has the potential to disadvantage providers with less market power, such as rural hospitals or safety net hospitals, which typically receive larger portions of their payments from Medicaid than from commercial payers. These providers typically are not able to negotiate rates with commercial payers on par with providers with more market power.

To provide States the flexibility they need to design SDPs to direct resources as they deem necessary to meet their programmatic goals, we proposed to require an ACR demonstration using payment data specific to the service type (that is, by the specific type of service). This will allow States to provide an ACR analysis at just the service level instead of at the service and provider class level. For example, States could establish a tiered fee schedule or series of uniform increases, directing a higher payment rate to facilities that provide a higher share of services to Medicaid enrollees than to the payment rate to facilities that serve a lower share of services to Medicaid enrollees. States will still have a limit of the ACR, but allowing this to be measured at the service level and not at the service and provider class level will provide States flexibility to target funds to those providers that serve more Medicaid beneficiaries. Based on our experience, facilities that serve a higher share of Medicaid enrollees, such as rural hospitals and safety net hospitals, tend to have less market power to negotiate higher rates with commercial plans. Allowing States to direct plans to pay providers using a tiered payment rate structure based on different criteria, such as the hospital's payer mix, without limiting the total payment rate to the ACR specific to each tier (which will be considered a separate provider class), but rather at the broader service level will provide States with tools to further the goal of parity with commercial payments, which may have a positive impact on access to care and the quality of care delivered. Under this proposal, we would still permit States to elect to provide a demonstration of the ACR at both the service and provider class level or just at the service level if the State chooses to provide the more detailed and extensive analysis, but this level of analysis would no longer be required. We reminded States that the statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (FFS or managed care).

At § 438.6(c)(2)(iii)(B), we proposed to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval of the SDP is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services (that is, inpatient hospital services, outpatient hospital services, nursing facility services or qualified practitioner services at an academic medical center) included in the SDP submitted to CMS for review and approval.

The proposed comparison of the total payment rate to the ACR would align with current practice with one exception. We proposed to codify that the total payment rate comparison will be specific to each Medicaid managed care program to which the SDP under review will apply. Evaluating payment at the managed care program level will be consistent with the payment analysis described in section I.B.1.d. of this final rule. The total payment rate comparison proposed at § 438.6(c)(iii)(B) will be a more detailed analysis than is currently requested from States for SDP reviews. Under our proposal, these more detailed total payment rate comparisons would also have to be updated and submitted with each initial preprint, amendment and renewal per proposed § 438.6(c)(2)(iii)(C). In addition, we proposed that the total payment rate comparison to ACR must be specific to both the service and the provider class; this is current practice today but differs from our proposal for the ACR demonstration, which is proposed to be service specific only.

We have proposed a set of standards and practices States would be required to follow in conducting their ACR analysis. However, we did not propose to require that States use a specific source of data for the ACR analysis. Further, at this time, we did not propose to require States to use a specific template or format for the ACR analysis. In our experience working with States on conducting the analysis of the ACR, the availability of data differs by State and service. States are familiar with the process used for conducting a code-level analysis of the ACR for the qualified practitioner services at academic medical centers for Medicaid FFS.[106] Some States have continued to use this same process for documenting the ACR for SDPs as well, particularly when there is a limited number of providers from which to collect such data (for example, academic medical centers). However, code-level data analysis to determine the ACR has proven more challenging for other services, particularly when that service is provided by large numbers of providers. For example, the number of hospitals furnishing inpatient services in a given State can be hundreds of providers.

Data for inpatient and outpatient hospital service payment rates tend to be more readily available in both Medicare and the commercial markets. States with SDPs for hospital services have provided analyses using hospital cost reports and all-payer claims databases. Others have relied on actuaries and outside consultants, which may have access to private commercial databases, to produce an ACR analysis. At times, States have purchased access to private commercial databases to conduct these analyses. We believe each of these approaches,

[106] *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html.*

provided the data used for the analyses meet the proposed requirements in § 438.6(c)(2)(iii), will be acceptable to meet our proposed requirements.

4. Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance

We proposed at § 438.6(c)(2)(iii)(C) to require States to submit the ACR demonstration and the total payment rate comparison for review as part of the documentation necessary for written prior approval for payment arrangements, initial submissions or renewals, starting with the first rating period beginning on or after the effective date of this rule. The total payment rate comparison will need to be updated with each subsequent preprint amendment and renewal.

In recognition of the additional State resources required to conduct an ACR analysis, we proposed to require that States update the ACR demonstration once every 3 years as long as the State continues to seek to include the SDP in the MCO, PIHP, or PAHP contract. This time period aligns with existing policy for ACR demonstrations for qualified practitioners in Medicaid FFS programs; specifically, those that demonstrate payment at the Medicare equivalent of the ACR.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

Expenditure Limit for SDPs. The increasing use of SDPs by States has been cited as a key area of oversight risk for CMS. Several oversight bodies and interested parties, including MACPAC, Office of Inspector General (OIG), and GAO, have authored reports focused on CMS oversight of SDPs.[107] [108] [109] Both GAO and MACPAC have noted concerns about the growth of SDPs in terms of spending as well as fiscal oversight. Additionally, as States' use of SDPs in managed care programs continues to grow, some interested parties have raised concerns that the risk-based nature of capitation rates for managed care plans has diminished. Medicaid managed care plans generally have the responsibility under risk-based contracts to negotiate with their providers to set payment rates, except when a State believes the use of an SDP is a necessary tool to support the State's Medicaid program goals and objectives. In a risk contract, as defined in § 438.2, a managed care plan assumes risk for the cost of the services covered under the contract and incurs loss if the cost of furnishing the services exceeds the payments under the contract. States' use of SDPs and the portion of total costs for each managed care program varies widely and, in some cases, are a substantial portion of total program costs on an aggregate, rate cell, or category of service basis in a given managed care program or by managed care plan. For example, in one State, one SDP accounted for nine percent of the total projected capitation rates in a given managed care program, and as much as 43 percent of the capitation rates by rate cell for SFY 2023. In another State, SDPs accounted for over 50 percent of the projected Medicaid managed care hospital benefit component of the capitation rates in CY 2022. In a third State, the amount of SDP payments as a percentage of the capitation rates were between 12.5 percent and 40.3 percent by managed care plan and rate cell for SFY 2022. Some interested parties have raised concerns that such percentages are not reasonable in rate setting, and that States are potentially using SDP arrangements to circumvent Medicaid FFS UPLs by explicitly shifting costs from Medicaid FFS to managed care contracts.

In the proposed rule, CMS considered and invited comment on potentially imposing a limit on the amount of SDP expenditures in the final rule based on comments received. Specifically, we sought public comment on whether we should adopt a limit on SDP expenditures in the final rule.

We summarize and respond to public comments received on our proposals regarding the standard for total payment rates for each SDP, the establishment of payment rate limitations for certain SDPs, and the expenditure limit for all SDPs (§ 438.6(c)(2)(ii)(I), 438.6(c)(2)(iii)) below.

Standard for Total Payment Rates for Each SDP (§§ 438.6(a), 438.6(c)(2)(ii)(I))

Comment: Some commenters supported the proposal at § 438.6(c)(2)(ii)(I) that each SDP must ensure that the total payment rate for each service and provider class included in the SDP must be reasonable, appropriate, and attainable but recommended that the standards of ''reasonable, appropriate, and attainable'' be further defined to avoid confusion between States, managed care plans and CMS. One commenter noted that the use of ''reasonable, appropriate, and attainable'' is understood as it relates to capitation rate development, but not in assessing provider rates, providers' costs, or the level of rates that will incentivize providers to accept a Medicaid contract in a given region. We did not receive any comments on the definition of ''total payment rate'' proposed in § 438.6(a).

Response: We appreciate commenters support for our proposal at § 438.6(c)(2)(ii)(I) to require that all SDPs must ensure that the total payment rate for each service and provider class included in the SDP must be reasonable, appropriate, and attainable; and upon CMS request, the State must provide documentation demonstrating the total payment rate for each service and provider class (or, depending on the timing, a projection of the total payment rate for the SDP). We believe that monitoring the total payment rate for all SDPs is important for proper monitoring and oversight, and finalizing this provision codifies an existing standard in the SMDL published on January 8, 2021. We are finalizing the proposed definition of the term ''total payment rate.'' When the total payment rate analysis and documentation are to be submitted with the SDP preprint, it will largely be a projected amount, based on projections of the payments and effects of those payments under the SDP. Therefore, when we are referring specifically to projected amounts, we occasionally use the term ''projected total payment rate'' or something similar. We use the term consistent with the definition throughout this discussion.

In reviewing all SDPs, CMS may request that States provide additional information to assess whether payments to providers are reasonable, appropriate, and attainable. Information specific to each SDP and State Medicaid delivery system may be used and taken into account to assess whether and when that standard is not met for SDPs that are not subject to the more specific standards that we discuss in the section below entitled ''Establishment of Total Payment Rate Limitation for Certain SDPs'' in section I.B.2.f. of this final rule (§§ 438.6(a), 438.6(c)(2)(iii)). To demonstrate whether total payment rates for such services are reasonable, appropriate, and attainable, States could provide an actuarial analysis, use similar Medicaid FFS State plan

[107] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[108] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[109] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' *June 28, 2022, available at https://www.gao.gov/assets/gao-22-105731.pdf.*

services as a comparative benchmark for provider payment analysis or, provide another methodologically sound analysis deemed acceptable by CMS. As finalized in this rule, § 438.6(c)(2)(ii)(I) requires States to provide documentation demonstrating compliance with this requirement upon CMS request for all SDPs. We will continue to review and monitor all projected payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that SDP total payment rates are reasonable, appropriate, and attainable. Further, we clarify here that although we are only finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark by which we will evaluate whether all SDP total payment rates are reasonable, appropriate, and attainable.

We are finalizing the definition of ''Total payment rate'' at § 438.6(a) as proposed. We are also finalizing § 438.6(c)(2)(ii)(I) with minor revisions. First, we are replacing ''must be'' with ''is'' so that subparagraph (I) is consistent with the introductory paragraph in § 438.6(c)(2)(ii) to require that each SDP must ensure the total payment rate standard. Second, we are adding a comma after ''appropriate'' and before the ''and'' for consistency with the requirement at § 438.4(a), and to acknowledge that ''reasonable, appropriate, and attainable'' are distinct components for the assessment of the total payment rate. Finally, we are adding a semicolon after ''attainable'' and removing ''and,'' to ensure a consistent format throughout § 438.6(c)(2)(ii).

Comment: One commenter suggested that CMS revise § 438.6(c)(2)(ii)(I) to require that the total payment rate by provider type rather than for each service and provider class (for example, all hospitals together rather than by provider class) be reasonable, appropriate, and attainable in recognition that some provider classes may be disadvantaged in negotiating higher rates with commercial payers (88 FR 28125–28124).

Response: We appreciate the commenter's suggestion to revise § 438.6(c)(2)(ii)(I) in the final rule. However, given that States have significant flexibility in designing the provider classes eligible for SDPs and that providers can furnish more than one type of service (that is, clinics can provide primary care services and mental health services), we believe it is appropriate to finalize the provision as proposed with minor grammatical and punctuation edits described in the prior response. We reiterate here that we will continue to review and monitor all total payment rates information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that total payment rates are reasonable, appropriate, and attainable.

Comment: Some commenters requested clarification on the State documentation requirement demonstrating the total payment rate by service and provider class specified in § 438.6(c)(2)(ii)(I). One commenter requested that CMS allow a comparison by service category rather than per specific CPT code to avoid administrative burden and provide appropriate transparency and flexibility to balance the interest of all provider classes. One commenter also suggested that this documentation could be a comparison to contiguous or regional State's Medicaid rates when services do not have a Medicaid State plan rate or a Medicare rate, and this commenter noted that this was frequently relied upon by States as they utilize providers that are located on a State's borders or region. Another commentor requested that CMS clarify if States could use an empirical analysis, such as a provider rate study, as sufficient documentation demonstrating the total payment rate for each service and provider class.

Response: In the proposed rule (88 FR 28126), we did not propose to require States to provide documentation in a specified format to demonstrate that the total payment rate is reasonable, appropriate, and attainable for all services using a standardized measure. We do not believe or anticipate that we would request a State to conduct and provide a total payment rate analysis at the CPT code level when exercising our authority under § 438.6(c)(2)(ii)(I) to request documentation demonstrating the total payment rate for each service and provider class. Frequently, States complete total payment rate analyses at the service category level as part of our current SDP review process and it is not our intention for § 438.6(c)(2)(ii)(I) to prohibit this practice. States could choose to conduct this analysis at the CPT code level. For example, some States conduct the total payment rate analysis at the CPT code level if they design their SDPs to focus only on specific CPT codes.

We appreciate the suggestion by commenters that we consider a comparison to contiguous or regional State's Medicaid rates when services do not have a Medicaid State plan rate or a Medicare rate. This issue has not come up very often in SDP reviews, but when it has, it is usually in reference to HCBS delivered in a MLTSS program. In these cases, the States did not provide the services in an FFS delivery system so there was not a comparison point available for the analysis in Medicaid FFS. While we would encourage States to use data that is State specific, § 438.6(c)(2)(ii)(I) (unlike § 428.6(c)(2)(iii)) does not require use of State-specific data. If a State does not utilize State specific data, we recommend that the State provide a rationale in its analysis to reduce questions from CMS during our review.

While we provided examples of standardized measures that have commonly been used in total payment rate analyses such as the Medicaid State plan approved rates or the total published Medicare payment rate, we did not specify that States must use a specific standardized measure. We may issue additional guidance further detailing documentation requirements and a specified format based on our ongoing monitoring and oversight.

Comment: One commenter supported the standards proposed at § 438.6(c)(2)(ii)(I) but recommended CMS go further and revise the proposal to require all States provide documentation demonstrating the total payment rate for each service and provider class under § 438.6(c)(2)(ii)(I), not just at CMS's request, and require that this documentation be available publicly to increase transparency.

Response: We appreciate the commenter's suggestion to expand the documentation requirements included in § 438.6(c)(2)(ii)(I), as finalized. We support increased transparency in States' use of SDPs and with this same aim in mind, we began publishing approved SDP packages starting in February 2023. These approval packages include the final SDP preprint form which includes the analysis of the total payment rate. We additionally noted in the proposed rule (88 FR 28126) that we intend to continue requesting information from all States for all SDPs documenting the different components of the total payment rate as described earlier in section I.B.2.f. of this final rule using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. We formalized this process in the revised

preprint form [110] published in January 2021, and described it in the accompanying SMDL. We reiterate here that we will continue to review and monitor all projected payment rate information submitted by States for *all* SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class in an SDP be reasonable, appropriate, and attainable.

After reviewing public comments, we are finalizing the definition of ''Total payment rate'' at § 438.6(a) and the standard for the provider payment rate applicable to all SDPs at § 438.6(c)(2)(ii)(I) with revisions as described in the above section.

Establishment of Total Payment Rate Limitation for Certain SDPs (§§ 438.6(a), 438.6(c)(2)(iii))

Comment: Many commenters supported finalizing a total payment rate limit that may not exceed the ACR as proposed at § 438.6(c)(2)(iii) for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center. These commenters believe ACR is a reasonable threshold that allows managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to services. Other commenters provided support for this proposal as they believe it is consistent with the goal of equity in payment across delivery systems. Some of the commenters that supported this proposal stated that if accurately calculated, ACR would generally represent an approximation of fair market value for the services provided and would function as an appropriate fiscal guardrail to ensure that individual program spending is reasonable, appropriate, and attainable.

Some commenters stated significant concerns with finalizing a total payment rate limit lower than ACR on any SDP, not just the four services proposed in § 438.6(c)(2)(iii), as they believe a total payment rate limit lower than ACR would be financially destabilizing, would have damaging ramifications on healthcare providers that would affect their ability to provide services to Medicaid patients, potentially threatening the viability of some providers, and this in turn would have devastating consequences on access to and quality of healthcare services for Medicaid patients.

Some of these commenters opposed codifying a total payment rate limit for certain SDPs (that is, SDPs for the four services proposed in § 438.6(c)(2)(iii)) at the Medicare rate as the commenters believe that such a limit would not actually cover the cost of treatment due to many unallowed charges under Medicare payment principles. Many of these commenters noted that implementing Medicare rates as the total payment rate limit for SDPs for these four service types would result in significantly lower payment arrangements for providers that rely on the SDP payments to fill Medicaid payment gaps. Many of these commenters noted that finalizing a total payment rate limit below ACR or at the Medicare rates for these SDPs would reduce the ability of managed care plans to compete with commercial plans for providers to participate in their networks and could result in a reduction of access, particularly for States that already have SDPs at ACR.

Response: We acknowledge the concerns raised by commenters about finalizing a total payment rate limit lower than ACR. One of the primary goals of this rulemaking is to improve beneficiary access to and quality of care. We believe payment policy is a critical component in not only ensuring but improving access to and quality of care for Medicaid beneficiaries. SDPs are an optional tool for States to use to direct how managed care plans pay providers to further the State's overall Medicaid program goals and objectives, including those related to access and health equity. In establishing a total payment rate limit, it was not our intent to restrict States' ability to effectively use SDPs to further the State's overall Medicaid program goals and objectives. Our goal was to balance the need for increased transparency and fiscal integrity with the need for State flexibility to accomplish State policy objectives, such as increasing access to care.

Our internal analysis indicates that establishing a total payment rate limit less than the ACR could result in reductions in total payment rates from existing total payment rate levels for some SDPs, particularly given the number of States with approved SDPs that exceed the Medicare rate. It is difficult to specify the impact such policies would have for each State. States are not required to utilize SDPs and there are separate regulatory requirements that require States that contract with an MCO, PIHP or PAHP to deliver Medicaid services to address network adequacy and access to care, regardless of the use of SDPs. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark, to evaluate whether total payment rates for all SDPs are reasonable, appropriate, and attainable.

As we monitor implementation of this SDP policy, in future rulemaking we may consider establishing additional criteria for approval of SDPs at the ACR, such as meeting minimum thresholds for payment rates for primary care and behavioral health care, to ensure the State and its managed care plans are providing quality care to Medicaid and CHIP enrollees and to support State efforts to further their overall program goals and objectives, such as improving access to care. These additional criteria could incorporate a transition period to mitigate any disruption to provider payment levels.

Comment: Some commenters recommended that CMS finalize a total payment rate limit at the Medicare rate rather than ACR for the four service types. These commenters noted that Medicare rates are published yearly and available to the public, which would increase transparency and predictability of costs and the commenters believe that using Medicare as the threshold for a total payment rate limit is more in alignment with the UPL for Medicaid FFS supplemental payments to hospitals and other institutional providers. A few commenters also supported utilizing the Medicare rate as the total payment rate limit for SDPs for these four services for fiscal integrity reasons as they noted concerns that SDPs increasing payments to the ACR will accelerate hospital consolidation and create strong inflationary pressure on both commercial hospital prices and Federal Medicaid spending.

Response: While we recognize that setting a total payment rate limit at the Medicare rate would provide a strong fiscal guardrail for SDPs, we also recognize that this limit could impact States' efforts to further their overall Medicaid program goals and objectives. Under risk-based managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers at levels that will ensure network adequacy. Subject to certain exceptions, States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan, or to make payments to providers

[110] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). SDPs allow States to direct how managed care plans pay providers to further the State's overall Medicaid program goals and objectives.

Our internal analysis indicates that instituting a total payment rate limit at the Medicare rate may result in total payment rate reductions compared to existing total payment rates for some SDPs, particularly given the number of States with approved SDPs that exceed Medicare. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark to evaluate whether total payment rates are reasonable, appropriate, and attainable.

As finalized, § 438.6(c)(2)(iii) establishes a total payment rate limit when States choose to implement SDPs for one of the four service types at the ACR (inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center); it does not require States to implement SDPs that are projected to increase the total payment rate to the ACR. We agree with the concerns raised by commenters about hospital consolidation and inflationary pressures that SDPs can have on hospital prices in other markets and on State and Federal spending. We encourage States to take such factors into account when considering the implementation and design of an SDP. States have significant flexibility in designing the SDP, including the provider class(es) and the type of payment arrangement. States are required to monitor the impact of SDPs after implementation and adjust SDPs appropriately to address any unintended consequences.

Comment: Some commenters stated concerns with our proposal at § 438.6(c)(2)(iii) to require that the total payment rate projected for each SDP for four specific services (inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center) not exceed the ACR. They suggested that CMS consider using the ACR as a guideline for measuring the reasonableness of SDP rates when considering whether the managed care plans' capitation rates are reasonable, appropriate, and attainable, which is the key standard for actuarial soundness described at § 438.4(a), rather than applying this standard as a limit on SDP payment rates. These commenters believe this alternative would maximize flexibility for States to address concerns with access to care. A number of these commentors also noted that in other contexts, Medicaid payment limits have led to retrospective audits and unanticipated recoupments, often years after the fact; these commenters stated that using a guideline instead of a limit would lessen the burden on providers. Some commenters suggested that CMS not institute a total payment rate limit for SDPs for these four service types as proposed, but instead use the detailed data gathered as required in other provisions in § 438.6(c) of the final rule to inform policies and address a total payment rate limit for SDPs in future rulemaking, if warranted.

Response: As noted in the proposed rule, we have been using the ACR as an internal benchmark in assessing SDPs since 2018. However, States and interested parties over time as part of SDP reviews have often stated confusion about what that internal ACR benchmark means and have requested significant technical assistance on how to demonstrate that the total payment rate for SDPs is reasonable, appropriate, and attainable. Finalizing a total payment rate limit for these four service types will provide clarity and transparency in what CMS considers reasonable, appropriate, and attainable. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark for all provider types and services by which we'll evaluate whether total payment rates are reasonable, appropriate, and attainable for all SDPs.

Further, SDPs are contractual obligations between the State and managed care plan; as noted in proposed rule (88 FR 28144), all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). In accordance with § 438.4(a), actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract, and capitation rates are developed in accordance with the requirements in § 438.4(b). This includes the requirement in § 438.4(b)(1) that the capitation rates must be developed with generally accepted actuarial principles and practices and the requirement in § 438.4(b)(7) that the capitation rates account for any applicable special contract provisions as specified in § 438.6, including SDPs, to ensure that all contractual arrangements are considered as the actuary develops the actuarially sound capitation rates.

We continue to believe that it is appropriate to implement additional regulatory requirements to ensure fiscal guardrails and oversight of SDPs while also balancing the need to ensure States have the flexibility to utilize SDPs as a mechanism to improve access to care and advance health equity. As SDP spending continues to grow, we believe there must be appropriate fiscal protections in place to ensure that SDPs further the objectives of the Medicaid programs and that the total payment rate under SDPs for each service and provider class do not grow unfettered beyond what is reasonable, appropriate, and attainable.

We reiterate that the total payment rate limit at § 438.6(c)(2)(iii)—meaning the ACR limit—would apply to the total payment rate(s) for these four service types only when a State chooses to implement an SDP for one of these four service types. States are not required to implement SDPs. The proposed total payment rate limit would not apply to rates negotiated between plans and their providers in the absence of an SDP and we note it may not be appropriate for States to implement SDPs in instances when their plans negotiate provider payment rates that support recruitment of robust provider networks. Further, the regulatory text proposed by CMS at § 438.6(c)(2)(iii) limits the total payment rate for each SDP and provides an important fiscal guardrail for these contractual obligations that would have to be accounted for in development of capitation rates paid to managed care plans. As part of CMS' monitoring and oversight of SDPs and review of preprint submissions, CMS plans to use T–MSIS data (see section I.B.2.o. of this final rule for further discussion) to assess historical total payment rates for SDPs and could, for example, request corrective modifications to future SDP submissions to address discrepancies between projections of the total payment rate under the SDP and the actual payments made to eligible providers. Future approval of SDPs may be at risk if we identify these discrepancies.

We are finalizing § 438.6(c)(2)(iii) as proposed.

Comment: A few commenters noted concerns with applying a total payment rate limit for these four service types to VBP models, and multi-payor or Medicaid-specific delivery system reform, or performance improvement initiatives. These commenters noted a numeric limit was not necessary and

inconsistent for these types of SDPs and that a total payment rate limit would disincentivize the development of VBP SDPs. The commenters noted that there does not appear to be a problem with payment levels in these VBP SDPs identified by CMS.

Response: We appreciate commenters' concerns. We support States increasing the use of VBP initiatives, including through SDPs in Medicaid managed care risk-based contracts. We are finalizing in this rule several regulatory changes to address challenges States have identified in current regulations governing SDPs to provide easier pathways to reasonably and appropriately adopt VBP SDPs (see section I.B.2.i. of this final rule). However, we continue to believe that implementing a total payment rate limit at the ACR for SDPs for these four service types provides a necessary fiscal guardrail and a prudent oversight mechanism to ensure program integrity of these SDPs as States pursue new payment models. While many of the VBP SDPs that we have reviewed to-date do not increase provider payment rates to ACR, we believe that it is important to establish an ACR limit for the four service types across all types of SDPs to ensure alignment and, so that States have a clear standard for what is approvable by CMS in the future as opposed to a changeable standard that would require repeated rulemaking. Further, we clarify here that although we are only finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark through by which we will evaluate whether SDP total payment rates are reasonable, appropriate, and attainable.

Comment: Some commenters questioned applying the total payment rate limit to only SDPs for the four service types outlined in the proposed rule (for example, inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center). These commenters suggested that instituting a total payment rate limit at the ACR for just four service types was inequitable treatment that does not have a basis in statute nor in the best interest of Medicaid clients. The commenters noted that hospitals, nursing facilities and academic medical centers often serve a disproportionate number of Medicaid clients as part of their total client care and subjecting such provider types or services to an arbitrary payment limit is contrary to CMS's goal of ensuring access to quality care because it indicates that CMS is willing to authorize higher payment amounts for other service providers because they are unaffiliated with training medical professionals for the future.

Response: We appreciate commenters' concerns. However, we disagree with commenters' characterization. There is currently enough evidence to support that the ACR is an appropriate total payment rate limit for Medicaid managed care coverage of inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services. As noted in the proposed rule, private insurers are the primary payer for hospital expenditures as well as physician and clinical expenditures. For these three service types, commercial payers typically pay the highest rates followed by Medicare, followed by Medicaid (88 FR 28122). This is generally reflected in our internal review of total payment rate analyses collected from States for inpatient hospital services, outpatient hospital services, and professional services provided at academic medical centers. As noted in the proposed rule (88 FR 28122), we have also approved a few SDPs for nursing facility services that were projected to increase total payment rates to the ACR. There have also been some concerns raised as part of published audit findings about a particular nursing facility SDP.[111]

As noted in the proposed rule, further research is needed before codifying a specific payment rate limit for other services beyond these four service types, particularly where there is a lack of data due to Medicaid being the primary payer in the market.

We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Based on our continued review of SDPs and monitoring of payment rates, we may revisit codifying a specific payment rate limit for other services depending on future experience.

SDPs are a tool that States have the option to use to direct how managed care plans pay providers to further the State's overall Medicaid program goals and objectives. States are not required to use SDPs; in fact, under risk-based managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers. Subject to certain exceptions, States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). The total payment rate limit we are finalizing at § 438.6(c)(2)(iii) applies to SDPs; it is a limit on the State's ability to direct the managed care plan's expenditures. However, as noted earlier, although we are finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark by which we will evaluate whether SDP total payment rates are reasonable, appropriate, and attainable. The total payment rate limit does not apply outside of the context of approved SDPs and therefore, does not apply to rates independently negotiated between managed care plans and providers; managed care plans will still be allowed to negotiate payment rates with network providers to furnish covered services.

Comment: Some commenters supported applying the ACR limit to all service types, not just those four service types proposed. Other commenters noted that specifying an ACR limit beyond the four service types (inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center) was not necessary and that they supported limiting the total payment rate limit to the four service types proposed given the administrative work necessary to comply with the documentation requirements.

Response: We appreciate commenters' feedback. As noted in an earlier response, there is currently enough evidence to support that the ACR is an appropriate limit for the total payment rate for SDPs for inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services.

Further research is needed before codifying a specific total payment rate limit for other services beyond these four service types. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring

[111] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP is reasonable, appropriate, and attainable. Based on our continued review of SDPs and monitoring of payment rates, we may revisit codifying a specific total payment rate limit for other services.

Comment: Some commenters requested clarification on how CMS intends to enforce the SDP total payment rate limit for the four service types (inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services) if actual payments made by the plans to eligible providers exceeds the total payment rate limit.

Response: We appreciate the request for clarification. As discussed in section I.B.2.o. of this final rule, we are requiring States to submit to CMS no later than 1 year after each rating period, data to the T–MSIS specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs, including amounts paid to individual providers (§ 438.6(c)(4)). States are required to regularly monitor payments made by plans to providers as part of standard monitoring and oversight, including ensuring plans comply with the contractual requirements for SDPs in alignment with the requirements in § 438.6(c). CMS will use the data collected from States on the actual final payment rate through T–MSIS (discussed in section I.B.2.o. of this final rule) as part of our monitoring and oversight; if the actual final payment rates differ from what was projected, at minimum, we will use this information to inform future reviews of SDPs.

Comment: Some commenters agreed with CMS's decision to not codify a specific total payment rate limit for some services such as HCBS or behavioral health. Commenters also supported not implementing a total payment rate limit for physician services.

Response: We appreciate commenters' support for the proposal. As noted in response to an earlier comment, we agree that limiting SDP approval based on the total payment rate not exceeding the ACR is appropriate. However, we will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable.

We continue to believe that additional experience is needed before codifying a specific limit for the total payment rate for SDPs directing plan expenditures for services beyond the four service types enumerated in § 438.6(c)(2)(iii).

We did not propose to establish a specific, set limit for the total payment rate for practitioners that are not affiliated with or employed by an academic medical center; this would include physician services. As noted in the proposed rule, we have not seen a comparable volume or size of SDP preprints for provider types not affiliated with hospitals or academic medical centers, and do not believe there is currently enough evidence to support ACR as an appropriate limit on the total payment rates for physician services. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Depending on our future experience, we may revisit this issue as necessary.

Comment: We received a wide range of comments on establishing a total payment rate limit at the ACR for nursing facilities. Many commenters broadly supported establishing a total payment rate limit at the ACR for all four service types. However, some commenters encouraged CMS to not finalize a total payment rate limit for nursing facilities. They noted that Medicaid, not commercial insurance, is the primary payer for nursing facilities. These commenters also noted that Medicare is not a reasonable benchmark for nursing facilities services since Medicare adopted the Patient-Driven Payment Model reimbursement methodology. Some commenters suggested that CMS consider a total payment rate limit for nursing facilities that would be the greater of the ACR or what Medicare would have paid to accommodate circumstances in which a provider may serve a low volume of commercial clients and therefore have insufficient negotiation ability. Other commenters suggested CMS consider a benchmark, but not a total payment rate limit, for nursing facilities based on cost as this would be State-specific and market-based.

Response: We appreciate commenters' concerns. We acknowledge the change in Medicare payment policy from the resource utilization groups system to the Patient-Driven Payment Model and the implications it has for States in determining Medicaid payment policies for SNFs.[112] As noted in the proposed rule, we have received SDP proposals that increase total payment rates up to the ACR for nursing facilities. We have also received a growing number of SDP proposals for nursing facilities that are projected to increase the total payment rate above the Medicare rate. There have also been concerns raised as part of published audit findings about a particular nursing facility SDP unlike other service category types.[113] We believe it is important to have oversight and monitor fiscal integrity risks for nursing facility services and other services where Medicaid is a payer. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Depending on our future experience, we may revisit this issue as necessary.

Comment: We received many comments that supported establishing a total payment rate limit at the ACR for qualified practitioner services provided at an academic medical center. Some commenters stated that a total payment rate limit at the ACR is critical because commercial plans typically pay the highest rates for these services and academic medical centers furnish a significant volume of services to Medicaid beneficiaries ensuring access to care. These commenters noted that academic medical centers are often the only source for certain specialty and sub-specialty care.

Response: We appreciate the support for finalizing a total payment rate limit at the ACR for qualified practitioner services provided at an academic medical center. This will align with the long-standing Medicaid FFS payment policy [114] and we believe it is critical to

[112] *https://www.medicaid.gov/sites/default/files/2023-02/smd22005.pdf.*

[113] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[114] CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional

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ensure continued access to services that are often not available elsewhere.

Comment: We received mixed comments on our proposed definition of ''qualified practitioner services at an academic medical center'' and ''academic medical center.'' Some commenters supported these definitions as proposed. Other commenters raised concerns that the proposed definitions were unclear on which types of services or practitioners would be included and would exclude many academic medical centers that are ''affiliated with'' but do not ''include'' a health professional school. The commenters noted that many academic medical centers include clinical facilities (for example, hospitals and clinics) that have affiliations with health professionals schools, and they are concerned that the proposed definition does not sufficiently define ''facility.'' Another commenter suggested that CMS streamline the definition of an academic medical center to include ''any facility that both provides patient care and educates healthcare providers in connection with at least one health professional school.''

Response: We appreciate commenters support on our proposed definition of ''qualified practitioner services at an academic medical center.'' To the comments that the definition of ''academic medical center'' should be more inclusive and use ''affiliated with,'' we acknowledge that the use of ''includes'' may result in some facilities being excluded but we believe that the definition aligns with common practices and understanding. Therefore, we are finalizing the definition as proposed. We will continue to monitor and may revisit this definition in future rulemaking.

Comment: One comment supported our proposed definitions of inpatient hospital services and outpatient hospital services as proposed in § 438.6(a) and recommended that all definitions of Part 440 Subpart A be codified as applicable to Medicaid managed care more generally to align with Medicare Advantage.

Response: We appreciate the commenter's support for our proposed definitions of inpatient hospital services and outpatient hospital services. As the commenter notes, the definitions proposed and finalized in § 438.6(a) for inpatient hospital services and outpatient hospital services are specific to SDPs and are intended to help determine which SDPs are subject to the requirements in § 438.6(c)(2)(iii). We appreciate the suggestion to apply these definitions and others more broadly than proposed; however, we did not propose to expand the applicability of these terms in the proposed rule and have not considered, or received public comment on, broader use of part 440 definitions for all regulations in part 438; there may be unintended consequences for such a wholesale approach to importing the defined terms used in the FFS context to the managed care context given how certain flexibilities in coverage are limited to the managed care context (see for example, § 438.3(e)). We also note that § 438.206 already provides that ''all services covered under the State plan [must be] available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner'' and that § 438.210 provides that the amount, duration and scope of coverage benefits through the managed care plan must be no less than in the Medicaid state plan.

Comment: Some commenters suggested establishing national floors for payment levels at the Medicare rate.

Response: States have the option to implement minimum fee schedule requirements through SDPs provided they comply with the regulatory requirements in § 438.6(c). While we recognize the importance of adequate payment rates to ensure access to care, we did not propose, nor was it our intent to propose, a national minimum payment level at the Medicare payment rate for Medicaid managed care plans.

Comment: A few commenters requested confirmation that the proposed total payment rate limit for SDPs did not impact existing Federal requirements related to payment for Indian Health Care Providers at the IHS All-Inclusive Encounter Rate.

Response: In § 438.6(c), it explicitly provides an exception to the prohibition on State direction of a managed care plan's expenditures for certain payments by stating: ''Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers . . .'' Because payment of Indian health care providers by MCOs is specified in Title XIX, including section 1932(h) and section 1902(bb) for those that are FQHCs, and associated implementing regulations also generally extend those payment provisions to PIHPs and PAHPs in § 438.14, the SDP provisions in § 438.6(c) do not apply to State direction of managed care plan expenditures necessary to ensure compliance with the applicable statutory and regulatory requirements. States are required to ensure that Indian health care providers receive the minimum payment rates set forth under the aforementioned statutes and implementing regulations (such as § 438.14).

Comment: Some commenters supported our proposals in § 438.6(c)(2)(iii)(A) and (B) for data standards for the ACR demonstration and the total payment rate comparison. These commenters believe these proposals would improve fiscal integrity and ensure that SDPs advance the objectives of the Medicaid program. Commenters also supported the proposals outlined in § 438.6(c)(2)(iii)(C) regarding the submission process for the ACR demonstration and the total payment rate comparison, including the requirement for these to be provided with the initial SDP preprint and then updated at least once every 3 years thereafter. These commenters believe these proposals would allow for State flexibility and lessen the administrative burden to implement and report on ACR demonstrations since § 438.6(c)(2)(iii) does not require specific data sources or templates.

Response: We appreciate commenters' support for the proposed data standards at § 438.6(c)(2)(iii)(A) and (B), and the submission process for the ACR demonstration and the total payment rate comparison in § 438.6(c)(2)(iii)(C). The total payment rate comparison required at § 438.6(c)(2)(iii)(B) must be updated and submitted with each initial preprint, amendment, and renewal and that it must be specific to both the service and the provider class, which differs from the ACR demonstration requirements (specific to the service type only and updated at least once every three years). We may publish additional guidance on best practices for ACR demonstrations and total payment rate demonstrations as well as a template to help facilitate CMS's review.

Comment: Several commenters requested clarification on the data sources that should be utilized for ACR demonstrations and total payment rate

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information on this and other payment demonstrations is published on Medicaid.gov. Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used.* As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

comparisons proposed in § 438.6(c)(iii)(A) and (B). Some commenters noted that commercial rate data are difficult for States to provide absent an all-payer claims database. Other commenters noted it was unclear if the data in the ACR demonstration and total payment rate comparison will be collected in a way to clearly identify non-Medicaid covered services in commercial payments or third-party liability amounts. Commenters requested that CMS provide guidance and technical assistance about the data sources that would be appropriate for States to utilize for the ACR demonstrations and total payment rate comparisons. A few commenters questioned if States should utilize Medicare cost reports or whether CMS will make all-payer claims databases publicly accessible to States. Other commenters requested that CMS identify appropriate ACR sources (including any national data sources) and methods for developing total payment rate comparisons.

Response: We appreciate the request for clarification and additional guidance on data sources to utilize for ACR demonstrations and total payment rate comparisons. We reiterate that we are not requiring States to use specific data sources at this time (88 FR 28126) for the SDP submissions of the information required by § 438.6(c)(2)(iii). We agree that all-payer claims databases are good sources of data, though not all State Medicaid agencies have access to such data. Additionally, commercial data are often proprietary and to our knowledge, there are no publicly available data sources for commercial data. Some States conduct a code-level analysis of the ACR as is currently used for the qualified practitioner services at academic medical centers supplemental payments for Medicaid FFS while others have provided analyses using hospital cost reports. Actuaries and consultants may have access to private commercial databases to aid States to produce an ACR analysis or some States have purchased access to private commercial databases to inform these analyses. Finally, other States have required providers to provide commercial payment data as a condition of eligibility for the SDP. We expect to publish additional guidance in the future that highlights best practices from States consistent with the regulatory requirements finalized in § 438.6(c)(2)(iii)(A) and (B). Whatever data source the State uses will need to comply with the standards set in § 438.6(c)(2)(iii)(A) and (B), including that data must exclude non-Medicaid covered services and third-party liability amounts.

Comment: Many commenters supported our proposal at § 438.6(c)(2)(iii)(A)(3) to allow ACR demonstrations that are specific to the service included in the SDP and appreciated that the ACR demonstrations are not required to be specific to both each service type and each provider class. Commenters noted that this flexibility would allow States to better target funding for financially vulnerable providers, such as rural and safety net hospitals than current practice allows for today. A few commenters disagreed with our proposal and recommended that CMS revise the regulatory text in § 438.6(c)(2)(iii)(A)(3) about what States must use to demonstrate the ACR to ''is specific to the service(s) and provider class(es) addressed by the State directed payment;'' to align with current practice. These commenters noted that if a State chooses to create separate classes of providers, then each class should be limited to the ACR for that service and that provider class, and States should be prohibited from relying on a cumulative ACR calculation to increase payment to some provider classes at the expense of other provider classes. These commenters stated that this practice undermines the equal access to services that SDPs are intended to advance. Other commenters suggested that CMS allow States maximum flexibility to calculate the ACR demonstration by service, by provider class, or by geography or market at the State's option.

Response: We appreciate the support for the proposal to allow ACR demonstrations that are specific to the service addressed by the SDP at § 438.6(c)(iii)(A)(3). We agree that requiring the ACR demonstration to be specific to the service addressed by the SDP but not specific to both the service and provider class provides additional flexibility to States to target resources to accomplish Medicaid program goals and objectives. In the proposed rule (88 FR 28125), we provided a lengthy discussion of our experience working with States and how requiring an ACR analysis that is specific to both to the service and provider class for SDPs can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries through SDPs. For example, we have often heard from States that rural hospitals commonly earn a larger share of their revenue from the Medicaid program than they do from commercial payers, tend to be less profitable than urban hospitals which often have a wider mix of payers, and are at a greater risk of closure. These hospitals often serve a critical role in providing access to services for Medicaid beneficiaries living in rural areas where alternatives to care are very limited or non-existent. If States want to target funding to increase managed care plan payments for hospital services to rural hospitals through SDPs, limiting the total payment rate limit for such payments to the ACR for rural hospitals only would result in a lower total payment rate limit for such SDPs than if the State were to broaden the provider class in the SDP to include hospitals with a higher commercial payer mix (for example, payment data for hospital services provided at a specialty cardiac hospital, which typically can negotiate a higher rate with commercial plans). However, in doing so, the regulatory requirement for SDPs at § 438.6(c)(2)(ii)(B) requires that SDPs direct expenditures equally using the same terms of performance for a class of providers—meaning the rural hospitals and the specialty cardiac hospitals in our examples would get the same uniform increase, even though the State may not have the same access to care concerns for Medicaid beneficiaries receiving specialty care at cardiac hospitals.

The focus on the ACR for the service at the provider class level has the potential to disadvantage providers with less market power to negotiate rates with commercial payers on par with providers with more market power. Therefore, we proposed and are finalizing the more flexible approach.

While we understand commenters' concerns about our proposal at § 438.6(c)(2)(iii)(A)(3) to allow ACR demonstrations that are specific to the service addressed by the SDP and not to the provider classes, we believe that the commenter may have misunderstood the proposal. The commenter asserts that allowing the ACR demonstrations to be specific to the broad service type and not the individual provider class will result in unequal treatment among provider classes. In fact, the final rule would provide States the option to use the same ACR analysis as the comparison point for the total payment rate comparison (which is required to be conducted at the service and provider level) for all classes providing the same service affected by the SDP. Further, there is nothing in the final rule that permits SDP payments above ACR or to favor one class of providers at the expense of another. We remind commenters that there is no requirement that States implement SDPs. In addition, States have broad discretion in defining

provider classes for SDPs. This provision (at § 438.6(c)(2)(iii)(A)(3)) would also not change the existing regulatory requirement § 438.6(c)(2)(ii)(B) that SDPs direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract. We are finalizing § 438.6(c)(2)(iii)(A)(3) as proposed.

Finally, we appreciate the recommendations to allow States maximum flexibility to use ACR and to calculate ACR by service, by provider class, or by geography or market. States retain the discretion to use payment data that is specific to the service(s) and provider classes in the SDP and can also consider further specifics such as market and geography so long as the payment data are still specific to the State. We proposed at § 438.6(c)(2)(iii)(A)(1) that States would be required to use payment data specific to the State for the analysis as opposed to regional or national data to provide more accurate information for assessment. We noted that there is wide variation in payment for the same service from State to State and that regional or national analyses that cut across multiple States can be misleading, particularly when determining the impact on capitation rates that are State specific (88 FR 28125). For these reasons, we believe that finalizing § 438.6(c)(2)(iii)(A)(1) as proposed is appropriate.

We received no other comments on the remaining portions of § 438.6(c)(2)(iii)(A) and are finalizing as proposed.

Comment: One commenter suggested that CMS allow Medicaid agencies to increase the ACR level used to set the payment amounts in an SDP between ACR demonstrations submitted to CMS, so that the State could direct increased payments to account for inflation. While the commenter supports only requiring States to submit an ACR demonstration every three years in § 438.6(c)(2)(iii)(C) to reduce State burden, they noted that medical inflation trends are not static over three-year periods (meaning, between ACR demonstration submissions). The commenter recommended that CMS allow States to account for medical inflation within their jurisdiction in their ACR during the three-year period without requiring States to revise the ACR demonstration.

Response: We recognize that medical inflation may continue to increase over the three-year period between ACR demonstrations. If medical inflation has a notable impact during the three-year period between demonstrations, States have the option to update the ACR demonstration any time a preprint is submitted, and that updated ACR demonstration is subject to CMS review as part of review of the SDP preprint. We believe this is a reasonable approach that provides us the ability to review such updates.

Comment: One commenter requested that CMS delay implementation of § 438.6(c)(2)(iii) for 1 year after the effective date of this final rule. The commenter believes States will need more time than the proposed applicability date, the first rating period after the effective date of the final rule, provides.

Response: We appreciate the concern raised by commenters. This requirement is largely in alignment with existing practices and should not cause significant burden for States to implement. Therefore, we are finalizing at § 438.6(c)(8)(ii) the applicability date of the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as proposed.

Expenditure Limit for All SDPs

Comment: Many commenters did not support the alternative options we outlined in the proposed rule for an expenditure limit on SDPs. Some commenters stated that any limit on SDP expenditures as a proportion of managed care spending could be an arbitrary limit that could have deleterious effects on enrollee access to care and impede State flexibility to meet the goals and objectives of their managed care program. A few commenters raised concerns that any SDP expenditure limits could penalize States with lower base managed care expenditures due to the relative size of the State or managed care program. Other commenters believed that the proposed total payment rate limit at ACR for inpatient and outpatient hospital services, nursing facilities and professional services at academic medical centers provided a reasonable limit on SDPs and that an additional limit on total expenditures for SDPs was unnecessary. A few commenters recommended that CMS complete additional studies including using future SDP evaluations to better understand the impact of an SDP expenditure limit and assess whether an SDP expenditure limit, either in totality or for specific provider classes, was truly needed.

Response: We carefully considered alternative options for the SDP expenditure limit outlined in the proposed rule. We recognize that the alternative options for the SDP expenditure limit outlined in the proposed rule could have unintended consequences to States' efforts to further their overall Medicaid program goals and objectives, such as improving access to care for Medicaid beneficiaries and reduce health disparities through SDPs. We agree with commenters that the total payment limit at the ACR that we are finalizing for the four specific categories of services listed in § 438.6(c)(2)(iii) is the reasonable and appropriate policy to ensure the fiscal integrity of SDP arrangements.

Comment: Several commenters recommended that if CMS finalizes an expenditure limit for SDPs, existing SDPs be either exempted from the expenditure limit or provided a transition period for States to develop alternative frameworks.

Response: As we explain in the prior response, we are not finalizing an overall SDP expenditure limit in this final rule.

We did not receive any comments on our proposed definitions of ''average commercial rate'' or ''nursing facility services'' in § 438.6(a). After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed definitions in § 438.6(a). We are also finalizing § 438.6(c)(2)(ii)(I) with minor revisions also discussed earlier. Finally, we are finalizing 438.6(c)(2)(iii) as proposed, with one modification in paragraph (c)(2)(iii)(B)(*3*) to clarify that the prior approval referenced is ''prior approval of the State directed payment . . .''.

g. Financing (§ 438.6(c)(2)(ii)(G) and (c)(2)(ii)(H))

From our experience in working with States, it has become clear that SDPs provide an important tool for States in furthering the goals and objectives of their Medicaid programs within a managed care environment. In finalizing the standards and limits for SDPs and pass-through payments in the 2016 and 2017 final rules, we intended to ensure that the funding that was included in Medicaid managed care rate development was done so appropriately and in alignment with Federal statutory requirements applicable to the Medicaid program. This includes Federal requirements for the source(s) of the non-Federal share of SDPs.

Background on Medicaid Non-Federal Share Financing. Medicaid expenditures are jointly funded by the Federal and State governments. Section 1903(a)(1) of the Act provides for Federal payments to States of the Federal share of authorized Medicaid expenditures. The foundation of Federal-State shared responsibility for

the Medicaid program is that the State must participate in the financial burdens and risks of the program, which provides the State with an interest in operating and monitoring its Medicaid program in the best interest of beneficiaries (see section 1902(a)(19) of the Act) and in a manner that results in receiving the best value for taxpayers for the funds expended. Sections 1902(a)(2), 1903(a), and 1905(b) of the Act require States to share in the cost of medical assistance and in the cost of administering the Medicaid program. FFP is not available for expenditures for services and activities that are not medical assistance authorized under a Medicaid authority or allowable State administrative activities. Additionally, FFP is not available to States for expenditures that do not conform to approved State plans, waivers, demonstration projects, or contracts, as applicable.

Section 1902(a)(2) of the Act and its implementing regulation in 42 CFR part 433, subpart B require States to share in the cost of medical assistance expenditures and permit other units of State or local government to contribute to the financing of the non-Federal share of medical assistance expenditures. These provisions are intended to safeguard the Federal-State partnership, irrespective of the Medicaid delivery system or authority (for example, FFS or managed care delivery system, and State plan, waiver, or demonstration authority), by ensuring that States are meaningfully engaged in identifying, assessing, mitigating, and sharing in the risks and responsibilities inherent in operating a program as complex and economically significant as Medicaid, and that States are accordingly motivated to administer their programs economically and efficiently (see, for example, section 1902(a)(4) of the Act).

There are several types of permissible means for financing the non-Federal share of Medicaid expenditures, including, but not limited to: (1) State general funds, typically derived from tax revenue appropriated directly to the Medicaid agency; (2) revenue derived from health care-related taxes when consistent with Federal statutory requirements at section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; (3) provider-related donations to the State which must be ''bona fide'' in accordance with section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; [115] and (4) IGTs from units of State or local government that contribute funding for the non-Federal share of Medicaid expenditures by transferring their own funds to and for the unrestricted use of the Medicaid agency.[116] Regardless of the source or sources of financing used, the State must meet the requirements at section 1902(a)(2) of the Act and § 433.53 that obligate the State to fund at least 40 percent of the non-Federal share of total Medicaid expenditures (both medical assistance and administrative expenditures) with State funds.

Health care-related taxes and IGTs are a critical source of funding for many States' Medicaid programs, including for supporting the non-Federal share of many payments to safety net providers. Health care-related taxes made up approximately 17 percent ($37 billion) of all States' non-Federal share in 2018, the latest year for which data are available.[117] IGTs accounted for approximately 10 percent of all States' non-Federal share for that year. The Medicaid statute clearly permits certain health care-related taxes and IGTs to be used to support the non-Federal share of Medicaid expenditures, and CMS supports States' adoption of these non-Federal financing strategies where consistent with applicable Federal requirements. CMS approves hundreds of State payment proposals annually that are funded by health care-related taxes that appear to meet statutory requirements. The statute and regulations afford States flexibility to tailor health care-related taxes within certain parameters to suit their provider community, broader State tax policies, and the needs of State programs. However, all health care-related taxes must be imposed in a manner consistent with applicable Federal statutes and regulations, which prohibit direct or indirect ''hold harmless'' arrangements (see section 1903(w)(4) of the Act; § 433.68(f)).

States first began to use health care-related taxes and provider-related donations in the mid-1980s as a way to finance the non-Federal share of Medicaid payments (Congressional Research Service, ''Medicaid Provider Taxes,'' August 5, 2016, page 2). Providers would agree to make a donation or would support (or not oppose) a tax on their activities or revenues, and these mechanisms (donations or taxes) would generate funds that could then be used to raise Medicaid payment rates to the providers. Frequently, these programs were designed to hold Medicaid providers ''harmless'' for the cost of their donation or tax payment. As a result, Federal expenditures rapidly increased without any corresponding increase in State expenditures, since the funds used to increase provider payments came from the providers themselves and were matched with Federal funds. In 1991, Congress passed the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments (Pub. L. 102–234, December 12, 1991) to establish limits for the use of provider-related donations and health care-related taxes to finance the non-Federal share of Medicaid expenditures. Statutory provisions relating to health care-related taxes and donations are in section 1903(w) of the Act.

Section 1903(w)(1)(A)(i)(II) of the Act requires that health care-related taxes be broad-based as defined in section 1903(w)(3)(B) of the Act, which specifies that the tax must be imposed for a permissible class of health care items or services (as described in section 1903(w)(7)(A) of the Act) or for providers of such items or services and generally imposed at least for all items or services in the class furnished by all non-Federal, nonpublic providers or for all non-Federal, nonpublic providers; additionally, the tax must be imposed uniformly in accordance with section 1903(w)(3)(C) of the Act. However, section 1903(w)(1)(A)(iii) of the Act disallows the use of revenues from a broad-based health care-related tax if there is in effect a hold harmless arrangement described in section

[115] ''Bona fide'' provider-related donations are truly voluntary and not part of a hold harmless arrangement that effectively repays the donation to the provider (or to providers furnishing the same class of items and services). As specified in § 433.54, a bona fide provider-related donation is made to the State or a unit of local government and has no direct or indirect relationship to Medicaid payments made to the provider, any related entity providing health care items or services, or other providers furnishing the same class of items or services as the provider or entity. This is satisfied where the donations are not returned to the individual provider, provider class, or a related entity under a hold harmless provision or practice. Circumstances in which a hold harmless practice exists are specified in § 433.54(c).

[116] Certified public expenditures (CPEs) also can be a permissible means of financing the non-Federal share of Medicaid expenditures. CPEs are financing that comes from units of State or local government where the units of State or local governmental entity contributes funding of the non-Federal share for Medicaid by certifying to the State Medicaid agency the amount of allowed expenditures incurred for allowable Medicaid activities, including the provision of allowable Medicaid services provided by enrolled Medicaid providers. States infrequently use CPEs as a financing source in a Medicaid managed care setting, as managed care plans need to be paid prospective capitation payments and CPEs by nature are a retrospective funding source, dependent on the amount of expenditures the unit of State or local government certifies that it already has made.

[117] U.S. Government Accountability Office, ''Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight,'' GAO–21–98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98*.

1903(w)(4) of the Act for the tax. Section 1903(w)(4) of the Act specifies that, for purposes of section 1903(w)(1)(A)(iii) of the Act, there is in effect a hold harmless provision for a broad-based health care-related tax if the Secretary determines that any of the following applies: (A) the State or other unit of government imposing the tax provides (directly or indirectly) for a non-Medicaid payment to taxpayers and the amount of such payment is positively correlated either to the amount of the tax or to the difference between the amount of the tax and the amount of the Medicaid payment; (B) all or any portion of the Medicaid payment to the taxpayer varies based only upon the amount of the total tax paid; or (C) the State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax. Section 1903(w)(1)(A) of the Act specifies that, for purposes of determining the Federal matching funds to be paid to a State, the total amount of the State's Medicaid expenditures must be reduced by the amount of revenue received by the State (or by a unit of local government in the State) from impermissible health care-related taxes, including, as specified in section 1903(w)(1)(A)(iii) of the Act, from a broad-based health care-related tax for which there is in effect a hold harmless provision described in section 1903(w)(4) of the Act.

In response to the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, we published the ''Medicaid Program; Limitations on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals'' interim final rule with comment period in the November 24, 1992 **Federal Register** (57 FR 55118) (''November 1992 interim final rule'') and the subsequent final rule published in the August 13, 1993 **Federal Register** (58 FR 43156) (August 1993 final rule) establishing when States may receive funds from provider-related donations and health care-related taxes without a reduction in medical assistance expenditures for the purposes of calculating FFP.

After the publication of the August 1993 final rule, we revisited the issue of health care-related taxes and provider-related donations in the ''Medicaid Program; Health-Care Related Taxes'' final rule (73 FR 9685) which published in the February 22, 2008, **Federal Register** (February 2008 final rule). The February 2008 final rule, in part, made explicit that certain practices will constitute a hold harmless arrangement, in response to certain State tax programs that we believed contained hold harmless provisions. For example, five States had imposed a tax on nursing homes and simultaneously created programs that awarded grants or tax credits to private pay residents of nursing facilities that enabled these residents to pay increased charges imposed by the facilities, which thereby recouped their own tax costs. We believed that these payments held the taxpayers (the nursing facilities) harmless for the cost of the tax, as the tax program repaid the facilities indirectly, through the intermediary of the nursing facility residents. However, in 2005, the Department of Health and Human (HHS) Departmental Appeals Board (the Board) (Decision No. 1981) ruled that such an arrangement did not constitute a hold harmless arrangement under the regulations then in place (73 FR 9686 and 9687). Accordingly, in discussing revisions to the hold harmless guarantee test in § 433.68(f)(3), the February 2008 final rule preamble noted that a State can provide a direct or indirect guarantee through a direct or indirect payment. We stated that a direct guarantee will be found when, ''a payment is made available to a taxpayer or party related to the taxpayer with the reasonable expectation that the payment will result in the taxpayer being held harmless for any part of the tax'' as a result of the payment (73 FR 9694). We noted parenthetically that such a direct guarantee can be made by the State through direct or indirect payments. *Id.* As an example of a party related to the taxpayer, the preamble cited the example of, ''as a nursing home resident is related to a nursing home'' (73 FR 9694). As discussed in the preamble to the February 2008 final rule, whenever there exists a ''reasonable expectation'' that the taxpayer will be held harmless for the cost of the tax by direct or indirect payments from the State, a hold harmless situation exists, and the tax is impermissible for use to support the non-Federal share of Medicaid expenditures.

Non-Federal Share Financing and State Directed Payments. The statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (FFS or managed care). We employ various mechanisms for reviewing State methods for financing the non-Federal share of Medicaid expenditures. This includes, but is not limited to, reviews of FFS SPAs, reviews of managed care SDPs, quarterly financial reviews of State expenditures reported on the Form CMS–64, focused financial management reviews, and reviews of State health care-related tax and provider-related donation proposals and waiver requests.

We reiterated this principle in the 2020 Medicaid managed care final rule, noting ''certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, FFS, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c)'' (85 FR 72765). Further, section 1903(m)(2)(A) of the Act limits FFP in prepaid capitation payments to MCOs for coverage of a defined minimum set of benefits to cases in which the prepaid payments are developed on an actuarially sound basis for assuming the cost of providing the benefits at issue to Medicaid managed care enrollees. CMS has extended this requirement, through rulemaking under section 1902(a)(4) of the Act, to the capitation rates paid to PIHPs and PAHPs under a risk contract as well.

As part of our review of SDP proposals, we are increasingly encountering issues with State financing of the non-Federal share of SDPs, including use of health care-related taxes and IGT arrangements that may not be in compliance with the underlying Medicaid requirements for non-Federal share financing. In January 2021, CMS released a revised preprint form that systematically collects documentation regarding the source(s) of the non-Federal share for each SDP and requires States to provide additional assurances and details specific to each financing mechanism, which has contributed to our increased awareness of non-Federal share financing issues associated with SDPs.[118] Concerns around the funding of the non-Federal share for SDPs have been raised by oversight bodies.[119] [120]

[118] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[119] See U.S. Government Accountability Office, ''Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight,'' GAO–21–98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98.*

[120] See Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://*

Through our review of SDP preprint proposals over the past few years, we have identified various non-Federal share sources that appeared unallowable. Primarily, the potentially unallowable non-Federal share arrangements have involved health care-related taxes. Specifically, we have identified multiple instances in which States appear to be funding the non-Federal share of Medicaid SDP payments through health care-related tax programs that appear to involve an impermissible hold harmless arrangement. In one particular form of a hold harmless arrangement, with varying degrees of State awareness and involvement, providers appear to have pre-arranged agreements to redistribute Medicaid payments (or other provider funds that are replenished by Medicaid payments). These redistribution arrangements are not described on the States' SDP applications; if an SDP preprint stated that Medicaid payments ultimately will be directed to a recipient without being based on the delivery of Medicaid-covered services, we could not approve the SDP, because section 1903(a) of the Act limits FFP to expenditures for medical assistance and qualifying administrative activities (otherwise stated, FFP is not available in expenditures for payments to third parties unrelated to the provision of covered services or conduct of allowable administrative activities). Similarly, under 1903(w), FFP is not permissible in payments that will otherwise be matchable as medical assistance if the State share being matched does not comply with the conditions in section 1903(w) of the Act, such as in the case of the type of hold harmless arrangement described above. The fact that these apparent hold harmless arrangements are not made explicit on SDP preprints should not affect our ability to disapprove SDPs when we cannot verify they do not employ redistribution arrangements.

These arrangements appear designed to redirect Medicaid payments away from the providers that furnish the greatest volume of Medicaid-covered services toward providers that provide fewer, or even no, Medicaid-covered services, with the effect of ensuring that taxpaying providers are held harmless for all or a portion of their cost of the health care-related tax. In the arrangements, a State or other unit of government imposes a health-care related tax, then uses the tax revenue to fund the non-Federal share of SDPs that require Medicaid managed care plans to pay the provider taxpayers. The taxpayers appear to enter a pre-arranged agreement to redistribute the Medicaid payments to ensure that all taxpayers, when accounting for both their original Medicaid payment (from the State through a managed care plan) and any redistribution payment received from another taxpayer(s) or another entity, receive back (and are thereby held harmless for) all or at least a portion of their tax amount.

Providers that serve a relatively low percentage of Medicaid patients or no Medicaid patients often do not receive enough Medicaid payments funded by a health care-related tax to cover the provider's cost in paying the tax. Providers in this position are unlikely to support a State or locality establishing or continuing a health care-related tax because the tax will have a negative financial impact on them. Redistribution arrangements like those just described seek to eliminate this negative financial impact or turn it into a positive financial impact for taxpaying providers, likely leading to broader support among the provider class of taxpayers for legislation establishing or continuing the tax. Based on limited information we have been able to obtain from providers participating in such arrangements, we believed providers with relatively higher Medicaid volume agree to redistribute some of their Medicaid payments to ensure broad support for the tax program, which ultimately works to these providers' advantage since the tax supports increased Medicaid payments to them (even net of Medicaid payments that they redistribute to other providers) compared to payment amounts for delivering Medicaid-covered services they would receive in the absence of the tax program. Therefore, these redistribution arrangements help ensure that State or local governments are successful in enacting or continuing provider tax programs.

The Medicaid statute at section 1903(w) of the Act does not permit us to provide FFP in expenditures under any State payment proposal that would distribute Medicaid payments to providers based on the cost of a health care-related tax instead of based on Medicaid services, so payment redistribution arrangements often occur without notice to CMS (and possibly States) and are not described as part of a State payment proposal submitted for CMS review and approval (see, section 1903(w)(4) of the Act). Given that we cannot knowingly approve awarding FFP under this scenario, we noted our belief that it would be inconsistent with the proper and efficient operation of the Medicaid State plan to approve an SDP when we know the payments would be funded under such an arrangement. For example, we would not approve an SDP that would require payment from a Medicaid managed care plan to a hospital that did not participate in Medicaid, in any amount. Nor would we approve an SDP that would require payment from a Medicaid managed care plan (that is, a Medicaid payment) to a hospital with a low percentage of Medicaid revenue based on the difference between the hospital's total cost of a health care-related tax and other Medicaid payments received by the hospital. As a result, the redistribution arrangements seek to achieve what cannot be accomplished explicitly through a CMS-approved payment methodology (that is, redirecting Medicaid funds to hold taxpayer providers harmless for their tax cost, with a net effect of directing Medicaid payments to providers based on criteria other than their provision of Medicaid-covered services).

Redistribution arrangements undermine the fiscal integrity of the Medicaid program and are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements. Currently, § 433.68(f)(3), implementing section 1903(w)(4)(C) of the Act, provides that a hold harmless arrangement exists where a State or other unit of government imposing a health care-related tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount. The February 2008 final rule on health care-related taxes specified that hold harmless arrangements prohibited by § 433.68(f)(3) exist ''[w]hen a State payment is made available to a taxpayer or a party related to the taxpayer (for example, as a nursing home resident is related to a nursing home), in the reasonable expectation that the payment will result in the taxpayer being held harmless for any part of the tax'' (73 FR 9694, quoting preamble discussion from the proposed rule). Regardless of whether the taxpayers participate voluntarily, whether the taxpayers receive the Medicaid payments from a Medicaid managed care plan, or whether taxpayers themselves or another entity make redistribution payments using the very dollars received as Medicaid payments or with other provider funds that are replenished by the Medicaid payments, the taxpayers participating in these

www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.

redistribution arrangements have a reasonable expectation that they will be held harmless for all or a portion of their tax amount.

We stated that the addition of the words ''or indirectly'' in the regulation indicates that the State itself need not be involved in the actual redistribution of Medicaid funds for the purpose of returning tax amounts to taxpayers in order for the arrangement to qualify as a hold harmless (73 FR 9694). We further noted in the same preamble that we used the term ''reasonable expectation'' because ''State laws were rarely overt in requiring that State payments be used to hold taxpayers harmless'' (73 FR 9694). Hold harmless arrangements need not be overtly established through State law or contracts but can be based upon a reasonable expectation that certain actions will take place among participating entities to return to taxpaying providers all or any portion of their tax amounts. The redistribution arrangements detailed earlier constitute a hold harmless arrangement described in section 1903(w)(4) of the Act and implementing regulations in part 433. Such arrangements require a reduction of the State's medical assistance expenditures as specified by section 1903(w)(1)(A)(iii) of the Act and § 433.70(b).

Approving an SDP under which the State share is funded through an impermissible redistribution agreement would also be inconsistent with ''proper and efficient administration'' of the Medicaid program within the meaning of section 1902(a)(4) of the Act, as it would result in expenditures for which FFP will ultimately have to be disallowed, when it would be more efficient to not allow such expenditures to be made in the first place. Therefore, we also rely on our authority under section 1902(a)(4) of the Act to specify methods of administration that are necessary for proper and efficient administration to support the authority to make explicit in § 438.6 that CMS may disapprove an SDP when we are aware the State share of the SDP would be based on an arrangement that violates section 1903(w) of the Act. We note that in addition to the foregoing, SDPs that are required by Medicaid managed care contracts must be limited to payments for services that are covered under the Medicaid managed care contract and meet the definition of medical assistance under section 1903(a) of the Act. Thus, to the extent the funds are not used for medical assistance, but diverted for another purpose, matching as medical assistance would not be permissible.

In the past, we have identified instances of impermissible redirection or redistribution of Medicaid payments and have taken action to enforce compliance with the statute. For example, the Board upheld our decision to disallow a payment redirection arrangement in a State under a FFS State plan amendment, citing section 1903(a)(1) of the Act, among other requirements (HHS, Board Decision No. 2103, July 31, 2007). Specifically, the Board found that written agreements among certain hospitals redirected Medicaid payments. The payments were not retained by the hospitals to offset their Medicaid costs, as required under the State plan. Instead, pre-arranged agreements redirected Medicaid payments to other entities to fund non-Medicaid costs. In its decision, the Board stated, ''Hence, they were not authorized by the State plan or Medicaid statute[.]'' When providers redistribute their Medicaid payments for purposes of holding taxpayers harmless or otherwise, in effect, the State's claim for FFP in these provider payments is not limited to the portion of the payment that the provider actually retains as payment for furnishing Medicaid-covered services, but also includes the portion that the provider diverts for a non-Medicaid activity ineligible for FFP (for example, holding other taxpayers harmless for their tax costs). This payment of FFP for non-qualifying activities also has the effect of impermissibly inflating the Federal matching rate that the State receives for qualifying Medicaid expenditures above the applicable, statutorily-specified matching rate (see, for example, sections 1903(a), 1905(b), 1905(y), and 1905(z) of the Act).

Ensuring permissible non-Federal share sources and ensuring that FFP is only paid to States for allowable Medicaid expenditures is critical to protecting Medicaid's sustainability through responsible stewardship of public funds. State use of impermissible non-Federal share sources often artificially inflates Federal Medicaid expenditures. Further, these arrangements reward providers based on their ability to fund the State share, and disconnect the Medicaid payment from Medicaid services, quality of care, health outcomes, or other Medicaid program goals. Of critical concern, it appears that the redistribution arrangements are specifically designed to redirect Medicaid payments away from Medicaid providers that serve a high percentage of Medicaid beneficiaries to providers that do not participate in Medicaid or that have relatively lower Medicaid utilization.

States have cited challenges with identifying and providing details on redistribution arrangements when we have requested such information during the review of SDPs. The current lack of transparency prevents both CMS and States from having information necessary for reviewing both the proposed non-Federal share financing source and the proposed payment methodology to ensure they meet Federal requirements. Some States have also stated concerns with ongoing oversight activities in which CMS is attempting to obtain information that may involve arrangements to which only private entities are a party. We are only interested in business arrangements among private entities that could result in a violation of Federal statutory and regulatory requirements.

As noted above, we recognize that health care-related taxes can be critical tools for financing payments that support the Medicaid safety net, but they must be implemented in accordance with applicable statutory and regulatory requirements. The policies in the rule will help ensure that CMS and States have necessary information about any arrangements in place that would redistribute Medicaid payments and make clear that we have the authority to disapprove proposed SDPs if States identify the existence of such an arrangement or do not provide required information or ensure the attestations are made and available as required under paragraph (c)(2)(ii)(H). The new attestation requirement will help ensure appropriate transparency regarding the use of Medicaid payments and any relationship to the non-Federal share source(s), and aims to do so without interfering with providers' normal business arrangements.

All Federal legal requirements for the financing of the non-Federal share, including but not limited to, subpart B of part 433, apply regardless of delivery system, although currently, § 438.6(c) does not explicitly state that compliance with statutory requirements and regulations outside of part 438 related to the financing of the non-Federal share is required for SDPs to be approvable or that CMS may deny written prior approval for an SDP based on a State's failure to demonstrate that the financing of the non-Federal share is fully compliant with applicable Federal law. The requirements applicable to health care-related taxes, bona fide provider related donations, and IGTs also apply to the non-Federal share of expenditures for payments under part 438. Currently,

§ 438.6(c)(1)(ii)(E) provides that a State must demonstrate to CMS, in writing, that an SDP does not condition provider participation in the SDP on the provider entering into or adhering to intergovernmental transfer agreement. We believe additional measures are necessary to ensure compliance with applicable Federal requirements for the source(s) of non-Federal share. We believe updating the regulations to explicitly condition written prior approval of an SDP on the State demonstrating compliance with applicable Federal requirements for the source(s) of non-Federal share will strengthen our ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Given the growing number of SDPs that raise potential financing concerns, and the growing number of SDPs generally, we believe it is important to be explicit in the regulations governing SDPs that the same financing requirements governing the sources of the non-Federal share apply regardless of delivery system, and that CMS will scrutinize the source of the non-Federal share of SDPs during the preprint review process. We are finalizing § 438.6(c)(2)(ii) to add a new paragraph (c)(2)(ii)(G) that will explicitly require that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, subpart B of part 433, as part of the CMS review process.

We are also finalizing our proposed revision to § 438.6(c)(2)(ii) to ensure transparency regarding the use of SDPs and to ensure that the non-Federal share of SDPs is funded with a permissible source. Under our regulation, States will be required to ensure that participating providers in an SDP arrangement attest that they do not participate in any hold harmless arrangement for any health care-related tax as specified in § 433.68(f)(3) in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount. Such hold harmless arrangements include those that produce a reasonable expectation that taxpaying providers will be held harmless for all or a portion of their cost of a health care-related tax. States will be required to note in the preprint their compliance with this requirement prior to our written prior approval of any contractual payment arrangement directing how Medicaid managed care plans pay providers. States will comply with this proposed requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation.

After reviewing comments, we have determined that we should make explicit that the failure of one or a small number of providers to submit an attestation would not necessarily lead to disapproval of the State's proposed SDP preprint. CMS may disapprove the SDP preprint proposal because some attestations are not obtained or are not made available by the State. However, CMS will still perform our standard, comprehensive review of whether a health care-related tax is allowable, and through this review may approve the proposed SDP preprint if the available information establishes that there is not likely to be a prohibited hold harmless arrangement in place. This policy recognizes that the presence or absence of provider attestations does not conclusively establish whether a hold harmless arrangement exists or not, but merely provides information that is relevant in determining whether there is or may be a hold harmless arrangement. It further recognizes that the actions of one or a small number of providers should not automatically invalidate the efforts of the State (and other providers in the State who would receive the SDP) to comply with financing requirements.

For example, the fact that a few providers (who would be eligible for an SDP) expect to pay more in taxes than they will receive in payments might lead these providers not to complete an attestation, even if no hold harmless arrangement is in place, because they find it to be in their interest not to make the attestation in order to interfere with implementation of the tax and/or the SDP. If that is the reason the State is unable to obtain attestations from all providers who would receive the SDP and there are no other indicia that a prohibited hold harmless arrangement is in place, we intend to leave flexibility to approve the SDP under this final rule. On the other hand, even if all providers who are eligible for an SDP attest that they do not participate in a hold harmless arrangement, we may disapprove the SDP or initiate actions to defer or disallow FFP under a previously approved SDP if we learn that a prohibited hold harmless arrangement is or appears to be in place despite the attestations.

We proposed, at § 438.6(c)(2)(ii)(H), to require that the State ensure that such attestations are available upon CMS request. To better reflect our standard review process for SDPs, we are finalizing the proposal to require States to, upon request, submit to CMS the provider attestations, with the modification that States may, as applicable, provide an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations. For an explanation to be satisfactory, it must demonstrate to CMS why the missing attestation(s) does not indicate that a hold harmless arrangement is or is likely to be in place and why the absence of the attestation(s) therefore should not impact our evaluation of the permissibility of the health care-related tax. We discuss this modification further in response to comments.

Under this rule, we note that CMS may deny written prior approval of an SDP if it does not comply with any of the standards in § 438.6(c)(2), including where the financing of the non-Federal share is not fully compliant with all Federal legal requirements for the financing of the non-Federal share and/or the State does not require an attestation from providers receiving a payment based on the SDP that they do not participate in any hold harmless arrangement. As part of our restructuring of § 438.6(c)(2), these provisions will apply to all SDPs, regardless of whether written prior approval is required. We relied on our authority in section 1902(a)(4) of the Act to require methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the Medicaid State Plan to finalize these requirements for ensuring that the source of the non-Federal share of the financing for SDPs is consistent with section 1903(w) of the Act. It is consistent with the economic and efficient operation of the Medicaid State Plan to ensure that State expenditures are consistent with the requirements to obtain FFP, and thereby avoid the process of recouping FFP when provided inappropriately, which is needlessly burdensome for States and CMS. Given that all Federal legal requirements for the financing of the non-Federal share, including but not limited to, subpart B of part 433, apply regardless of delivery system, we also solicited public comment on whether the proposed changes in § 438.6(c)(2)(ii)(G) and (H) should be incorporated more broadly into part 438.

For discussion on the proposed applicability dates for the provisions outlined in this section, see section I.B.2.p. of this final rule. Please note that we are updating the effective date for § 438.6(c)(2)(ii)(H) to no later than

the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, as discussed in the responses to comments on that provision.

We solicited public comments on these proposals.

We summarize and respond to public comments received on Financing (§ 438.6(c)(2)(ii)(G) and (H)) below.

Comments on § 438.6(c)(2)(ii)(G)

Please note that some commenters cited paragraph (G) in their comments; however, upon review we determined the comments were referencing the attestation policies contained in paragraph (H), and those comments are discussed separately after the paragraph (G) comments.

Comment: Some commenters stated that the proposed rule will restrict States' ability to raise funds to finance the non-Federal share of the Medicaid programs in the same manner as States have in the past. The commenters indicated that such a change would reduce the payment rates to providers, which may harm access to care for Medicaid beneficiaries.

Response: We recognize that any changes to States' financing can be challenging, given limited budgets. However, CMS disagrees that the regulation would restrict non-Federal share financing sources. Rather, this regulation emphasizes States' responsibilities to adhere to existing Federal financing requirements. If a State believes this regulation will require them to end a particular financing arrangement, then such an arrangement is already impermissible even absent the rule. When a State finds that it needs to transition to another financing source or modify an existing one, CMS works with that State to ensure such a transition can be executed as seamlessly as possible under Federal law.

CMS has worked with many States to modify financing arrangements over the years. To the extent that States find that they must change the source of their financing to comply with Federal law, States have several types of permissible means for financing the non-Federal share of Medicaid expenditures. As discussed earlier in this section, those include, but are not limited to: (1) State general funds, typically derived from tax revenue appropriated directly to the Medicaid agency; (2) revenue derived from health care-related taxes when consistent with Federal statutory requirements at section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; (3) provider-related donations to the State which must be ''bona fide'' in accordance with section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; and (4) IGTs from units of State or local government that contribute funding for the non-Federal share of Medicaid expenditures by transferring their own funds to and for the unrestricted use of the Medicaid agency.

The final rule is not designed to limit the amount of funds that States spend on qualifying services by reducing provider payment rates or otherwise. Rather, the rule is intended to ensure compliance with existing Federal requirements for financing the non-Federal share of program expenditures. CMS understands the critical role that health care-related taxes have in financing the non-Federal share of Medicaid expenditures in many States. According to MACPAC, for State fiscal year 2018, 17 percent of the non-Federal share of nationwide Medicaid expenditures was derived from health care-related taxes, totaling $36.9 billion.[121] The scale at which health care-related taxes have come to be used as the non-Federal share of Medicaid expenditures throughout the country underscores the importance of ensuring that these funds meet Federal requirements when used to pay for Medicaid expenditures.

Comment: One commenter stated that they understood that States are already required to follow all rules related to financing the non-Federal share of Medicaid payments, but did not provide any additional information.

Response: The commenter is correct that all Federal legal requirements for the financing of the non-Federal share, including those stated in section 1903(w) of the Act and implementing regulations in 42 CFR part 433, subpart B, apply to all non-Federal share financing arrangements. We assume the commenter meant to indicate that the need for this provision of the proposed rule was unclear, since the commenter understood that the existing requirements apply regardless of delivery system. However, before this final rule, § 438.6(c) did not explicitly state that compliance with statutory requirements and regulations outside of part 438 related to the financing of the non-Federal share is required for SDPs to be approvable or that CMS may deny written prior approval for an SDP based on a State's failure to demonstrate that the financing of the non-Federal share is fully compliant with applicable Federal law. We are concerned that the failure of the current regulations to explicitly condition written prior approval of an SDP on compliance with the non-Federal share financing requirements may create some ambiguity with regard to our ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Although this commenter is correct about the funding requirements already existing, the proposed rule and this final rule were written to remove any possibility of confusion and codify that SDPs may be disapproved on the basis of impermissible financing.

Comment: One commenter indicated that the broad language in paragraph (G) requiring compliance ''with all Federal legal requirements for the financing of the non-Federal share,'' coupled with the use of ''including but not limited to,'' would cause uncertainty regarding CMS' interpretation of Federal requirements, does not provide enough information for providers to know what they are attesting to, and that sub-regulatory guidance would be an inappropriate means to provide clarifications because such guidance would in effect be requirements.

Similarly, another commenter objected to the way that they anticipated CMS would implement a final regulation through the issuance of sub-regulatory guidance that goes beyond the regulatory requirements. The commenter stated concerns that CMS would impose further requirements on States using sub-regulatory guidance, rather than through the rulemaking process.

Response: The provision at § 438.6(c)(ii)(G) explicitly requires that an SDP comply with all Federal statutory and regulatory requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, as part of the CMS review process. The regulatory citation following ''including but not limited to'' is an illustrative example, and one we wanted to state explicitly, but it does not change the requirement to comply with all financing requirements. For example, the provision also requires compliance with section 1903(w) of the Act. This requirement will help ensure that States are compliant with all Federal requirements regarding non-Federal share financing. Paragraph § 438.6(c)(ii)(H) requires States to ensure that providers receiving an SDP attest that they do not participate in any hold harmless arrangement for any health care-related tax. Providers will not be required to attest to a State's compliance

[121] *See https://www.macpac.gov/wp-content/uploads/2020/01/Health-Care-Related-Taxes-in-Medicaid.pdf.*

with financing rules; rather, States will be required to ensure that providers attest to their own conduct.

Any guidance CMS would release to clarify the requirement in § 438.6(c)(ii)(G) would not change requirements, because the regulation already encompasses all Federal statutory and regulatory requirements. CMS uses sub-regulatory guidance to, among other things, explain how we interpret a statute or regulation, or provide additional clarifications. One of the main purposes of guidance is to explain and help States comply with agency regulations, particularly for circumstances that were not necessarily anticipated when issuing a regulation and when additional clarifications are needed. CMS cannot anticipate every scenario that States will encounter as they implement requirements, but the inability to anticipate every possible future scenario does not mean that such scenarios will not already be subject to the requirements finalized in regulation, which underscores the potential need for and role of sub-regulatory guidance. As such, CMS will continue to issue interpretive subregulatory guidance, as appropriate, to help ensure that requirements for States are clear and transparent.

Comment: One commenter objected to CMS imposing new financing requirements on SDPs and indicated that the proposed rule would create inconsistency between requirements for FFS payments and payments under managed care arrangements.

Response: As we noted in the preamble to the proposed rule [122] and in this final rule, the statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, already apply to all Medicaid expenditures regardless of delivery system (FFS or managed care). We are not imposing new financing requirements on SDPs. Rather, we reiterate that it is important to be explicit in the regulations governing SDPs that the same financing requirements governing the sources of the non-Federal share apply regardless of delivery system. CMS views these finalized regulations as improving financing consistency.

Comment: One commenter supported CMS' proposals related to SDPs on the basis that these requirements would help ensure that provider payments are consistent with Federal requirements.

Response: We are finalizing the changes to the financing regulations at § 438.6(c)(2)(ii)(G) as proposed.

Comments on § 438.6(c)(2)(ii)(H)

Comment: Some commenters were concerned that the proposed rule requiring States to ensure that providers receiving an SDP attest to their compliance with certain financing requirements would add burden to States, providers, or managed care plans. Two commenters noted that, under the proposed rule, States could delegate to managed care plans the responsibility for gathering the attestations and suggested that doing so would be burdensome to providers, which may be under contract with a number of different managed care plans. Commenters suggested limiting the number of attestations to one per provider, or requiring States to collect the attestations, rather than allowing States to delegate to managed care plans.

Response: We understand that some States may have to take on new responsibilities to implement the requirements of § 438.6(c)(2)(ii)(H). To assist in these efforts, we will work with States to provide technical assistance, and we are also available to assist States with questions about matching funds for qualifying State Medicaid administrative activities to implement the regulation.

After consideration of the public comments, as further discussed in this section, we are finalizing § 438.6(c)(2)(ii)(H) with modifications discussed in other responses in this section of the final rule. To help ease the transition to the collection of required provider attestations, we are establishing an applicability date at § 438.6(c)(8)(vii) of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, for the attestation provisions located at § 438.6(c)(ii)(H), to allow States sufficient time to establish the attestation collection process that works best for their individual circumstances. This will also provide time for States to restructure SDPs that may involve arrangements that prevent providers from truthfully attesting that they do not engage in hold harmless arrangements. We will utilize this time to collect additional information about the prevalence of hold harmless arrangements and work with States to come into compliance.

We acknowledge that, if States delegate to Medicaid managed care plans the responsibility for collecting attestations, providers may need to submit multiple attestations if they participate in multiple managed care networks. Furthermore, providers may need to submit multiple attestations if they are subject to multiple State taxes and/or receive multiple SDPs, in particular if the provider participates in multiple tax and payment programs that operate on different timelines. To minimize burden on providers, Medicaid managed care plans, and States, we recommend States that delegate the collection of provider attestations to Medicaid managed care plans furnish standardized attestation language or forms that reflect which tax or taxes it concerns and what time period it covers, and that, in general, are as comprehensive as reasonably possible under the circumstances in the State. Ultimately, States will be responsible for implementing the attestation requirement under this final rule, and CMS encourages States to consider the complexities that may arise from delegating the responsibility to plans. States may find it is ultimately more efficient to gather the attestations, one per provider, to limit complexity or variations in process with the multiple managed care plans with which a provider may participate.

Our goal of ensuring compliance with the law warrants the additional State and Federal resources required to implement these provisions, as we are increasingly encountering issues with States financing the non-Federal share of SDPs using potentially impermissible hold harmless arrangements. CMS has a duty to ensure that Federal financial participation is paid only in accordance with Federal law. In addition, the applicability date of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, will allow sufficient time for States to develop systems to collect attestations in the most efficient, least burdensome way for each.

Comment: Some commenters noted that the requirement for providers to sign attestations was ''overly broad,'' which could lead to confusion among States, managed care plans, and providers. One commenter stated that CMS needs to clarify the scope of the attestation requirement to specify exactly what parties are attesting to generally and particularly for hold harmless relationships.

Response: We understand that States will be taking on increased responsibility for ensuring that providers receiving SDPs attest that they do not participate in hold harmless arrangements under § 433.68(f)(3). We

[122] 88 FR 28092 at 28129.

also understand that providers may be confused by the requirement to attest to matters concerning laws they may not have considered previously. The regulation at paragraph § 438.6(c)(2)(ii)(H) makes clear that providers would need to attest to their compliance with § 433.68(f)(3), and we would expect States to guide providers on this provision and the types of arrangements prohibited under that regulation before they are expected to sign. We also note that States have flexibility in how they frame their attestations and in the specific instructions they make to providers, so long as the requirements of the regulation are met. As always, CMS will work diligently with States to provide technical assistance as necessary to guide a State through any unique circumstances. We will also release sub-regulatory guidance if needed to highlight use cases and best practices.

Comment: One commenter recommended that CMS collect the attestations from providers rather than requiring States to do so, to avoid imposing additional burdens on State governments.

Response: We recognize that States have responsibility for managing Medicaid programs, and the new attestation requirement may increase some States' responsibilities further when States use SDPs. However, we generally do not have the direct relationship that each State has with its Medicaid providers and managed care plans, as providers enroll through States and are paid by States or State-contracted plans and generally do not interact with us. Conversely, we have an extensive partnership with States. As such, we determined the most appropriate mechanism to ensure compliance with financing requirements is for States (or plans, at the direction of States) to collect these attestations. The rule is clear that States are not required to submit these attestations to us en masse, but rather to retain and make them available to us upon request. As always, we will work diligently with States to provide technical assistance and sub-regulatory guidance as necessary, and when possible, to reduce burden on States. In addition, the effective date of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, for § 438.6(c)(ii)(H) will allow States sufficient time to develop processes to minimize State administrative burden.

Comment: One commenter sought clarification on how the proposed regulation would be applied if a provider declined to sign the attestation or if a provider did sign the attestation and was later found to be in violation of § 433.68(f)(3). Another commenter requested clarity about how CMS would treat States when a provider fails to comply with the signed attestation.

Response: As noted in the preamble to the proposed rule [123] and in this final rule, States would be required to note in the preprint their compliance with this requirement prior to our written approval of SDPs. As a result, if a State sought approval of an SDP preprint for which not every provider that would receive an SDP had submitted an attestation under § 438.6(c)(ii)(H), then the SDP preprint would be at risk of disapproval.

However, as discussed earlier in this section, CMS will still be performing a comprehensive review of the permissibility of the SDP and the source(s) of non-Federal share that support the SDP, including any applicable health care-related taxes. In the case of a health care-related tax, the presence or absence of one or more attestations will be a component of our review. We do not believe that it would represent sound Medicaid policy to allow one or a small number of providers, for reasons unrelated to participation in impermissible arrangements, to obstruct approval of an entire SDP that could apply to hundreds of providers. Similarly, it would not represent sound Medicaid policy to automatically approve SDPs when 100 percent of relevant attestations are provided by the State, if CMS has specific information indicating that a hold harmless arrangement is, or is likely to be, in place.

There are several possible scenarios where a State might be unable to collect one or more attestations, yet CMS would determine that the absence of those attestations does not indicate that an impermissible hold harmless arrangement is likely to exist. For example, a provider might expect to pay more under a health care-related tax than it will receive in Medicaid payments supported by the tax, and therefore might refuse to provide an attestation in an attempt to interfere with implementation of the tax and the SDP even if no hold harmless arrangement exists. In instances where not all providers sign the required attestations, CMS will expect the State to provide sufficient information to determine the reason(s) behind the failure to obtain attestations from all providers eligible for an SDP, which is a component of CMS's overall review of approvability. The requirement for States to collect all attestations nevertheless remains a necessary component of this process, as it will allow CMS to still consider available attestations in our review of whether the non-Federal share meets Federal requirements. Additionally, through the process of collecting provider attestations, we expect the State will gain information about why certain providers may fail to submit them, which the State will need to share with us under the requirement in this final rule that the State provide an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make required attestations. CMS will view the lack of an attestation or attestations as evidence that there are impermissible hold harmless arrangements, unless the State satisfactorily explains how the absence of the attestation(s) does not suggest that a hold harmless arrangement is in place or is otherwise unrelated to the permissibility of the health care-related tax.

When a provider signs an attestation, they affirm the attested information to be true. States should treat these attestations in the same manner as they treat other attestations supplied by providers that affirm that the provider complies with various requirements to receive payment. As with all Federal requirements, States must oversee their programs to ensure that the State can identify noncompliant providers. As described earlier in the preamble to this section, if a provider submits an inaccurate attestation or refuses to submit a signed attestation, FFP could be at risk, because the State may be claiming Medicaid expenditures with an impermissible source of non-Federal share (due to the existence of a hold harmless arrangement). In such a situation (for example, where a provider fails to provide a required attestation), the State could make signing an attestation a condition of eligibility for the SDP, according to the terms of the contract that conditions receipt of SDP funds on compliance with provision of an attestation, as a risk mitigation strategy, to avoid making a payment that guarantees to hold the taxpayer harmless. Some States have already undertaken this approach. If the State chooses this risk mitigation strategy, the State should include the requirement that a provider sign an attestation to qualify for the SDP in its contracts with the managed care plans making the payments to providers.

After consideration of the public comments, we are modifying the regulatory text at § 438.6(c)(ii)(H) to include language saying States must

[123] 88 FR 28092 at 28132.

''ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.'' This change will help protect States, and other providers submitting attestations, in cases of uncooperative and/or unresponsive providers. We emphasize that, while providers refusing to sign the attestations may result in an SDP disapproval, it does not mean that it necessarily will. Conversely, we also want to emphasize that the ability to provide CMS an explanation should not be regarded as a pathway to automatic approval in the absence of one or more provider attestations, as CMS will not approve an SDP where there is evidence that the payments would be funded by an impermissible arrangement. CMS will still perform our standard, comprehensive review to determine whether the SDP is approvable considering a variety of factors, including the underlying source(s) of non-Federal share and will consider all available information, which includes attestations and State explanations about missing attestations, as applicable.

As stated previously, for a State's explanation for a missing attestation to be satisfactory to CMS, it must demonstrate why the absence of the attestation(s) is not indicative of a hold harmless arrangement. The State should demonstrate how it made a good faith effort to obtain the attestation and why it does not believe that the absence of the attestation(s) should be considered evidence of the existence of a hold harmless arrangement. A State could do this in many ways. For example, an explanation could include relevant information about the business status of the provider(s) in question, such as information about solvency, and demonstrate how these circumstances reflect that a hold harmless arrangement is not in place. In this example, a State might note if the providers in question lacked sufficient resources to obtain a timely review of the attestation by legal counsel. As another example, a State could include relevant information about the providers' revenue. In this case, the State might describe its efforts to obtain all attestations and indicate that of 150 participating providers, only two providers with an extremely small amount of all-payer revenue (who may be less motivated to assist with SDP approval) did not file an attestation. A State could note further any information that may indicate a hold harmless arrangement does not exist with respect to the SDP and related taxes, such as how the absence of a single attestation with all remaining participating providers attesting would tend to suggest that there is not an impermissible arrangement in place among providers eligible for an SDP. However, if the State's explanation is insufficient to establish that a hold harmless arrangement is unlikely to exist, then CMS can and may deny the SDP.

As described in the proposed rule, CMS's statutory obligation is to ensure proper and efficient operation of the Medicaid program. We will disapprove an SDP when we know the payments would be funded under an impermissible arrangement, or if upon request, the State does not provide sufficient information to establish that the non-Federal share source is permissible. The attestation requirement is an assurance measure that is in furtherance of that obligation, but at no point was it intended as the sole indicator of whether an SDP would be supported by a permissible source of non-Federal share or as the sole deciding factor for whether the SDP can be approved. We believe it would be unnecessarily punitive on States and unrealistic to not provide an opportunity to explain why one or more provider attestations could not be obtained, and for CMS to consider whether the circumstances for the failure to obtain such attestations might not suggest the existence of a hold harmless arrangement, before deciding whether to approve an SDP.

Comment: A few commenters stated that they did not agree with how CMS interprets the statute's definition of hold harmless arrangements. Specifically, several commenters stated that CMS' interpretation overstepped or misinterpreted the ''plain language'' of the statute. Some of those commenters asserted that the statute specifies that States must be responsible for arranging the hold harmless agreement. They stated that, if private actors create an arrangement without State involvement, it should not be considered a violation of the statute. They noted that the proposed rule would further codify what they consider to be CMS' erroneous interpretation of the statute's hold harmless definition, and illegally interferes with private providers engaging in private arrangements to mitigate the impact of a provider tax. Several commenters specifically referenced a lawsuit that was brought by the State of Texas against CMS that has resulted in the court preliminarily enjoining CMS from disapproving or acting against certain financing arrangements within Texas.

Response: We do not agree with commenters' characterization that the proposed regulation and the requirements of this final rule overstep the plain language of the statute. The statute requires all Medicaid payments be supported by financing that complies with section 1903(w) of the Act, which, as relevant to the provider attestation requirement in § 438.6(c)(ii)(H), defines a hold harmless arrangement to exist if the State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax. Regulations at § 433.68(f)(3) interpret this provision to specify that a hold harmless arrangement exists where a State or other unit of government imposing a health care-related tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount. By providing a payment that is then redistributed through private arrangements that offset the amount paid by a taxpayer, a State has indirectly provided for a payment that guarantees to hold the taxpayer harmless.

As such, we do not agree with commenters' assertion that the proposed rule would require providers to attest to anything beyond what is currently required under statute and regulation, as arrangements that redistribute Medicaid payments to hold providers harmless for the tax amounts they pay are prohibited under current law. The February 2008 final rule on health care-related taxes specified that hold harmless arrangements prohibited by § 433.68(f)(3) exist ''[w]hen a State payment is made available to a taxpayer or a party related to the taxpayer (for example, as a nursing home resident is related to a nursing home), in the reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax.'' [124]

Regardless of whether the taxpayers participate mandatorily or voluntarily, or receive the State's Medicaid payment directly from the State or managed care plan or indirectly from another provider or other entity via redistribution payments (using the dollars received as Medicaid payments or with other provider funds that are replenished by Medicaid payments), the taxpayers participating in these redistribution arrangements have a reasonable

[124] 73 FR 9694.

expectation that they will be held harmless for all or a portion of their tax amount. We have consistently noted that we use the term ''reasonable expectation'' because ''State laws were rarely overt in requiring that State payments be used to hold taxpayers harmless.'' [125]

We acknowledge that on June 30, 2023, a Federal district court in Texas issued a preliminary injunction enjoining the Secretary from implementing or enforcing the Bulletin dated February 17, 2023, entitled ''CMCS Informational Bulletin: Health Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments,'' or from otherwise enforcing the interpretation of the scope of 42 U.S.C. 1396b(w)(4)(C)(i) (section 1903(w)(4)(C)(i) of the Act) found therein. That injunction remains in effect, and we will abide by it as long as it remains in effect, in implementing the attestation requirements contained in § 438.6(c)(ii)(H) of this final rule.

Comment: One State commenter objected to the proposed rule because they currently have a pooling arrangement that the State says is compliant with Federal law and working well. Specifically, the commenter noted that in their State, providers have had various private agreements to redistribute funds among themselves for decades, with the full knowledge and approval of CMS.

Response: We do not agree with the commenter that an arrangement that pools and redistributes Medicaid payments to hold providers harmless for tax payments would comply with Federal law and regulations. The foundation of Federal-State shared responsibility for the Medicaid program is that the State must participate in the financial burdens and risks of the program. This requirement for a State financial interest in operating and monitoring its Medicaid program helps ensure that the State operates the program in the best interest of beneficiaries (see section 1902(a)(19) of the Act) and in a manner that results in receiving the best value for Federal and State taxpayers for the funds expended.

Section 1902(a)(2) of the Act and its implementing regulation in 42 CFR part 433, subpart B require States to share in the cost of medical assistance expenditures and permit other units of State or local government to contribute to the financing of the non-Federal share of medical assistance expenditures where applicable Federal requirements are met. These provisions are intended to safeguard the Federal-State partnership, irrespective of the Medicaid delivery system or payment authority. The provisions do so by ensuring that States are meaningfully engaged in identifying, assessing, mitigating, and sharing in the risks and responsibilities inherent in operating a program as complex and economically significant as Medicaid. States are accordingly motivated to administer their programs economically and efficiently. Medicaid payment redistribution arrangements undermine the fiscal integrity of the Medicaid program by their apparent design to redirect Medicaid payments away from Medicaid providers that serve a high percentage of Medicaid beneficiaries to providers that do not participate in Medicaid or that have relatively lower Medicaid utilization. Further, they are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements and artificially inflate Federal Medicaid expenditures.

Comment: One commenter noted that in its State, some institutional providers have complex partnership and ownership relationships with other institutions, both within and outside of the State. The commenter anticipated needing more guidance as to what arrangements would be permissible.

Response: We recognize that the requirement to obtain attestations from providers that would receive an SDP places additional responsibilities on States, and we recognize that many States impose taxes on and pay providers that have multiple business and financial relationships with one another. Large ownership groups operate in multiple States and with different types of providers. CMS does not intend to interfere with the normal business operations of any providers, large or small. However, the final rule will help avoid arrangements in which providers are explicitly connecting taxes to payments in a manner that holds taxpayers harmless. CMS will work with each State as needed to ensure that the law can be applied appropriately in all circumstances, consistent with applicable statutory and regulatory requirements.

Comment: One commenter lauded what they called the ''safe harbor Hold Harmless provisions'' as an important tool for financing States' share of Medicaid payments and recommended that, rather than finalizing the proposed rule, CMS should more vigorously enforce ''safe harbor'' compliance.

Response: We agree that enforcing the existing requirements concerning health care-related taxes would be beneficial. As such, CMS believes that the attestation requirement is necessary to ensure that SDPs are financed appropriately.

In addition, the ''safe harbor'' threshold located at 42 CFR 433.68(f)(3)(i)(A) states that taxes that are under 6 percent of net patient revenue attributable to an assessed permissible class pass the indirect hold harmless test. This test is an important financing accountability requirement, but it is not addressed in this rulemaking. We also remind the commenter that the 6 percent indirect hold harmless limit does not mean that States are permitted to have direct hold harmless arrangements if the amount of the tax is less than 6 percent of net patient revenue. The 6 percent indirect hold harmless test is an additional requirement on top of, not in place of, the prohibition against having a direct hold harmless arrangement, including through indirect payments.

Comment: One commenter stated that CMS should not adopt a new substantive rule governing Medicaid financing that is limited to managed care, but rather such requirements should apply broadly to all delivery systems and payments by amending financing rules generally. The commenter stated concerns that an inconsistent application of a new policy would result in arbitrary and capricious distinctions between Medicaid FFS and managed care expenditures, as well as between Medicaid managed care directed and non-directed payments.

Response: We appreciate the commenter's perspective on ensuring consistency across payment types and delivery systems. Partly in response to this shared concern, in the proposed rule, we requested public comment on whether the proposed changes in § 438.6(c)(2)(ii)(G) and (H) should be incorporated more broadly into 42 CFR part 438 in future rulemaking. We appreciate the commenter's feedback.

We also note that as part of our review of SDP proposals, we are increasingly encountering issues with State financing of the non-Federal share of SDPs that may not comply with the underlying Medicaid statute and regulations. In addition, concerns around the funding of the non-Federal share for SDPs have been raised by oversight bodies. Further, CMS at times denies approval of proposed State plan amendments affecting FFS payments due to unallowable sources of non-Federal share. States that have SDPs disapproved because of impermissible financing will also have the opportunity to engage in an administrative appeals process if they choose, similar to how

[125] *Id.*

States may administratively appeal the disapproval of a FFS payment State plan amendment.

Comment: We received a few comments that addressed this provision generally, and opposed implementation, but the commenters did not provide further explanation.

Response: We do not agree with these comments, we appreciate the concerns stated, and wherever possible we will seek to assist States with meeting these new requirements.

After reviewing the public comments, we are finalizing the following changes to the financing attestation provision in § 438.6(c)(2)(ii)(H):

- Updating the proposed language, ''ensure that providers receiving payment under a State directed payment attest that providers do not participate in any hold harmless arrangement'' to read, in paragraph (H)(*1*), ''ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement.''
- Updating the proposed language, ''directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount'' to read, in paragraph (H)(*1*), ''directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount.''
- Updating § 438.6(c)(2)(ii)(H) with an organizational change to divide the provision into paragraphs (H)(*1*) and (H)(*2*).
- Updating the proposed language, ''ensure that such attestations are available upon CMS request'' to read, in paragraph (H)(*2*), ''ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.''

h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))

A fundamental requirement of SDPs is that they are payments related to the delivery of services under the contract. In the 2016 final rule, we stated how actuarially sound payments, which are required under section 1903(m)(2)(A)(iii) for capitation payments to MCOs and under part 438 regulations for capitation payments to risk-based PIHPs and PAHPs, must be based on the provision of covered benefits and associated administrative obligations under the managed care contract (81 FR 27588). This requirement that SDPs be tied to the utilization and delivery of covered benefits differentiates SDPs from pass-through payments. We described the differences between pass-through payments and SDPs in the 2016 final rule and in the 2017 Pass-Through Payment Rule, where we noted that pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services (81 FR 27587 through 27592, 82 FR 5415).

The current regulations at § 438.6(c)(2)(ii)(A) require that States demonstrate in writing that SDPs that require prior written approval be based on the utilization and delivery of services to Medicaid enrollees covered under the managed care plan contract. We have interpreted and applied this requirement to mean that SDPs must be conditioned upon the utilization or delivery of services during the rating period identified in the preprint for which the State is seeking written prior approval. Requiring SDPs to be based on the utilization and delivery of services is a fundamental and necessary requirement for ensuring the fiscal and program integrity of SDPs, but we believe further clarification is appropriate due to the variety of payment mechanisms that States use in their SDP arrangements. Ensuring that payments are based on the delivery of services in SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii) is relatively straightforward since fee schedules explicitly link a rate to each code (for example, CPT or HCPCS), compared to SDPs that are VBP initiatives described in § 438.6(c)(1)(i) and (ii). As discussed in further detail in section I.B.2.i. of the proposed rule and in this final rule, ensuring that payments in VBP initiatives are based on the delivery of services in ways that do not hinder States' ability to pursue VBP efforts is more difficult because, by their nature, VBP initiatives seek to move away from paying for volume (or per services) in favor of paying for value and performance. We proposed revising § 438.6(c) to address how different types of SDPs must be based on utilization and delivery of covered services; this section discusses these requirements for fee schedule arrangements and section I.B.2.i. of this final rule discusses the requirements for VBP initiatives.

For SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii), the tie to utilization and delivery of services means that States require managed care plans to make payments when a particular service was delivered during the rating period for which the SDP was approved. Thus, the State could not, under our interpretation of the requirement, require managed care plans to make payments for services that were delivered outside of the approved rating period. However, in working with States, we found that this was not always understood. Therefore, we clarified this in SMDL #21–001,[126] and noted that SDPs need to be conditioned on the delivery and utilization of services covered under the managed care plan contract for the applicable rating period and that payment cannot be based solely on historical utilization.

We proposed to codify this clarification in a new § 438.6(c)(2)(vii)(A) for SDPs described in § 438.6(c)(1)(iii)—that is, minimum fee schedules, maximum fee schedules, and uniform increases. The proposal would require that any payments made under the SDP are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only. This will preclude States from making any SDP payment based on historical utilization or any other basis that is not tied to the delivery of services in the rating period itself.

Our proposal also addressed SDPs that require reconciliation. In SMDL #21–001,[127] we noted that in capitation rate development, States can use historical data to inform the capitation rates that will be paid to managed care plans for services under the rating period, and this is consistent with § 438.5(b)(1) and (c). However, in accordance with current requirements in § 438.6(c)(2)(ii)(A), payment to providers for an SDP must be made based on the delivery and utilization of covered services rendered to Medicaid beneficiaries during the rating period documented for the approved SDP. We have reviewed and approved SDPs, typically SDPs that establish uniform increases of a specific dollar amount, in which States require managed care plans to make interim payments based on historical utilization and then after the close of the rating period, reconcile the payments to actual utilization that occurred during the rating period approved in the SDP. For these SDPs, States include the SDP in the rate certification and then once actual utilization for the current rating year is known, we observe that in many cases States have their actuaries submit an amendment to adjust the amount paid to plans (whether through a separate payment term or an adjustment to base

[126] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

[127] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

rates) to account for this reconciliation. These amendments typically come near to or after the close of the rating period and are most common when the reconciliation will result in increased costs to the plan absent the adjustment. As a result, risk is essentially removed from the managed care plans participating in the SDP. We are concerned with this practice as we believe tying payments in an SDP, even interim payments, to utilization from a historical time period outside of the rating period approved for the SDP, is inconsistent with prospective risk-based capitation rates that are developed for the delivery of services in the rating period. Further, rate amendments that are submitted after the rating period concludes that adjust the capitation rates retroactively to reflect actual utilization under the SDP goes against the risk-based nature of managed care. To address this, we proposed a new § 438.6(c)(2)(vii)(B) which will prohibit States from requiring managed care plans to make interim payments based on historical utilization and then to reconcile those interim payments to utilization and delivery of services covered under the contract after the end of the rating period for which the SDP was originally approved.

To illustrate our concern and need for the proposed regulatory requirement, we share the following example for a State that has an SDP approved to require a uniform increase to be paid for inpatient hospital services for CY 2020. During CY 2020, the State's contracted managed care plans pay the inpatient hospital claims at their negotiated rates for actual utilization and report that utilization to the State via encounter data. Concurrently, the State directs its managed care plans, via the SDP, to make a separate uniform increase in payment to the same inpatient hospital service providers, based on historical CY 2019 utilization. Under this example, the increase in January CY 2020 payment for the providers is made based on January CY 2019 data, the increase in February CY 2020 payment is based on February CY 2019 data, and so forth. This pattern of monthly payments continues throughout CY 2020. After the rating period ends in December 2020, and after a claims runout period that can be as long as 16 months, the State then in mid-CY 2021 or potentially early 2022, reconciles the amount of CY 2019-based uniform increase payments to the amount the payments should be based on CY 2020 claims. The State then requires its managed care plans to make additional payments to, or recoup payments from, the hospitals for under- or over-payment of the CY 2019-based uniform increase.

In the inpatient hospital uniform increase example above, the State may initially account for the SDP in the CY 2020 rate certification and, after the rating period is over, the State submits an amendment to their rate certification to revise the total dollar amount dedicated to the SDP and the capitation rates to reflect the SDP provider payments that were made based on actual utilization in the CY 2020 rating period—thereby, making the managed care plans ''whole'' and removing risk from the managed care plans participating in the SDP. We do not find these practices consistent with the nature of risk-based managed care.

Capitation rates must be actuarially sound as required by section 1903(m)(2)(A)(iii) of the Act [128] and in § 438.4. Specifically, § 438.4(a) requires that actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements outlined in § 438.4(b). ''Rating Period'' is defined at § 438.2 as a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a). We described in the proposed rule our belief that SDPs that make payments based on retrospective utilization and include reconciliations to reflect actual utilization, while eventually tying final payment to utilization and delivery of services during the rating period approved in the SDP, are contrary to the nature of risk-based managed care. SDPs must tie to the utilization and delivery of services to Medicaid enrollees covered under the contract for the rating period approved in the SDP.

We have previously issued regulations and guidance in response to payments we found to be inconsistent with the statute concerning actuarial soundness. In the 2016 rule we noted our belief that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services under the contract. We further noted that based on our review of capitation rates, we found pass-through payments being directed to specific providers that generally were not directly linked to the delivered services or the outcomes of those services; thereby noting that pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services.[129] These concerns led CMS to phase out the ability of States to utilize pass-through payments as outlined in § 438.6(d). In the proposed rule, we noted that we reached a similar conclusion in our review of SDP proposals which use reconciliation of historical to actual utilization; if States are seeking to remove risk from managed care plans in connection with these types of SDPs, it is inconsistent with the nature of risk-based Medicaid managed care. As further noted in the 2016 rule, ''[t]he underlying concept of managed care and actuarial soundness is that the [S]tate is transferring the risk of providing services to the MCO and is paying the MCO an amount that is reasonable, appropriate, and attainable compared to the costs associated with providing the services in a free market. Inherent in the transfer of risk to the MCO is the concept that the MCO has both the ability and the responsibility to utilize the funding under that contract to manage the contractual requirements for the delivery of services.'' [130]

States use retrospective reconciliations even though there are less administratively burdensome ways to ensure payment rates for specific services are at or above a certain level. States could accomplish this through the establishment of a minimum fee schedule, which we proposed to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s). If a State's intent is to require that managed care plans pay an additional amount per service delivered, States could accomplish this through the establishment of a uniform increase, which we proposed to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay the same amount (the same dollar or the same percentage increase) per covered service(s) in addition to the rates the managed care plan negotiated with providers. In addition to being less administratively burdensome, both options will provide more clarity to providers on payment rates and likely result in more timely

[128] The actuarial soundness requirements apply statutorily to MCOs under section 1903(m)(2)(A)(ii) of the Act and were extended to PIHPs and PAHPs under our authority in section 1902(a)(4) of the Act in the 2002 final rule.

[129] 81 FR 27587 and 27588.

[130] 81 FR 27588.

payments than a retrospective reconciliation process. Both options would also allow States' actuaries to include the SDPs into the standard capitation rate development process using the same utilization projections used to develop the underlying capitation rates. States can require both minimum fee schedules and uniform increases under current regulations and the amendments made in this final rule to § 438.6(c).

Requiring managed care plans to make interim payments based on historical utilization and then reconciling to actual utilization instead suggests an intent by State to ensure payment of a specific aggregate amount to certain providers or, in some cases, removal of all risk related to these SDPs from managed care plans. Prohibiting this practice and removing post-payment reconciliation processes as we proposed in § 438.6(c)(2)(vii)(B) will alleviate oversight concerns, align with the risk-based nature of capitation rates, as well as restore program and fiscal integrity to these kinds of payment arrangements.

We proposed to prohibit the use of post-payment reconciliation processes for SDPs; specifically, we proposed that States establishing fee schedules under § 438.6(c)(1)(iii) could not require that plans pay providers using a post-payment reconciliation process. These post-payment reconciliation processes that we proposed to prohibit here directs how the plans pay providers. We have raised concerns about the removal of risk from the plan and their use by some States in ways that are contrary to the risk-based nature of Medicaid managed care.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comments on our proposals.

We summarize and respond to public comments received on our proposal for tying utilization and delivery of services for fee schedule arrangements (proposed § 438.6(c)(2)(vii)) below.

Comment: Some commenters supported our proposal to prohibit States from requiring plans to make interim payments based on historical utilization and then reconciling these interim payments to utilization and delivery of services at the end of the rating period (meaning the proposal at § 438.6(c)(2)(vii)(B) and agreed that this change would ensure that payments made under an SDP be conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only, as specified at proposed § 438.6(c)(2)(vii)(A). Commenters stated these were reasonable and appropriate guardrails to ensure that SDPs are prospective and appropriately funded within capitation rates.

Response: We appreciate commenters' support for these proposals. These provisions are fundamental and necessary protections to ensure the fiscal and program integrity of SDPs and the risk-based nature of Medicaid managed care.

Comment: Many commenters opposed the requirements specified at § 438.6(c)(2)(vii)(A) and (B). Some commenters stated concern that these proposals would preclude States and managed care plans from making SDP payments to providers based on historical data altogether. Other commenters stated concerns that these policies could create cash flow problems for providers and thus impact access to care. Other commenters stated concern that payments from the managed care plans to providers could not be completed within the rating period which would mean that plans and States could not comply with this requirement. Some commenters suggested including a grace period after the rating period ends to allow for claims run out to occur. These commenters stated concern that these provisions would create State challenges for verifying that SDP rate increases are properly paid on each claim when paying contemporaneously. Many commenters requested that CMS clarify what practices would be allowable within these requirements.

Response: We acknowledge that many commenters stated either concern that historical data, interim payments and reconciliation could not be used at all under § 438.6(c)(2)(vii)(A) and (B) or requested additional clarification to ensure that reconciliation was still available in addition to claims runout practices. Our goal is to ensure the integrity of risk-based managed care. Payments to providers under SDPs must be based on utilization and delivery of services during the rating period in order to ensure that the payments are consistent with the nature of risk-based care and do not unnecessarily undermine the managed care plan's ability to manage its risk under the managed care contract.

To be clear, this provision, as proposed and as finalized here, does not prohibit all administrative reconciliation processes such as those standard provider payment processes associated with claims processing such as runout, adjudication, and appeal which may not be completed within the rating period. These processes can continue. We also note managed care plans should pay providers in a timely manner pursuant to § 447.46, and we believe this can be accomplished within the parameters of these requirements finalized in § 438.6(c).

For a broader example, we revisit our example from proposed rule (88 FR 28133) and adapt it to illustrate permissible uses of historical data, claims data, interim payments, reconciliation, and claims runout.

During CY 2020, the State's contracted managed care plans pay the inpatient hospital claims at their negotiated rates for actual utilization and report that utilization to the State via encounter data. Concurrently, the State directs its managed care plans, via the SDP, to make a uniform increase percentage payment of 3 percent per service rendered to the same inpatient hospital service providers. The total amount of the dollars to be paid during the rate period under the SDP was determined during capitation rate development using historical data from CY 2019, consistent with § 438.5(b)(1) and (c) and utilizing adjustments in rate development as appropriate in accordance with § 438.5(b)(4). During the rating period, the plans make estimated interim payments (negotiated base provider payment rates plus the 3 percent increase to those payment rates as directed by the SDP) quarterly to the qualifying providers based on utilization within a timeframe in the rating period (for example, an interim estimated payment is made in April based on utilization in January through March). When the claims runout is complete, which may take as long as 16 months, the plans make a final payment to the providers based on total actual utilization for services rendered during the rating period.

Under this example, historical data are used appropriately in capitation rate development for the managed care plans, consistent with § 438.5(b)(1) and (c), and not as the basis for interim payments from the plans to providers. Estimated interim payments are made by the plans to providers based on actual experience for a timeframe within the rating period to ensure there is no disruption in cash flow for providers. Claims can be continued to be paid by the plans to the providers after the end of the rating period, provided they are for utilization that occurred within the rating period, either by date of receipt of the claim or date of service, depending on the State's consistent methodology. Payment adjustments from the plan to the provider can still be used to ensure the plan's payments

to providers have been accurately tied to utilization within the rating period. The regulation at § 438.6(c)(2)(vii)(B), as proposed and finalized, does not prohibit reconciliation of payments to actual utilization during the rating period when interim payments were also based on utilization during the rating period. there is no need for a capitation rate amendment as the State has prospectively and appropriately assigned the risk to the plans and developed actuarially sound capitation rates.

However, in the example previously, the most straight forward way for plans to pay providers consistent with the required uniform increase is to increase the base payment to providers by 3 percent. When the base payment is adjusted this way, there is no need for plans to make adjustments to provider payments at a later date, and providers will receive full payment initially, rather than waiting a potentially significant amount of time for the plan to reconcile to actual utilization.

Comment: Some commenters opposed the provisions specified at § 438.6(c)(2)(vii)(A) and (B) given concerns that these provisions would reduce or remove States' ability to mitigate risk using SDPs. Another commenter did not agree that retroactively adjusting the payment amount circumvents the prospective, risk-based nature of the managed care arrangement; instead, the commenter stated that SDPs are intended to allow States to direct payment amounts through managed care plans, which by their nature removes some of the risk from the arrangement.

Response: As we have stated in the past, we believe that allowing States to direct the expenditures of a managed care plan to make payments to providers in a specified manner can reduce the plan's ability to effectively manage costs, and as we described in the proposed rule preamble, this is why we finalized specific parameters for SDPs in the 2016 final rule (88 FR 28110). We disagree that it is reasonable and appropriate for SDPs to be designed in a manner to fully remove risk from the managed care plans participating in the SDP as this is contrary to the nature of risk-based Medicaid managed care. For these reasons, we are finalizing 438.6(c)(2)(vii)(A) and (B) as proposed.

Comment: One commenter recommended that CMS create ''a threshold (perhaps 5 percent) of change in payment per-enrollee beyond which an additional [rate] certification would be required'' rather than prohibiting the use of interim payments as specified in § 438.6(c)(2)(vii)(B) if CMS's primary concern is that the SDP reconciliation would result in final capitation rates that are potentially different than the actuarially sound capitation rates. The commenter did not provide further details on this recommendation.

Response: We are unclear on the recommended alternative that the commenter suggested and there is not adequate detail to evaluate it further. We believe that States have appropriate flexibility under § 438.6(c)(2)(vii)(A) and (B), as we have outlined in the illustrative example above. All SDPs must be documented within rate certifications (see section I.B.2.l. of this final rule for further detail) and the types of changes in rates that do not require an amended rate certification are not changing in this rulemaking. For these reasons, we decline to revise § 438.6(c)(2)(vii)(A) and (B).

Comment: Some commenters opposed the provisions specified in § 438.6(c)(2)(vii)(A) and (B) as they noted that it would increase State administrative burden, and one of these commenters indicated it is administratively easier to reconcile payments from historical data. Some commenters also requested that if CMS does implement these provisions that they be delayed until ongoing challenges with the process of SDP preprint submissions, and CMS review and approval of these preprints are resolved.

Response: We do not agree that these provisions will create new administrative burden. As discussed in the proposed rule (88 FR 28134), retrospective reconciliation for SDP payments is administratively burdensome and we believe States can meet their goals using appropriate processes that eliminate the need to pay interim payments on experience outside of the rating period or conduct associated reconciliation processes. See a previous response to comment in this section in which we provide an illustrative example. We do not believe revisions to State and managed care plan processes to comply with § 438.6(c)(2)(vii)(A) and (B) would create excessive new administrative burden, as outlined in the illustrative example, and we are hopeful these changes could create administrative efficiencies. However, we acknowledge that States frequently pair separate payment terms with post payment reconciliation processes to ensure that the full separate payment term amount is paid out. Therefore, we are finalizing the applicability date for § 438.6(c)(2)(vii)(A) and (B) to align with the applicability date for the prohibition we are finalizing against separate payment terms in § 438.6(c)(6). State will be required to come into compliance with § 438.6(c)(2)(vii)(A) and (B) no later than the first rating period beginning on or after 3 years after the effective date of the final rule instead of the proposed 2-year compliance period. For discussion on the elimination of separate payment terms and related changes to the proposed regulation text, refer to sections I.B.2.k., I.B.2.l., I.B.2.m. and I.B.2.p. of this final rule.

We agree that improvements in the SDP preprint submission process are necessary. We believe our proposals related to SDP submission timeframes will improve the fiscal oversight of these SDPs and CMS's review and approval of SDP preprints (see section I.B.2.e. of this final rule for further details); and as such, we decline to further delay the implementation of these provisions. We also acknowledge that if a minimum fee schedule SDP is not approved until after the start of the rating period, plans are not prohibited from making retroactive payments to providers so long as the payments are made consistent with § 438.6(c), including that the payments are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(vii)(A) and (B) as proposed.

i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))

We also proposed several changes to § 438.6(c) to address how VBP initiatives, which include value-based purchasing, delivery system reform, and performance improvement initiatives as described in § 438.6(c)(1)(i) and (ii), can be tied to delivery of services under the Medicaid managed care contract, as well as to remove barriers that prevent States from using SDPs to implement these initiatives. Currently § 438.6(c)(2)(ii)(A) requires SDPs to be based on the utilization and delivery of services, so SDPs that require use of VBP initiatives must base payment to providers on utilization and delivery of services. Further, current § 438.6(c)(2)(iii)(A) requires States to demonstrate in writing that the SDP will make participation in the VBP initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the initiative. (As finalized in this rule, the same requirement is codified at

§ 438.6(c)(2)(vi)(A).) Existing regulations at § 438.6(c)(1)(i) and (ii) allow States to direct Medicaid managed care plans to implement value-based purchasing models with providers or to participate in delivery system reform or performance improvement initiatives; these types of SDPs require written prior approval from CMS. These provisions were adopted as exceptions to the overall prohibition on States directing the payment arrangements used by Medicaid managed care plans to pay for covered services. Since the 2016 rule, States have used SDPs to strengthen their ability to use their managed care programs to promote innovative and cost-effective methods of delivering care to Medicaid enrollees, to incent managed care plans to engage in State activities that promote certain performance targets, and to identify strategies for VBP initiatives to link quality outcomes to provider reimbursement. As the number of SDPs for VBP initiatives continues to grow, we have found that the existing requirements at § 438.6(c)(2)(iii) can pose unnecessary barriers to implementation of these initiatives in some cases. We proposed revisions to § 438.6(c) to address such barriers. First, we proposed to redesignate current paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase ''demonstrate in writing'' to be consistent with the effort to ensure that SDP standards apply to all SDPs, not only those that require prior approval. We also proposed to redesignate current paragraph (c)(2)(iii)(A) as paragraph (c)(2)(vi)(A).

To remove provisions that are barriers to implementation of VBP initiatives, add specificity to the types of arrangements that can be approved under § 438.6(c), and strengthen the link between SDPs that are VBP initiatives and quality of care, we proposed the following changes to the requirements that are specific to SDPs that involve VBP initiatives:

(1) Remove the existing requirements at § 438.6(c)(2)(iii)(C) that currently prohibit States from setting the amount or frequency of the plan's expenditures.

(2) Remove the existing requirements at § 438.6(c)(2)(iii)(D) that currently prohibit States from recouping unspent funds allocated for these SDPs.

(3) Redesignate § 438.6(c)(2)(iii)(B) with revisions and clarifications to § 438.6(c)(2)(vi)(B). The provision addresses how performance in these types of arrangements is measured for participating providers.

(4) Adopt a new § 438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these types of SDP arrangements.

Currently, § 438.6(c)(2)(iii)(C) prohibits States from setting the amount or frequency of expenditures in SDPs that are VBP initiatives. In the 2015 proposed rule,[131] we reasoned that while capitation rates to the managed care plans will reflect an amount for incentive payments to providers for meeting performance targets, the plans should retain control over the amount and frequency of payments. We believe that this approach balanced the need to have a health plan participate in a multi-payer or community-wide initiative, while giving the health plan a measure of control to participate as an equal collaborator with other payers and participants. However, VBP initiatives often include, by design, specific payment amounts at specific times. As States began to design and implement VBP initiatives, sometimes across delivery systems or focused on broad population health goals, many found that allowing plans to retain such discretion undermined the State's ability to implement meaningful initiatives with clear, consistent operational parameters necessary to drive provider performance improvement and achieve the goals of the State's program. Also, because some VBP initiatives provide funding to providers on bases other than ''per claim,'' these payment arrangements need to be designed and administered in a way that encourages providers to commit to meeting performance goals while trusting that they will receive the promised funding if they meet the performance targets. This is especially true for multi-delivery system arrangements or arrangements that do not make payments for long periods of time, such as annually. Inconsistencies in administration or payment can undermine providers' confidence in the arrangement. For example, States often direct their Medicaid managed care plans to distribute earned performance improvement payments to providers on a quarterly basis. Because these types of payment arrangements affect provider revenue differently than the usual per claim payment methodology, establishing strong parameters and operational details that define when and how providers will receive payment is critical for robust provider participation. While allowing States the flexibility to include the amount and frequency of payments when designing VBP and delivery system reform initiatives removes discretion from managed care plans, we believe this flexibility is necessary to ensure that States can achieve their quality goals and get value for the dollars and effort that they invest in these arrangements. Creating obstacles for States trying to implement VBP initiatives was not our intent in the 2016 final rule. Our goal then and now is to incent States to implement innovative initiatives that reward quality of care and improved health outcomes over volume of services. To accomplish this, we need to refine our regulations; we proposed to remove the existing text at § 438.6(c)(2)(iii)(C) that prohibits States from setting the amount and frequency of payment. We believe this will enable States to design more effective VBP initiatives using more robust quality measures to help ensure provider uptake, boost providers' confidence in the efficiency and effectiveness of the arrangement, and enable States to use VBP initiatives to achieve critical program goals.

Currently, § 438.6(c)(2)(iii)(D) prohibits States from recouping any unspent funds allocated for SDP arrangements from managed care plans when the SDP arrangement is for VBP, delivery system reform, or performance improvement initiatives. In the 2015 proposed rule, we noted that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds will remain with the MCO, PIHP, or PAHP. We believe this was important to ensure the SDPs made to providers were associated with a value relative to innovation and Statewide reform goals and not simply an avenue for States to provide funding increases to specific providers. However, allowing managed care plans to retain unspent funds when providers fail to achieve performance targets can create perverse incentives for States and managed care plans. States have described to us that they are often not incentivized to establish VBP arrangements with ambitious performance or quality targets if those arrangements result in managed care plans profiting from weak provider performance. Although States attempt to balance setting performance targets high enough to improve care quality and health outcomes but not so high that providers are discouraged from participating or so low that they do not result in improved quality or outcomes, many States struggle due to lack of experience and robust data. And unfortunately, failed attempts to implement VBP arrangements

[131] *https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered (pg 31124).*

discourage States, plans, and providers from trying to use the arrangements again. It was never our intent to discourage States from adopting innovative VBP initiatives, so we seek to address the unintended consequence created in the 2016 final rule by proposing to remove the regulation text at § 438.6(c)(2)(iii)(D) that prohibits States from recouping unspent funds from the plans. We noted in the proposed rule that removing this prohibition could enable States to reinvest these unspent funds to further promote VBP and delivery system innovation. To the extent a state intends to recoup unspent funds from plans for any State directed payment, this would need to be described in the State's preprint.

To expand the types of VBP initiatives that will be allowed under § 438.6(c)(1)(i) and (ii) and ensure a focus on value over volume, we also proposed additional revisions in § 438.6(c)(2)(vi) to distinguish between performance-based payments and the use of proposed population-based or condition-based payments to providers. These different types of VBP initiatives have different goals and conditions for payment, and we believe that establishing different requirements for them is necessary to establish the appropriate types of parameters for payment.

The existing regulations at § 438.6(c)(1)(i) and (ii) were intended both to incent State activities that promote certain performance targets, as well as to facilitate and support delivery system reform initiatives within the managed care environment to improve health care outcomes. We recognize that certain types of multi-payer or Medicaid-specific initiatives, such as patient-centered medical homes (PCMH), broad-based provider health information exchange projects, and delivery system reform projects to improve access to services, among others, may not lend themselves to being conditioned upon provider performance during the rating period.[132] Instead, these arrangements are conditioned upon other factors, such as the volume and characteristics of a provider's attributed population of patients or upon meeting a total cost of care (TCOC) benchmark, for example, through the provision of intense case management resulting in a reduction of poor outcomes related to chronic disease. Due to the diversity of VBP initiatives, we believe that the existing language at § 438.6(c)(2)(iii)(B), which requires that all SDPs that direct plan expenditures under § 438.6(c)(1)(i) and (ii) must use a common set of performance measures across all of the payers and providers, cannot be broadly applied to arrangements or initiatives under § 438.6(c)(1)(i) and (ii) that do not measure specific provider performance measures.

We believe the best way to address the limitations in current regulation text is to specify different requirements for VBP initiatives that condition payment upon performance from ones that are population or condition-based. Therefore, we proposed to use new § 438.6(c)(2)(vi)(B) for requirements for SDPs that condition payment on performance. We also proposed to adopt requirements in addition to redesignating the provision currently at § 438.6(c)(2)(iii)(B) to newly proposed § 438.6(c)(2)(vi)(B)(*2*). We proposed new requirements at new (c)(2)(vi)(B)(*1*) and (*3*) through (*5*) that are clarifications or extensions of the current requirement that SDPs use a common set of performance metrics.

We further proposed to add new § 438.6(c)(2)(vi)(C) to describe the requirements for SDPs that are population-based payments and condition-based payments.

Performance-Based Payments. Under current § 438.6(c)(2)(ii)(A), SDPs that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) and (ii) must be based on the utilization and delivery of services. Therefore, we have required that SDPs that are VBP initiatives be based on performance tied to the delivery of covered services to Medicaid beneficiaries covered under the Medicaid managed care contract for the rating period. This means that we have not allowed these types of SDPs to be based on ''pay-for-reporting'' because the act of reporting, alone, is an administrative activity and not a covered service. Instead, when States seek to design SDPs that pay providers for administrative activities rather than provider performance, we have encouraged States to use provider reporting or participation in learning collaboratives as a condition of provider eligibility for the SDPs and then tie payment under the SDP to utilization under (as required by § 438.6(c)(1)(iii)). At § 438.6(c)(2)(vi)(B)(*1*), we proposed to codify our interpretation of this policy by requiring payments to providers under SDPs that are based on performance not be conditioned upon administrative activities, such as the reporting of data, nor upon the participation in learning collaboratives or similar administrative activities. The proposed regulation explicitly stated our policy so that States have a clear understanding of how to design their SDPs appropriately. We recognize and understand the importance of establishing provider reporting requirements, learning collaboratives, and similar activities to help further States' goals for performance and quality improvement and want to support these activities; however, while these activities can be used as eligibility criteria for the provider class receiving payments, they cannot be the basis for receiving payment from the Medicaid managed care plan under an SDP described in § 438.6(c)(1)(i) or (ii) that is based on performance.

Currently, our policy is that the performance measurement period for SDPs that condition payment based upon performance must overlap with the rating period in which the payment for the SDP is made. However, we have found that States frequently experience delays in obtaining performance-based data due to claims run out time and the time needed for data analyses and validation of the data and the results. All of this can make it difficult, if not impossible, to comply with this requirement. Therefore, we proposed to permit States to use a performance measurement period that precedes the start of the rating period in which payment is delivered by up to 12 months. Under this aspect of our proposal, States would be able to condition payment on performance measure data from time periods up to 12 months prior to the start of the rating period in which the SDP is paid to providers. We believe that this flexibility will allow States adequate time to collect and analyze performance data for use in the payment arrangement and may incentivize States to adopt more VBP initiatives. We solicited comment on whether 12 months is an appropriate time period to allow for claims runout and data analysis, or if the time period that the performance period may precede the rating period should be limited to 6 months or extended to 18 or 24 months, or if the performance period should remain consistent with the rating period. We also proposed that the performance measurement period must not exceed the length of the rating period. Although we proposed to extend the length of time between provider performance and payment for administrative simplicity, we did not propose to extend the performance measurement time. Finally, we also proposed that all payments will need to be documented in the rate certification for the rating period in which the payment is delivered.

[132] *http://hcp-lan.org/workproducts/apm-framework-onepager.pdf.*

Identifying which rating period the payments should be reflected in is important since up to 2 rating periods may be involved between performance and payment, and we want States to document these payments consistently. Specifically, we proposed, at § 438.6(c)(2)(vi)(B)(*3*), that a payment arrangement that is based on performance must define and use a performance period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered.

In a December 2020 report,[133] the OIG found that a quality improvement incentive SDP implemented in one State resulted in incentive payments paid to providers whose performance declined during the measurement period. Other interested parties, such as MACPAC, have noted concerns with performance improvement SDPs that continue even when there has been a decline in quality or access. In alignment with our proposed evaluation policies at § 438.6(c)(2)(iv) (see section I.B.2.j. of this final rule) that seek to better monitor the impact of SDPs on quality and access to care, and in an effort to establish guardrails against payment for declining performance in VBP initiative SDPs, we proposed to add § 438.6(c)(2)(vi)(B)(*4*) and (*5*). Measurable performance targets that demonstrate performance relative to a baseline allow States (and CMS) to assess whether or not a provider's performance has improved. Therefore, at § 438.6(c)(2)(vi)(B)(*4*), we proposed to require that all SDPs that condition payment on performance include a baseline statistic for all metrics that are used to measure the performance that is the basis for payment from the plan to the provider; these are the metrics (including, per proposed paragraph (c)(2)(iv)(A)(*2*), at least one performance measure, as that term is proposed to be defined in § 438.6(a)) that are specified by the States in order to comply with proposed § 438.6(c)(2)(vi)(B)(*2*). At § 438.6(c)(2)(vi)(B)(*5*), we proposed to require that all SDPs that condition payment on performance use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the payment arrangement applies, that demonstrate improvement over baseline data on all metrics selected in § 438.6(c)(2)(vi)(B)(*2*). We believe that our proposals are consistent with how quality improvement is usually measured, as well as be responsive to oversight bodies and will help promote economy and efficiency in Medicaid managed care.

Population-Based Payments and Condition-Based Payments. As discussed previously in this section of this rule, States often adopt VBP initiatives that are intended to further goals of improved population health and better care at lower cost. We support these efforts and encourage the use of methodologies or approaches to provider reimbursement that prioritize achieving improved health outcomes over volume of services. Therefore, we proposed to add new § 438.6(c)(2)(vi)(C) to establish regulatory pathways for approval of VBP initiatives that are not conditioned upon specific measures of performance.

We proposed to define a ''population-based payment'' at § 438.6(a) as a prospective payment for a defined Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group. We proposed to define a ''condition-based payment'' as a prospective payment for a defined set of Medicaid service(s), that are tied to a specific condition and delivered to Medicaid managed care enrollees. One example of a population-based payment would be an SDP that is a primary care medical home (PCMH) that directs managed care plans to pay prospective per member per month (PMPM) payments for care management to primary care providers, where care management is the service being delivered under the contract and covered by the PMPM. An attributed population could also be condition-based. For example, States could direct managed care plans to pay a provider or provider group a PMPM amount for Medicaid enrollees with a specific condition when the enrollee is attributed to the provider or provider group for treatment for that condition.

At § 438.6(c)(2)(vi)(C)(*1*), we proposed to require that population-based and condition-based payments be based upon either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider during the rating period. This proposed requirement aligns with the requirement, currently at § 438.6(c)(2)(ii)(A), that SDP arrangements base payments to providers on utilization and delivery of services under the Medicaid managed care contract. States, consistent with section 1903(m)(2)(A)(xi) of the Act and §§ 438.242(d), and 438.818, must collect, maintain, and submit to T–MSIS encounter data showing that covered service(s) have been delivered to the enrollees attributed to a provider that receives the population-based payment. Further, if the payment is based upon the attribution of a covered enrollee to a provider, we proposed § 438.6(c)(2)(vi)(C)(*2*) to require that the attribution methodology uses data that are no older than the 3 most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; account for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers.

States have submitted proposals for VBP initiatives that include prospective PMPM population-based payments with no direct tie to value or quality of care and that would be paid in addition to the contractually negotiated rate. Because population-based payments should promote higher quality and coordination of care to result in improved health outcomes, it is imperative that these type of PMPM payments are used to ensure that enrollees are receiving higher quality and coordinated services to increase the likelihood of enrollees experiencing better outcomes. Therefore, we proposed to add § 438.6(c)(2)(vi)(C)(*3*) to require that population-based payments and condition-based payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP to prevent any duplicate payment(s) for the same service. Also, at § 438.6(c)(2)(vi)(C)(*3*), we proposed to add a requirement that prevents payments from being made in addition to any other payments made by plans to the same provider on behalf of the same enrollee for the same services included in the population- or condition-based payment. We believe that the requirements in paragraph (c)(2)(vi)(C)(3) would prevent States from implementing SDPs under § 438.6(c)(2)(vi)(C) that are PMPM add-on payments made in addition to negotiated rates with no further tie to quality or value.

We recognize the importance of providing a regulatory pathway for States to implement SDPs that are VBP

[133] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

initiatives designed to promote higher quality care in more effective and efficient ways at a lower cost. Because quality of care and provider performance are integral and inherent to all types of VBP initiatives, we proposed that SDPs under § 438.6(c)(2)(vi)(C) designed to include population-based or condition-based payments must also include in their design and evaluation at least one performance measure and set the target for such a measure to demonstrate improvement over baseline at the provider class level for the provider class receiving the payment. As such, we proposed new § 438.6(c)(2)(vi)(C)(*4*) to require that States include at least one performance measure that measures performance at the provider class level as a part of the evaluation plan outlined in proposed § 438.6(c)(2)(iv). We also proposed that States be required to set the target for such a performance measure to demonstrate improvement over baseline. This balances the need to provide States the flexibility to design VBP initiatives to meet their population health and other value-based care goals, while providing accountability by monitoring the effect of the initiatives on the performance of the provider class and the subsequent health outcomes of the enrollees.

Approval Period. In the 2020 Medicaid managed care rule, we finalized a revision to § 438.6(c)(2)(i) providing SDPs that are VBP initiatives as defined in § 438.6(c)(1)(i) and (ii) and that meet additional criteria described in § 438.6(c)(3)(i)(A) through (C) would be eligible for multi-year approval if requested. Because of the tie to the managed care quality strategy, which in § 438.340 is required to be updated at least once every 3 years, CMS has never granted written prior approval of an SDP for more than 3 years. We proposed to modify § 438.6(c)(3)(i) to add that a multi-year written prior approval for SDPs that are for VBP initiatives described in paragraphs (c)(1)(i) and (ii) may be for of up to three rating periods to codify our existing policy. Requiring States to renew multi-year SDPs at least every 3 years will allow us to monitor changes and ensure that SDPs remains aligned with States' most current managed care quality strategy. We proposed minor revisions in paragraphs (c)(3)(i)(A) through (C) to use the term ''State directed payment'' as appropriate and to revise paragraph (c)(3)(ii) to specify it is about written prior approvals. Finally, we proposed to redesignate paragraph (c)(2)(F) to new paragraph (c)(3)(iii) to explicitly provide that State directed payments are not automatically renewed.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comments on these proposals.

We summarize and respond to public comments received on our proposals regarding value-based payments and delivery system reform initiatives (§ 438.6(c)(2)(vi)) below.

Comment: Many commenters were broadly supportive of our proposed changes to the VBP initiative SDP provisions (currently at § 438.6(c)(2)(iii)), including our proposals to remove existing requirements (currently at § 438.6(c)(2)(iii)(C) and (D)) that prevent States from setting the amount and frequency of payments or from recouping unspent funds from VBP initiative SDPs, respectively. Commenters stated support for removing barriers to allow for flexible collaboration and innovation. Some commenters encouraged CMS and States to engage with interested parties to determine if there are additional barriers to implementation of VBP initiative SDPs described in paragraphs (c)(1)(i) and (ii).

Response: We appreciate the support for the proposed policies regarding VBP initiative SDPs. Addressing barriers that prevent States from designing VBP initiative SDPs based on prospective payments is key to supporting States that wish to adopt innovative models intended to promote quality and value over volume, such as hospital global budgets and other delivery system reform initiatives. We will continue to engage with interested parties to assess barriers and support States wishing to implement VBP initiative SDPs.

Comment: Some commenters supported the removal of the prohibition on States recouping unspent funds from VBP initiative SDPs but requested that CMS provide further direction and requirements for how recouped funds can be spent.

Response: As proposed, we are removing this existing prohibition on recouping unspent funds because States have struggled to balance setting performance targets that are ambitious enough that, if achieved, they would meaningfully improve care quality and health outcomes but not so ambitious that providers are discouraged from participating or so unambitious that they do not result in improved quality or outcomes. We believe States will be more likely to implement VBP initiative SDPs if they are able to establish ambitious performance or quality targets without being concerned that managed care plans will profit from weak provider performance.

We did not propose and are not finalizing spending requirements for recouped unspent State funds that were initially designated for payment of VBP initiative SDPs. We remind States that any recoupments made from plans as a part of VBP initiative SDPs are subject to the return of the Federal share via the CMS–64.

Additionally, we refer readers to section I.B.2.k. of the proposed rule for our discussion of proposed managed care contract requirements for SDPs. Specifically, under this final rule, States are required by § 438.6(c)(5)(iii)(D)(*6*) to document how any unearned payments will be handled, and any other significant relevant information. These contract requirements will help ensure that States and plans have explicit documentation of the goals of each VBP initiative SDP and the disposition of unspent funds.

Comment: One commenter requested clarification about how the newly proposed VBP initiative SDP criteria may impact existing VBP arrangements that span both Medicare and Medicaid as a part of integrated plans such as FIDE SNPs, and stated concern that the potential for conflicting reporting requirements could deter States from implementing VBP arrangements in a dual space.

Response: Because SDPs are not a venue for directing Medicare dollars, the proposed VBP initiative SDP criteria will not impact payment arrangements that exist under integrated Medicare Advantage (MA) plans, such as FIDE SNPs, where the State contracts with MA organizations offering the MA plan and directs how the MA plan pays its providers for Medicare covered services or MA supplemental benefits. However, if a State wishes to implement or direct payments by Medicaid managed care plans for benefits under the Medicaid managed care contract then the State would need to comply with 438.6(c). Written approval of SDPs described in §§ 438.6(c)(1)(iii)(A) and (B) is not required, but it is required for other SDP arrangements under § 438.6(c). For currently existing arrangements and the application of changes adopted in this final rule, please see section I.B.2.p. of this final rule regarding the applicability dates.

Comment: Many commenters supported the provisions for performance-based VBP initiative SDPs at proposed § 438.6(c)(2)(vi)(B). Specifically, commenters showed support for requiring that performance-

based VBP initiative SDPs use measurable and understandable performance targets as well the proposed expansion of the performance measurement period to up to 12 months prior to the start of the contract rating period.

Response: We appreciate the support of these provisions. In our experience, these proposals are consistent with how quality improvement is usually measured and will help promote economy and efficiency in Medicaid managed care.

Comment: Several commenters either opposed the proposal that performance-based VBP initiative SDPs must not condition payment on administrative activities, such as the reporting of data, or they suggested revisions to the provision so that ''pay-for-reporting'' would be allowed at least in the initial years of a performance-based VBP initiative SDP. Commenters noted that often these initiatives are multi-year and States need time to collect the data necessary to build baselines to measure performance against. Some commenters stated concern that it may not be possible to comply with the proposal to require States to identify baseline statistics and performance targets for all metrics tied to provider payment in the SDP because data for the most appropriate measure for the payment strategy is not yet collected.

Response: Because payment for performance-based VBP initiative SDPs must be based on provider performance tied to the delivery of covered services under the Medicaid managed care contract for the rating period, we have never allowed these types of SDPs to be based on ''pay-for-reporting.'' Our rationale has been and remains that the act of reporting is an administrative activity and not a covered service. To make this explicit, we proposed and are finalizing this requirement at § 438.6(c)(2)(vi)(B)(1). Although we recognize the challenges of gathering the baseline data needed for establishing the performance metrics and targets used in VBP initiative SDPs, we are finalizing paragraph (c)(2)(vi)(B)(1) as proposed. For situations in which States wish to support administrative activities that are necessary for successful implementation of VBP initiatives, we encourage them to explore alternative program designs. For example, a State could start first by designing a fee-based payment arrangement that is tied to utilization and delivery of services under the contract and to use provider reporting or participation in learning collaboratives as a condition of provider eligibility for the fee-based SDP. This allows States, plans and providers time to develop their systems of reporting and to collect the data necessary to establish baselines and performance targets. Once established, the arrangement can be transitioned to a performance-based VBP initiative SDP and payment to providers can be tied to performance measured against the baseline.

Comment: Some commenters suggested revisions to the proposal that the performance measurement period must not precede the start of the rating period by more than 12 months; commenters suggested extending the period of time for which the performance period could precede the baseline to 18 or 24 months to allow for an adequate claims runout period, provider reporting, and data analysis.

Response: We believe that the flexibility to use a performance period that precedes the rating period by 12 months is sufficient to allow adequate time for claims runout and for States time to collect and analyze performance data for use in the payment arrangement. As an illustration, if a State that uses a calendar year contract rating period implements a performance-based VBP initiative SDP on January 1, 2025, the State could pay providers through December 31, 2025, based on performance that occurred as far back as January 1, 2024, because the performance measurement can proceed the start of the rating period in which the payment is delivered by up to 12 months. In this example, we believe that this would be enough time to allow for claims run out and quality measure reporting. If the State needs extra time to analyze the data and determine provider payments amounts, it should specify at the start of the payment arrangement that payments to providers will not occur prior to the 3rd or 4th quarter to establish clear expectations for managed care plans and providers.

Comment: A few commenters were opposed to the proposal requiring States to choose performance targets that show improvement over baseline for all measures used in SDPs that condition payment on performance. Commenters stated that it is impractical to require such improvement year after year.

Response: We proposed that the performance targets used in VBP initiative SDPs that condition payment on performance must show improvement over a baseline for a performance-based payment to occur to ensure that performance-based VBP initiative SDPs do not pay providers for performance that is declining. We recognize that the proposed provision was more restrictive than necessary to guard against that. Therefore, we are finalizing proposed § 438.6(c)(2)(vi)(B)(*5*) with a revision, which aligns with § 438.6(c)(2)(iv)(C), that performance targets must demonstrate either maintenance or improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment. States have flexibility to choose performance measures and targets that are meaningful to their managed care quality goals, and we will not preclude States from setting performance targets that represent maintenance of baseline performance if the State believes those targets help further State goals. We will work with States to ensure that these arrangements are dynamic and drive continual performance improvement rather than reward provider performance over several contract periods that should become the minimum expectation over time. However, if a State wishes to deliver payments to providers irrespective of their performance on specified measures, then those payment arrangements should be structured as fee-based SDPs under § 438.6(c)(1)(iii) and therefore must be tied to the delivery of a Medicaid-covered service(s) under the managed care contract (however, we note such an SDP is required to comply with all requirements, including that it advance at least one of the goals and objectives in the State's quality strategy). If CMS finds that a State is using a VBP SDP to deliver payment irrespective of performance then, at minimum, CMS will not approve the subsequent SDP preprint renewal submission and may provide technical guidance to the State on how to transition the VBP SDP to a fee-based SDP.

Comment: Some commenters supported the proposed provisions at § 438.6(c)(2)(vi)(C) that establishes a pathway for approval of population-based and condition-based VBP initiative SDPs. Commenters stated that these proposals increase States' flexibility in designing and implementing VBP initiatives by removing barriers.

Response: We appreciate the support for these provisions. Addressing regulatory barriers that limit payment for VBP SDPs to only being tied to provider performance during the rating period is key to allowing States to adopt and participate in innovative payment arrangements designed to promote quality and value over volume. These provisions, in tandem with removal of the restrictions preventing States from setting the amount and frequency of VBP initiative SDPs or recouping unspent funds from VBP initiative SDPs, will create a pathway for approval

of such SDPs that are based on prospective PMPM payments. We believe that these flexibilities will allow for the implementation of innovative models that include payment arrangements, such as hospital global budgets, which emphasize value and that rely on robust quality improvement frameworks but that to date have not been allowable under § 438.6(c).

Comment: A few commenters requested clarification regarding the provisions at proposed § 438.6(c)(2)(vi)(C) for population-based or condition-based payments used in SDPs. Commenters inquired about whether the provisions pertain only to VBP initiative SDPs described at § 438.6(c)(1)(i) and (ii), or if these provisions would also be applied to SDPs described at § 438.6(c)(1)(iii). Some commenters were also concerned about whether SDPs that include components of attribution and care management and that are currently allowed under the regulations at § 438.6(c)(1)(iii) would continue to be permitted under the new provisions.

Response: As proposed and finalized, § 438.6(c)(2)(vi)(C) applies solely to SDPs that are VBP, delivery system reform, and performance improvement initiatives as described in § 438.6(c)(1)(i) and (ii) that use population-based and condition-based payments. These new provisions for population-based and condition-based VBP initiative SDPs allow approval of certain types of innovative payment arrangements that focus on value and that, to date, have not been approvable under § 438.6(c)(1)(i) and (ii) either because they rely on prospective PMPM payments that are not tied to a specific measure of provider performance during the rating period or because they set the amount and frequency of payments or recoup unspent funds. Because innovative models that include prospective PMPM payments (such as hospital global budgets) alongside robust quality frameworks are emerging in the current landscape of value-based care, it is crucial to provide a regulatory framework for approving VBP initiative SDPs that include these models.

Several States have successfully designed SDPs described in § 438.6(c)(1)(iii) that include innovative payment models (such as PCMHs) by tying the prospective payments to a Medicaid covered service (such as case management) delivered under the managed care plan contract during the rating period. We will not preclude States from seeking approval of renewal preprints of previously approved SDPs using the described existing pathway if States choose. Instead, we are seeking to remove barriers and to provide a more flexible pathway for approval of innovative payment models that focus on the delivery of quality care to Medicaid beneficiaries.

Comment: Commenters requested additional information regarding how population-based and condition-based payments must replace the negotiated provider rate for a set of services, how to account for the attribution of a patient population, and how these factors will affect the development of Medicaid managed care capitation rates.

Response: We proposed and are finalizing a pathway for States to implement population-based and condition-based payments, which are VBP initiative SDPs that are prospective payments tied to specific groups of Medicaid managed care enrollees covered under the contract; these payments must be based on either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period to the covered group or upon the attribution of covered enrollees to the provider during the rating period. If the payment is based on the attribution of covered enrollees to the provider, the attribution methodology must use data that are no older than the 3 most recent and complete years of data; seek to preserve existing provider-enrollee relationships; account for enrollee preference in choice of provider; and describe when patient panels are attributed, how frequently they are updated. Additionally, we are finalizing the requirement that population-based and condition-based payments must replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the payment and that no other payment may be made by an MCO, PIHP, or PAHP to the same provider on behalf of the same enrollee for the same services included in the payment. We note that this final rule maintains the requirement that SDPs must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8.

We believe that the regulation text and explanations in the proposed rule and our summary of the proposed rule are sufficiently clear to establish the requirements for use of these types of payments. However, we appreciate that the implementation of these provisions will introduce new operational and technical considerations for States and interested parties, and we plan to publish guidance that includes practical examples of implementation strategies to help guide States as they design SDPs, particularly those that are VBP initiatives that include population- and/or condition-based payments. Additionally, we encourage States interested in establishing VBP initiative SDPs to consult with their actuaries during rate development.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(vi)(B)(5) as proposed but with revisions to allow performance targets that demonstrate either maintenance of or improvement over baseline. We are finalizing all other provisions at paragraphs (c)(2)(vi)(B) and (C) as proposed but with minor grammatical revisions in paragraphs (c)(2)(vi)(C)(1) and (2) and with a technical correction in (c)(2)(vi)(C)(*2*). We are also finalizing the removal of certain requirements currently codified at § 438.6(c)(2)(iii)(C) and (D) (related to directing the timing and amount of expenditures and recouping unspent funds) and the redesignation of the current provision at § 438.6(c)(2)(iii)(A) to § 438.6(c)(2)(vi)(A).

j. Quality and Evaluation (§ 438.6(c)(2)(ii)(C), (c)(2)(ii)(D), (c)(2)(ii)(F), (c)(2)(iv), (c)(2)(v) and (c)(7))

We proposed several changes to the SDP regulations in § 438.6(c) to support more robust quality improvement and evaluation. Existing regulations at § 438.6(c)(2)(ii)(C) and (D) specify that to receive written prior approval, States must demonstrate in writing, amongst other requirements, that the State expects the SDP to advance at least one of the goals and objectives in the State's managed care quality strategy and has an evaluation plan that measures the degree to which the SDP advances the identified goals and objectives. We issued guidance in November 2017 [134] that provided further guidance on what evaluation plans should generally include: the identification of performance criteria which can be used to assess progress on the specified goal(s) and objective(s); baseline data for performance measure(s); and improvement targets for performance measure(s).

To monitor the extent to which an SDP advances the identified goals and objectives in a State's managed care quality strategy, we request that States submit their SDP evaluation results from prior rating periods to aid our review of preprint submissions that are renewals of an existing SDP. If an SDP proposal meets regulatory requirements but the State is unable to provide the

[134] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf.*

requested evaluation results, we will usually approve a renewal of the SDP with a ''condition of concurrence'' that the State submit evaluation results with the following year's preprint submission for renewal of the SDP for the following rating period. For example, one common condition of concurrence for Year 2 preprints is the provision of SDP evaluation results data for year one of the SDP with the Year 3 preprint submission.

In 2021, CMS conducted an internal analysis to assess the effectiveness of SDP evaluation plans in measuring progress toward States' managed care quality strategy goals and objectives and whether SDP evaluation findings provided us with sufficient information to analyze whether an SDP facilitated quality improvement. We analyzed data from 228 renewal preprints submitted by 33 States between April 2018 and February 2021. Over half (63 percent) of the evaluation plans submitted were incomplete, and only 43 percent of the renewal preprints included any evaluation results. Our analysis also found only a 35 percent compliance rate with conditions of concurrence requesting States submit SDP evaluation results with the preprint for the following rating period. Our policy goals in this area are frustrated by the lack of a regulation requiring submission of these evaluation results. By adopting requirements for submission of evaluation plans and reports, we intend to increase compliance and improve our oversight in this area.

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives and recognize that meaningful evaluation results are critical for ensuring that these payments further improvements in quality of care. Moreover, consistent submission of evaluation results is important for transparency and for responsiveness to oversight bodies. Consistent with our internal findings, other entities, including MACPAC [135] and GAO,[136] have noted concerns about the level of detail and quality of SDP evaluations. In MACPAC's June 2022 Report to Congress, the Commission noted concern about the lack of availability of information on evaluation results for SDPs, even when the arrangements had been renewed multiple times. The report also noted examples of evaluation results showing a decline in quality or access, but the SDPs were renewed without changes. MACPAC recommended in its report that CMS require more rigorous evaluation requirements for SDPs, particularly for arrangements that substantially increase provider payments above Medicaid FFS reimbursement. The report also suggests that CMS provide written guidance on the types of measures that States should use to evaluate progress towards meeting quality and access goals and recommended that we should clarify the extent to which evaluation results are used to inform approval and renewal decisions.

We proposed several regulatory changes to enhance CMS's ability to collect evaluations of SDPs and the level of detail described in the evaluation reports. CMS's intent is to shine a spotlight on SDP evaluations and use evaluation results in determining future approvals of State directed payments. We also plan to issue additional technical assistance on this subject, as well to assist States in the development of evaluation plans in alignment with the proposed regulatory requirements and preparing the subsequent evaluation reports.

To strengthen reporting and to better monitor the impact of SDPs on quality and access to care, we proposed at § 438.6(c)(2)(iv) that the State must submit an evaluation plan for each SDP that requires written prior approval and that the evaluation plan must include four specific elements. Our proposal is to establish minimum content requirements for SDP evaluation plans but is not intended to limit States in evaluating their SDP arrangements. Currently, § 438.6(c)(2)(ii)(D) requires that States develop an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the State's managed care quality strategy (which is required by § 438.340).

We proposed at § 438.6(c)(2)(iv)(A) that the evaluation plan must identify at least two metrics that will be used to measure the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the State's managed care quality strategy on an annual basis. In addition, proposed paragraph (c)(2)(vi)(C)(*4*) further specifies that at least one of those metrics must measure performance at the provider class level for SDPs that are population- or condition-based payments. Under § 438.6(c)(2)(iv)(A)(*1*), we proposed that the metrics must be specific to the SDP and attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the SDP applies, when practicable and relevant. We proposed the standard ''when practicable and relevant'' to allow flexibility to account for situations in which contract or program level specificity may be either impossible to obtain or may be ineffective in measuring the identified quality goal(s) and objective(s). For example, States may implement a quality improvement initiative in both the Medicaid FFS program and Medicaid managed care program(s) but measuring the impact of that initiative on each program separately will not produce valid results due to the small sample sizes. The proposed flexibility would allow States to produce an evaluation inclusive of both Medicaid managed care and FFS data and comprised of measures relevant to the approved SDP to demonstrate the effect the SDP arrangement is having on advancing the State's overall quality goals.

We proposed at § 438.6(c)(2)(iv)(A)(*2*) to require that at least one of the selected metrics be a performance measure, for which we proposed a definition in § 438.6(a) as described in section I.B.2.i. of this final rule. We currently allow, and will continue to allow States to select a metric with a goal of measuring network adequacy, or of maintaining access to care when that is the goal of the SDP. While access metrics provide valuable information, they do not measure service delivery (such as enrollee experience or HIE interoperability goals), quality of care, or outcomes attribute to the providers receiving the SDP, and they do not provide insight into the impact that these payment arrangements have on the quality of care delivered to Medicaid enrollees. Therefore, if a State elects to choose a metric that measures maintenance of access to care or other network adequacy measures, our proposal requires States to choose at least one additional performance metric that measures provider performance. Because we recognize that performance is a broad term and that the approach to evaluating quality in health care is evolving, and because we understand the importance of preserving States' flexibility to identify performance measure(s) that are most appropriate for evaluating the specific SDP, we did not

[135] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

[136] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

propose additional requirements for the other minimum metric so as not to preclude innovation. However, we recommend that States use existing measure sets which are in wide use across Medicaid and CHIP, including the Medicaid and CHIP Child and Adult Core Sets,[137] the Home and Community-Based Services Quality Measure Set,[138] or the MAC QRS measures adopted in this final rule to facilitate alignment and reduce administrative burden. We acknowledged in the proposed rule that in some cases, these existing measures may not be the most appropriate choice for States' Medicaid managed care goals; therefore, we stated that we will issue subregulatory guidance to provide best practices and recommendations for choosing appropriate performance measures when not using existing measure sets.

Concerns around access to primary care, maternal health, and behavioral health have been raised nationally. The current administration considers increasing access to care for these services to be a national priority.[139] [140] We encourage States to implement SDPs for these services and providers to improve access. We also encourage States to include measures that focus on primary care and behavioral health in their evaluation plans when relevant. This could include using existing measures from the Medicaid and CHIP Child and Adult Core Sets [141] or other standardized measure sets. CMS also expects that States consider examining parity in payment rates for primary care and behavioral health compared to other services, such as inpatient and outpatient hospital services, as part of their evaluation of SDPs.

It is crucial to monitor and evaluate the impact of SDP implementation, and as such we proposed at § 438.6(c)(2)(iv)(B) to require States to include baseline performance statistics for all metrics that will be used in the evaluation since this data must be established in order to monitor changes in performance during the SDP performance period. This aspect of our proposal is particularly necessary because we found in our internal study of SDP submissions that, among the SDP evaluation plan elements, a baseline statistic(s) was the most commonly missing element. We proposed the requirement at § 438.6(c)(2)(iv)(B) in an effort to ensure that States' evaluation plans produce reliable results throughout the entirety of the SDP's implementation.

Measurable SDP evaluation performance targets that demonstrate performance relative to the baseline measurement allow States to determine whether the payment arrangement is having the intended effect and helping a State make progress toward its quality goals. Our internal analysis showed that nearly 20 percent of performance measures selected by States were not specific or measurable. Therefore, at § 438.6(c)(2)(iv)(C), we also proposed to require that States include measurable performance targets relative to the baseline statistic for each of the selected measures in their evaluation plan.

Overall, we believe that the proposed regulations at § 438.6(c)(2)(iv) would ensure that States collect and use stronger data for developing and evaluating payment arrangements to meet the goals of their Medicaid programs and that States would also be responsive to recommendations for more clarity for SDP evaluation plans. We recognize and share the concerns raised by oversight bodies and interested parties regarding the limited availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care. While we ask States for evaluation results as part of the review process for SDP renewals, current regulations do not explicitly require submission of completed evaluation reports and results or use by CMS of prior evaluation reports and results in reviewing current SDPs for renewal or new SDPs. As a result, because most States do not comply with our request for evaluation data, we proposed to revise § 438.6(c)(2) to ensure CMS has access to evaluation plans and reports for review to determine if SDPs further the goals and objectives identified in the State's managed care quality strategy. We proposed at § 438.6(c)(2)(iv)(D) that States must provide commitment to submit an evaluation report in accordance with proposed § 438.6(c)(2)(v), if the final State directed payment cost percentage exceeds 1.5 percent.

Finally, we proposed to amend § 438.6(c)(2)(ii)(D) to further require the evaluation plan include all the elements outlined in paragraph (c)(2)(iv). These proposed changes in § 438.6(c)(2)(ii)(D) and the new proposed requirements in § 438.6(c)(2)(iv) are intended to further identify the necessary components of a State's SDP evaluation plan and make clear that we have the authority to disapprove proposed SDPs if States fail to provide in writing evaluation plans and reports (if required) for their SDPs that comply with these regulatory requirements.

Section 1902(a)(6) of the Act requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. We proposed to add new § 438.6(c)(2)(v) to require that States submit to CMS, for specified types of SDPs that have a final State directed payment cost percentage that exceeds 1.5 percent, an evaluation report using the evaluation plan the State outlined under proposed § 438.6(c)(2)(iv). As proposed in § 438.6(c)(2)(v), the evaluation reporting requirement is limited to States with SDPs that require prior approval and exceed a certain cost threshold. However, we note that all SDPs, including those described in § 438.6(c)(1)(iii)(A) and (B), would still need to comply with the standards listed in the finalized § 438.6(c)(2)(ii). Therefore, even in situations where the SDP evaluation report would not need to be submitted to CMS for review at a specified time, the State is required to continue to evaluate the SDP to comply with § 438.6(c)(2)(ii)(D) and (F), and such evaluation must be made available to CMS upon request. We recognize that submitting an evaluation report will impose some additional burden on States. We proposed a risk-based approach to identify when an evaluation report must be submitted to CMS based on the actual total amount that is paid as a separate payment term described in § 438.6(c)(6) or portion of the actual total capitation payments attributable to the SDP, as a percentage of the State's total Medicaid managed care program costs for each managed care program. This approach will allow States and CMS to focus resources on payment arrangements with the highest financial risk. We have selected the 1.5 percent threshold as it aligns with existing Medicaid managed care policy for when rate amendments are necessary (often referred to as a *de minimis* threshold or *de minimis* changes) and with proposed policies for in lieu of services (see section I.B.4. of this final rule).

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[137] Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*, the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.htm*).

[138] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

[139] Executive Order 14009, *https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act.*

[140] Executive Order 14070, *https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage.*

[141] Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*, the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html*.)

We proposed to define ''final State directed payment cost percentage'' in § 438.6(a) as the annual amount calculated, in accordance with paragraph (c)(7)(iii) of § 438.6, for each State directed payment for which prior approval is required under § 438.6(c)(2)(i) and for each managed care program. In § 438.6(c)(7)(iii)(A), we proposed for SDPs requiring prior written approval that the final SDP cost percentage numerator be calculated as the portion of the total capitation payments that is attributable to the SDP. In § 438.6(c)(7)(iii)(B), we proposed the final SDP cost percentage denominator be calculated as the actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total amount of State directed payments that are paid as a separate payment term as described in paragraph (c)(6). We explained in the proposed rule that to calculate the numerator for a minimum or maximum fee schedule type of SDP that is incorporated into capitation rates as an adjustment to base capitation rates, an actuary should calculate the absolute change that the SDP has on base capitation rates. Over time, as the SDP is reflected in the base data and incorporated into base capitation rates, it is possible that the absolute effect may decrease or no longer be apparent, and the numerator may decrease to zero. We solicited comment on whether the numerator for a minimum or maximum fee schedule SDP that is incorporated into capitation rates as an adjustment to base capitation rates should be calculated in a different manner (for example, estimating a portion of the capitation rates resulting from the SDP). We did not find it necessary to propose regulation text to codify this approach as we intend to issue additional guidance in the Medicaid Managed Care Rate Development Guide in accordance with § 438.7(e). The proposed numerator and denominator are intended to provide an accurate measurement of the final expenditures associated with an SDP and total program costs in each managed care program in a risk-based contract.

We believe the final SDP cost percentage should be measured distinctly for each managed care program and SDP, as reflected in the definition proposed for this term. This is appropriate because capitation rates are typically developed by program, SDPs may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We believe it would be contrary to our intent if States were to develop a final SDP cost percentage by aggregating data from more than one managed care program since that would be inconsistent with rate development, the unique elements of separate managed care programs, and the SDPs that vary by managed care program. We noted in the proposed rule how we intend to use this interpretation of managed care program in other parts of this section of this final rule, including, but not limited to, the discussion of calculating the total payment rate in section I.B.2.f. of this final rule, measurement of performance for certain VBP arrangements discussed in section I.B.2.i. of this final rule and separate payment terms in section I.B.2.l. of this final rule.

With § 438.6(c)(7)(i) and in the definition of the phrase ''final State directed payment cost percentage,'' we proposed that the final State directed payment cost percentage be calculated on an annual basis and recalculated annually to ensure consistent application across all States and managed care programs. To ensure that final State directed payment cost percentage will be developed in a consistent manner with how the State directed payment costs will be included in rate development, we proposed at § 438.6(c)(7)(ii) to require that the final SDP cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An ''actuary'' is defined in § 438.2 as an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates.

Although we proposed that all States would be required to develop and document evaluation plans for SDPs that require CMS's written prior approval in compliance with the provisions proposed in § 438.6(c)(2)(iv), proposed § 438.6(c)(2)(v) requires States to submit an evaluation report for an SDP if the final SDP cost percentage is greater than 1.5 percent. We acknowledged that States may choose to submit evaluation reports for their SDPs regardless of the final SDP cost percentage, and, under our proposal, submission of the evaluation report could be done voluntarily even if not required. We proposed in § 438.6(c)(7) that, unless the State voluntarily submits the evaluation report, the State must calculate the final State directed payment cost percentage, and if the final State directed payment cost percentage is below 1.5 percent, the State must provide a final State directed payment cost percentage report to CMS. Under this proposal, States would be required to provide the final SDP cost percentage to demonstrate that an SDP is exempt from the proposed evaluation reporting requirement. If, regardless of the final SDP cost percentage, a State elects to prepare and submit an evaluation report, the final SDP cost percentage report is not required. For SDP arrangements that do not exceed the 1.5 percent cost threshold, as demonstrated in the final SDP cost percentage report, and for SDPs for which there is no written prior approval requirement, we proposed that the State would not be required to submit an evaluation report (at proposed § 438.6(c)(2)(v)). However, we encourage States to monitor the evaluation results of all their SDPs. We recognize that in order to monitor the 1.5 percent threshold, we will need a reporting mechanism by which States will be required to calculate and provide the final SDP cost percentage to CMS. Therefore, we proposed (at new § 438.6(c)(7)(iv)) that, for SDPs that require prior approval, the State must submit the final State directed payment cost percentage annually to CMS for review when the final State directed payment cost percentage does not exceed 1.5 percent and when the State has not voluntarily submitted the evaluation report. The submission of the final SDP cost percentage data would be submitted concurrent with the rate certification submission required in § 438.7(a) no later than 2 years after the completion of each 12-month rating period that included a State directed payment. It is appropriate for States' actuaries to develop a separate report to document that the final State directed payment cost percentage does not exceed 1.5 percent, rather than

including it in a rate certification, because the final State directed payment cost percentage may require alternate data compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). We note that this proposal is similar to the concurrent submission for the proposed MLR reporting at § 438.74 and proposed ILOS projected and final cost percentage reporting at § 438.16(c). We described an alternative approach in the proposed rule that would require States to submit the final SDP cost percentage to CMS upon completion of the calculation, separately and apart from the rate certification. However, consistency across States for when the final SDP const percentage is submitted to CMS for review is important and, we believed receiving the final SDP cost percentage and the rate certification at the same time will enable CMS to review them concurrently.

As proposed, the denominator for the final SDP cost percentage will be based on the actual total capitation payments and the actual total State directed payments paid as a separate payment term (see section I.B.2.l. of this final rule for details on the proposals for separate payment terms) paid by States to managed care plans. We noted in the proposed rule that calculating the final SDP cost percentage will take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final capitation payments that are a component of the calculation. Given these factors, we concluded that 2 years is an adequate amount of time to accurately perform the calculation and proposed that States must submit the SDP cost percentage report no later than 2 years after the rating period for which the SDP is included. Under this proposal, for example, the final SDP cost percentage report for a managed care program that uses a CY 2024 rating period will be submitted to CMS with the CY 2027 rate certification.

For the evaluation reports, we proposed to adopt three requirements in new § 438.6(c)(2)(v)(A). First, in § 438.6(c)(2)(v)(A)(*1*), we proposed that evaluation reports must include all of the elements approved in the evaluation plan required in § 438.6(c)(2)(iv). In § 438.6(c)(2)(v)(A)(*2*), we proposed to require that States include the 3 most recent and complete years of annual results for each metric as required in § 438.6(c)(2)(iv)(A). Lastly, at § 438.6(c)(2)(v)(A)(*3*), in acknowledgement of MACPAC's recommendation to enhance transparency of the use and effectiveness of SDP arrangements, we proposed to require that States publish their evaluation reports on their public facing website (the public facing website is required under § 438.10(c)(3).

States consistently have difficulty providing evaluation results in the first few years after implementation of an SDP due to the time required for complete data collection. Our internal analysis found that States' ability to provide evaluation results improved over time. Although only 21 percent of proposals included evaluation results in Year 2, 55 percent of proposals included results data in Year 3, and 66 percent of Year 4 proposals included the results of the evaluation. For this reason, we did not propose that States submit an annual evaluation and proposed instead at § 438.6(c)(2)(v)(B) to require States to submit the first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period and that subsequent evaluation reports must be submitted to CMS every 3 years after.

In § 438.6(c)(2)(v)(A)(*2*), we proposed to require that evaluation reports include the 3 most recent and complete years of annual results for each metric as approved under the evaluation plan approved as part of the preprint review. Under the proposal, the first evaluation report would be due no later than with the submission of the preprint for the sixth rating period after the applicability date for the evaluation plan. The evaluation plan would contain results from the first 3 years after the applicability date for the evaluation plan. The approach to implementation was intended to allow adequate time for States to obtain final and validated encounter data and performance measurement data to compile and publish the first evaluation report. We also considered a 5 and 10-year period evaluation period, but we concluded that seemed to be an unreasonably long time to obtain actionable evaluation results. We concluded that a 3-year period will provide sufficient time to collect complete data and demonstrate evaluation trends over time.

After submission of the initial evaluation report, States would be required to submit subsequent evaluation reports every 3 years. This means that States would submit the second evaluation report with the SDP preprint submission for the first rating period beginning 9 years after the applicability date for the evaluation plan; this evaluation report will contain results from years four through six after the applicability date for the evaluation plan. States will be required to continue submitting evaluation reports with this frequency as long as the SDP is implemented. We acknowledge that some SDPs will have been operational for multiple years when these proposed regulations take effect. We did not propose a different implementation timeline for SDP arrangements that predate the compliance deadline for this proposal. For these mature payment arrangements, States would be required to submit an evaluation report in the fifth year after the compliance date that includes the 3 most recent and complete years of annual results for the SDP. However, because these types of long-standing payment arrangements have been collecting evaluation data since implementation, we will expect States to include the evaluation history in the report to provide the most accurate picture.

We recognize and share the concerns that oversight bodies and other interested parties have stated regarding the extent to which CMS uses evaluation results to inform SDP written prior approval decisions. In response to these concerns and as a part of the proposed revisions to § 438.6(c)(2)(ii), which include the standards that all SDPs must meet, we proposed a new standard at § 438.6(c)(2)(ii)(F) requiring that all SDPs must result in achievement of the stated goals and objectives in alignment with the State's evaluation plan. The proposed changes are designed to help us to better monitor the impact of SDPs on quality and access to care and will help standardize our review of SDP proposal submissions under § 438.6(c) while allowing us to disapprove SDPs that do not meet their stated quality goals and objectives.

We also proposed a concurrent proposal at § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which will give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs. The proposed optional EQR activity will reduce burden associated with these new SDP requirements and is discussed in more detail in section I.B.5.c. of this final rule. We described in the proposed rule, and invited public comment on, a requirement that States procure an independent evaluator for SDP evaluations in the final rule based on comments received. In consideration of the myriad new proposed requirements within this final rule, we weighed the value of independent evaluation with increased State burden. We noted in the proposed rule a concern that it would be overly burdensome for States to procure independent evaluators for SDPs due, in part, to the timing of the final SDP cost

percentage submission. We proposed that the final SDP cost percentage be submitted 2 years following completion of the applicable rating period, and that if the final SDP cost percentage exceeds the 1.5 percent, States will be required to submit an evaluation report to CMS. While we encourage all States to evaluate their SDPs, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the SDP evaluation since States will not know whether an evaluation is required until 2 years following the rating period. We solicited comment on whether we should instead require that States use an independent evaluator for SDP evaluations.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comments on our proposals and the alternatives under consideration.

We summarize and respond to public comments received on quality and evaluation requirements for SDPs (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7)) below.

Comment: Several commenters were broadly supportive of our proposed SDP evaluation plan policies at § 438.6(c)(2)(iv). These commenters stated appreciation for the framework we proposed and our goal to incentivize quality improvement efforts through SDP evaluations. Some commenters also offered specific support for our efforts to monitor and quantify the extent to which SDPs advance the identified goals and objectives in a State's managed care quality strategy.

Response: We appreciate the support for the proposed SDP evaluation plan policies. As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs contribute to Medicaid quality goals and objectives. Meaningful evaluation results are critical for ensuring that these payments further improvements in quality of care.

Comment: Some commenters opposed the proposed standard at § 438.6(c)(2)(ii)(F) requiring all SDPs to result in the achievement of the stated goals and objectives identified in the State's evaluation plan(s) for the SDPs, noting concern that it will result in States setting overly modest targets to avoid putting initiatives at risk if performance does not meet the established targets.

Response: We believe that States should have the flexibility to choose meaningful targets based on the goals of the payment arrangement within their Medicaid managed care program and its quality strategy. Even modest goals, such as maintaining a certain level of access to care or provider performance, can be worthwhile and are allowable under § 438.6(c)(2)(iv)(C). We understand the commenters' concerns about underachievement and unnecessarily low-quality targets putting SDP initiatives at risk, and we encourage States to request technical assistance from CMS for choosing targets that are commensurate to the size and scope of their SDP and that are compliant with § 438.6(c)(2)(iv). Ultimately, we believe that requiring SDPs to achieve the identified goals and objectives in their evaluation plans is a reasonable way to ensure that SDP spending supports the delivery of quality care to Medicaid managed care enrollees. In alignment with our original intent in the proposed rule to be able to request an evaluation report from a State to assess compliance with the standard at § 438.6(c)(2)(ii)(F), we are revising paragraph (c)(2)(ii)(F) to make abundantly clear that, at CMS's request, States must provide an evaluation report for each SDP demonstrating the achievement of the stated goals and objectives identified in the State's evaluation plan.

Comment: Some commenters stated concern that requiring SDPs to meet the goals and objectives in the State's evaluation plan for that SDP year after year is unreasonable because clinical outcome data can be unpredictable and vulnerable to external factors. One commenter requested further clarification on what flexibilities would be in place for unforeseen circumstances that impact quality and performance (such as a provider strike, a natural disaster, a new training protocol, or an electronic medical record migration) that may take time to resolve.

Response: This standard gives CMS the authority to disapprove renewal SDPs that repeatedly pay providers despite failure to meet the identified quality strategy goals. For SDPs that require written prior approval and have a final State-directed payment cost percentage greater than 1.5 percent, States will be required (by § 438.6(c)(2)(v)) to submit evaluation reports every 3 years that contain the 3 most recent and complete years of available data. We believe that this gives States adequate opportunity to show trends and explain anomalies or other issues over time so long as States show attainment of their goals. If an evaluation report fails to show attainment of any of the identified quality strategy goals, we will work with the State to help ensure that the subsequent evaluation report, which would be required after another 3 years, demonstrates that the quality goals or outcomes have been *attained.* However, if the subsequent evaluation report does not show attainment of the identified quality strategy goals, we would not approve a renewal of the SDP. Ultimately, spending through SDPs should promote quality care to Medicaid managed care enrollees and SDPs that consistently fall short of their targets likely indicate misalignment with the State's quality strategy.

We appreciate that clinical outcomes can be unpredictable and vulnerable to external factors as suggested by the commenters. In the case of emergency and natural disasters that may impact clinical outcome data, States could evaluate if flexibilities under section 1135 of the Act would be applicable and beneficial. For other unforeseen circumstances, we are available to provide technical assistance to States to understand the impact of these unforeseen circumstances on the SDP's evaluation and determine how best to reflect the information in the evaluation report.

Comment: Some commenters stated concern about the administrative burden of the evaluation plans and suggested that CMS implement either an optional requirement or a minimal level of monitoring for SDPs that do not require CMS written prior approval of associated preprints.

Response: We acknowledge that SDP evaluations pose some administrative burden. While having an evaluation plan that meets the requirements in § 438.6(c)(2)(ii)(D) is a requirement that all SDPs must meet, States will not be required to submit their evaluation plans for SDPs that are exempt from the written prior approval process, which will significantly decrease administrative burden. However, States are required to monitor and evaluate access and quality for all SDPs to ensure and document compliance with § 438.6(c)(2)(ii)(F) which will require each SDP to result in achievement of the stated goals and objectives in alignment with the State's evaluation plan. Further, we note evaluation plans and reports must be made available to CMS upon request for all SDPs, including for SDPs that are exempt from the written prior approval process per § 438.6(c)(2)(ii)(F). States may consider leveraging existing monitoring and evaluation frameworks to meet these requirements.

Comment: Some commenters were opposed to the expanded evaluation

plan requirements for SDPs that are designed solely to maintain access to care. Other commenters recommended that § 438.6(c)(2)(iv)(A) be revised to allow States to select only access measures for these types of SDPs. Commenters noted that maintaining access is a worthwhile goal, and requiring performance measures may not be appropriate for the community or payment arrangement. Some commenters encouraged CMS to provide guidance on how to choose appropriate measures.

Response: While we recognize and agree that preserving access to care is a worthwhile goal for some SDPs, monitoring access to care should not be done in a vacuum that excludes monitoring provider service delivery, quality of care, or outcomes. We believe that requiring States to choose at least 2 metrics, one of which must be a performance measure, will ensure adequate monitoring of both access and quality. States have flexibility to determine which goal(s) from their quality strategies best align with the goals of each SDP, and States have flexibility to choose metrics in § 438.6(c)(2)(iv)(A)(*2*) that are appropriate for the payment arrangement, provider type, and population served. As such, there is ample flexibility for States to identify metrics that are most appropriate for evaluating each SDP in § 438.6(c)(2)(iv)(A)(*1*) which requires the metrics to be specific to the SDP, and when practicable and relevant, attributable to the performance by the providers for enrollees in all a State's managed care program(s) to which the SDP applies. We encourage States to request technical assistance to help determine appropriate measures that comply with the requirements in § 438.6(c)(2)(iv)(A).

We also remind States of the reporting requirements finalized in Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting in the August 31, 2023 **Federal Register** (88 FR 60278) [142] which established requirements for mandatory annual State reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP), the behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid, and the Core Sets of Health Home Quality Measures for Medicaid. This rule requires States, the District of Columbia (DC) and certain territories to mandatorily report on these Core Set measures at the State level. Additionally, Subpart G of this final rule contains requirements and the initial mandatory measure list (which will be reported at the plan level) for the Medicaid and CHIP Managed Care Quality Rating System. We encourage States to evaluate the appropriateness of the measures required on these measure sets against their measures for each SDP to leverage efficiencies and reduce administrative burden. We also encourage States to stratify all disparity sensitive measures by at least one dimension in their SDP evaluation plan, whenever possible.

Comment: One commenter opposed proposed § 438.6(c)(2)(iv)(A)(*1*) and suggested removal of the requirement that evaluation metrics must be attributable to the performance by the providers for enrollees in each of the State's managed care program(s) noting that some programs may be carve outs for specific service or set of services, making it difficult to evaluate them relative to larger managed care programs.

Response: The proposed provision at § 438.6(c)(2)(iv)(A)(*1*) requires that the chosen metrics are attributable to the performance by the providers for enrollees in all the State's managed care program(s) to which the SDP applies, when *practicable and relevant.* We proposed the standard ''when practicable and relevant'' to allow flexibility to account for situations in which the type of data required for managed care program-level specificity may be either impossible to obtain or may be ineffective in measuring the performance of the providers for the identified quality goal(s) and objective(s). We refer the commenter to section I.B.2.j. of the proposed rule where we discussed examples of situations where measuring performance at the specific program level would not be considered practicable or relevant. Additionally, for SDP evaluations, we believe it would be practicable and relevant to attribute metrics to the providers participating in the SDPs when the selected metrics can be calculated at the provider-level based on data reporting practices. For example, if provider data are reported to the State at the managed care program level and include providers contracted with several payers, the evaluation could pool the data from a group of providers participating in the SDP to conduct the evaluation. We encourage States to leverage existing quality reporting for this purpose, and we will continue to offer technical assistance to States to help both select relevant metrics that can be specified at the provider level and identify strategies to analyze and isolate data to those participating SDP providers for their SDP evaluations.

Comment: Many commenters supported our proposed SDP evaluation reporting requirements at § 438.6(c)(2)(v), including the proposed 3-year submission timeframe and the submission threshold of 1.5 percent of the final SDP cost percentage.

Response: We recognize that submitting an evaluation report that complies with the requirements in § 438.6(c)(2)(v) would impose some additional burden on States but believe the 1.5 percent final SDP cost percentage threshold allows States and CMS to focus resources on payment arrangements with the highest financial risk.

Comment: Many commenters supported the proposed requirement that evaluation reports be made publicly available on States' websites noting that these proposals would help to bring more transparency to Medicaid managed care spending. A few commenters encouraged CMS to also consider making SDP evaluations publicly available on *Medicaid.gov,* similar to the process currently used for section 1115 demonstration evaluations.

Response: We appreciate the suggestion, and we intend to make States' evaluation results available on *Medicaid.gov.*

Comment: One commenter requested more details on how CMS intends to operationalize the new 3-year submission timeframe for evaluation reporting. The commenter stated concern about how CMS will use SDP evaluations to make renewal decisions for SDPs that are reviewed on an annual basis when the evaluation reports are not required every year, noting that this could introduce uncertainty and frustration for States, managed care plans, and providers.

Response: In determining whether to approve an existing SDP once the original approval period is over (that is, a renewal of an SDP), CMS will take into account the achievement of the identified goals and objectives from States' quality strategies based on a review of the evaluation report (outlined in § 438.6(c)(2)(v)) required for that SDP. Because those evaluation reports, when required, are collected on a 3-year running cycle, we can only make renewal determinations based on the achievement of goals and objectives when States have submitted the report. In the interim years, SDP approval determinations will be made based on

[142] *https://www.federalregister.gov/documents/2023/08/31/2023-18669/medicaid-program-and-chip-mandatory-medicaid-and-childrens-health-insurance-program-chip-core-set.*

the adequacy of the State's responses to the preprint showing that the SDP has met all of the other applicable standards in § 438.6(c)(2)(ii). With regards to the evaluation elements, States will continue to submit their evaluation plans each year with the annual preprint submission for SDPs that require written prior approval at § 438.6(c)(2)(iv). In years when States are not required to submit evaluation reports, renewal determinations will also take into account the adequacy of the evaluation plan, its required elements, and any updates to those required elements.

To illustrate, after a State receives approval of its initial SDP submission, a State would expect to submit its evaluation report with its Year 5 renewal preprint submission as § 438.6(c)(2)(iv)(B) requires that the State submit the initial evaluation report no later than 2 years after the conclusion of the 3-year evaluation period; States are required to continually monitor the progress towards their goals and objectives during the 3 years. We believe this gives States adequate time to collect and monitor data and to anticipate trends. In this example, Year 5 is the first year that CMS would make an approval determination based on the achievement of the stated goal(s) and objective(s) in alignment with the evaluation plan, as well as based on the other requirements in § 438.6(c). In Years 2, 3, and 4, approval determinations will be made based on the adequacy of the plan and its required elements, and any other information provided by the State on this topic in the preprint, as well as based on the other requirements in § 438.6(c). If helpful, States can submit interim reports for feedback from CMS to help alleviate the uncertainty of interested parties.

If a State continues the SDP beyond Year 5, the next evaluation report, which would be used in making renewal determinations that take into account compliance with paragraph (c)(2)(ii)(F), will be required in Year 8 as § 438.6(c)(2)(iv)(B) requires subsequent evaluation reports to be submitted to CMS every 3 years. In Years 6 and 7, approval determinations will be made based on the adequacy of the plan and its required elements and compliance with the other requirements in paragraph (c) (including paragraphs (c)(2)(ii)(A) through (E) and (G) through (J)).

In addition, we proposed and are finalizing § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs as finalized at § 438.6(c)(2)(v). We believe this optional activity could reduce burden associated with this requirements and is discussed in more detail in section I.B.5.c. of this final rule. We can provide technical guidance on evaluations that are commensurate to the size and scope of SDPs for which written prior approval is required under § 438.6(c)(2)(i).

Comment: Some commenters were in favor of revising the 1.5 percent threshold for evaluation report submission, suggesting that it should be higher because the administrative burden of providing the report could discourage States from using SDPs to advance quality and value-based goals. One commenter opposed the 1.5 percent threshold altogether in favor of requiring evaluation reports on all SDPs requiring written prior approval.

Response: We appreciate the comments and continue to believe that the 1.5 percent threshold strikes the right balance between the reduction of State administrative burden and the availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(ii)(D), (c)(2)(iv) and (v) as proposed. As described in I.B.2.l, the final regulation at § 438.6(c)(6) prohibits separate payment terms; therefore, we are finalizing § 438.6(c)(7) with modifications to be consistent with that policy decision. We are finalizing § 438.6(c)(2)(ii)(F) with a revision to clarify that, at CMS's request, States must provide an evaluation report to demonstrate that an SDP resulted in achievement of the stated goals and objectives in alignment with the State's evaluation plan.

k. Contract Term Requirements (§ 438.6(c)(5) and 438.7(c)(6))

SDPs are contractual obligations in which States direct Medicaid managed care plans on how or how much to pay specified provider classes for certain Medicaid-covered services. The current heading for § 438.6(c) describes paragraph (c) as being about delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts. Further, the regulation refers to SDPs throughout as provisions in the contract between the MCO, PIHP or PAHP and the State that direct expenditures by the managed care plan (that is, payments made by the managed care plan to providers). SDPs are to be included in a State's managed care rate certification per § 438.7(b)(6) and final capitation rates for each MCO, PIHP, and PAHP must be identified in the applicable contract submitted for CMS review and approval per § 438.3(c)(1)(i). Thus, every SDP must be documented in the managed care contract and actuarial rate certification.

Per previous guidance issued to States, including in the January 2022 State Guide to CMS Criteria for Medicaid Managed Care Contract Review and Approval (State Guide), contractual requirements for SDPs should be sufficiently detailed for managed care plans to operationalize each payment arrangement in alignment with the approved preprint(s).[143] The State Guide includes examples of information that States could consider including in their managed care contracts for SDPs.[144] However, despite this guidance, there is a wide variety of ways States include these requirements in their contracts, many of which lack critical details to ensure that plans implement the contractual requirement consistent with the approved SDP. For example, some States have sought to include a broad contractual requirement that their plans must comply with all SDPs approved under § 438.6(c) with no further details in the contract to describe the specific payment arrangements that the State is directing the managed care plan to implement and follow. Other States have relied on broad contract requirements stating that plans must comply with all applicable State laws as a method of requiring compliance with State legislation requiring plans to pay no less than a particular fee schedule for some services. These types of vague contractual provisions represent significant oversight risk for both States and CMS.

To reduce this risk and improve the clarity of SDPs for managed care plans, we proposed to codify at § 438.6(c)(5) minimum requirements for the content of a Medicaid managed care contract that includes one or more SDP contractual requirement(s). Minimum requirements for SDP contract terms will assist States when developing their contracts, ensure that managed care plans receive necessary information on the State's intent and direction for the SDP, facilitate CMS's review of managed care contracts, and ensure compliance with the approved SDP preprint. At § 438.6(c)(5)(i) through (v), we proposed

[143] *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*

[144] *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*

to specify the information that must be documented in the managed care contract for each SDP. Proposed § 438.6(c)(5)(i) would require the State to identify the start date and, if applicable, the end date within the applicable rating period. While most SDPs, particularly long-standing contractual requirements, are in effect throughout the entire rating period, some SDPs begin in the middle of the rating period or are for a limited period of time within a rating period. This requirement is designed to ensure that the time period for which the SDP applies is clear to the managed care plans.

Proposed § 438.6(c)(5)(ii) would require the managed care contract to describe the provider class eligible for the payment arrangement and all eligibility requirements. This proposal would ensure compliance with the scope of the written prior approval issued by CMS because we have implemented paragraph (c)(2)(ii)(B) by requiring States to provide a description of the class of providers eligible to participate and the eligibility criteria. In addition, a clear contract term provides clear direction to plans regarding the provider class that is eligible for the SDPs.

Proposed § 438.6(c)(5)(iii) would require the State to include a description of each payment arrangement in the managed care contract and is a requirement to ensure compliance with the written prior approval issued by CMS and provide clear direction to plans while also assisting CMS in its review and approval of Medicaid managed care contracts. For each type of payment arrangement, we proposed to require that specific elements be included in the contract at a minimum. For SDPs that are minimum fee schedule arrangements, we proposed that the contract must include: in § 438.6(c)(5)(iii)(A)(1), the fee schedule the plan must ensure payments are at or above; in paragraph (c)(5)(iii)(A)(2), the procedure and diagnosis codes to which the fee schedule applies; and in paragraph (c)(5)(iii)(A)(3), the applicable dates of service within the rating period for which the fee schedule applies. We proposed the requirement at paragraph (c)(5)(iii)(A)(3) to be clear that payment can only be triggered based on service delivery within the applicable rating period.

For minimum fee schedules set at the State plan approved rate as described in § 438.6(c)(1)(iii)(A), we proposed to require at § 438.6(c)(5)(iii)(A)(4) that the contract reference the applicable State plan page, the date it was approved, and a link to where the currently approved State plan page is posted online when possible. For minimum fee schedules set at the Medicare rate as described in § 438.6(c)(1)(iii)(B), we proposed to require at § 438.6(c)(5)(iii)(A)(5), that the contract include the Medicare fee schedule and any specific information necessary for implementing the payment arrangement. For example, CMS updates many Medicare fee schedules annually using a calendar year, but Medicaid managed care contracts may not be based on a calendar year, such as those that use a State fiscal year. Therefore, States will have to identify, for each SDP using a Medicare fee schedule, the specific Medicare fee schedule and the time period for which the Medicare fee schedule to be used during the rating period is in effect for Medicare payment. As another example, the Medicare physician fee schedule (PFS) includes factors for different geographic areas of the State to reflect higher cost areas; the Medicaid managed care contract will have to specify if the plans are required to apply those factors or use an average of those factors and pay the same rate irrespective of the provider's geographic region.

For uniform increases as described in paragraph (c)(1)(iii)(D), we proposed at § 438.6(c)(5)(iii)(B)(1) through (5) to require the contract to include: (1) whether the uniform increase will be a specific dollar amount or a specific percentage increase over negotiated rates; (2) the procedure and diagnosis codes to which the uniform increase will be applied; (3) the specific dollar amount of the increase or percent of increase, or the methodology to establish the specific dollar amount or percentage increase; (4) the applicable dates of service within the rating period for which the uniform increase applies; and (5) the roles and responsibilities of the State and the plan, as well as the timing of payment(s), and any other significant relevant information.

For maximum fee schedules as described in paragraph (c)(1)(iii)(E), we proposed at § 438.6(c)(5)(iii)(C)(1) through (4) to require the contract to include: (1) the maximum fee schedule the plan must ensure payments are below; (2) the procedure and diagnosis codes to which the fee schedule applies; (3) the applicable dates of service within the rating period for which the fee schedule applies; and (4) details of the State's exemption process for plans and providers to follow if they are under contract obligations that result in the need to pay more than the maximum fee schedule. An exemption process is necessary for payment arrangements that limit how much a managed care plan can pay a provider to ensure that the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract. Therefore, this proposed requirement would ensure that the exemption process exists and that the managed care contract describes it, in addition to the preprint.

For contractual obligations described in paragraph (c)(1)(i) and (ii) that condition payment based upon performance, we proposed at § 438.6(c)(5)(iii)(D)(1) through (6) to require that managed care plan contracts must include a description of the following elements approved in the SDP arrangement: (1) the performance measures that payment will be conditioned upon; (2) the measurement period for those metrics; (3) the baseline statistics against which performance will be based; (4) the performance targets that must be achieved on each metric for the provider to obtain the performance-based payment; (5) the methodology to determine if the provider qualifies for the performance-based payment, as well as the amount of the payment; and (6) the roles and responsibilities of the State and the plan, the timing of payment(s), what to do with any unearned payments if applicable, and other significant relevant information. Some States perform the calculations to determine if a provider has achieved the performance targets necessary to earn performance-based payments, while others delegate that function to their managed care plans. Adding this specificity to the contract is intended to ensure clarity for both the States and the managed care plans.

For contractual obligations described in paragraphs (c)(1)(i) and (ii) that are population or condition-based payments as defined in § 438.6(a), we proposed at § 438.6(c)(5)(iii)(E) to require the contract to describe: (1) the Medicaid covered service(s) that the population or condition-based payment is made for; (2) the time period that the population-based or condition-based payment covers; (3) when the population-based or condition-based payment is to be made and how frequently; (4) a description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how that attribution model will be communicated to providers; and (5) the roles and responsibilities of the State and the plan in operationalizing the attribution

methodology if an attribution methodology is used.

Proposed § 438.6(c)(5)(iv) would require that the State include in the managed care contract any encounter reporting and separate reporting requirements that the State needs in order to audit the SDP and report provider-level payment amounts to CMS as required in § 438.6(c)(4).

Proposed § 438.6(c)(5)(v) would require that the State indicate in the contract whether the State will be using a separate payment term as defined in § 438.6(a) to implement the SDP. We noted in the proposed rule that this information would provide additional clarity for oversight purposes for both States and CMS.

We also proposed to require in § 438.6(c)(5)(vi) that all SDPs must be specifically described and documented in MCO, PIHP, and PAHP contracts no later than 120 days after the start of the SDP or approval of the SDP under § 438.6(c)(2)(i), whichever is later. That proposed timeframe was consistent with the timeframe proposed for documenting separate payment terms in the managed care contract under § 438.6(c)(6)(v).

Finally, we proposed a new regulatory requirement at § 438.7(c)(6) to require that States must submit the required rate certification documentation for SDPs (either the initial rate certification or a revised rate certification) no later than 120 days after either the start date of the SDP approved under § 438.6(c)(2)(i) (redesignated from current § 438.6(c)(2)(ii)) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later. We proposed regulatory changes in §§ 438.6(c)(5)(vi) and 438.7(c)(6) to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date we granted written prior approval of the SDP, whichever is later. States should submit their rate certifications prior to the start of the rating period, and § 438.7(c)(2) currently requires that any rate amendments comply with Federal timely filing requirements. However, we believe given the nature of SDPs, there should be additional timing restrictions on when revised rate certifications that include SDPs can be provided for program integrity purposes. We also reminded States that these proposals do not supersede other requirements regarding submission of contract and rate certification documentation when applicable, including but not limited to those that require prior approval or approval prior to the start of the rating period such as requirements outlined in §§ 438.3(a), 438.4(c)(2), and 438.6(b)(1). (This proposal was in section I.B.2.l. of the proposed rule and is also discussed in section I.B.2.l. of this final rule.)

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comments on our proposals.

We summarize and respond to public comments received on our proposals for contract term requirements for SDPs and submission of associated rate certifications (§§ 438.6(c)(5) and 438.7(c)(6)) below.

Comment: Some commenters stated support for accurate documentation of SDPs in the applicable managed care plan contracts and noted that timely incorporation of this SDP documentation, and associated submission of the contracts to CMS, is essential to ensure efficient and proper administration of the Medicaid program. A few commenters suggested that CMS consider making § 438.6(c)(5) applicable sooner than proposed.

Response: We agree that timely and accurate documentation of SDPs in applicable contracts and rate certifications is critical to efficient and proper administration of the Medicaid program. Because SDPs are contractual obligations between the State and its managed care plans, it is imperative that they be documented in the contract with sufficient granularity for plans to operationalize the SDP accurately as approved. Therefore, we are finalizing the minimum contract documentation requirements proposed in § 438.6(c)(5)(i) through (iv). Due to the separate payment term prohibition being finalized in § 438.6(c)(6) (see section I.B.2.l. of this final rule for further details), we are not finalizing § 438.6(c)(5)(v) as proposed and § 438.6(c)(5)(vi) is finalized, with modifications, as paragraph (c)(5)(v). We also appreciate the suggestion to make § 438.6(c)(5) applicable sooner than proposed but believe that States will need to sufficient time to implement this requirement, in concert with other requirements finalized in this rule and therefore, decline to change the applicability date of this provision. As proposed and finalized, the requirements in § 438.6(c)(5)(i) thorough (iv) are applicable for any rating periods beginning on or after 2 years after the effective date of this final rule and the requirement finalized at § 438.5(c)(5)(v) (proposed at (c)(5)(vi)) is applicable for any rating periods beginning on or after 4 years after the effective date of this final rule. See section I.B.2.p. of this final rule for more discussion of the applicability dates for the regulatory amendments regarding SDPs.

Comment: One commenter recommended that CMS require a general statement in managed care contracts specifying that the managed care plan is expected to incorporate a rate adjustment for certain providers or services as a result of an SDP. The commenter stated that providers may advocate for increased State general revenue appropriations for provider reimbursement rates and States then increase the Medicaid FFS reimbursement rates and make a corresponding capitation rate adjustment to account for base provider payment rate assumptions aligned with the Medicaid FFS reimbursement rates. However, without an SDP, the managed care plans are not bound to incorporate these rate increases into their provider rates. The commenter stated that it is important that a State be able to memorialize legislative direction.

Response: SDPs are contractual requirements whereby States direct their managed care plans' expenditures, and we are finalizing requirements § 438.6(c)(5) to ensure that SDPs are clearly described and documented in managed care plan contracts. However, that is different from when a State and its actuary use information as part of rate development, such as provider payment rate assumptions aligned with Medicaid FFS reimbursement rates, to make adjustments to base capitation rates. Without a contractual obligation that directs the managed care plans' expenditures (and such contractual obligations are required to comply with our regulations), an adjustment included in rate development and that meets the requirements for a rate adjustment in § 438.7, is not an SDP.

Comment: A few commenters supported our proposal to require States to submit managed care plan contracts and rate certifications that include SDPs no later than 120 days of the start date or approval date while other commenters questioned the feasibility of the contract submission timeframes proposed in § 438.6(c)(5)(vi). One commenter noted that 120 days may not be sufficient time for the State to process contracts from language development, legal review, and State clearance to managed care plan execution. Some commenters stated that using a ''later of'' submission date scheme was unnecessarily complicated, prone to error, and would leave managed care plans and providers unclear on final details about the SDP for too long. A few commenters noted that contracts and rate certifications

should be submitted at the same time as the SDP preprint to ensure that they are all consistent. A few commenters stated it is critical that managed care plans receive timely information about SDPs as delays in programming managed care plans claims processing and reporting systems accurately have the potential to delay payments to providers.

Response: We noted in the proposed rule that contracts or amendments can be submitted to CMS in draft form so long as it includes all required elements in § 438.6(c)(5)(i) through (iv), as applicable, to meet the requirement proposed and finalized in this rulemaking to document SDP terms in contract documents in a certain timeframe (88 FR 28144). Between the publication of the proposed rule and this final rule, CMS published the CMCS Informational Bulletin ''Medicaid and CHIP Managed Care Monitoring and Oversight Tools'' on November 7, 2023.[145] Within the CIB, CMS published guidance on the components of a complete submission for managed care plan rate certifications, contracts, and SDP, respectively. Like the submission requirement finalized in § 438.6(c)(2)(viii), the submission requirement finalized at § 438.6(c)(5)(v) must be met for approval of the associated Medicaid managed care contract(s). To make this requirement even clearer, we are finalizing 438.6(c)(5)(v) with a revision to replace ''contracts that are submitted to CMS . . .'' to ''contract that must be submitted to CMS . . .'' If a State does not submit the required contract and rate certification documenting the SDP within 120 days of the SDP start date, CMS will require the State to cease SDP implementation and submit a corrective SDP amendment establishing a prospective SDP start date, as is required for all amendments to approved SDPs.

Similar to our reasoning for revising the SDP submission timeframe in § 438.6(c)(2)(viii) (see section I.B.2.e. of this final rule), we are persuaded by comments that our proposal was overly complex with the ''later of'' submission timelines. We also believe that we need to ensure consistency between the final regulations at § 438.6(c)(5)(vi) for contract submission and § 438.7(c)(6) for rate certification submission given their relationship to each other's approval.

We stated in the proposed rule that we intended to make our processes more responsive to States' needs while ensuring that reviews linked to SDP approvals are not unnecessarily delayed (88 FR 28116). Given the finalized version of § 438.6(c)(2)(viii) for SDP preprint submission (see section I.B.2.e. of this final rule), we believe simplification of the timeframes for submission of the contract and rate certifications inclusive of SDPs is also needed to prevent unnecessary delays for States, managed care plans, and providers. In section I.B.2.e. of this final rule, we acknowledged the importance of contracts that include SDPs containing timely and accurate information on each SDP to enable managed care plans to implement them as intended. Proper implementation of an SDP also reduces uncertainty for providers expecting to receive payments from it. After careful consideration, we will finalize a single submission timeframe that is clear, facilitates compliance, and does not cause unnecessary delays in review and approval. Therefore, we are finalizing § 438.6(c)(5)(v) (originally proposed at § 438.6(c)(5)(vi)) to require all SDPs to be specifically described and documented in the managed care contracts that must be submitted to CMS no later than 120 days after the start date of the SDP and we are not finalizing ''or 120 days after the date CMS issued written approval of the SDP under (c)(2) of this section, whichever is later.'' As noted previously and in the proposed rule, submission of the draft contract documents reflecting the SDP terms will establish compliance with the deadline in § 438.6(c)(5)(v) so long as those draft contract documents include all of the required elements in § 438.6(c)(5)(i) through (v), as applicable. As proposed and finalized, § 438.6(c)(5) does not require a final signed copy of the contract amendment within 120- days of the start of the SDP However, States are required to submit a final signed contract action that complies with all content requirements before CMS will approve the managed care contract. Section 438.6(c)(5)(v) as finalized requires States to submit contracts documenting SDPs no later than 120 days after the SDP start date. The submission requirement at § 438.6(c)(5)(v) may be met using a draft complete contract or draft excerpt of the contract that provides the information about the SDP required by § 438.6(c). This submission deadline applies to all contracts (and, as required by § 438.7(c)(6), discussed in detail later in this response, all rate certifications) that include SDPs, regardless—of whether the SDP requires written prior approval from CMS.

As discussed in section I.B.2.e. of this final rule, we are finalizing § 438.6(c)(2)(viii) to require States to submit all required complete documentation for each SDP requiring written approval before the specified start date of the payment arrangement. Required documentation for the SDP includes at least the completed preprint, the total payment rate analysis and the ACR demonstration as described in § 438.6(c)(2)(iii) and the evaluation plan as required in 438.6(c)(2)(iv) as applicable. Therefore, States would be required to submit the preprint to CMS prior to the start date of the SDP and then the corresponding contract(s) and rate certification(s) inclusive of the applicable SDP no later than 120 days following the start date of the SDP. We believe this submission timeline is the clearest and least burdensome for States, facilitates States submitting contracts that contain accurate information about each SDP, enables managed care plans to implement payment arrangements accurately, and facilitates timely payments to providers.

Lastly, we are finalizing the proposed applicability deadlines for § 438.6(c)(5). Those deadlines provide States sufficient time to come into compliance with the requirements finalized in § 438.6(c)(5). We are finalizing § 438.6(c)(8)(iii) and (v), respectively, to require compliance with the minimum contract documentation requirements in § 438.6(c)(5)(i) through (iv) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule. We are finalizing § 438.6(c)(5)(v) to require compliance with the 120-day contract submission timeframe by the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of the final rule. We believe staggering these applicability dates by 2 years provides States ample time to consider contracting best practices and design processes to ensure timely submission of the required SDP contract documentation.

In response to part of the comments about the submission of ''rate certifications,'' the discussion about the timing of submission to CMS of contracts that contain SDPs are equally applicable to rate certifications. To align rate certification submission timeframes with that of contracts, we are also finalizing § 438.7(c)(6) with revisions compared to the proposed rule. We are finalizing § 438.7(c)(6) to specify a single submission timeframe of no later than 120 days after the start date of the SDP. We are also not finalizing as part of § 438.7(c)(6) the phrase ''for which the State has obtained written approval under § 438.6(c)(2)(i)'' as that is not

[145] *https://www.medicaid.gov/sites/default/files/2023-11/cib11072023.pdf.*

consistent with long standing rate certification requirements (as specified at § 438.7(b)(6)) that a description of any special contract provisions related to payment must be included in the rate certification. For clarity, we remind States that § 438.7(b)(6) is applicable regardless of whether an SDP requires written prior approval of a preprint and for all special contract terms specified in § 438.6 (including incentive payments, withholds, and pass-through payments). We believe finalizing § 438.7(c)(6) as described here provides States time to ensure that rate certifications accurately and consistently reflect each SDP. We are finalizing as proposed (but redesignated to § 438.7(f)(2)) that § 438.7(c)(6) as revised here is applicable no later than the first rating period for managed care plans beginning on or after 4 years of the effective date of this final rule; this applicability date aligns with the applicability of the 120-day contract submission timeframe finalized in § 438.6(c)(5)(v). (This proposal was in section I.B.2.l. of the proposed rule and is also discussed in section I.B.2.l. of this final rule.)

Comment: Some commenters stated concern about the administrative burden of incorporating such detailed information about each SDP in applicable managed care plan contracts. A few of these commenters suggested CMS reduce burden by allowing States to incorporate SDPs in contracts via formal reference to the approved preprints or through an all-plan letter.

Response: Our goal with this provision was to ensure transparency for SDPs, improve clarity for the managed care plans that are responsible for implementing these payment arrangements, and to ensure fidelity to SDP design and approval. As noted in the proposed rule, despite guidance from CMS, States have used a wide variety of approaches to include SDP requirements in their contracts, many of which lack critical details to ensure that managed care plans implement the contractual requirement consistent with the approved SDP. We believe that the minimum requirements for SDP contract terms finalized in § 438.6(c)(5)(i) through (iv) will ensure that managed care plans receive detailed direction on each SDP, facilitate CMS's review of managed care contracts, and facilitate compliance with the approved SDP preprint so that providers receive timely and accurate payments. State directed payments must be included in a State's rate certification per § 438.7(b)(6) and final capitation rates for each MCO, PIHP, and PAHP and must be identified in the applicable contract submitted for CMS review and approval per § 438.3(c)(1)(i) (88 FR 28142). References to an approved preprint is not sufficient to meet this requirement. The preprint is the vehicle for CMS review and approval of SDPs, when required, and they were never intended to serve as a vehicle for managed care plan communication or direction. We do not believe it is reasonable to expect managed care plans to interpret an SDP preprint to operationalize an SDP, and States need to provide clear and transparent contractual requirements for SDPs in the managed care plan contracts to ensure successful implementation. For these same reasons and because an SDP is ultimately a contractual obligation between the State and managed care plans, we also do not believe that it is appropriate for States to provide the information specified in § 438.6(c)(5)(i) through (iv) to their plans via all-plan letters or other communications outside of the contract itself.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are:

- finalizing § 438.6(c)(5)(i), (ii) and (iv) as proposed;
- finalizing § 438.6(c)(5)(iii) as proposed with grammatical minor edits to (§ 438.6(c)(5)(iii)(B) and (C) to remove, ''the contract must include the following'';
- not finalizing the proposed provision (proposed at paragraph (c)(5)(v)) related to contract terms for separate payment terms;
- finalizing, at new § 438.6(c)(5)(v), a requirement for submission of minimum contract documentation for an SDP to CMS no later than 120 days after the SDP start date but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP; and
- finalizing § 438.7(c)(6) to require submission of rate certifications that includes an SDP no later than 120 days after the start date of the SDP but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP. See sections I.B.2.l. and I.B.2.m. of this final rule for further discussion of separate payment terms and rate certifications related to SDPs.

The dates when these new requirements apply to SDPs are addressed in section I.B.2.p. of this final rule.

l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J) and (c)(6), and 438.7(f))

Including SDPs in rate certifications. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of our proposed amendment and redesignation of current § 438.6(c)(2)(i), we proposed to redesignate the existing regulatory requirement at § 438.6(c)(2)(i) as (c)(2)(ii)(J) to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. We also proposed to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. We proposed this edit because inclusion of the language ''generally accepted actuarial principles and practices'' is duplicative of the language included in § 438.4.

We noted in the proposed rule a concern that inclusion of the duplicative language that SDPs must be developed in accordance with generally accepted actuarial principles and practices could be interpreted as a requirement for an actuary to be involved in the development of the SDP arrangement and adherence to actuarial standards of practice (ASOPs) in connection with the SDP, potentially creating unnecessary State administrative burden associated with the preprint development process. However, we did not propose to change the existing requirement that SDPs must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. As noted in the proposed rule, although we believe that an actuary must develop the capitation rates to ensure they are actuarially sound and account for all SDPs when doing so, establishment of SDPs is a State decision and States should have the flexibility to determine if they wish to involve actuaries in the development of each specific SDP arrangement. Practically, because actuaries must account for all SDPs approved by CMS and included in the State's approved managed care contract in the applicable rate certifications, providing all documentation required by CMS, we do recommend that States consult with and keep actuaries apprised of SDPs to facilitate their development of actuarially sound capitation rates. We also believe that for certain SDPs, specifically bundled payments, episode-based payments, population-based payments and accountable care

organizations, it will be beneficial for actuaries to assist States in the development of these arrangements.

In accordance with § 438.4(a), actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract, and capitation rates are developed in accordance with the requirements in § 438.4(b) to be approved by CMS. This includes the requirement in § 438.4(b)(1) that the capitation rates must be developed with generally accepted actuarial principles and practices and in § 438.4(b)(7) that the capitation rates must meet any applicable special contract provisions as specified in § 438.6, to ensure that all SDPs, which are contractual arrangements, are considered as the actuary develops actuarially sound capitation rates. (Similarly, withhold and incentive arrangements and pass-through payments must be taken into account when capitation rates are developed.) We did not propose changes to the requirements for actuarially sound capitation rates; therefore, we will retain and reaffirm here applicability of the requirements that SDPs must be developed in such a way as to ensure compliance with § 438.4 and the standards specified in § 438.5 and specify further that SDPs must also be developed in such a way to ensure compliance with §§ 438.7 and 438.8.

We did not receive any comments on the proposed redesignation of the existing regulatory requirement at § 438.6(c)(2)(i) as (c)(2)(ii)(J) and the proposed amendment to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8 and to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. After reviewing public comments and for the reasons outlined in the proposed rule and here, we are finalizing § 438.6(c)(2)(ii)(J) as proposed.

Separate Payment Terms. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of the Medicaid Managed Care Rate Development Guide, we have historically provided guidance on two ways that States could make payment to cover SDP obligations in Medicaid managed care contracts: through adjustments to the base capitation rates [146] in alignment with the standards described in § 438.5(f), or through a ''separate payment term'' [147] which was described in guidance applicable to rating periods beginning between July 1, 2019 and June 30, 2021. Separate payment terms are unique to Medicaid managed care SDPs. CMS has not previously formally defined separate payment terms in regulation.

The most common structure for separate payment terms is a State first establishes a finite and predetermined pool of funding that is paid by the State to the plan(s) separately and in addition to the capitation payments for a specific SDP. The pool of funds is then disbursed regularly throughout the rating period (for example, quarterly) based on the services provided in that portion of the rating period (for example, quarter) to increase total provider payments or reach a specific payment rate target. Typically, States divide the dedicated funding pool into equal allotments (for example, four allotments if the State is making quarterly payments to their plans). The State then reviews the encounter data for the service(s) and provider class identified in the approved preprint for the quarter that has just ended and divides the allotment by the total service utilization across all providers in the defined class (for example, inpatient discharges for all rural hospitals) to determine a uniform dollar amount to be paid in addition to the negotiated provider payment rate by the managed care plan for rendered services. The State then pays the quarterly allotment to the managed care plans, separate from the capitation rate payment, and directs the plans to use that allotment for additional retroactive payments to providers for the utilization that occurred in the quarter that just ended. The State repeats this process each quarter, with the uniform increase changing for each quarter depending on utilization but being paid uniformly to providers in the defined class for the services within that quarter (for example, inpatient discharges for rural hospitals). Other States have chosen to make payments semi-annually, annually, or monthly. States have also utilized separate payment terms for SDPs that are performance-based payments rather than uniform increases (for example, pay for performance under which payment is conditioned upon provider performance).

As noted earlier, separate payment terms are paid separate and apart from capitation rate payments; they are not included in capitation rates. The development of the separate payment term is frequently done by the State rather than the State's actuaries; we have never required actuaries to certify the reasonableness of the amount of the separate payment term, but only that the separate payment term is consistent with what was approved in the SDP preprint. However, CMS has always required that separate payment terms be documented in the State's rate certification and that SDPs, including those that utilize separate payment terms, must be developed in accordance with § 438.4 and the standards in §§ 438.5, 438.7 and 438.8. CMS has requested actuaries to document the separate payment terms in the State's rate certification because they are required payments for services under the risk-based contract.

Depending on the size and scope of the SDP and the provider payment rates assumed in the capitation rate development, separate payment terms can have a significant impact on the assessment of the actuarial soundness of the rates. In some cases, capitation rates may not be sufficient without taking the existence of the separate payment term amounts paid into account. When examined in conjunction with the capitation rates, we have found that amounts included in separate payment terms can, when combined with capitation payment amounts, represent a significant portion of the total payment made under the Medicaid managed care contract. For example, in one State, the separate payment term for an SDP for inpatient hospital services represented 40 percent of the total amount paid in certain rate cells.

In some cases, the provider payment rates assumed in the development of the capitation rates, absent the SDP paid through a separate payment term to the plan(s), are so low that the capitation rates would likely not be actuarially sound. In the example above, considering how low the payment rates were absent the SDP paid to the plans through a separate payment term in this State, it will be difficult for an actuary to determine that the capitation rates are actuarially sound. However, the additional payments made as part of the SDP for these providers raise the effective provider payment rates, and

[146] As defined in § 438.2, capitation payments are a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan.

[147] This guidance has appeared in the Medicaid Managed Care Rate Development Guide for rating periods starting between July 1, 2019 and June 30, 2021. Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.*

after considering all payments made to the plan (the base capitation rates and the separate payment term payments for the SDP) the actuary may be able to determine that the capitation rates are actuarially sound. This is not the case for all States and for all SDPs; however, this example highlights the need to account for the impact of separate payment terms on the assessment of the actuarial soundness of the capitation rates. Additionally, since the contract requires that the managed care plans pay the SDP to providers, the separate payment term must be included within the actuarial certification for the rates to be considered actuarially sound as defined in § 438.4(a). For this reason, we consider separate payment terms part of the contract with the managed care plans that is subject to the requirements of section 1903(m)(2)(A) of the Act, and a necessary part of certifying the actuarial soundness of capitation rates under this provision. As such, we proposed to regulate them under this authority.

Over time, the number of SDPs approved by CMS using separate payment terms has increased substantially. According to our internal analysis, 41.5 percent of all SDPs that CMS reviewed and approved from May 2016 through March 2022 were included in the State's rate certification submission as a separate payment term. While there has been some fluctuation over time in this trend, the share of SDPs that use separate payment terms has increased from 42 percent of all SDPs that began in CY 2020 to 55 percent of all SDPs that began in CY 2021.[148]

In our January 2021 SMDL, we published additional guidance on SDPs, and stated our growing concern with the increased use of separate payment terms.[149] We noted, ''[a]s CMS has reviewed State directed payments and the related rate certifications, CMS has identified a number of concerns around the use of separate payment terms. Frequently, while there is risk for the providers, there is often little or no risk for the plans related to the directed payment, which is contrary to the nature of risk-based managed care. This can also result in perverse incentives for plans that can result in shifting utilization to providers in ways that are not consistent with Medicaid program goals.''

To better understand why States choose to pay plans for their SDPs through a separate payment term, we started collecting information from States as part of the revised preprint form published in January 2021. States were required to start using this revised preprint for SDP requests for rating periods beginning on or after July 1, 2021. In the revised preprint form, States must identify if any portion of the SDP will be included in the rate certification as a separate payment term and if so, to provide additional justification as to why this is necessary and what precludes the State from covering the costs of SDPs as an adjustment to the capitation rates paid to managed care plans.

Based on data we have collected, as well as discussions with States, we understand there are several reasons why States use separate payment terms. For example, States have noted challenges with including VBP arrangements in capitation rates. They have stated that it is difficult to project individual provider level performance in a way that lends itself to inclusion in standard rate development practices. Additionally, performance measurement often does not align with States' rating periods, further complicating the standard rate development process.

Several States also noted that even for fee schedule-based SDPs, such as uniform payment increases, incorporation into standard rate development practices presents challenges. States assert that using a separate payment term offers administrative simplicity to the State agency in administering the SDPs because distributing a pre-determined amount of funding among its managed care plans is much easier than relying on actuarial projections. Further, the use of a separate payment term also promotes the ease of tracking and verification of accurate payment to providers from the managed care plans required under the SDP. States have noted that this is particularly important when States are implementing legislative directives that require an appropriation of funding be dedicated to a specific purpose. State legislatures, in some instances, have identified a specific dollar amount that they want to invest in increasing reimbursement for a particular service, potentially to respond to an acute concern around access. Incorporating this funding into the State's capitation rates through standard rate development will not ensure plans do not use this funding, or portions of this funding, for other purposes. Additionally, even with the proper tracking, States will have to specify a particular minimum fee schedule or uniform increase at the start of the rating period to include in rate development and ensure it went to the appropriate providers for the appropriate services. While such a methodology is permissible and used effectively by several States today, some States have noted challenges in utilizing such an approach, particularly if the SDP is targeting a narrow set of providers because it can be difficult to specifically target funding to a certain group of providers through the standard process of capitation rate development.

States have also noted that utilization often cannot be predicted adequately; thus, including dedicated funding into base rates may not always result in the funding being distributed as intended by the legislature. Absent the ability to use separate payment terms, States have resorted to requiring plans to make interim payments based on historical utilization and then reconciling to current utilization, often after the end of the rating period, to ensure that all of the funding was used as directed by the legislature. As discussed in section I.B.2.h. of this final rule, we have significant concerns with this practice and we are prohibiting such payment methodologies in new § 438.6(c)(2)(vii).

States also have told us that separate payment terms reduce the burden on managed care plans by limiting the need to update claims systems. In fact, one State noted that they shifted from incorporating a particular SDP as an adjustment to capitation rates to implementing the SDP through a separate payment term because the State's managed care plans did not have the ability to update or modify their claims payment systems in a manner that will ensure accurate payment of the increases required under the State's SDP if the funding was built into the capitation payment. The State noted that the managed care plans had dedicated significant technical resources and still could not implement the changes needed accurately.

As noted earlier, CMS has a strong preference that SDPs be included as adjustments to the capitation rates since that method is most consistent with the nature of risk-based managed care. We noted in the proposed rule that States believe there is utility in the use of separate payment terms for specific programmatic or policy goals. Although we acknowledged in the proposed rule that separate payment terms are one tool

[148] Our internal analysis examines trends based upon when a payment arrangement began. Since States have different rating periods, this can refer to different timeframes for different States. For example, payment arrangements that began in CY 2020 will include payment arrangements that were in effect for CY 2020 rating periods, which operated between January 1, 2020 through December 31, 2020, as well as SFY 2021 rating periods, which for most States were operated between July 1, 2020 through June 30, 2021.

[149] *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

for States to be able to make targeted investments in response to acute concerns around access to care, we continue to believe that, while separate payment terms often retain risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to separate payment terms under an SDP, which is contrary to the nature of risk-based managed care.

Therefore, we proposed establishing regulatory requirements regarding the use of separate payment terms to fulfill our obligations for fiscal and programmatic oversight. Currently, we consider separate payment terms to be payment to the plan for services covered under the contract with the managed care plan that is subject to 1903(m)(2)(A) requirements because the use of separate payment terms is limited to SDPs that must be tied to utilization and delivery of services to Medicaid enrollees under the managed care contract and separate payment terms have an impact on the assessment of actuarial soundness and certification of capitation rates. Based on this, we proposed to regulate them under 1903(m)(2)(A) authority. Section 1903(m)(2)(A) of the Act is limited to MCOs so CMS is, consistent with well-established practice and policy, extending the same requirements to PIHPs and PAHPs using section 1902(a)(4) authority to adopt methods of administration for the proper and efficient operation of the State Medicaid plan. States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60) unless SDP requirements are satisfied.

Proposed Regulatory Changes—Contract Requirements

We proposed to amend § 438.6(a) to define ''separate payment term'' as a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a specific SDP for which the State has received written prior approval. Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for SDPs for which the State has received written prior approval and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i).

We recognize that some separate payment terms in the past may not have fit this definition. For example, one State makes one payment monthly that is inclusive of both the capitation payment and the separate payment term. The State then contractually requires the managed care plans to hold a portion of the monthly payment in a reserve that the State later directs the plans how to pay to providers under an approved SDP. In this example, the State initially indicated to CMS that the SDP was accounted for through adjustments to base data in capitation rates. However, the State later agreed with CMS that the contractual requirement to hold a portion of the monthly payment in a reserve that the State later directed was more in alignment with use of a separate payment term. To be clear, CMS does not consider this practice to be an adjustment to base rates or part of capitation rate development; instead it meets the proposed definition of a separate payment term and we stated in the proposed rule that arrangements like this would have had to comply with all proposed requirements for using separate payment terms for an SDP in the proposed revisions to § 438.6(c)(6).

We proposed a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. We proposed a new § 438.6(c)(6)(i) to require that all separate payment terms to be reviewed and approved as part of the SDP review process in § 438.6(c)(2). This is effectively current practice today; when a State indicates that an SDP is included in the applicable rate certification(s) through a separate payment term, the approved preprint is checked to ensure that it also indicates that the SDP utilizes a separate payment term. This proposed requirement would have codified this operational practice. We believed when developing the proposed rule that reviewing and approving the separate payment term as part of the SDP review and approval process would be mutually beneficial for CMS and States because they are inextricably linked given the proposed definition of a separate payment term. We believed this would also enable us to track of the use of separate payment terms more quickly and accurately.

Because we proposed to require that separate payment terms would be approved as part of the review and approval of the SDPs in § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)), we believed we should explicitly address those SDPs that do not require written prior approval to ensure clarity for States. Therefore, we proposed a new requirement at § 438.6(c)(6)(ii) that would expressly prohibit States from using separate payment terms to fund SDPs that are exempted from the written prior approval process—specifically, minimum fee schedules using State plan approved rates in § 438.6(c)(1)(iii)(A) and minimum fee schedules using approved Medicare fee schedules, as proposed in § 438.6(c)(1)(iii)(B). Under this proposal, such payment arrangements would have been required to be included as an adjustment to the capitation rates identified in the contract, as required under § 438.3(c)(1)(i).

At § 438.6(c)(6)(iii), we proposed to require that each separate payment term be specific to both an individual SDP approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) and to each Medicaid managed care program to provide clarity in the contract for the plan and facilitate State and Federal oversight of such terms. SDPs approved under § 438.6(c)(2) can apply to more than one Medicaid managed care program. We believed that requiring that each separate payment term be specific to both the SDP approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) and each Medicaid managed care program would have facilitated monitoring and oversight and helped to ensure clarity and consistency between the approval of the separate payment term and the SDP, the managed care plan contract, and the rate certification.

Additionally, we proposed a new requirement at § 438.6(c)(6)(iv) that the separate payment term would not exceed the total amount documented in the written prior approval for each SDP for which we have granted written approval. Under current practice, the total dollar amount for the separate payment term has acted as a threshold to ensure alignment between the rate certification and the SDP; States that documented more for the separate payment term in the rate certification(s) than the total dollars documented in the preprint under current practice have to either revise through a rate amendment so that the total dollars for the separate payment term does not exceed what was captured in the preprint or, submit an amendment to the preprint. If States choose to amend the preprint under current practice, the State is required to explain the cause of the increase (for example, a change in payment methodology, or expansion of the provider class); and then verify that the payment analysis has not changed or if it has, then update the payment analysis to ensure that the total payment rate is still reasonable, appropriate, and

attainable.[150] This proposed requirement would have strengthened this practice by requiring that the amount included in both the rate certification(s) and contract(s) for each separate payment term could not exceed the amount documented in the approved SDP preprint. The total dollar amount documented in the written prior approval for the State directed payment would instead act as a maximum that could not be exceeded in the Medicaid managed care contract(s) and rate certification(s) that include the SDP without first obtaining written CMS approval of an amendment to the SDP as noted below. We emphasized in the proposed rule that we currently review rate certifications to verify that the total dollars across all applicable Medicaid managed care programs do not exceed the total dollars identified in the State directed payment documentation approved by CMS. If the total dollars included in rate certifications exceed the total dollars identified in the State directed payment documentation, the State then has to either reduce the total dollars included in the rate certification for the separate payment term or, most commonly, submit an amendment to the preprint for review and approval by CMS. This process causes significant delays and administrative burden for both the State and the Federal government, and therefore, we believed that a regulation prohibiting States from exceeding the total dollars for the separate payment term identified in the State directed payment documentation would be appropriate and important.

We also described in the proposed rule an alternative that would require that the separate payment term must equal exactly the total amount documented for each SDP for which we have granted written prior approval. Instead of acting as a maximum, the total dollar amount for the separate payment term would have acted as both a minimum and a maximum; the State's contract and rate certifications would have had to include exactly the total dollar amount identified in the SDP approved by CMS. We did not propose this alternative because of a concern that requiring the total amount for the separate payment term to act as both a minimum and maximum could be too administratively burdensome; however, we solicited comments on both our proposal to require that the total dollars documented in the SDP approved by CMS under (c)(2) would have acted as a maximum, as well as this alternative option of the total dollars documented in the SDP approved by CMS under (c)(2)(i) as both a minimum and a maximum.

Historically, separate payment terms have only been documented in the State's preprint review and in the State's rate certifications; the details of when and how these payments were made by the State to the plans was often not clear to CMS or the plans. This lack of clarity presents significant oversight concerns for separate payment terms because it makes tracking the payments made from the State to the plan difficult to identify, particularly on the CMS–64 form on which States claim FFP. It also presents challenges for ensuring timely payment to plans and, ultimately, providers. We believed that just as the final capitation rates must be specifically identified in the applicable contract submitted for CMS review and approval, so too should separate payment terms associated with SDPs.

As previously noted in this section, while there is risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to the SDP to the extent it is included in contracts as a separate payment term. We believe that this lack of risk for the plan is contrary to the nature of risk-based managed care. This becomes even more concerning when States retroactively amend the separate payment term, sometimes even after the end of the rating period.

To illustrate this, we provided the following examples in the proposed rule.

Example 1: States that include SDPs into their contracts and rate certifications through separate payment terms must have the total dollars for the separate payment term certified in the rate certification(s). The State will then look at the utilization over a defined period, for example, one quarter, and divide one-fourth of the total dollars certified in the separate payment term by the utilization during that quarter to determine a uniform dollar amount increase. Example 1 illustrates a common practice for SDPs that use separate payment terms: it allows the uniform dollar amount applied to utilization to vary from one quarter to another, but it ensures that the total dollars dedicated to the State directed payment are fully expended.

Example 2: Some States have used this same methodology in Example 1, but instead of having their actuaries certify the total dollar amount prospectively, they will have their actuaries certify an estimate of the total dollars and then have their actuaries recertify a higher amount later, often after all the payments under the separate payment term have been made.

Example 2 not only removes all risk from the plans for the SDP, but also removes all risk from the providers when the actuary recertifies a total dollar amount later, often after all the payments under the separate payment term have been made. Such practices are contradictory to the prospective nature of risk-based managed care rate setting. In our experience, such payment arrangements are not driven by furthering particular goals and objectives identified in the State's managed care quality strategy, but rather by the underlying financing of the non-Federal share associated with the SDPs. We note financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, FFS, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c) or not.

To curtail these concerning practices described in Example 2 above, we proposed to require as part of § 438.6(c)(6)(v) that States document the separate payment term in the State's managed care contracts no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later. We believed requiring States to document the separate payment term within these timeframes would be reasonable given that the contract amendment would only have to document the separate payment term and the related SDP; the contract action could be submitted to CMS in draft form so long as it included all of the required elements. Under this proposal, CMS would not require a final signed copy of the amendment within this proposed 120-day timeframe; however, consistent with current regulations and practice, States would still be required to submit a final signed contract action prior to CMS's approval of the managed care contract.

To further the fiscal and programmatic integrity of separate payment terms, we proposed in § 438.6(c)(6)(v)(A) to prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology that was first

[150] As noted in section I.B.2.f. of this final rule, CMS requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process in alignment with the guidance published in SMDL #21–001 published on January 8, 2021. We proposed to codify this requirement in § 438.6(c)(2(ii)(I).

approved by CMS as an amendment to the approved State directed payment. We recognized that a change in payment methodology could potentially result in the need to amend the separate payment term as it could impact the total dollar amount. However, to avoid the current practice where States include a total dollar amount in the rate certification(s) other than what is in the approved SDP preprint, we proposed to require that CMS approve the amendment to the preprint before the separate payment term could be amended. This proposal was also intended to ensure that some level of risk is maintained, and that States do not retroactively add additional funding to the managed care capitation rates with the goal of removing all risk from the SDP arrangement. Such actions do not align with the fundamental principles of risk-based managed care or Medicaid managed care rate setting.

We also discussed an alternative to permit amendments to the separate payment term to account for a change in the total aggregate dollars to be paid by the State to the plan where there was no change in the non-Federal portion of the total aggregate dollars. This alternative would account for how the Federal portion of the total aggregate dollars may fluctuate due to Federal statute changes that are outside the State's control. We acknowledged that due to this, the total dollars, which includes the Federal share, could not be perfectly predicted by States at the start of a State's rating period. We did not propose this alternative proposal out of concern that it could have negative unintended consequences but solicited comment on both the exception we proposed and the alternative exception that we considered.

To improve transparency of States' use of separate payment terms and to ensure that managed care plans have clear information on the contractual requirements associated to State directed payments linked to a separate payment term, in § 438.6(c)(6)(v)(B)(*1*) through (*4*), we proposed four pieces of information that would be documented in the State's Medicaid managed care plan contracts: (1) the total dollars that the State would pay to the plans for the individual SDP that CMS gave written prior approval; (2) the timing and frequency of payments that would be made under the separate payment term from the State to the plans; (3) a description or reference to the contract requirement for the specific SDP for which the separate payment term would be used; and (4) any reporting that the State required to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8.

Proposed Regulatory Changes—Rate Certification for Separate Payment Terms

To reflect the proposals discussed above that would require States to document separate payment terms in their managed care rate certifications, we also proposed changes to § 438.7. Specifically, we proposed to add a new § 438.7(f) requiring the State, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the State's Medicaid managed care contract, consistent with the proposed requirements of § 438.6(c)(6). Requiring that all separate payment terms be included in the rate certification to plans is also current practice today and would provide a complete picture of all payments made by States to plans under risk contracts.

We also proposed to codify many existing practices that we currently employ when reviewing State directed payments that use separate payment terms. In § 438.7(f)(1), we proposed that the State could pay each MCO, PIHP, or PAHP a different amount under the separate payment term compared to other MCOs, PIHPs, or PAHPs so long as the aggregate total dollars paid to all MCOs, PIHPs, and PAHPs did not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract. In § 438.7(f)(2), we proposed that the State, through its actuary, would have to provide an estimate of the impact of the separate payment term on a rate cell basis, as paid out per the SDP approved by CMS under § 438.6(c)(2)(i). Both of these proposed regulatory requirements are part of current operational practice today as documented in the Medicaid Managed Care Rate Development Guide.[151] Understanding the estimated impact of the separate payment term on a rate cell basis has been helpful for assessing the actuarial soundness of the capitation rates. In § 438.7(f)(3), we proposed that no later than 12 months following the end of the rating period, the State would have to submit documentation to CMS that included the total amount of the separate payment term in the rate certification consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval to facilitate oversight and monitoring of the separate payment term.

Finally, we proposed at § 438.7(f)(4) to require States to submit a rate certification or rate certification amendment incorporating the separate payment term within 120 days of either the start of the payment arrangement or written prior approval of the SDP, whichever is later. This proposal was aligned with the proposed contract requirement in § 438.6(c)(6)(v).

As previously noted, we stated that we preferred that SDPs be included as adjustments to capitation rates since that method is most consistent with the nature of risk-based managed care. Our proposals to amend § 438.6(a) to add a new definition for separate payment term and the proposed addition of §§ 438.6(c)(6) and 438.7(f) were intended to maintain the State's ability to use separate payment terms while implementing necessary guardrails for fiscal and programmatic oversight. However, given our longstanding concern with separate payment terms, we invited comment on requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminating the State's ability to use separate payment terms altogether in the final rule based on comments received. We indicated in the proposed rule that we were considering prohibiting the use of separate payment terms to align with CMS's stated preference and greater consistency with the nature of risk-based managed care.

Another alternative we outlined, and invited comment on, was prohibiting the use of separate payment terms for SDPs described in paragraph (c)(1)(iii). Under this alternative, States would only be able to use separate payment terms for VBP initiatives described in paragraphs (c)(1)(i) and (ii). This alternative would still have allowed States to use separate payment terms for some payment arrangements and could have incentivized States to consider quality-based payment models that could better improve health outcomes for Medicaid managed care enrollees. We believed this alternative could address the difficulties States and their actuaries potentially face when incorporating some VBP initiatives into capitation rate development as compared to fee schedules as described in paragraph (c)(1)(iii).

For each of these two alternatives, we acknowledged that many States currently use separate payment terms and that finalizing either alternative to prohibit the use of separate payment terms for SDPs could cause some disruptions. CMS therefore sought

[151] Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.*

public comment on whether or not we should consider a transition period in order to mitigate any disruptions.

We solicited public comment on our proposals.

We summarize and respond to public comments received on whether either of these alternative approaches we are considering should be adopted in the final rule, below.

Comment: We received a wide array of comments on our proposals in §§ 438.6(c)(6) and 438.7(f) on the use of separate payment terms, as well as on our discussion in the proposed rule preamble regarding whether to eliminate the use of them. We did not receive any comments on § 438.6(c)(2)(ii)(J). Many commenters supported our proposal to codify States' ability to implement SDPs using separate payment terms in regulation to formally recognize what has been an operational flexibility to date. Most of these commenters did not support our specific proposals in § 438.6(c)(6) to require that the total amount of each separate payment terms be documented in the SDP preprint and managed care plan contract and to prohibit exceeding the approved amount without obtaining approval of an SDP amendment. These commenters stated that States should not be hampered from using separate payment terms as they provide greater transparency, ensure that payments flow to providers as intended, minimize administrative burden for States, and make it easier for States to track SDPs. Some commenters noted that separate payment terms are a useful tool for targeting investments in response to acute concerns around access to care. A few commenters supported finalizing some of the proposed guardrails as they could mitigate risks associated with the use of separate payment terms.

Conversely, other commenters agreed with CMS that SDPs are best implemented through adjustments to base capitation rates. These commenters noted that accounting for SDPs through adjustments to base capitation rates is consistent with the transfer of risk to managed care plans for all of their contractual obligations. These commenters encouraged CMS to eliminate or at least limit the use of separate payment terms to enable managed care plans to fulfill their contractual obligations, including SDPs, using the actuarially sound capitation payments provided by the State. These commenters noted that CMS would need to consider giving States and their actuaries time to transition; one commenter suggested that if CMS eliminated separate payment terms a transition period of 3 years should be provided for States to accommodate necessary changes.

Response: We stated our concern regarding the appropriateness of separate payment terms in risk-based managed care programs and proposed a list of seven new requirements in regulation that we believed when developing the proposed rule could assert a measure of control on an increasingly problematic practice (see 88 FR 28144 through 28146). The comments in support of the continued use of separate payment terms with none of the guardrails proposed in § 438.6(c)(6) added to our concern that some States are increasingly relying on this payment mechanism to circumvent risk-based payment to managed care plans. More specifically, it is a way to circumvent compliance with the requirement that SDPs be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, 438.8, and generally accepted actuarial principles and practices. Since being finalized in 2016, § 438.6(c)(2)(i) has required that all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of that section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices; as explained earlier in this section, we are finalizing a revision to this standard in new paragraph (c)(2)(ii)(J). However, after reviewing public comments, we are concerned that the proposed parameters do not adequately address how the use of separate payment terms for SDPs erodes the risk-based nature of payment to managed care plans and fiscal integrity in Medicaid managed care.

We originally permitted the use of separate payment terms to provide flexibility to States as they adjusted to using SDPs. We expected States to transition over time to including all SDPs in capitation rates in a risk-based manner and outlined our concerns with the use of separate terms in guidance published in 2021.[152] Public comments on our proposals in § 438.6(c)(6) reflect that some States believe they need to use separate payment terms to have transparency, accuracy, and administrative simplicity. However, we are concerned that the use of separate payment terms for SDPs erodes the risk-based nature of payment to managed care plans and fiscal integrity in Medicaid managed care. These separate payment terms are separate funding streams for services covered under the contract over which plans have no control and for which they bear no risk. As we noted in the proposed rule, we have found that amounts included in separate payment terms can represent a significant portion of the total payment made under the Medicaid managed care contract. In one State, the separate payment term for an SDP for inpatient hospital services represented 40 percent of the total amount paid in certain rate cells. These payments are commonly made separate and apart from capitation rates. Commentors reaffirmed that separate payment terms are developed by the State rather than the State's actuaries, and the reasonableness of the amount of the separate payment term is not generally certified by States' actuaries (See 88 FR 28145 for further details). Separate payment terms are commonly paid in allotments divorced from a per member per month basis. The nature of separate payment terms makes assessing the total payments made by the State to the plan on a prospective basis more difficult and severely hampers CMS's ability to ensure the capitation rates are actuarially sound.

As noted in the proposed rule and reaffirmed by commentors, the total dollar amount of separate payment terms is not informed by an analysis of what constitutes actuarially sound Medicaid managed care capitation rates, or what constitutes reasonable, appropriate and attainable costs in Medicaid managed care payment. . In our experience, the amounts paid over the course of the year change from month to month or quarter to quarter. These changes in the payments to providers are again driven not by furthering particular goals and objectives identified in the State's managed care quality strategy, but rather by the specific dollar amount dedicated to the payment arrangement.

Robust encounter data reporting requirements in § 438.242, including paragraph (c)(3) requiring reporting of the allowed and paid amounts, should provide sufficient transparency to validate accurate payment to providers. We remind States that the encounter data reporting requirements in § 438.242(c)(2) specifically require managed care plan contracts to provide for the submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight, and program integrity needs. Should States determine that standardized encounter data formats do not provide sufficient detail to validate accurate payments as specified in an approved SDP, States should identify additional levels of required detail and

[152] *https://www.medicaid.gov/sites/default/files/2021-12/smd21001.pdf.*

reporting from plans in their managed care plan contracts.

After reviewing public comments on proposed § 438.6(c)(6), our concerns persist, and we are not persuaded that codifying separate payment terms as a permissible option for SDPs, even with the additional fiscal integrity guardrails proposed, aligns with the regulatory objectives of SDPs or the overall structure of risk-based managed care.

Therefore, we are not finalizing § 438.6(c)(6) as proposed and will instead, as we invited comments on, adopt a new provision at paragraph (c)(6) requiring that all SDPs be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates and prohibiting the use of separate payment terms. In § 438.6(c)(8)(iv), we establish that this new prohibition is applicable beginning with the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after July 9, 2024, which will provide three rating periods for States to transition from use of separate payment terms. The heading for new paragraph (c)(6) is ''Payment to MCOs, PIHPs, and PAHPs for State Directed Payments'' and the finalized regulatory text requires that the final capitation rates for each MCO, PIHP, or PAHP as described in § 438.3(c) must account for all SDPs and that each SDP must be accounted for in the base data, as an adjustment to trend, or as an adjustment as specified in §§ 438.5 and 438.7(b). The final rule regulatory text also prohibits the State from either withholding a portion of the capitation rate to pay the MCO, PIHP, or PAHP separately for a State directed payment, or requiring an MCO, PIHP, or PAHP to retain a portion of the capitation rate separately to fulfill the contractual requirement of a State directed payment. Consistent with this final policy, we will also not finalize the proposed rate certification requirements for separate payment terms in § 438.7(f) nor the definition of ''separate payment term'' at § 438.6(a).

Comment: Some commenters noted that separate payment terms are effective at removing financial incentives for managed care plans to steer utilization away from specific services and deny coverage of services by providers that receive SDPs.

Response: We do not believe that separate payment terms are necessary or appropriate as a tool to address such concerns. States are required to ensure adequate mechanisms are in place to monitor their managed care programs, including actual spending and utilization patterns, generally and after implementation of an SDP for accurate execution, as well as to prevent unintended consequences. States have identified multiple ways to address this without the use of a separate payment term. For example, States can implement payment arrangements that link payments to provider performance instead of utilization. This approach has been effective at lessening any financial incentives for inappropriate steering by managed care plans. Other examples include States using tiered payment structures, requiring plans to include all the providers in a particular provider class as network providers, or using risk mitigation strategies consistent with the requirements in § 438.6(b)(1). Under this final rule, States are also now permitted to recoup unspent SDP funds from plans as long as the recoupment methodology, recoupment process and any other necessary details for recoupment are detailed in the SDP preprint and the contract documentation required in § 438.6(c)(5); previously States were only permitted to recoup funds for certain types of SDP arrangements. We are available to provide States with technical assistance on ways to address this issue, with or without the use of SDPs.

Comment: Some commenters noted concerns with incorporating SDPs through adjustments to base rates. These comments noted that while Medicaid program changes are included in the rate setting process at the rate cell level, rates are not currently adjusted at the provider level for SDPs.

Response: We noted in the proposed rule preamble that more than half of current SDPs are incorporated into managed care rate development as adjustments to base rates. This indicates that States are able to make adjustments at the provider level as part of capitation rate development as appropriate. Further, States are required to use validated encounter data as base data for rate development among other sources of data per § 438.5(c) and encounter data contains provider level information. At § 438.242(c)(3), States must require via their managed care contracts that MCOs, PIHPs and PAHPs submit all enrollee encounter data, including allowed amount and paid amount. This information should allow States to account for the impact of SDPs in actuarially sound capitation rates. To evaluate the effectiveness of SDPs, States must be able to ensure that the payment arrangement is being implemented as intended by monitoring payments at the provider level. This aligns with other provisions finalized in this rule—such as monitoring the payment analysis required in § 438.207(b)(3) and requiring provider level reporting of actual SDP expenditures through T–MSIS. We also are finalizing a requirement at § 438.6(c)(5)(iv) that the MCO, PIHP or PAHP contracts must include any encounter data reporting and separate reporting requirements necessary for auditing the SDP in addition to the reporting requirements in § 438.6(c)(4).

Comment: Several commenters that supported the use of separate payment terms for SDPs stated that CMS's concerns about separate payment terms removing risk from managed care plans for SDP expenditures are inconsistent with the original purpose for SDPs; that is, to provide an exception and permit States to direct payment. These commenters stated that the text of § 438.6(c)(1) ''Except as specified in this paragraph (c), . . .'' explicitly condones exceptions to risk-based Medicaid managed care.

Response: We disagree with this interpretation of the regulatory text and this misinterpretation further highlights the need to eliminate the use of separate payment terms in SDPs. SDPs are an exception to the prohibition on States paying for or specifying payment rates for providers in a risk-based managed care system and were never intended to be an exception to the risk-based payment requirements. The exception to the prohibition on State payment or direction of payment by the plan to providers is an effort to balance our belief about the level of discretion managed care plans need to manage risk for their populations with the unique policy goals and interests of States.

Currently, § 438.6(c)(2) explicitly requires, ''All contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.'' This requirement is retained in this final rule in § 438.6(c)(2)(ii)(J) for all SDPs specified in § 438.6(c)(1)(i) through (iii), with a revision to remove compliance with ''generally accepted actuarial principles and practices'' and to add the standards specified in §§ 438.7 and 438.8; these changes are discussed earlier in section I.B.2.l. of this final rule. As noted in earlier responses and in the preamble to the proposed rule, we have historically required States to account for separate payment terms in rate certifications because they can have a significant impact on the assessment of actuarial soundness of the capitation rates. As we noted, in some cases, the provider payment rates assumed in development of the capitation rates,

absent the SDP paid through a separate payment term to the plan(s), are so low that the capitation rates would likely not be actuarially sound. As specified at § 438.4(a), actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract. This requirement includes all SDPs included in a risk-based contract.

Comment: Other commenters noted that safety-net providers would be at particular risk if CMS prohibited States' from using separate payment terms for SDPs. One commenter stated that safety-net providers are often not in a position to negotiate rates and are forced to accept whatever payment a managed care plan deems appropriate, which can result in these providers being at risk more than the managed care plan.

Response: We appreciate commenters raising this concern. As noted in the proposed rule, we recognize that some providers that serve a higher share of Medicaid enrollees, such as safety net hospitals and rural hospitals, tend to have less market power to negotiate higher rates with commercial plans (88 FR 28125). We recognize that SDPs can be used effectively to further the State's overall Medicaid program goals and objectives, which can include increased access to care. However, we disagree with commenters that using separate payment terms is necessary for States to accomplish such goals. States have significant flexibility in designing SDPs under this final rule, including determining the provider class. We have approved SDPs that defined provider classes based on payer case mix or solely focused on safety net providers, including VBP initiative arrangements that are targeted to safety net providers and reward them based on performance on quality metrics. All of these options can be implemented without the use of a separate payment term.

Comment: Many commenters noted that eliminating separate payment terms would be a notable departure from current practice as CMS has been approving SDPs with separate payment terms for 6 years. Eliminating separate payment terms, according to commenters, could cause significant disruption for existing SDPs. Some commenters also suggested that limiting States' ability to use separate payment terms could threaten the viability of existing SDPs and jeopardize CMS's compliance with the statutory mandate to safeguard equal access to care.

Response: We recognize that nearly half of SDPs that we have approved use separate payment terms. We are confident that States can transition existing SDPs that use separate payment terms into adjustments to base rates, and recognize this transition will take time and that States are facing a number of competing priorities. As noted earlier, we are revising the applicability date for § 438.6(c)(6) to the first rating period that begins on or after 3 years following the effective date of the final rule. We believe that this transition period will provide States time to work with interested parties and actuaries to incorporate SDPs into capitation rates through standard rate development practices.

Further, we disagree with commenters that limiting State's ability to use separate payment terms could jeopardize compliance with the statutory requirement to safeguard equal access to care. SDPs are an optional tool that States can use to direct the expenditures of MCOs, PIHPs or PAHPs; States are not required to utilize SDPs. There are separate regulatory requirements that require States that contract with an MCO, PIHP or PAHP to deliver Medicaid services to address network adequacy and access to care regardless of the use of SDPs. For example, States must develop and enforce network adequacy standard consistent with § 438.68, ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs and PAHPs in a timely manner in compliance with § 438.206, ensure that each MCO, PIHP and PAHP gives assurances to the State and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with § 438.207. Further, the managed care capitation rates must be adequate to meet these requirements as required under § 438.4(b)(3).

Comment: Some commenters supported maintaining States' ability to use separate payment terms but opposed defining separate payment terms as a finite and predetermined amount documented in the managed care plans' contract and instead suggested only requiring States to document (1) a specific dollar amount or (2) a percentage unit price or increase in the contracts. A few commenters stated concern that requiring that SDPs incorporated into rates as separate payment terms not exceed the total dollars documented in the written prior approval for each SDP was a cap on total spending.

Response: As noted in prior responses, we are not finalizing the regulatory framework we proposed at §§ 438.6(c)(6), 438.7(f) or the definition proposed in § 438.6(a) for separate payment terms. We take this opportunity to clarify that States could use an SDP to require managed care plans to pay a specific dollar amount or a percentage increase as a uniform increase or a fixed unit price as a minimum and/or maximum fee schedule without using a separate payment term. When the uniform increase is a fixed dollar amount or a fixed percentage increase, States can use standard rate development processes to include it as an adjustment to capitation rate development; the same is true for a minimum and/or maximum fee schedule. Accounting for SDPs in the standard rate development process removes the need to reduce the payments as expenditures near the predetermined amount. Incorporating SDPs into capitation rates in every situation accounts for changes in enrollment and utilization without arbitrarily changing the amount per service paid to providers.

Comment: Some commenters noted that requiring SDPs to be included in capitation rates instead of separate payment terms puts States at greater financial risk if program enrollment is greater than projected and puts providers at risk if utilization is lower than projected. These commenters noted that they believe including SDPs in separate payment terms would help promote fiscal stability.

Response: We acknowledge that changes in utilization and program enrollment are inevitable, and States must ensure that they provide the most robust data available to their actuaries to facilitate the development of accurate capitation rates that reflect all contractual requirements for managed care plans, including any SDPs. State's actuaries are experienced in addressing unforeseen changes through the development of risk mitigation strategies, which is an appropriate mechanism for addressing uncertainty in risk-based managed care programs.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(ii)(J) as proposed, finalizing a prohibition on separate payment terms at § 438.6(c)(6) as described in this section, and are not finalizing § 438.7(f).

m. SDPs Included Through Adjustments to Base Capitation Rates (§§ 438.7(c)(4) Through 438.7(c)(6))

We also proposed two additional changes to § 438.7(c) to address adjustments to managed care capitation rates that are used for SDPs. (A third change to § 438.7(c) to add a new paragraph (c)(6) is addressed in section I.B.2.k. of this final rule) Specifically, we proposed to add a new regulatory requirement at § 438.7(c)(5) specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract, an amendment to an already approved SDP, a State directed payment described in § 438.6(c)(1)(iii)(A) or (B), or a material error in the data, assumptions, or methodologies used to develop the initial rate adjustment such that modifications are necessary to correct the error. We noted that proposed § 438.7(c)(5) was necessary, at minimum, to ensure fiscal integrity of SDPs and their impact on rate development. While not as frequent, we have also observed States, through their actuaries, submitting amendments to rates for SDPs included through adjustments to base rates that do not reflect changes in payment methodology, changes in benefit design, or general actuarial practices, but instead appear to be related to financing of the non-Federal share. We do not view such actions as consistent with the prospective and risk-based nature of Medicaid managed care. It also creates significant administrative burden for both States and the Federal government by delaying review of associated rate certifications.

Additionally, we proposed a new regulatory requirement at § 438.7(c)(4) that States must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under § 438.7(a) for any special contract provisions related to payment in § 438.6 not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell. Currently, States are permitted the flexibility under § 438.7(c)(3) to increase or decrease the capitation rate per rate cell up to 1.5 percent during the rating period without submitting a revised rate certification for rate changes that are unrelated to special contract provisions, including SDPs, and ILOS provisions. Providing this same flexibility for changes to capitation rates for special contract provisions (including SDPs) is incongruent with the existing requirement at § 438.7(b)(6) that the rate certification include a description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract. In addition, we believe it is also inconsistent with ensuring appropriate program integrity, such as the 105 percent threshold in § 438.6(b)(2) and existing and proposed SDP standards. Therefore, we proposed to clarify the requirements for submitting rate certifications and amendments to rate certifications.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comment on our proposals.

We summarize and respond to public comments received on our proposals related to including SDPs through adjustments to base capitation rates (§ 438.7(c)(4) and (5)) below.

Comment: Many commenters supported our proposals to add clarity to how SDPs are documented in rate certifications and improve alignment between §§ 438.7(b)(6) and 438.7(c). Some commenters also supported our proposal to keep the long-standing practice in § 438.7(c) that does not permit States to utilize de minimis flexibility to amend capitation rates for SDPs and expand it to include ILOSs. This commenter supported the requirement that States must always submit amendments to the rate certifications when changes are required for SDPs or ILOSs. One commenter requested that CMS consider revising its proposal at § 438.7(c)(4) as they believed the proposal would increase State administrative expenses and not result in improved oversight.

Response: We appreciate the support and agree that these provisions will support program integrity and our contract and rate certification reviews by requiring additional specificity for any changes in the capitation rate per rate cell, regardless of the size of the change. We disagree with the commenter that the requirement for States to submit a revised rate certification for any changes in the capitation rate per rate cell for special contract terms (described in § 438.6, which includes SDPs) and ILOS provisions (described in § 438.3(e)(2)) would not improve oversight. This new provision will ensure consistency with the existing regulatory requirement at § 438.7(b)(6) which requires a description of any of the special contract provisions related to payment in § 438.6 that are applied to the contract, as well as ensure that we are aware of changes being made to each SDP's impact on capitation rates. Additionally, this level of detail facilitates robust review of rate certifications by ensuring specificity on any capitation rate changes. We acknowledge, as pointed out by the commenter that this provision could increase State administrative burden if a revised rate certification is solely done for a change to an SDP or ILOS arrangement and not for other programmatic purposes; as a result, we have revised the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details) to address this burden. However, the increased burden is outweighed by the benefits from additional program oversight afforded by submission of amended rate certifications when an SDP or ILOS results in changes to the capitation rate payable to the Medicaid managed care plan. Even relatively small changes in SDPs and ILOS, both areas of growing interest and State uptake, can have notable fiscal impacts and depending on the nature of the change, may also trigger an associated SDP and contract amendment that CMS would not know to request, absent a required rate certification action.

Comment: Some commenters supported our proposal at § 438.7(c)(5) to limit the retroactive adjustments that can be made to capitation rates resulting from an SDP where these adjustments must be the result of an approved SDP being added to the contract, an amendment to an already approved SDP, a State directed payment described in § 438.6(c)(1)(iii)(A) or (B), or a material error in the data, assumptions or methodologies used to develop the initial rate adjustment such that modifications are necessary to correct the error. Other commenters opposed limitations on retroactive adjustments that can be made to capitation rates resulting from an SDP, stating that there are circumstances not related to a material error when retroactive adjustments to capitation rates are appropriate. The commenters offered the example of the COVID–19 PHE, when the actuarial assumptions used to develop rates were uncertain and necessitated continual monitoring and adjusting noting that this uncertainty is likely to continue through the ''unwinding'' of the continuous coverage requirement. Commenters further noted that it is possible for there to be significant disparities between the amounts paid by States to managed care plans for SDP arrangements and the amounts subsequently paid by the managed care plans to providers. Without sufficient oversight and the ability to adjust capitation rates as

needed, the commenters noted that managed care plans could be incentivized to steer utilization away from the providers receiving SDPs. The commenters noted that retroactive adjustments are an effective tool to mitigate this risk by ensuring that managed care plans cannot benefit financially from such behavior.

Response: We appreciate the range of comments on our proposal to limit retroactive adjustments to capitation rates for an SDP. SDPs are utilized in a risk-based contract; therefore, capitation rate development must be developed in a risk-based manner. While we recognize the challenges States face in developing capitation rates impacted by the COVID–19 PHE, we believe that the uncertainty faced by actuaries and States was not specific to SDPs but applied across all aspects of rate development. For this reason, we recommended that States implement risk-sharing arrangements such as 2-sided risk corridors in response to the uncertainty. Risk corridors that comply with the regulatory requirements in § 438.6 are an effective tool in mitigating risk from uncertainty and can be used by States during this period of unwinding, as well as in other instances. We remind States that, in accordance with § 438.6(b)(1), risk sharing mechanisms may not be added or modified after the start of the rating period. Regardless of unique circumstances such as PHEs, we believe that SDPs should be accounted for in rate certifications and that retroactive adjustments must be a result of adding or amending any State directed payment consistent with the requirements in § 438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that are necessary to correct an error. We remind States that they are required to return to CMS the Federal government's share of any remittance a State collects, taking into account the applicable Federal matching rate. See for example, § 437.74(b). We also remind States that they have an on-going responsibility to monitor all aspects of managed care programs as required in § 438.66, including contract requirements such as SDPs (see § 438.66(b)(14)). States must ensure that managed care plans are operationalizing SDPs consistent with approved Medicaid preprints, when written approval of a preprint is required, and consistent with Federal requirements in 42 CFR part 438. This State monitoring should also take into consideration as appropriate any provider and enrollee complaints or concerns related to inappropriate plan actions, including those that constitute efforts to steer utilization away from the providers receiving SDPs. State oversight of the implementation of SDP contractual obligations by plans is critical to ensuring not only fiscal integrity, but that the SDP furthers the State's goals and objectives of the SDP identified by the State.

Comment: One commenter appreciated the additional clarity that CMS provides regarding actuarial certification standards but encouraged CMS to maintain sufficient flexibility in the rules to allow each State to work with CMS through the SDP approval process in meeting SDP requirements and for managed care plans to retain flexibility to design and enter incentive payments with providers in accordance with their own private negotiations.

Response: We appreciate the commenters' support for the clarification regarding actuarial certification standards in §§ 438.7(c)(4) through (6). We take this opportunity to clarify that the regulations at §§ 438.6(c) and 438.7(c)(4) through (6) are for SDPs; that is, contract requirements whereby the State directs a managed care plan's expenditures. Provider incentive payments that a plan and provider negotiate without State direction or involvement are not SDPs. For further discussion on provider incentive payments, refer to section I.B.3.a. of this final rule.

Comment: One commenter stated that requiring SDP funds to be built into managed care plans' capitation rates would reduce transparency and create opportunities for managed care plans to leverage funds meant for providers to advance quality outcomes.

Response: Since SDPs were codified in the 2016 final rule, we have consistently stated that they were to be built into the capitation rates as actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population(s) covered under the terms of the contract. Although we have historically permitted flexibility through the use of separate payment terms for SDPs, as outlined in the proposed rule (88 FR 28144–28148), we have consistently raised concerns about the use of separate payment terms given the construct of a risk-based contract. As further noted in section I.B.2.l. of this final rule, we are not finalizing § 438.6(c)(6) as proposed but will instead phase out the use of separate payment terms and require that all SDPs be included in base capitation rates no later than the first rating period beginning on or after three years following the effective date of this rule. State directed payments are part of risk-based managed care contract and as such, must be built into capitation rates. The regulations adopted in this final rule are clear on that. In addition, we are finalizing other provisions (such as § 438.6(c)(5) requiring specific documentation requirements in managed care plan contracts for SDPs) that will improve the accuracy of how SDPs are implemented. Lastly, we now publish approved SDP preprints on Medicaid.gov to improve transparency. Together, these provisions will ensure more accurate and timelier implementation of SDPs while ensuring appropriate levels of oversight by CMS.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.7(c)(4) and (5) as proposed. We are finalizing § 438.7(c)(6) with revisions as described further in section I.B.2.k. of this final rule.

n. Appeals (§ 430.3(e))

As outlined under § 438.6(c), SDPs are arrangements that allow States to require managed care plans to make specified payments to health care providers when the payments support overall Medicaid program goals and objectives (for example, funding to ensure certain minimum payments are made to safety net providers to ensure access or that providers are appropriately rewarded for meeting certain program goals). Section 438.6(c) was issued by CMS because this type of State direction of managed care payment goes against the general premise of managed care in which a contracted organization assumes risk from the State for the delivery of care to its beneficiaries. As a result, we established a process whereby States must submit a ''preprint'' form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c). If the proposal complies, we issue written prior approval. Subsequent to written prior approval, the SDP is permitted to be included in the relevant managed care plan contract and rate certification documents. This process is required by CMS for most SDPs.

As discussed throughout this final rule, the volume of State requests for written prior approval to implement State directed payment arrangements has grown significantly in both number and total dollars included in managed care plan capitation rates since

§ 438.6(c) was issued in the 2016 final rule.

Based on our review of SDP prior approval requests, we have observed that States use SDPs not only as routine payment mechanisms, such as to set minimum fee schedules or provide uniform increases, but also for more complex payment arrangements, such as to implement Total Cost of Care (TCOC) programs, and multi-metric and multi-year VBPs. CMS provides technical assistance to States at all stages of SDP development to help States develop SDP arrangements that meet their programmatic goals and comply with § 438.6(c). This technical assistance can involve both verbal and written assistance, as well as the exchange of CMS-generated question sets and State responses. The State responses are shared internally with Federal review partners who provide subject matter expertise, which may include those representing managed care policy and operations, quality, financing, and actuarial science, which is then shared with the State to inform SDP revisions and ensure compliance with the regulations.

Providing this technical assistance has become increasingly challenging as the number and complexity of States' SDP requests has increased. To date, typically when CMS and States have found themselves unable to reach agreement on SDP proposals and we have been unable to issue prior written approval, States have agreed to withdraw the submission. However, as SDPs have matured as a State tool, they have outgrown this informal process. We believe it is appropriate to establish a process for formally disapproving proposals that do not comply with the Medicaid requirements and regulations. Accordingly, this final rule will strengthen the SDP process, as well as further specify the requirements for SDPs under our regulations.

A disapproval of an SDP could be issued for many reasons, including impermissible financing of the non-Federal share, failure to show improvement in the proposed quality evaluation report in the timeframe required, or non-compliance with the controlling regulations in part 438. To be consistent with other CMS processes that issue formal disapprovals, such as those for State plan amendment submissions and disallowances of State Medicaid claims, there should be a formal process for States to appeal CMS's disapproval of a State's SDP proposal. The alternative is that a State may seek redress in the courts, which can be costly and slow for both CMS and States. We believe that States will benefit from an established, efficient administrative process with which they are familiar. However, nothing in this final rule precludes any State from seeking redress in the courts.

Under our authority under section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid, we proposed to add a new § 430.3(d) that would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the Health and Human Services (HHS) Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16. As described in that section, the Board is comprised of members appointed by the HHS Secretary and conducts *de novo* (from the beginning) review of certain agency decisions under the procedures at 45 CFR part 16 and its corresponding appendix A. The Board has a robust administrative adjudication process as well as experience resolving disputes between CMS and States involving the Medicaid program, as it already reviews Medicaid disallowances under Title XIX of the Act using the procedures set forth at 45 CFR part 16.

Applying those procedures to CMS's decision to deny a State's SDP request, after a State receives a final written decision from CMS communicating its disapproval of that State's SDP preprint, the State would have 30 days to file a notice of appeal with the Board. (45 CFR 16.7(a)). The case would then be assigned a presiding Board member who would conduct the conference or hearing if one is held. (45 CFR 16.5). Within 10 days of receiving the notice of appeal, the Board would acknowledge the notice and outline the next steps in the case. (45 CFR 16.7(b)). Under existing 45 CFR 16.16, the Board may allow additional parties to participate if there is a ''clearly identifiable and substantial interest in the outcome of the dispute'' in the discretion of the Board. The State would then have 30 days to file its appeal brief, which would contain its arguments for why CMS's final decision was in error, and its appeal file, which would include the documents on which its arguments are based. (45 CRF 16.8(a)). Then, CMS would have 30 days to submit its brief in response as well as any additional supporting documentation not already contained in the record. (45 CRF 16.8(b)). The State would be given fifteen days to submit an optional reply. (45 CFR 16.8(c)). The Board may extend any given deadline, but only if the party provides ''a good reason'' for an extension. (45 CFR 16.15(a); *Id*) (noting that ''the Board has the flexibility to modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case'').

Under the Board's process, parties would be encouraged to work cooperatively to develop a joint appeal file and stipulate to facts, reducing the need to separately submit documentation. (45 CFR 16.8(d)). At any time, the Board may request additional documentation or information, request additional briefings, hold conferences, set schedules, issue orders to show cause, and take other steps as appropriate to ''develop a prompt, sound decision'' per existing 45 CFR 16.9. Although there is no general right to a hearing in cases heard under 45 CFR 16 and 45 CFR 16.4 States appealing a CMS disapproval of a proposed State directed payment under this proposed process could request a hearing or oral argument, or the Board may call for one *sua sponte (*of one's accord; voluntarily), should it determine that its decision-making would be enhanced by such proceedings. (45 CFR 16.11(a)). Generally, Board's proceedings are conducted by videoconference, or in person in Washington, DC, but may be held in an HHS Regional Office or ''other convenient facility near the appellant.'' 45 CFR 16.11(c)). The Board's decisions are issued by the Board in three-member panels. (45 CFR 16.5(a)). Under 45 CFR 16.23, the paramount concern of the Board is to take the time needed to review a record fairly and adequately to produce a sound decision. Under 45 CFR 16.18, the Board, in consultation with the parties, may suggest use of mediation or other alternative dispute resolution services to resolve the dispute between the parties or clarify issues.

As an alternative to our proposal described above to use the Board for such decisions, we also considered permitting appeals of SDP written disapprovals to be heard by the CMS Offices of Hearings and Inquiries (OHI) and the CMS Administrator for final agency action, as governed by part 430, subpart D. The current jurisdiction of OHI stems from section 1902 of the Act, under which it hears appeals arising from decisions to disapprove Medicaid State Plan material under § 430.18 or to withhold Federal funds under § 430.35 for noncompliance of a State Plan. The OHI process is overseen by a presiding officer who makes a recommendation to the Administrator, who issues the final decision. The process is initiated upon issuance of a written disapproval.

If we were to use this process for disapproval of SDPs, the hearing officer would mail the State a notice of hearing

or opportunity for hearing related to an SDP disapproval that is also published in the **Federal Register**. (42 CFR 430.70). The hearing will be scheduled either in the CMS Regional Office or another place designated by the hearing officer for convenience and necessity of the parties between 30 and 60 days after notice. (42 CFR 430.72). Before the hearing, issues may be added, removed, or modified, to also be published in the **Federal Register** and with 20 days' notice to the State before the hearing, unless all issues have been resolved, in which case the hearing is terminated. (42 CFR 430.74).

Under this process, the State and CMS will be given 15 days to provide comment and information regarding the removal of an issue. (42 CFR 430.74(c)). Before the hearing, other individuals or groups will be able to petition to join the matter as a party within 15 days after notice is posted in the **Federal Register**. (42 CFR 430.76). The State and CMS will be able to file comments on these petitions within five days from receipt. *Id.* The presiding officer will determine whether to recognize additional parties. *Id.* Alternatively, any person or organization will be able to file an *amicus curia* (friend of the court) as a non-party, should the presiding officer grant their petition. *Id.* The parties will have the right to conduct discovery before the hearing to the extent set forth under § 430.86 and to participate in prehearing conferences consistent with § 430.83.

At the hearing, parties would make opening statements, submit evidence, present, and cross-examine witnesses, and present oral arguments.[153] The transcript of the hearing along with stipulations, briefs, and memoranda will be filed with CMS and may be inspected and copied in the office of the CMS Docket Clerk. (42 CFR 430.94). After the expiration of the period for post hearing brief, the presiding officer will certify the record and recommendation to the Administrator. (42 CFR 430.102(b)(1)). The Administrator will serve a copy to the parties who have 20 days to file exceptions or support to the recommendation. (42 CFR 430.102(b)(1)–(2)). The Administrator will then issue its final decision within 60 days. (42 CFR 430.102(b)(3)). The decision of the Administrator under this section is the final decision of the Secretary and constitutes ''final agency action'' within the meaning of 5 U.S.C. 704 and a ''final determination'' within the meaning of section 1116(a)(3) of the Act and § 430.38. (42 CFR 430.102(c)). Should the Administrator preside directly, they will issue a decision within 60 days after expiration of the period for submission of post hearing briefs. (42 CFR 430.102(a)).

We believe the Board will be the most appropriate entity to hear appeals of disapprovals of SDPs proposals for the following reasons. Foremost, while both the Board's and OHI's processes can resolve disputes, we believe the Board will better facilitate timely approval of managed care plan contracts and the payment of capitation payments. Medicaid managed care uses a prospective payment system of capitation payments and anything that delays approval of the managed care plans' contracts can have a significant adverse impact on a State's managed care program. Additionally, the Board's processes have the added procedural flexibilities of allowing for mediation under 45 CFR 16.18, as well as not requiring, but allowing, a hearing, as described in 45 CFR 16.11. These differences in the Board regulations give additional options and possible efficiencies to the parties. Therefore, while we believe both processes will be adequate for appeals of any disapproval of a State directed payment, for the reasons described above, we believe the processes under the Board will be the most appropriate proposal for inclusion in § 430.3(d).

We solicited public comments on whether the Board or OHI appeals processes will best serve the purposes of resolving disputes fairly and efficiently. We summarize and respond to public comments received on Appeals (§ 430.3(d)) below.

Comment: A few commenters supported our proposal at § 430.3(d) to use the HHS Departmental Appeals Board for the administrative appeals process and agreed that having a formal process is appropriate given that written prior approval is required for most SDPs.

Response: We agree that the Board is the most appropriate entity to adjudicate an agency appeal process for denial of written prior approval for SDPs. We believe that States will benefit from and appreciate an established, consistent administrative process with which they are familiar. We are finalizing § 430.3(d) as proposed, however, we are redesignating as § 430.3(e) to reflect new § 430.3(d) in the interim final rule *Enforcement of State Compliance with Reporting and Federal Medicaid Renewal Requirements under the Social Security Act* (88 FR 84733) published December 2023.[154]

Comment: Many commenters stated concern that establishing an administrative appeals process for denials of written prior approval of an SDP would deny a potential appellant access to the courts. Some commenters stated that the courts would be the preferred venue for appeals of SDP denials based on statutes outside of the parameters of § 438.6(c) (for example, financing issues governed by the statute).

Response: The administrative process finalized at § 430.3(e) is at the option of the appellant, and States may seek redress in the courts at any time (88 FR 28150). It was never our intent to imply that use of an administrative appeals process was a barrier or deterrent for States electing to utilize the courts. As we stated in the proposed rule, we believe that an administrative appeals process is a timelier and more cost-effective path to resolution than the court system. Nothing in this final rule precludes any party from seeking redress in the courts. To the comment on appeals of SDP denials based on statutes outside of the parameters of § 438.6(c), the Board has sufficient legal authority and expertise to adjudicate appeals regardless of their statutory basis. However, as we clarify above, States always have the option to utilize the courts if they prefer.

Comment: Some commenters supported the use of an administrative process but stated concern at the timeliness of decisions and the effect on the SDP's use during a specific rating period. Some commenters stated that the CMS OHI would be a more expeditious decisionmaker in practice, despite the Board's faster timelines in regulation. Some commenters stated that both bodies were frequently backlogged rendering them ineffective for issues such as SDPs and recommended that an expedited appeal process be codified. One commenter noted OHI's ability to waive hearings as an efficiency that could be useful for SDP appeals. Another commenter stated concern that the amicus mechanism of the Board would slow their process.

Response: We share the commenters' goal of an expeditious process for the benefit of all parties. We are confident that the Board has the capacity to effectively adjudicate appeals of SDP disapproval by CMS. We do not have concerns that the amicus mechanism of the Board will prove a hindrance as it is an existing part of their processes, and the option exists in the courts and OHI as well. Regardless, we do not believe that utilization of the courts would produce a faster resolution. To the suggestion that OHI would provide

[153] 42 CFR 430.83.

[154] 45 CFR part 16 (Notice of Proposed Rulemaking—CMS–2447–IFC).

faster resolution because of their ability to waive hearings as an efficiency, we note that under 45 CFR part 16, the Board does not automatically schedule a hearing, but rather ''only if the Board determines that there are complex issues or material facts in dispute, or that the Board's review would otherwise be significantly enhanced by a hearing.''

Comment: Some commenters supported using OHI as opposed to the Board for subject matter expertise. Some of these commenters stated that OHI's expertise in SPAs was more akin to SDPs and thus, the more appropriate venue.

Response: We acknowledge that OHI could also be an appropriate venue for SDP appeals; however, we do not agree that their expertise in SPAs makes them more competent than the Board to hear an appeal of disapproval by CMS of an SDP. On balance, we believe the Board's shorter goal resolution time would better facilitate timely approval of managed care plan contracts and the payment of capitation payments. Medicaid managed care uses a prospective payment system of capitation payments and anything that delays approval of managed care plans' contracts can have a significant adverse impact on a State's managed care program. Additionally, the Board's processes have the added flexibilities of allowing for mediation under 45 CFR 16.18, as well as not requiring, but allowing, a hearing, as described in 45 CFR 16.11. These differences in the Board regulations give additional options and possible efficiencies to the parties (88 FR 28151).

Comment: One commenter objected to codification of any appeals process for SDP program approvals because, unlike the State plan amendment process or other administrative actions subject to appeals processes, SDPs are merely providing direction to MCOs under an existing, approved authority.

Response: We do not agree that SDPs are not appropriate for an administrative appeals process. As stated in the proposed rule, there is an administrative process for SDPs under § 438.6(c), which includes review and, when appropriate, issuance of written approval prior to the SDP being included in the corresponding managed care plan contract and rate certification (88 FR 28149). As such, we believe the issuing of a disapproval by CMS of SDPs is an administrative action suitably addressed through an administrative appeals process when requested.

Comment: Some commenters stated concern with the remedy should an appellant prevail in an appeal of an SDP disapproval. The commenter stated that Medicaid managed care is a prospective payment system and if the contract year ends and the appeal is not resolved, clarity is needed on whether the SDP will only be approved going forward or if it could be approved retroactively. Another commenter echoed the same comment but emphasized that this concern is particularly acute in performance-based payments. One commenter requested that the remedies available be made explicit in regulation.

Response: The Board has broad discretion in the appropriate remedy should an appellant prevail in its appeal, and we do not intend for this regulation to either limit or broaden the Board's powers. For example, the Board could opt to issue a remedy to permit the State to implement the SDP retroactive to the arrangement start date proposed by the State in the initial SDP preprint submission. Generally, we share commenters' concerns that any issue should be resolved in a timely fashion. We note that these concerns exist now under our existing informal resolution process, but we believe that an administrative process will provide cost and time efficiencies for all parties as an alternative venue. Nothing in this final rule precludes any party from seeking redress in the courts.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, at § 430.3, we are redesignating paragraph (d) as paragraph (e) and finalizing as proposed.

o. Reporting Requirements To Support Oversight and Inclusion of SDPs in MLR Reporting (§§ 438.6(c)(4), and 438.8(e)(2)(iii)(C) and (f)((2)(vii))

States' increasing use of SDPs has been cited as a key area of oversight risk for CMS. Oversight bodies and other interested parties, including GAO and MACPAC, have issued reports recommending that we collect and make available provider-specific information about Medicaid payments to providers, including SDPs.[155] [156] [157] [158]

As discussed in this final rule, CMS's current review and approval process for SDPs is prospective; that is, we do not consistently nor systematically review the actual amounts that States provide to managed care plans for these SDPs [159] nor do we review the actual amounts that managed care plans pay providers. We are also aware that some States are permitting managed care plans to retain a portion of SDPs for administrative costs when plans make these payments to providers. Because States are not required to provide the actual expenditures associated with these arrangements in any separate or identifiable way, we cannot determine exactly how much is being paid under these arrangements, to what extent actual expenditures differ from the estimated dollar amounts identified by States in the approved preprint by CMS, and whether Federal funds are at risk for impermissible or inappropriate payment.

We proposed new reporting requirements for Medicaid SDPs in §§ 438.8 and 438.74 to align with the reporting that is currently required for Medicaid FFS supplemental payments. CMS FFS supplemental payment guidance notes that ''[i]nformation about all supplemental payments under the State plan and under demonstration is necessary to provide a full picture of Medicaid payments.'' [160] While States must provide CMS with the amounts for FFS supplemental payments, there is no requirement for States or managed care plans to provide actual payment data separately for SDPs. Implementing a new requirement for both State and managed care plan reporting of actual SDP expenditures will support CMS oversight activities to better understand

[155] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

[156] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

[157] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

[158] U.S. Government Accountability Office, ''Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency,'' December 14, 2023, available at *https://www.gao.gov/products/gao-24-106202*.

[159] Because CMS does not routinely perform retrospective review of SDPs, the Medicaid Managed Care Rate Development Guide requires States using separate payment terms to (1) submit documentation to CMS that includes the total amount of the payment into the rate certification's rate cells consistent with the distribution methodology included in the approved State directed payment preprint, as if the payment information had been known when the rates were initially developed; and (2) submit a rate amendment to CMS if the total amount of the payment or distribution methodology is changed from the initial rate certification. As part of this final rule, CMS is finalizing a prohibition on separate payment terms, see § 438.6(c)(6) and section I.B.2.l. of this final rule for further details.

[160] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf*.

provider-based payments across delivery systems.

To address the need for additional information on the actual amounts paid as SDPs, we proposed to require Medicaid managed care plans to include SDPs and associated revenue as separate lines in the reports required at § 438.8(k). The managed care MLR reporting requirements at § 438.8(k) were codified in the 2016 final rule, and States have substantial experience in obtaining and reviewing MLR reports from their managed care plans. To date, our MLR guidance has not addressed the inclusion of SDPs in the MLR; the proposed rule specified these requirements by proposing to amend § 438.8(k) to ensure that Medicaid SDPs will be separately identified in annual MLR reporting.

Specifically, at § 438.8(e)(2)(iii)(C), we proposed to require that managed care plan expenditures to providers that are directed by the State under § 438.6(c), including those that do and do not require prior CMS approval, must be included in the MLR numerator. In § 438.8(f)(2)(vii), we proposed to require that State payments made to Medicaid MCOs, PIHPs, or PAHPs for approved arrangements under § 438.6(c) be included in the MLR denominator as premium revenue. We proposed that States and managed care plans are required to comply with these changes in § 438.8(e)(2)(iii)(C) and (f)(2)(vii) 60 days after the effective date of the final rule as we believe these proposals are critical for fiscal integrity in Medicaid. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

We also proposed to require that the managed care plans' MLR reports to States as required in § 438.8(k) include two additional line items. The first item at § 438.8(k)(1)(xiv) would require reporting of Medicaid managed care plan expenditures to providers that are directed by the State under § 438.6(c). The second item at § 438.8(k)(1)(xv) would require reporting of Medicaid managed care plan revenue from the State to make these payments. We proposed, in § 438.8(k)(xvi), that States and managed care plans would be required to comply with § 438.8(k)(1)(xiv) and (xv) no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after the effective date of the final rule. We considered an alternative effective date where States and plan would comply with these requirements 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeframe for compliance as the new reporting requirements may require State and managed care plans to make changes to financial reporting systems and processes. We sought public comment on this proposal.

For separate CHIPs, we did not propose to adopt the new reporting requirements at § 438.8(k)(1)(xiv) and (xv) because SDPs are not applicable to separate CHIP managed care plans. For this reason, we proposed to amend § 457.1203(f) to exclude any references to SDPs for managed care plan MLR reporting. For clarity, we also proposed to make a technical change at § 457.1203(f) to include the word ''in'' before the cross-reference to § 438.8.

To assist in CMS oversight of these arrangements, we proposed that the plan-level SDP expenditure reporting should be reflected in States' annual summary MLR reports to CMS. As part of States' annual summary MLR reporting that is required under § 438.74, we proposed to require two additional line items. The first item at § 438.74(a)(3)(i) would require State reporting of the amount of payments made to providers that direct Medicaid MCO, PIHP, or PAHP expenditures under § 438.6(c). The second item at § 438.74(a)(3)(ii) would require State reporting of the amount of payments, including amounts in the capitation payments, that the State makes to Medicaid MCOs, PIHPs, or PAHPs for approved SDPs under § 438.6(c). We proposed, in § 438.74(a)(4), that States would be required to comply with § 438.74(a)(3) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believed this was a reasonable timeframe for compliance. We considered an alternative effective date where States would comply with the new requirement 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeline for compliance as these changes may require States to make changes to financial reporting systems and processes. We sought public comment on this proposal.

We did not propose to adopt the new SDP reporting requirements at § 438.74 for separate CHIPs since expenditures under § 438.6(c) are not applicable to separate CHIP managed care plans. However, since existing separate CHIP regulations at § 457.1203(e) currently cross-reference to the reporting requirements at § 438.74, we proposed to amend § 457.1203(e) to exclude any references to SDPs in State MLR reporting.

While we expected that some managed care plans and States may oppose these proposals as increasing administrative burden, we believed that the increased transparency associated with these enhanced standards would benefit both State and Federal government oversight of SDPs. Implementing these new requirements for both State and managed care plan reporting of actual SDP expenditures will support CMS's understanding of provider-based payment across delivery systems.

We also proposed to establish a new requirement at § 438.6(c)(4) for States to annually submit data, no later than 180 days after each rating period, to CMS's T–MSIS, and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs that were in effect for the rating period, including amounts paid to individual providers. The purpose of this reporting would be to gain more information and insight into actual SDP spending at the individual provider-level. As MACPAC noted in their June 2022 Report to Congress, ''[State directed payments] are a large and rapidly growing form of Medicaid payments to providers, but we do not have provider-level data on how billions of dollars in directed payments are being spent.'' [161] The Commission noted that SDPs are larger than disproportionate share hospital (DSH) and upper payment limit (UPL) supplemental payments, but there is much less data on who is receiving them.[162] Currently, States must provide CMS with specific information for FFS supplemental payments that are made to individual providers; however, there is no such requirement for States or managed care plans to provide this type of quantitative, provider-specific data separately for SDPs. We believe implementing a provider-level SDP reporting requirement will facilitate our understanding of provider-level Medicaid reimbursement across delivery systems.

We proposed to develop and provide the form through which the reporting

[161] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

[162] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

would occur so that there will be one uniform template for all States to use. We proposed in § 438.6(c)(4) the minimum data fields that will need to be collected to provide the data needed for CMS to perform proper oversight of SDPs. Proposed § 438.6(c)(4)(i) through (v) outlines the minimum data fields: provider identifiers, enrollee identifiers, managed care plan identifiers, procedure, and diagnosis codes, and allowed, billed, and paid amounts. Under the proposal, paid amounts would include the amount that represents the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. When contemplating the FFS supplemental payment reporting, we considered how States should have the information being requested readily available, ''[i]ncluding the provider-specific payment amounts when approved supplemental payments are actually made and claimed for FFP, as the aggregate expenditures reported on the CMS–64 comprise the individual, provider-specific payment amounts.'' [163] Similarly, we believe States and their managed care plans already collect provider-level SDP data, including the negotiated rate between the plan and provider and any additional SDPs. We sought comment on whether these are the appropriate minimum data fields to require and what provider-level SDP data States currently collect as part of their monitoring and oversight of SDPs.

We recognize that there are existing data collection processes and systems established between CMS and States that could potentially support this SDP reporting, and stated in the proposed rule that we could use these systems to the extent they could help minimize additional or duplicative reporting by States. For instance, we considered the existing system and reporting structure that States are using for FFS supplemental payment reporting. The Consolidated Appropriations Act (CAA) of 2021 established new reporting requirements in section 1903(bb) of the Act for Medicaid FFS supplemental payments under both State plan and demonstration authorities consistent with section 1902(a)(30)(A) of the Act.[164] [165] We issued guidance in December 2021 outlining the information that States must report to CMS as a condition of approval for a State plan or State plan amendment that will provide for a supplemental payment, beginning with supplemental payments data about payments made on or after October 1, 2021.[166]

Under these FFS requirements, each quarter, each State must submit reports on supplemental payment data through the Medicaid Budget and Expenditure System (MBES), as a requirement for a State plan or State plan amendment that will provide for a supplemental payment. The data collection involves both narrative information, as well as quantitative, provider-specific data on supplemental payments. The narrative information includes descriptions of the supplemental payment methodology, determination of eligible providers, description of the timing of the payments, and justification for compliance with section 1902(a)(30)(A) of the Act. The quantitative, provider-specific data collection includes detailed provider-specific accounting of supplemental payments made within the quarter, including: provider name, provider ID number, and other provider identifiers; Medicaid authority (FFS or demonstration authority); Medicaid service category for the supplemental payments; aggregate base payments made to the provider; and aggregate supplemental payments made to the provider, which will reflect the State's claim for FFP.

This supplemental payment reporting is included in the MBES to capture the entire set of data reporting elements required in section 1903(bb)(1)(B) of the Act in one central location. MBES is familiar to States, in part because of State's quarterly expenditure reporting on the CMS–64 form. We stated in the proposed rule we could consider taking a similar approach for SDPs by adding reporting in MBES to capture provider-specific SDP payment data.

As another option, we described encounter data reported through T–MSIS as the method for collecting SDP provider-specific payment amounts. Specifically, T–MSIS could work well for SDPs that are specifically tied to an encounter or claim, such as minimum fee schedules or uniform dollar or percentage increases. Current regulations at § 438.242(c)(3) require States to submit all enrollee encounter data, including the allowed amount and paid amounts, and these paid amounts should be inclusive of State directed payments that are tied to an encounter or claim. We could build additional data fields in T–MSIS to capture more details about the paid amount, including the amount that was the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total payment amount paid to the provider. As noted in the proposed rule, this level of detail would provide the information we need for analysis and oversight of SDP spending, and it would be consistent with the managed care plan payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this final rule). There are various fields currently captured in T–MSIS via monthly encounter submissions (for example, national provider identifier, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, billed, allowed, and paid amounts) that could help us determine provider-specific SDP reimbursement. Utilizing T–MSIS in this manner could substantially reduce unnecessary or duplicative reporting from States, be an effective method to collect the data with minimal additional burden on managed care plans and States and enable comprehensive analyses since the data will be included with all other T–MSIS data.

Lastly, we described using a separate reporting mechanism for this new reporting of SDP provider-level data. For example, we could explore building a new reporting portal, similar to the one developed for submission of the Managed Care Program Annual Report. However, this would take considerable time and resources to develop and would be separate and distinct from all other SDP data, making it more difficult to perform comprehensive analyses. We described the potential option of permitting States to submit the proposed reporting using a Word or Excel template sent to a CMS mailbox. While this option would be the fastest way to collect the data, it too presents challenges for integrating the data with other data collected by CMS for analyses.

Based on our evaluation and description of other options, using T–MSIS appears to be the most efficient option and we proposed in § 438.6(c)(4) to require States to submit data to T–MSIS as the method for collecting provider-specific payment amounts under SDPs. As specified in proposed

[163] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

[164] The CAA included Division CC, Title II, Section 202 (section 202), which added section 1903(bb) of the Act to specify new supplemental payment reporting requirements.

[165] Demonstration authority includes uncompensated care (UC) pool payments, delivery system reform incentive payments (DSRIP), and possibly designated State health program (DSHP) payments to the extent that such payments meet the definition of supplemental payment as specified in section 1903(bb)(2) of the Act.

[166] *https://www.medicaid.gov/sites/default/files/2021-12/smd21006.pdf.*

§ 438.6(c)(4)(v),[167] provider-specific paid amounts would include a plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. Under this proposal, States would submit this data to CMS no later than 180 days after each rating period. We proposed a 180-day deadline because we believed this timeframe would permit adequate time for claims run out, submission of the necessary data to the State, and for the State to format the data for submission to CMS. We also proposed in § 438.6(c)(4) that States comply with this new reporting requirement after the rating period that begins upon our release of the reporting instructions for submitting the information required by this proposal. We sought public comment on our proposal to use T–MSIS for this new reporting, or whether another reporting vehicle such as MBES or other alternatives described in this final rulemaking would be better suited for SDP reporting. We also sought comment on how T–MSIS or another reporting vehicle could support capturing value-based payment arrangements in which payment is not triggered by an encounter or claim.

We also proposed a conforming requirement at § 438.6(c)(5)(iv) to align with the proposal in § 438.6(c)(4); proposed paragraph (c)(5)(iv) would require States to document in their managed care contracts any reporting requirements necessary for auditing SDPs in addition to the reporting necessary to comply with § 438.6(c)(4).

We described these data reporting proposals as a two-prong approach, with the MLR proposed requirements serving as a short-term step and the provider-specific data reporting proposed in § 438.6(c) being a longer-term initiative. We noted that this approach would ensure the appropriate content and reporting flows to CMS while also giving States sufficient time to prepare for each proposal based on the level of new burden. We acknowledged that States and managed care plans may consider this an unnecessary increase in administrative burden but noted that the increased transparency associated with these enhanced standards would benefit both State and Federal government oversight of SDPs. Implementing these proposals for State and managed care plan reporting of actual SDP expenditures will provide CMS more complete information when evaluating, developing, and implementing possible changes to Medicaid payment policy and fiscal integrity policy. As we noted in the proposed rule (88 FR 28160), our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c) (that is SDPs).

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this final rule.

We solicited public comment on these proposals.

We summarize and respond to public comments received on our proposals related to reporting of SDPs in the medical loss ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74, 457.1203(e) and (f)), and SDP reporting requirements to support oversight (§ 438.6(c)(4)) below.

Comment: Some commenters supported including SDPs in MLR reporting as a reasonable step to increase transparency and improve oversight of SDPs.

Response: We agree that including SDPs in MLR reporting will increase transparency and improve CMS and State oversight of SDPs. We are finalizing § 438.8(e)(2)(iii)(C) with technical clarifications to require States and managed care plans to report State directed payments made by managed care plans to providers under § 438.6(c) as incurred claims within the MLR numerator and to refer to the newly defined term ''State directed payment-'' in § 438.2. We are finalizing § 438.8(f)(2)(vii) to require States and managed care plans to report all State payments made to Medicaid managed care plans for arrangements under § 438.6(c) be included in the MLR denominator as premium revenue and to refer to the newly defined term ''State directed payment.'' We are finalizing the regulation text in § 438.8(f)(2)(vii) to remove the word ''approved'' as we require the MLR denominator to include all State directed payments, including those that are exempted from written prior approval as well as those that require written prior approval from CMS under § 438.6(c)(2)(i). All SDPs, including those that do not require CMS written approval under § 438.6(c)(2)(i), are within the scope of these new regulatory provisions. State directed payments that are paid to managed care plans as separate payment terms must also be included as plan revenue within the MLR denominator until the rating period in which separate payment terms are no longer permissible (see section I.B.2.l. of this final rule for discussion of separate payment terms).

Comment: Many commenters questioned the feasibility of the SDP line item MLR reporting proposals in §§ 438.8(k)(1)(xiv) and (xv) noting that the required SDP line item reporting would prove administratively burdensome for managed care plans given the necessary changes to financial reporting systems and processes. Commenters indicated it would be significantly challenging to identify and report managed care plan expenditures associated with minimum fee schedule SDPs and managed care plan revenue associated with those SDPs incorporated into capitation rates as these arrangements are not easily identifiable especially when the SDP has been accounted for within base capitation rates for several years. Commenters raised similar challenges with distinguishing between multiple SDPs that impact the same services or provider classes. Commenters stated additional technical guidance would be necessary to clarify how plans should calculate the portion of the capitation rates attributable to these SDPs, and commenters noted there was minimal value to CMS or States of this information given other available SDP data. Commenters cautioned against overly rigid regulatory language that could result in distorted MLR reporting that does not accurately reflect SDP arrangements. One commenter requested additional time for States and plans to comply with §§ 438.8(k)(1)(xiv) and (xv) noting the extensive system and MLR reporting template changes that would be required for implementation.

Response: We appreciate the feasibility concerns raised by commenters as to how managed care plans would separately report SDPs within the plan-level MLR reports required under § 438.8(k) and as part of the State's annual summary MLR reporting required under § 438.74. While we are finalizing provisions at § 438.8(e)(2)(iii)(C) and 438.8(f)(2)(vii) to require that all SDPs be included in plan-level and State summary MLR reports, we agree that requiring plans and States to report SDPs on a line item basis would require extensive State and plan administrative work, as well as CMS technical assistance. In the proposed rule (88 FR 28160), we noted that our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c). After careful consideration, we believe that at this time, we can work towards these goals using other provisions that

[167] In the proposed rule (88 FR 28153), we mistakenly cited to 438.6(c)(4)(i)(E) instead of proposed 438.6(c)(4)(v).

we are finalizing, including the requirement that all SDPs be incorporated as adjustments to the risk-based capitation rates and the SDP T–MSIS reporting requirements (see sections I.B.2.m. of this final rule and earlier paragraphs of this section in this final rule for further discussion). Therefore, we are not finalizing §§ 438.8(k)(1)(xiv) and (xv) or 438.74(a)(3) through (4) to require State and plan line-level reporting of SDPs. Because we are not finalizing the line item-level reporting provisions in §§ 438.8(k)(1)(xiv) and (xv) or 438.74(a)(3) nor the respective compliance dates in proposed §§ 438.8(k)(xvi) or 438.74(a)(4), States will likely not be required to make as many modifications to systems and MLR reporting templates. We continue to believe that it is reasonable to require States to comply with the requirement in §§ 438.8(e)(2)(iii)(C) and 438.8(f)(2)(vii) that States and plans include all SDPs within MLR reporting no later than 60 days following the effective date of this final rule. We will monitor implementation of this final rule and may consider additional future rulemaking if necessary.

Comment: Many commenters supported the proposal for States to report SDP expenditure data in the T–MSIS. Several commenters stated that it would lead to greater transparency and accountability, as well as facilitate and provide insights to provider reimbursement rates. Some commenters appreciated that T–MSIS could enable better data aggregation. One commenter stated that reporting aggregate spending on SDPs as a separate line on CMS–64 reports could help validate whether the data submitted to T–MSIS are complete. Another commenter supported the specific requirement to have provider-level payment amounts. Some State commenters questioned how certain data characteristics of SDPs would be reported in T–MSIS; however, we did not receive comments from State Medicaid agencies opposing the use of T–MSIS for SDP reporting.

Response: We agree that explicitly requiring States to report SDP expenditure data to T–MSIS will lead to greater transparency, oversight, and accountability. Even though States are already required to report all enrollee encounter data per § 438.818, including the allowed and paid amounts, explicitly identifying SDPs as part of that reporting will ensure clarity as T–MSIS evolves over time and includes more granular levels of data to support CMS oversight and monitoring. More robust and comprehensive data will improve data integrity, and T–MSIS captures detailed beneficiary, service, and provider data that provides important insights for administering and overseeing the Medicaid program, including CMS's monitoring of State compliance with SDP payment limits, contractual requirements, and alignment with CMS approval of the SDP. We note that the allowed, billed, and paid amounts do not need to be inclusive of pass-through payments under the final version of § 438.6(c)(4) as part of SDP T–MSIS reporting. This is a technical correction as pass-through payments are not required to be tied to utilization or the delivery of services and therefore would not be included in the same financial transaction as SDPs.

Although we realize that requiring States to report SDPs through T–MSIS will require encounter system changes for both States and managed care plans, we believe that the additional detail provided by T–MSIS is critical given the high levels of spending associated with SDPs. We will evaluate actual SDP expenditures. SDP reporting through T–MSIS will provide detailed information on the characteristics of enrollees who receive services paid for using SDPs, the kinds of services that are provided through these arrangements as well as the providers who received the payments. In 88 FR 28160, we noted that our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c).

Having detailed information on enrollees, procedure and diagnosis codes, and provider identifiers available from T–MSIS will allow CMS to analyze potential reimbursement and health disparities in one or more States. T–MSIS SDP encounter data will allow for comparisons of reimbursement for specific services across a State for SDP and non-SDP providers. For example, with the procedure codes available from T–MSIS, we could analyze primary care reimbursement for a State with an SDP for teaching hospitals compared to reimbursement for primary care providers without SDPs and determine if primary care reimbursement disparities exist in the state. The enrollee characteristic detail combined with the service and diagnosis codes in T–MSIS will allow CMS to determine if SDPs are providing improved access to high-risk enrollees or to groups of enrollees who have historically lacked access to critical services.

The detailed information from T–MSIS will also provide CMS with information to assist in determining if an SDP should be renewed. The SDP provider-level data from T–MSIS will allow CMS to verify if SDP payments were made according to the provisions in the contract. For example, we will be able to determine if the managed care plans made payment in accordance with the SDP as included in the State's managed care contract. Having the actual spending amounts from T–MSIS encounter data will allow CMS to compare the projected amount(s) provided by the State in the preprint to the actual payments made by the managed care plan to ensure compliance with the SDP as included in the State's managed care contract. This comparison will also provide important insights into the accuracy of States' total payment rate analysis and inform CMS' review of future total payment rate analyses provided for the same payment arrangements to ensure compliance with § 438.6(c)(2)(ii)(I) and (c)(2)(iii) as applicable. If a State's total payment rate analyses are not appropriately adjusted to account for errors later identified in comparing projected spending to actual expenditures, CMS may not renew the SDP for future years.

SDP reporting through T–MSIS will also improve program integrity. The detailed records will allow us for most encounter-based SDPs (for example, uniform dollar increases, minimum or maximum fee schedules) to identify and confirm compliance with the SDP as included in the State's managed care contract by showing SDP payment amounts. The finalized regulation at § 438.6(c)(4)(v) requires that for each encounter, the State must report the allowed, billed and paid amounts and that the paid amounts include the amount that represents the MCO's, PIHP's or PAHP's negotiated payment amount, the amount of the State directed payment, and any other amounts included in the total amount paid to the provider. This requires the State to report, on each encounter or financial transaction, the total amount paid which includes the managed care plan's negotiated payment amount, the amount of the State directed payment, and any other amounts included in the total amount paid to the provider. While some payment arrangements, like uniform dollar increases, may lend themselves to more easily disaggregating a separate SDP amount from the negotiated rate, CMS recognizes that other types of SDPs (for example, minimum or maximum fee schedules), particularly those that have been in effect for a significant period, may not due to the nature of the SDP. Currently CMS has an established process that reviews T–MSIS data needs, proposes revisions to the T–MSIS submission file format(s), and provides opportunity for

States' review and comment. CMS intends to use this process for any updates that may be needed to the T–MSIS file layout and technical specifications to facilitate reporting of the total paid amount for SDPs than the file currently supports. These detailed records will provide CMS with a better understanding of how SDPs are implemented by States and managed care plans. Currently, we review SDP payments and calculations through MLR audits and financial management reviews (FMRs) on a State-by-State basis. With the encounter-level data from T–MSIS, we will be able to review the SDP data for more than one State at a time and can identify potentially inappropriate payments as part of more comprehensive and timely reviews of these payments once the reporting requirement applies. In addition, we will be able to analyze how well plans are administering the distribution of SDPs across provider classes specified in the approved SDPs; that is, are managed care plans making the payments to providers as required by the State and are the payments made on a timely basis.

Comment: A few commenters stated that MBES would be the more appropriate system for reporting SDP data since it is already used to collect provider-level data on UPL payments. One commenter suggested MBES would not take as much time to implement as submission to T–MSIS. Another commenter suggested that the MBES forms that already collect provider-level data on UPL FFS supplemental payments could be modified to reduce State administrative burden.

Response: After further consideration, we disagree that MBES is a more appropriate vehicle for this data collection as State reporting of managed care expenditures within MBES is focused on capitation payments paid from the State to the managed care plans, not amounts paid by the managed care plan to a provider for a service delivered to a specific Medicaid managed care enrollee. In addition to widespread support by commenters, we conclude that T–MSIS is the more appropriate tool to capture this information as T–MSIS will provide substantially more detail on the affected enrollees, services, and providers and will allow for more sophisticated analyses of access and payment. Current regulations at § 438.242(c)(3) require States to submit all enrollee encounter data, and we have operationalized that using T–MSIS. Using T–MSIS as well for the new SDP reporting will align well with SDPs that are specifically tied to an encounter or claim, such as minimum fee schedules or uniform dollar or percentage increases.

Further, current regulations at § 438.242(c)(2) requires the submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight and program integrity needs. Building additional data fields in T–MSIS to capture more details about the paid amount, including elements that would allow CMS to understand more about the payment amount negotiated by the managed care plan, amount of the SDPs, and any other amounts included in the total payment amount paid to the provider, is appropriate and in alignment with the current regulatory requirements at § 438.242(c)(2).

Because of the numerous comments supporting the use of T–MSIS for State SDP reporting as well as the level of detail available from T–MSIS that will enable robust analysis of State SDP implementation, we believe T–MSIS is the appropriate vehicle for State SDP reporting. In addition, we note that the required file format for encounter data can support the additional, more detailed reporting requirements for SDPs. As previously noted, CMS currently has a standardized process that reviews T–MSIS data needs, proposes revisions to the T–MSIS submission file format(s), and provides opportunity for States' review and comment. After consideration of States' comments, the review cycle incorporates modifications that are in line with the standardized data formats required in § 438.242(c).

Comment: One commenter recommended that CMS ensure there was adequate time to collect the appropriate data and noted that the proposed effective date of this requirement would not give States sufficient time to begin gathering this information. The commenter indicated that States may need 2 to 3 years from the effective date of the final rule to begin this reporting.

Response: We do not agree with the commenter that States will be unable to report the data specified in § 438.6(c)(4) by the applicability date for several reasons. First, States have been responsible for submitting data to T–MSIS or its predecessor system since 1999 so they are very familiar with its requirements and processes. Second, most of the data elements specified in § 438.6(c)(4)(i) through (iv) are existing data fields in T–MSIS and States currently report these data; these fields include provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, as well as allowed, billed and paid amounts. Under § 438.242(c)(3) States and plans are already required to report paid amounts as part of encounter data submissions; the new SDP reporting requirement at § 438.6(c)(4)(v) now requires that the required paid amounts must include the amount that represents the managed care plan's negotiated payment amount, the amount of the State directed payments, and any other amounts included in the total paid to the provider. Any revisions made to T–MSIS in the future to include additional fields that capture different data will be introduced using standard T–MSIS modification and instruction procedures.

Lastly, after careful consideration of existing CMS processes for the release of T–MSIS specifications and the compliance dates typically established therein, we are modifying our applicability date for § 438.6(c)(4) in proposed § 438.6(c)(8)(vi) from the first rating period beginning on or after the release of T–MSIS reporting instructions by CMS to the applicability date set forth in the T–MSIS reporting instructions released by CMS. Our method of releasing new reporting instructions includes preparation time for States and managed care plans as we are aware that any changes to data systems require substantial programming and testing before implementation. For these reasons, we believe § 438.6(c)(4) as finalized in this rule provides States with ample time to comply.

Comment: Some commenters supported the choice of T–MSIS as the repository for SDP data, but shared concerns regarding some of the details of the data itself. One commenter urged close Federal-State partnership to finalize the elements and approach for the reporting. One commenter wanted to ensure that there was a uniform template for reporting. Another commenter requested that CMS explore ways that additional explanatory information can be included to accompany the dollar amounts being reported.

Response: We agree that T–MSIS is the appropriate data collection tool for SDP reporting. The required minimum data fields to be collected are specified in § 438.6(c)(4), which we are finalizing with the addition of ", as applicable" after "Minimum data fields to be collected include the following" to be clear that for some SDPs, such as value-based SDP arrangements in which there may not be an identifiable tie to a specific procedure code because the SDP provider payments are tied to

provider performance over the entire rating period, all of the minimum data fields may not apply. As indicated by preliminary T–MSIS specifications released in Fall 2023, we believe this data can be successfully captured elsewhere in T–MSIS, via financial transaction reporting, for example. To ensure consistent and accurate reporting, we also plan to publish additional associated T–MSIS reporting instructions through the established methods and mechanisms used for disseminating T–MSIS information to States. To the suggestion for additional explanatory information for the SDP data in T–MSIS, we remind commenters that approved SDP preprints are now available on Medicaid.gov. These preprints contain the information that was submitted by the State for written prior approval and reflects the purpose of each SDP.

Comment: One commenter was not sure that States and managed care plans collect the necessary data, in particular the negotiated rate between the plan and provider and any additional SDPs that are made to the provider. The commenter was particularly concerned that for fee schedule-related SDPs, managed care plans often are not provided enough information to calculate the amount paid and in order to comply with the proposals in this section, managed care plans will need to be allowed greater insight into how these calculations are made at the State level.

Response: We remind States and managed care plans that as specified in § 438.242(c)(3), all MCO, PIHP, and PAHP contracts must require the submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under § 438.818. We expect States and managed care plans to ensure the SDP data elements required under § 438.6(c)(4) meet the requirements for the encounter data submissions, including any calculation methods for the SDP. We expect the SDP T–MSIS reporting to follow the same process for data collection that is currently required for encounter data. That is, the SDP information required in 438.6(c)(4) will be part of each encounter record that is submitted in accordance with § 438.242(c)(3). Encounters with SDP data will not be submitted on a different schedule or timeline than other encounter data and will not use different transaction types except for some SDPs that are VBPs. We acknowledge that not all SDPs are paid on an FFS basis that clearly identifies allowed and paid amounts, and certain types of SDPs such as VBP provider incentive payments may not conform to this encounter data format. We would expect that some VBP SDPs, including provider incentive payments, would utilize a T–MSIS financial transaction format which differs from the T–MSIS encounter data format. The submission timing requirements for the T–MSIS VBP SDP financial transactions would not differ from those for T–MSIS encounters; those timing requirements for encounter data are delineated in § 438.242(c). Regardless, the submission of complete and accurate data to T–MSIS is critical to program oversight and managed care plans and States should ensure that reporting requirements are clear and consistently implemented. If States have questions about submission of data to T–MSIS, they should contact their CMS T–MSIS contact for technical assistance.

Comment: Some commenters cautioned CMS on any additional administrative reporting burden. One commenter stated that CMS should ensure that any reporting requirements, including around SDPs that advance VBP, could be met through the broader reporting at § 438.6(c)(4). Some commenters cautioned that any additional reporting around SDPs that advance VBP would disincentivize Medicaid agencies from using SDPs as a tool to transform payment and care delivery. Other commenters stated CMS should limit the trend toward more and more reporting, and suggested CMS combine the reporting requirements or eliminate some to further streamline. Conversely, a few commenters recommended that the reporting be more extensive than what was proposed in § 438.6(c)(4).

Response: We appreciate the range of comments on our reporting proposals. We attempted to strike the right balance between oversight and transparency, and additional administrative burden. As we noted in the proposed rule, we believe utilizing T–MSIS for reporting would substantially reduce unnecessary or duplicative reporting from States, would be an effective method to collect the data with minimal additional burden on managed care plans and States, and it would enable comprehensive analyses since the data would be included with all other T–MSIS data (88 FR 28153). As the commenters pointed out, VBP arrangements are sometimes difficult to capture in a data repository such as T–MSIS given the fixed file formatting and complex relationship between the trigger for the SDP, such as achievement of specific quality measures or global budgets, and the payment amount of the SDP. We intend to further revise T–MSIS reporting in the future to better enable States to report more complex SDP data easily and effectively.

Comment: Some commenters were concerned about the accessibility of the data, and that the information should be publicly posted on the State's Medicaid website or *Medicaid.gov.* Another commenter stated concern that the data was too transparent, stating that the requirements to report enrollee identifiers is troubling for data protection issues. For behavioral and mental health, commenters stated concerns that the reporting of identifying data and procedure information could violate HIPAA protections. Another commenter was concerned that requiring reporting on the allowed payment amounts by managed care plans may inappropriately expose plan competitive information, and that aggregate information by provider class and total utilization is the appropriate level of detail.

Response: States and managed care plans are currently required to report encounter data, including for mental health and SUD services, under various authorities including section 1903(i)(25) and (m)(2)(A)(xi) of the Act. While it is not feasible to publish raw T–MSIS data or the underlying State data on a website given that it contains protected health information, certain deidentified T–MSIS data are available for research purposes. State T–MSIS submissions are used to create a research-optimized version of the data known as the T–MSIS Analytic File. Researchers who desire access to Research Identifiable Files (RIF) must meet specific requirements before obtaining access to these data. All summary data published from T–MSIS, including Data Briefs, complies with applicable HIPAA and Privacy Act requirements.

Comment: Some commenters stated concern that requiring States to report the total dollars expended by each MCO, PIHP, and PAHP for SDPs within 180 days of the end of the rating period is not adequate time for claims runout, receipt, and processing of encounter data by the State, and submission to CMS.

Response: We appreciate the commenters' concern and acknowledge that all paid claims data would likely not be complete within 180 days of the end of a rating period, which was the deadline for submission of the SDP reporting data proposed in § 438.6(c)(4). In addition, it will be difficult for States to process, validate, and submit the encounter data to CMS within the proposed 180-day timeframe. Given these considerations, we are finalizing

the regulation to require States to report the total dollars expended by each managed care plan for SDPs no later than 1 year after the end of the rating period.

Comment: Some commenters shared concerns that reporting T–MSIS data would not go far enough to advance CMS's oversight goals and requested clarification of what CMS would do if T–MSIS data identified regulatory violations. The commenter also noted that CMS should use independently obtained information about the performance of the State's program, and not rely solely on attestations by States, to analyze and determine compliance.

Response: We are committed to our oversight role of the Medicaid program. CMS will review SDP data that is submitted via T–MSIS and will follow up with States as appropriate, including enforcement of regulatory requirements. CMS reserves its authority to enforce requirements in the Act and implementing regulations, including by initiating separate deferrals and/or disallowances of Federal financial participation.

States have been submitting their program data to CMS via T–MSIS and its predecessor since 1999, and we often rely on that data for program monitoring and analysis. We do not rely on T–MSIS alone and collect information from States in multiple ways, including MCPAR, NAAAR, and MLR reports. In addition, other oversight bodies such as the GAO and OIG, as well as MACPAC, provide information to CMS on the performance of States' programs. We believe § 438.6(c)(4) will strengthen the information in T–MSIS specific to SDPs, but we will continue to develop and utilize a comprehensive approach to monitoring managed care program and plan performance.

Comment: A few commenters questioned whether SDPs that use minimum fee schedules would be submitted to T–MSIS. These commenters stated that parsing the total paid amount to report how much is attributable to the SDP and how much is due to the plan's negotiations with the provider would require an untenable level of effort.

Response: We understand the commenters' concerns but point out that SDPs that use minimum fee schedules should already be reported to T–MSIS and the requirements finalized in § 438.6(c)(4) do nothing to change that at this time. Currently, when managed care plans submit their paid amounts in encounter data to States, those paid amounts inherently reflect the minimum fee schedule by reporting the paid amount. Currently CMS has standardized process that reviews T–MSIS data needs, proposes revisions to the T–MSIS submission file format(s), and provides opportunity for States' review and comment. CMS intends to use this process for any updates that may be needed to the T–MSIS file layout and technical specifications needed to obtain any additional, more detailed reporting for the total paid amount for SDPs that the file currently supports. After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, 457.1203(e), as proposed. We are finalizing §§ 438.8(e)(2)(iii)(C) and (f)(2)(vii) with technical clarifications and modifications to use the newly defined term ''State directed payment'' and to clarify the scope of the provisions. We are finalizing § 438.6(c)(4) with revisions to modify the 180-day timeframe to ''1 year'' and add '', as applicable'' At the end of the introductory text in § 438.6(c)(4). We are finalizing 438.6(c)(4)(v) with a technical edit to remove ''the amount for any pass-through payments under paragraph (d) of this section,'' in acknowledgement that pass-through payments are separate financial transactions not tied to the delivery of services to Medicaid managed care enrollees and therefore, are not identifiable within encounter-level data. We are not finalizing proposed §§ 438.8(k)(1)(xiv) through (xvi) or § 438.74(a)(3) through (4) to require SDP line-level reporting in the State summary and managed care plan specific MLR report.

p. Applicability and Compliance Dates (§§ 438.6(c)(4) and (c)(8), and 438.7(f)

We proposed that States and managed care plans would have to comply with § 438.6(a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv), and 438.7(c)(4), (c)(5), and (f)(1) through (3) upon the effective date of the final rule, as these proposals are either technical corrections or clarifications of existing policies and standards. We proposed that States and managed care plans would have to comply with § 438.6(c)(2)(iii), (vi)(B), (vi)(C)(*1*) and (*2*) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as these newly proposed requirements will provide States with increased flexibility and not require States to make changes to existing arrangements. We proposed that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(H), (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(vii), (c)(2)(viii) and (ix), and (c)(5)(i) through (v) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance because it allows States sufficient time to operationalize the timelines and requirements for preprint submissions that are newly established in these proposals while balancing the need to strengthen CMS oversight.

We further proposed that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v), and (c)(7) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule as we believe States will need a sufficient period of time to address the policy elements within these proposals and operationalize them via various reporting, documentation and submission processes. For § 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7), we also considered requiring compliance for the first rating period beginning on or after 1 year, or 2 years after the effective date of the final rule, but we proposed the first rating period beginning on or after 3 years after the effective date of the final rule because we believed it strikes a balance between the work States will need to do to comply with these proposals and the urgency with which we believed these proposals should be implemented in order to strengthen and ensure appropriate and efficient operation of the Medicaid program. We solicited comment on the proposal and alternatives.

We proposed that States and managed care plans would have to comply with §§ 438.6(c)(5)(vi) and (c)(6)(v), and 438.7(c)(6) and (f)(4) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of the final rule. Because these proposals establish new submission timelines and new requirements for contract and rate certification documentation, and because States could view the new requirements as substantial changes to the SDP process, we proposed a longer timeline for compliance. We stated that we were also considering requiring compliance no later than the first rating period beginning on or after 3 years after effective date of the final rule to align with the compliance dates in the proposals described in the paragraph above; however, to provide States adequate time to implement strong

policies and procedures to address the newly proposed requirements before submitting the relevant contract and rate certification documentation, we proposed the longer period for States to adjust and come into compliance. We solicited comment on the proposal and alternative.

Finally, as specified in proposed § 438.6(c)(4), we proposed that States would be required to submit the initial TMSIS report after the first rating period following the release of CMS guidance on the content and form of the report.

We proposed these applicability dates in §§ 438.6(c)(4) and (c)(8), and 438.7(g).

We solicited public comment on these proposals.

We summarize and respond to public comments received on our proposals for the applicability and compliance dates (§§ 438.6(c)(4) and (c)(8), and 438.7(g)(2)) for various proposals related to SDPs below.

Comment: We received several comments encouraging us to consider earlier applicability dates than those proposed in §§ 438.6(c)(4) and (8), and 438.7(g)(2) and (3) in recognition that many of the provisions would improve monitoring and oversight efforts related to State directed payments. Other commenters noted the array of new documentation requirements, including those proposed in § 438.6(c)(5), and requested that applicability dates for all SDP provisions be revised to be implemented at a later date than proposed in recognition of State burden.

Response: As described in the proposed rule (88 FR 28153), we carefully considered each proposed effective date for an applicable SDP provision compared to the benefit incurred to the State or additional administrative work that the State must undertake. We continue to believe that the proposed applicability dates strike the right balance, so we are finalizing most applicability dates as originally proposed in §§ 438.6(c)(8), and 438.7(g)(1) and (3), with technical revisions to the regulation citations to reflect that the separate payment term provisions proposed in §§ 438.6(c)(6)(i) through (iv) and 438.7(f) are not being finalized. We are modifying the applicability date in § 438.6(c)(8)(vi) to better align with existing CMS processes for the release of T–MSIS data reporting instructions and the compliance date established within such guidance. Finally, we are modifying the T–MSIS reporting deadline in § 438.6(c)(4) from 180 days to 1 year to acknowledge the time needed for more accurate and complete encounter data reporting. We are also modifying the applicability date for § 438.6(c)(2)(vii) to no later than 3 years after the effective date of the final rule to align with the applicability date for the prohibition on separate payment terms in § 438.6(c)(6). As this provides States an additional year to come into compliance with § 438.6(c)(2)(vii), we believe this is a reasonable modification. For discussion on the elimination of separate payment terms and related changes to the proposed regulation text, refer to sections I.B.2.k., I.B.2.l. and I.B.2.m. of this final rule.

After reviewing public comments, we are finalizing § 438.6(c)(8)(i) without the reference to paragraph (c)(6)(i) through (iv) given changes to regulatory text that remove this proposed text (see section I.B.2.l. of this final rule for further details) and, we are adding a reference to § 438.6(c)(1), which was excluded in error. We are also finalizing § 438.6(c)(8)(iii) with revisions to remove paragraph (c)(2)(ix) which is not being finalized (see section I.B.2.e. of this final rule for further details), and to remove the references to paragraphs (c)(5)(v) and (c)(2)(ii)(H), given the proposed requirement at § 438.6(c)(5)(v) is not being finalized (see section I.B.2.k. of this final rule for further details), and the updated applicability date for (c)(2)(ii)(H), respectively. To reflect the later applicability date for § 438.6(c)(2)(ii)(H), we are adding paragraph (c)(8)(vii) to say ''[p]aragraph(c)(2)(ii)(H) no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028.'' To reflect the later applicability date for § 438.6(c)(2)(vii), we are finalizing the reference to paragraph (c)(2)(vii) in paragraph (c)(8)(iv) instead of paragraph (c)(8)(iii) (see section I.B.2.h. of this final rule for further details). We are also finalizing § 438.6(c)(8)(iv) with a revision to add paragraph (c)(6) in recognition of the requirement that all separate payment terms be eliminated no later than the first rating period on or after 3 years after the effective date of the final rule (see section I.B.2.k. of this final rule for further details). Finally, we are revising § 438.6(c)(8)(v) with revisions to remove the reference to paragraph (c)(6)(v) which is not being finalized and to refer to (c)(5)(v) (instead of proposed paragraph (c)(5)(vi)) to account for changes in the regulation text compared to the proposed rule (see sections I.B.2.l. and I.B.2.k. respectively of this final rule for further details). Since we are also not finalizing § 438.7(f) as proposed, § 438.7(g) is redesignated as § 438.7(f) and we are not finalizing references therein to paragraphs (f)(1) through (4) (see section I.B.2.l. of this final rule for further details). We are also not finalizing the regulatory text proposed at § 438.7(g)(2) as we determined this was unnecessary as § 438.7(c)(4) and (5) are effective with the publication of this final rule; and therefore, § 438.7(g)(3) is redesignated as § 438.7(f)(2).

3. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3 and 457.1203)

In the 2016 final rule, we finalized Medicaid and CHIP managed care regulations in §§ 438.8(k) and 457.1203(f) respectively, that require managed care plans to annually submit reports of their MLR to States, and, at §§ 438.74 and 457.1203(e) respectively, we require States to submit annually a summary of those reports to CMS. These sections were issued based on our authority under sections 1903(m)(2)(A)(iii), 1902(a)(4), and 2101(a) of the Act based on the rationale that actuarially sound capitation rates must be utilized for MCOs, PIHPs, and PAHPs. Additionally, actuarial soundness requires that capitation payments cover reasonable, appropriate, and attainable costs in providing covered services to enrollees in Medicaid managed care programs. We proposed to amend our requirements under the same authority and rationale that we describe below.

Medical loss ratios are one tool that CMS and States can use to assess whether capitation rates are appropriately set by generally illustrating how capitation funds are spent on claims and quality improvement activities as compared to administrative expenses. More specifically, MLR calculation and reporting can be used to demonstrate that adequate amounts of the capitation payments are spent on services for enrollees. With MLR reporting, States have more information to understand how the capitation payments made for enrollees in managed care programs are expended, resulting in responsible fiscal stewardship of total Medicaid and CHIP expenditures.

Medicaid and CHIP managed care MLR reporting requirements align, generally, with MLR standards for the private market and Medicare Advantage standards for MA organizations. As we noted in the preamble to the 2015 managed care proposed rule,[168] alignment with private market or Medicare Advantage standards supports administrative simplicity for States and health plans to manage health care delivery across different product lines and eases the administrative burden on

[168] *https://www.govinfo.gov/content/pkg/FR-2015-06-01/pdf/2015-12965.pdf.*

issuers and regulators that work in all of those contexts and markets (80 FR 31101). We also noted that a consistent methodology across multiple markets (private, Medicare, Medicaid, and CHIP) will allow for administrative efficiency for the States in their roles regulating insurance and Medicaid/CHIP, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports. In addition, a common standard will allow comparison of MLR outcomes consistently from State to State and among private, Medicare, and Medicaid/CHIP managed care plans (80 FR 31107).

In general, Medicaid and CHIP managed care MLR reporting requirements have remained aligned over time with the private market MLR requirements; however, CMS finalized some regulatory changes to the private market MLR requirements in 45 CFR 158.140, 158.150, and 158.170 effective July 1, 2022.[169] To keep the Medicaid and CHIP managed care regulations aligned with these revised private market provisions, we proposed several revisions to our requirements in the following areas:

- Requirements for clinical or quality improvement standards for provider incentive arrangements;
- Prohibited administrative costs in quality improvement activity (QIA) reporting; and
- Additional requirements for expense allocation methodology reporting.

In addition, we proposed changes to specify timing of updates to credibility adjustment factors; when Medicaid and CHIP managed care plans are required to resubmit MLR reports to the State; the level of data aggregation required for State MLR summary reports to CMS; contract requirements related to reporting of overpayments; and new reporting requirements for SDPs.

a. Standards for Provider Incentives (§§ 438.3(i), 438.8(e)(2), 457.1201 and 457.1203)

We proposed revisions to standards for provider incentives to remain consistent with our goals of alignment with the private market MLR regulations when appropriate, and to ensure that capitation rates are actuarially sound and based on reasonable expenditures for covered services under the contract. Under section 1903(m)(2)(A)(iii) of the Act and implementing regulations, FFP is not available for State expenditures incurred for payment (as determined under a prepaid capitation basis or under any other risk basis) for services provided by a managed care plan unless the prepaid payments are made on an actuarially sound basis. While the same MLR requirements are made applicable to PIHPs and PAHPs under authority in section 1902(a)(4) of the Act, the requirements are enforced under section 1904 of the Act. As specified in current regulations at § 438.4(a), actuarially sound Medicaid capitation rates are projected to provide for all reasonable, appropriate, and attainable costs, as well as the operation of the MCO, PIHP, or PAHP required under the terms of the contract.

While Medicaid managed care plans are required to calculate and report an MLR to the State, States are not required to establish a minimum MLR requirement; although under current regulations at § 438.4(b)(9), capitation rates must be developed in a way that the managed care plan will reasonably achieve an MLR of at least 85 percent. Under current regulations at § 438.8(c), if a State elects to require that their managed care plans meet a minimum MLR requirement, the minimum must be set to at least 85 percent. Further, under § 438.8(j), States may establish a remittance arrangement based on an MLR requirement of 85 percent or higher. As a general matter, remittance arrangements based on minimum MLRs may provide value to States by requiring managed care plans to remit a portion of their capitation payments to States when spending on covered services and QIAs is less than the minimum MLR requirements.

At existing §§ 438.3(i)(1) and 457.1201(h), respectively, Medicaid and CHIP managed care plan contracts must require compliance with the provider plan incentive requirements in §§ 422.208 and 422.210.[170] In this section, we refer to the term ''incentive'' to mean both incentive and bonus payments to providers. Under § 422.208(c), managed care plans may enter into a physician incentive plan with a health care provider, but plans must meet requirements applicable to those arrangements in § 422.208(c) through (g), and under § 422.208(c)(1) plans cannot make a payment, directly or indirectly, as an inducement to reduce or limit medically necessary services. A Medicaid and CHIP managed care plan may make incentive payments to a provider if the provider agrees to participate in the plan's provider network. These payment arrangements may be based solely on an amount negotiated between the plan and the provider. Medicaid and CHIP managed care plans can implement provider incentive arrangements that are not based on quality improvement standards or metrics; however, provider incentive payments must be included as incurred claims when managed care plans calculate their MLR, per §§ 438.8(e)(2)(iii)(A) and 457.1203(c) respectively. Further, provider incentive payments may influence the development of future capitation rates, and Medicaid managed care plans may have a financial incentive to inappropriately pay provider incentives when the plans are unlikely to meet minimum MLR requirements. Additionally, these payments may inappropriately inflate the numerator of the MLR calculation and reduce or eliminate remittances, if applicable. Additionally, including such data in the base data used for rate development may inappropriately inflate future capitation rates.

Vulnerabilities With Managed Care Plans' Provider Incentive Contracting Practices

As part of our Medicaid managed care program integrity oversight efforts, CMS recently conducted several in-depth reviews of States' oversight of managed care plan MLR reporting. These reviews included examinations of the contract language for provider incentive arrangements between managed care plans and network providers. As part of these reviews, CMS identified several examples of managed care plan practices that could make an incentive payment inappropriate to include in the numerator. For example, there were inconsistent documentation and contracting practices for incentive payments in contracts between some Medicaid managed care plans and their network providers, including State acceptance of attestations of these arrangements from senior managed care plan leadership when contract documentation was lacking. These reviews also noted that many managed care plans' contracts with network providers did not base the incentive payments on a requirement for the providers to meet quantitative clinical or quality improvement standards or metrics. In fact, examination of these contracts between managed care plans and their network providers revealed that some managed care plans did not require a provider to improve their performance in any way to receive an

[169] *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.*

[170] As specified in § 438.3(i)(2), in applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP,'' ''State,'' and ''Medicaid beneficiaries,'' respectively.

incentive payment. Additionally, many of the incentive arrangements were not developed prospectively with clear expectations for provider performance. Finally, we identified provider incentive performance periods that did not align with the MLR reporting period and provider incentive contracts that were signed after the performance period ended.

Contract Requirements for Provider Incentive Payment Arrangements

Based on these reviews, we are concerned that if a provider incentive arrangement is not based on basic core contracting practices (including sufficient supporting documentation and clear, prospective quantitative quality or performance metrics), it may create an opportunity for a managed care plan to more easily pay network providers solely to expend excess funds to increase their MLR numerator under the guise of paying incentives. This potential loophole could also be used to help managed care plans avoid paying remittances. Also, this practice could allow for managed care plans that are integrated with a medical or hospital system to move revenue out of the managed care plan and into the affiliated medical or hospital system. Additionally, this practice could artificially inflate future capitation rates. To address these concerns, we proposed additional requirements on provider incentive arrangements in § 438.3(i).

In § 438.3(i)(3) and (4) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1201(h), we proposed to require that the State, through its contract(s) with a managed care plan, must include specific provisions related to provider incentive contracts. Specifically, the proposed changes required in § 438.3(i)(3)(i) and (ii) that incentive payment contracts between managed care plans and network providers have a defined performance period that can be tied to the applicable MLR reporting period(s), and such contracts must be signed and dated by all appropriate parties before the commencement of the applicable performance period. We also proposed, in § 438.3(i)(3)(iii), that all incentive payment contracts must include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment. In addition, in § 438.3(i)(3)(iv), we proposed that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of these metrics, as well as a date of payment. We noted that managed care plans would continue to have flexibility to determine the appropriate quality improvement or quantitative performance metrics to include in the incentive payment contracts. In addition, the proposed changes also required in § 438.3(i)(4)(i) that the State's contracts must define the documentation that the managed care plan must maintain to support these arrangements. In § 438.3(i)(4)(ii), we proposed that the State must prohibit managed care plans from using attestations as documentation to support the provider incentive payments. In § 438.3(i)(4)(iii), we proposed that the State's contracts require that managed care plans must make the incentive payment contracts and supporting documentation available to the State both upon request and at any routine frequency that the State establishes. Finally, we proposed that States and managed care plans will have to comply with § 438.3(i)(3) and (4) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We proposed this applicability date in § 438.3(v) for Medicaid, and through a proposed cross-reference at § 457.1200(d) for separate CHIPs, and we sought public comment on this proposal. Other changes proposed to § 438.3(v) are outlined in section I.B.3. and section I.B.4 of this final rule.

We also proposed to amend § 438.608 to cross-reference these requirements in the program integrity contract requirements section. Specifically, we proposed to add § 438.608(e) that notes the requirements for provider incentives in § 438.3(i)(3) and (4). This proposed requirement is equally applicable for separate CHIPs through an existing cross-reference at § 457.1285.

Alignment With Private Market Regulations for Provider Incentive Arrangements [171]

Effective July 1, 2022, the private market regulations at 45 CFR 158.140(b)(2)(iii), which are applicable to health insurance issuers offering group or individual health insurance coverage, were updated to clarify that only provider bonuses and incentives payments tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards qualify as expenditures in the MLR numerator. In contrast, current Medicaid and CHIP managed care regulations for provider incentive arrangements do not require these payments to be based on quality or performance metrics. This inconsistency hinders the comparison of MLR data between the private market issuers and Medicaid and CHIP managed care plans, which is important given the high number of health plans that participate both in the private market and Medicaid and CHIP, as well as the frequent churn of individuals between private market, Medicaid, and CHIP coverage. To address the potential for inappropriate inflation of the MLR numerator, as well as facilitate data comparability, we proposed in § 438.8(e)(2)(iii)(A) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to require that for a provider bonus or incentive payment to be included in the MLR numerator, the provider bonus or incentive arrangement will have to require providers to meet clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards to receive the bonus or incentive payment. This change will prohibit Medicaid and CHIP managed care plans from including provider bonus or incentive payments that are not based on clinical or quality improvement standards in their MLR numerator, which will improve the accuracy of their MLR, as well as other components of managed care programs that rely on reported MLRs, such as capitation rate development and remittances. Further, a consistent methodology across multiple markets will allow for administrative efficiency for the States as they monitor their Medicaid and CHIP programs, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports.

We believe that by requiring States' contracts with managed care plans to specify how provider bonus or incentive payment arrangements will be structured in managed care plans' provider contracts, transparency around these arrangements will improve. In addition, by requiring the contracts to include more specific documentation requirements, CMS and States will be better able to ensure that provider bonus or incentive payments are not being used either to inappropriately increase the MLR to avoid paying potential remittances, inflate future capitation rates, or to simply move funds from a Medicaid managed care plan to an affiliated company or provider. The

[171] *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.*

proposals will increase transparency into provider bonuses and incentives, improve the quality of care provided by ensuring that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care, and protect Medicaid and CHIP programs against fraud and other improper payments. We sought comment on these proposed requirements, including whether any additional documentation requirements should be specified in regulation. We proposed that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

We summarize and respond to public comments received on Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3, and 457.1203) below.

Comment: One commenter supported the proposal to require compliance with the new contract requirements for provider incentive arrangements on or after 60 days after the publication of the final rule. However, several commenters opposed the proposal regarding the effective date of these requirements for contracts with managed care plans. The commenters suggested that managed care plans need more time to engage with their contracted providers and conduct the legal reviews necessary to modify and finalize the incentive contracts. Many of the commenters suggested a one-year implementation timeframe, one commenter suggested 180 days, and one commenter suggested January 1, 2025.

Response: We appreciate these comments and considered them when finalizing the effective date of the new contract requirements for provider incentive arrangements in § 438.3(i). We acknowledge that 60 days may not be long enough to engage with the contracted providers and complete the legal review necessary to implement new provider incentive arrangements, as raised by several commenters. After considering the public comments, we believe 1 year after publication of this final rule is sufficient time to complete the necessary contract actions to come into compliance with these requirements. As such, we are finalizing an effective date for these new contract requirements for provider incentive arrangements as the first rating period beginning on or after 1 year after the effective date of this final rule for the provider incentive changes in §§ 438.3(i), 438.608(e), and applicable to separate CHIP through the existing cross-references at § 457.1200(d).

Comment: One commenter supported the proposal that State contracts with managed care plans require incentive payment contracts between managed care plans and network providers to have a defined effective period that can be tied to the applicable MLR reporting periods. Several other commenters opposed this proposal, with some commenters asking for more flexibility to align performance periods in § 438.3 with a calendar year to create better alignment across products and payors. In addition, one commenter stated that the proposal was prescriptive and vague, as it was unclear whether CMS was requiring the performance-related activity or the evaluation period to occur in the MLR reporting period.

Response: We believe that by requiring an incentive payment contract period of performance to be tied to a MLR reporting period, program integrity and transparency around these arrangements would vastly improve. Specifically, a defined performance period will allow for States and CMS to have better oversight over provider incentive payment arrangements and ensure that provider incentive payments are made in accordance with the contract, are made for the appropriate performance period, and can be tied to an MLR reporting period. The proposed and finalized requirement at § 438.3(i)(3)(i) would also allow for flexibility in determining the effective period for incentive payment contracts between managed care plans and network providers. Managed care plans and network providers would continue to have the option to implement effective periods on a calendar year, or other appropriate temporal basis that they choose as long as the incentive payment contract is clearly associated with a specific MLR reporting period. Under this proposal, the contract would be required to include a defined start and end date for the effective period so provider incentive payments can be tied to a specific MLR reporting period. By having a defined effective period, States and CMS would be able to confirm and verify the appropriateness of provider incentive payments included in the MLR for the relevant MLR reporting period.

Comment: A few commenters opposed the proposal to require that provider incentive contracts be signed prior to the performance period. Commenters contended that this requirement is overly restrictive and could deter managed care plans and network providers from implementing otherwise appropriate arrangements that support or improve access and quality of care. Some commenters suggested removing this requirement, and one commenter suggested that CMS should allow contracts to be signed within the first 60 days of the measurement period as long as there is no performance data available. One commenter requested CMS to clarify whether it is permissible for managed care plans to include prospective provider incentive arrangements that are not finalized until after the MLR filings are submitted.

Response: We respectfully disagree that the requirement for incentive payment contracts to be signed prior to the performance period is overly restrictive and would deter managed care plans and network providers from implementing otherwise appropriate arrangements. Provider incentive payments should be included as incurred claims in the MLR numerator and be tied to the MLR reporting period in which they are to be reported. Because of the importance of such contract payments in MLR calculations, we believe that allowing such contracts to be signed after the beginning of the performance period creates an opportunity for a managed care plan to more easily pay network providers solely to expend excess funds to increase their MLR numerator under the guise of paying incentives. Furthermore, it is a standard contracting practice for all parties to sign a contract prior to the period of performance to signal acceptance of the terms of the contract. We believe that allowing for contracting deadlines to occur after the beginning of the performance period would add further complexity to the provider incentive contracting process. Requiring such contracts to be signed before the period of performance increases transparency into provider bonuses and incentives, improves care by ensuring that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care, and protects Medicaid and CHIP managed care plans against fraud and other improper payments. Therefore, we believe it is in the best interest of the Federal government, States and other interested parties to require that all incentive payment contracts be signed prior to the performance period for the payments in order to be appropriately included in the MLR numerator.

Regarding the comment about whether it is permissible for managed care plans to include prospective provider incentive arrangements that are not finalized until after the MLR filings

are submitted, Federal regulations require that provider incentive payments be included as incurred claims in the MLR numerator and be tied to the MLR reporting period in which they are reported. Provider incentive payments that do not meet those requirements of a specific MLR reporting period may not be included.

Comment: Several commenters supported the proposal that State contracts with managed care plans must require that incentive payment contracts between managed care plans and network providers include well-defined quality improvement performance metrics that the provider must meet to receive the incentive payment. One commenter requested CMS to clarify if there is a difference between ''well-defined quality improvement performance metrics'' described in the Contract Requirements for Provider Incentive Payment Arrangements section of the 2023 proposed rule at § 438.3(i)(3)(iii) and ''clearly defined, objectively measurable, and well-documented clinical or quality improvement standards'' proposed in the MLR Standards section of the 2023 proposed rule at § 438.8(e)(2)(iii)(A) and found in the private market regulations at 45 CFR 158.140(b)(2)(iii).

Response: We believe that by requiring the contracts to include well-defined quality improvement performance metrics which providers must meet, CMS and States will be better able to ensure that providers are in compliance with the terms of the incentive payment contract and eligible to receive the payment. This in turn will help CMS and States ensure that incentive payments are not being used to inappropriately increase the MLR to avoid potential payment of remittances or inflate future capitation rates.

We did not intend for there to be a difference between ''well-defined quality improvement performance metrics'' proposed in the Contract Requirements for Provider Incentive Payment Arrangements section of the 2023 proposed rule at § 438.3(i)(3)(iii) and ''clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards'' proposed in the MLR Standards section of the 2023 proposed rule at § 438.8(e)(2)(iii)(A). We appreciate the commenter highlighting this inconsistency in language. To further clarify our intent with this requirement and align this provision with similar private market regulations, we revised the proposed language at § 438.3(i)(3)(iii) to include the following language, ''clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards,'' which also reflects the language used in the private market regulations at 45 CFR 158.140(b)(2)(iii). The finalized revision to § 438.3(i)(3)(iii) is equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h). We note that even with this slight revision to the proposed language at § 438.3(i)(3)(iii), managed care plans will continue to have the flexibility to determine any appropriate non-clinical metrics, such as quality improvement or quantitative performance metrics, to include in the incentive payment contracts.

Comment: Several commenters supported the proposal that State contracts with managed care plans require that incentive payment contracts between managed care plans and network providers specify a dollar amount that can be clearly linked to successful completion of the metrics. A few commenters requested additional flexibility with this requirement. Specifically, the commenters requested that beyond a specified dollar amount, CMS should allow for a percentage of a verifiable dollar amount. Commenters stated that this flexibility reflects current incentive payment practices and would allow for flexibility in how the provider incentive contracts are written, while maintaining the link between quality improvement and/or performance metrics and the receipt of incentive payments.

Response: Our intent with implementing this requirement is that by requiring provider incentive contracts to include a specified dollar amount or percentage of a verifiable dollar amount, CMS and States will be able to have better oversight over provider incentive payments to ensure that provider bonus or incentive payments are used appropriately. In considering comments received, we believe that providing additional flexibility regarding the financial terms of the incentive arrangement continues to meet our intent while reflecting current incentive arrangement practices identified by some commenters. As such, we are revising our proposal in § 438.3(i)(3)(iv) to also allow for the incentive payment contracts between managed care plans and network providers to specify either a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics. We note that the specification of the percentage of a dollar amount is an alternative to the specification of a dollar amount in the contract. The finalized revision to § 438.3(i)(3)(iv) is equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h).

Comment: One commenter supported the proposal to prohibit the use of attestations as supporting documentation for data that factors into the MLR calculation.

Response: We believe that by requiring the contracts to include specific documentation requirements, CMS and States will be better able to ensure that provider incentive payments are not being used to inappropriately increase the MLR to avoid paying potential remittances or inflate future capitation rates.

Comment: A few commenters supported the proposal that State contracts with managed care plans must require that managed care plans make the provider incentive contracts and supporting documentation available to the State both upon request and at the routine frequency that the State established.

Response: We believe that by requiring State contracts with managed care plans to include more specific documentation requirements, CMS and States will be better able to ensure that provider incentive payments are not being used to inappropriately increase the MLR to avoid paying potential remittances or inflate future capitation rates.

Comment: One commenter noted that the proposed changes for provider incentives should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to the Medicaid MLR regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized changes for provider incentives will make it more difficult for States and managed care plans to implement VBP. As one goal of VBP is to reduce excessive health spending and growth by limiting administrative waste,[172] we believe that the changes finalized in this rule at §§ 438.3, 438.8, and 457.1203 are very much aligned with the goals of VBP.

Comment: Several commenters supported the requirement for performance metrics in provider incentive arrangements and alignment with private market MLR regulations. Commenters noted that this change will

[172] Value-Based Payment As A Tool To Address Excess US Health Spending. Health Affairs Research Brief, December 1, 2022. DOI: *10.1377/hpb20221014.526546.*

prevent managed care plans from inappropriately transferring expenditures to providers to inflate their MLR and avoid paying remittances to States. Other commenters noted the importance of alignment with the private market regulations for consistency and equity across Federal health programs.

Response: Having a consistent methodology across multiple markets will allow for administrative efficiency for States as they monitor their Medicaid and CHIP managed care plans and for issuers and managed care plans to collect and measure data necessary to report and calculate their MLRs. We believe the requirement for prospective quantitative quality or performance metrics will increase transparency around these arrangements and ensure that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care and will protect Medicaid and CHIP against fraud and other improper payments. In addition, CMS and States will be better able to ensure that provider bonus or incentive payments are not being used either to inappropriately increase the MLR to avoid paying potential remittances, inflate future capitation rates, or to simply move funds from a Medicaid managed care plan to an affiliated company or provider.

Comment: Several commenters urged CMS to exercise greater oversight of Medicaid and separate CHIP managed care plans that own or are owned by companies that also own networks of providers and other health care services. The commenters described some potentially problematic reporting or business practices used by some vertically integrated health plans. The commenters noted that some large managed care plans channel excessive health care dollars to their affiliated health care providers and vendors and thereby increase health system costs while increasing profit for the managed care plan's parent company.

Response: We understand these concerns regarding managed care plans that are integrated with health care providers, and we will continue to encourage State oversight of Medicaid and separate CHIP managed care plan compliance with MLR reporting requirements for the different types of provider arrangements or payment models employed by managed care plans. As part of this effort, we encourage States to consider the impact of vertical integration on the reporting and treatment of provider payments under the MLR framework codified in § 438.8. Going forward, our Federal MLR reviews of the State Medicaid and CHIP managed care programs will also review State oversight practices for vertically integrated health plans' provider incentives.

Comment: Several commenters suggested that CMS require managed care plans to use the measure sets developed by the Core Quality Measures Collaborative (CQMC) for provider incentives. The commenters stated that the work done by a multidisciplinary committee to review and approve these measures makes them preferable to other measures a managed care plan may select for provider incentives.

Response: We appreciate the commenters' noting the CQMC performance measure review initiative and acknowledge the importance of alignment and harmonization in quality measurement. While we are not requiring the use of the CQMC measure sets, if a managed care plan's provider bonus and incentive program is based on CQMC measure sets, then any payments made based on the CQMC would qualify as a bonus or incentive includable in the MLR calculation. We believe that each State's Medicaid and CHIP managed care program is unique, and States are best positioned, in collaboration with managed care plans and interested parties, to design and determine the most appropriate metrics to use for provider incentive arrangements. Additionally, the private market MLR regulations did not specify a set of provider incentive metrics and as noted in the preamble of the proposed rule, we aim to remain aligned with the private market MLR regulations to the extent possible (88 FR 28154). Therefore, we decline to specify clinical or quality improvement standards for provider incentives in this final rule.

Comment: Several commenters stated that requiring performance metrics for provider incentives will lead to fewer providers participating in managed care networks and may lessen the ability of managed care plans to encourage creative solutions for access, such as providing bonus payments for evening and weekend physician office hours.

Response: We acknowledge that some providers may decline to participate in a managed care network if a provider incentive or bonus payment is tied to a clinical or quality improvement standard when previously these payment arrangements had not been held to this kind of standard. However, we believe that this would impact only a small percentage of providers as most providers share in Medicaid's and CHIP's goal of promoting the highest quality outcomes and safest care for all beneficiaries. The requirement for provider incentive payments to be based on clinical or quality improvement standards does not prevent managed care plans from developing innovative responses to improve access. In the commenter's example, the managed care plan could develop a provider incentive or bonus payment that requires physician offices to add evening and/or weekend hours but also requires improved access outcomes for one or more populations, for example, an increase in the proportion of adolescent enrollees who received a well-care visit.

Comment: Several commenters noted that excluding provider incentive payments that are based solely on total cost of care targets in the MLR numerator could have unintended consequences and negatively affect VBP arrangements in Medicaid managed care. One commenter noted that some CMS VBP programs, such as the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) program,[173] have arrangements where a percentage of the shared savings payment is linked directly to quality metrics and is separate from the total shared savings or loss from the ACO. The commenter stated concern that the portion of the shared savings arrangement that was not linked directly to quality metrics could not be included as a provider incentive payment in the MLR. The commenter recommended that incentive payments based on total cost of care targets be included in MLR calculations.

Response: We continue to support innovative alternative payment models that deliver efficient and high-quality care. We further note that the Medicaid managed care regulations in part 438 do not prohibit States and managed care plans from adopting a wide range of value-based payment models. The amendment to § 438.8(e)(2), which we are finalizing as proposed, is instead limited in applicability to the treatment and reporting of these amounts for MLR purposes. We believe that VBP models can reduce inappropriate utilization and lead to better outcomes, or lower costs, without compromising the quality of care. We confirm that the fact that a provider incentive or bonus program has a shared savings or other cost efficiency element does not disqualify the entire incentive or bonus from being classified as incurred claims, as long as the incentive or bonus is tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. States and managed care

[173] *https://innovation.cms.gov/innovation-models/aco-reach.*

plans employing such models or arrangements should be able to demonstrate this outcome through the use and documentation of appropriate clinical or quality metrics and thus such incentive or bonus payments would be eligible for inclusion in the MLR calculation as incurred claims. Further we are not aware of any CMS VBP initiatives (such as Medicare shared savings initiatives and alternative payment models) that do not include clinical or quality standard requirements. We clarify that when directed by a State to make provider incentive payments based on a VBP methodology, Medicaid managed care plans must include the full amount of these provider incentives in their MLR reports. That is, Medicaid managed care plans should include the full amount of provider incentives paid in their MLR reports if those payments are SDPs. Under § 438.6(c), States are required to tie SDPs to clinical or quality standards; however, if an SDP provider incentive or a portion of an SDP provider incentive is part of a VBP program, is tied to the total cost of care, and is not based on clinical or quality improvement standards, the managed care plan must include the SDP provider incentive expenditures based on the total cost of care in the MLR report. We encourage States to develop mechanisms for managed care plans to report SDP provider incentive payments separately from non-SDP provider incentive expenditures.

After consideration of public comments, we are finalizing § 438.8(e)(2) as proposed. We are also finalizing our proposals related to the Standards for Provider Incentives in § 438.3(i)(3) and § 438.3(i)(4). However, we are modifying a few proposals as described below. We are revising our proposal at § 438.3(v) to make these provisions effective on or after 60 days following the effective date of this final rule. We are instead finalizing that these provisions are effective for the rating period beginning on or after 1 year following the effective date of this final rule, based on public comments that 60 days may not be long enough to engage with the contracted providers and complete the legal review necessary to implement new provider incentive arrangements. Additionally, we are modifying our proposal at § 438.3(i)(3)(iii) describing the performance metrics, based on public comment that consistency is needed between the private market regulations and Medicaid managed care regulations. Therefore, we are finalizing revised text at § 438.3(i)(3)(iii) to mirror the text in the private market regulations at 45 CFR 158.140(b)(2)(iii). Finally, based on public comments, we are modifying our proposal at § 438.3(i)(3)(iv) that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of performance metrics to provide additional flexibility that would better align with current incentive payment practices. As such, we are finalizing the proposal at § 438.3(i)(3)(iv) to also allow a percentage of a verifiable dollar amount in the contract, as an alternative to a specific dollar amount, that can be clearly linked to successful completion of the metrics. We are finalizing the effective date for this provision as the first rating period beginning on or after 1 year after the effective date for the provider incentive changes in §§ 438.3(i), 438.608(e), and the existing cross-references at § 457.1200(d) for separate CHIP. The finalized revisions to § 438.3(i)(3)(iii) and (iv) are equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h).

b. Prohibited Costs in Quality Improvement Activities (§§ 438.8(e)(3) and 457.1203(c))

The preamble to the HHS Notice of Benefit and Payment Parameters for 2023 that adopted the updates to the private market regulations that took effect on July 1, 2022, noted that examinations of MLR reporting of issuers found ''wide discrepancies in the types of expenses that issuers include in QIA expenses'' and that inconsistency ''creates an unequal playing field among issuers'' (87 FR 27350). Therefore, to provide further clarity on the types of costs that may be included in MLR calculations, CMS modified the private market MLR regulations for QIA expenditures in 45 CFR 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes.

In Medicaid and separate CHIP regulations at §§ 438.8(e)(3) and 457.1203(c) respectively, we permit the inclusion of QIA expenses for activities that meet the private market MLR requirements, but we did not include language specifying that managed care plans may only include expenditures directly related to activities that improve health care quality when reporting QIA costs for MLR purposes in order to align with the private market regulations. As a result, the current Medicaid MLR regulations do not explicitly require managed care plans to exclude indirect or overhead QIA expenditures. Because the Medicaid regulation did not expressly disallow indirect or overhead QIA expenditures, we did not challenge States or Medicaid or CHIP managed care plans when these types of costs were included as QIA costs in the MLR numerator, which could result in inappropriately inflated MLRs as well as a different standard existing in the private market and Medicaid and CHIP. This difference in standards could pose a potential administrative burden for managed care plans that participate in Medicaid, CHIP and the private market because managed care plans and issuers may include different types of expenses in reporting QIA.

To align Medicaid and CHIP MLR QIA reporting requirements with the private market requirements and to improve clarity on the types of QIA expenditures that should be included in the MLR numerator, we proposed to amend § 438.8(e)(3)(i) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to add a reference to the private market regulation that specifies that only those expenses that are directly related to health care quality improvement activities may be included in the MLR numerator. This change will provide States with more detailed QIA information to improve MLR reporting consistency, allow for better MLR data comparisons between the private market and Medicaid and CHIP markets, and reduce administrative burden for managed care plans that participate in Medicaid, CHIP and the private market. We proposed that these requirements will be effective 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on the applicability date for these proposals.

We summarize and respond to public comments received on Prohibited Costs in Quality Improvement Activities (§§ 438.8(e)(3) and 457.1203(c)) below.

Comment: Many commenters supported the proposed exclusion of administrative costs in QIAs and alignment with private market regulations. Commenters noted that this alignment will promote consistency and equity across Federal health programs and will ensure an MLR calculation that more closely reflects the true value of services delivered.

Response: We agree that this alignment will result in more accurate MLR calculations and improve the value of managed care plans for Medicaid and CHIP beneficiaries.

Comment: Several commenters urged CMS to review how managed care plans are categorizing their utilization management expenses. These commenters noted that utilization management activities are often undertaken with the primary purpose to contain costs and encouraged CMS to set clear guardrails around when, if ever, such activities can be categorized as QIA.

Response: We agree with the commenters that certain utilization management activities are designed to contain costs rather than improve quality. To that end, under current regulations at §§ 438.8(e)(3)(i) and 457.1203(c), Medicaid and CHIP managed care plans cannot include in QIA any prospective or concurrent utilization management costs or any retrospective utilization management costs that do not meet the definition of QIA in 45 CFR 158.150. We remind States that they are required to monitor all managed care programs per § 438.66, including the QIA expenditures reported by managed care plans to determine if any of the reported expenditures have the primary goal of cost containment and should be excluded from the MLR numerator as QIA. States should also ensure that where managed care plans report all expenses from any given cost center as QIA, to the extent the cost center also performs non-QIA functions, only those qualifying expenses are included in the numerator. In such cases, the State should ensure that the managed care plan provides the State with documentation, such as time studies, showing how it determined the portion of time that staff expended on QIA programs versus non-QIA programs. In the future, our Federal MLR reviews of State Medicaid programs will also specifically examine State oversight practices for the review of utilization management expenses in QIA.

Comment: Several commenters requested that we allow health equity accreditation costs in QIA.

Response: Medicaid and CHIP managed care plans are currently permitted under §§ 438.8(e)(3)(i) and 457.1203(c) respectively, to include the costs associated with accreditation fees that are directly related to the quality of care activities in 45 CFR 158.150(b). The private market MLR regulations in 45 CFR 158.150(b)(2)(i)(A)(*5*) specifically note ''accreditation fees directly related to quality of care activities'' as permissible QIA expenditures. Therefore, if a health equity activity that requires accreditation meets the definition of QIA at 45 CFR 158.150, such accreditation costs can be reported as QIA expenses under §§ 438.8(e)(3)(i) and 457.1203(c).

Comment: Several comments requested alignment with Medicare QIA regulations, rather than the private market MLR regulations governing QIA, particularly for those plans serving beneficiaries that are eligible for both Medicare and Medicaid. The commenters stated that alignment with the Medicare Advantage regulations would better streamline and align program requirements for dually eligible beneficiaries. In addition, one commenter noted that CMS recently published a request for information for an integrated MLR for integrated dual eligible special needs plans (D–SNPs) [174] and recommended that CMS develop a prototype for a Medicaid-Medicare aligned model MLR.

Response: The proposed alignment with the private market MLR regulations governing QIA reflects the historical alignment of other Medicaid MLR regulations with private market MLR regulations. This proposed change does not affect Medicare MLR reporting for plans that serve individuals who are eligible for both Medicare and Medicaid. Those managed care plans should continue to report their Medicare MLR consistent with the Medicare regulations. We continue to review MLR reporting across CMS programs for potential opportunities to further align policies where such alignment makes sense based on how Medicaid and CHIP managed care plans operate compared to Medicare Advantage organizations and private market issuers.

Comment: Many commenters requested more detail and definitions about the types of overhead and indirect costs prohibited for QIA. A commenter noted that some managed care plans may have implemented QIAs that have associated administrative costs, such as a QIA that provides vouchers for culturally acceptable nutritious food that supports diabetes management and nutritional health. This commenter indicated that administrative expenditures for these types of QIAs that are part of quality improvement plan goals should be allowed in the MLR. One commenter noted that CMS should provide guidance if a managed care plan cannot report overhead expenses for QIA.

Response: In the proposed and finalized QIA changes, we did not delineate between QIAs used as part of quality improvement plan goals and other types of QIAs to ensure consistency in MLR reporting and to align with the private market MLR regulations. We decline to specify the types of administrative costs that would be prohibited for QIA in the regulation as those types of costs are numerous, and providing a list of prohibited costs in the regulation could lead to the inappropriate inclusion of costs that were not specified in the regulation. Many examples of inappropriate administrative costs were provided in the HHS Notice of Benefit and Payment Parameters for 2023 final rule preamble and include office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of counsel and executives, computer and telephone usage, travel and entertainment, company parties and retreats, IT systems, and marketing of issuers' products (87 FR 27351). In the example provided by the commenter, if the administrative expenses referred to fall into any of these categories, then the expenses cannot be included in QIA.

If a managed care plan indicates that it cannot separate indirect or overhead expenses for QIA, the State should disallow the entirety of QIA expenditures in the MLR. We remind States they are required to monitor managed care programs per § 438.66, which should include developing oversight processes along with managed care plan reporting tools to identify overhead and indirect expenses inappropriately reported as QIA expenditures.

Comment: Several commenters noted that although salaries and non-salary benefits are usually considered administrative costs, these costs should be allowable in the MLR as QIA expenditures. One commenter specified that salary and benefit costs for staff who are directly responsible for QIA should be allowed as QIA expenditures.

Response: We agree with the commenters that salary and non-salary benefits of employees performing QIA functions are directly tied to QIA, and we consider the salary costs, as well as the costs of the employee benefits to be direct QIA expenses. We take this opportunity to clarify that since §§ 438.8(e)(3) and 457.1203(c) were finalized in the 2016 final rule, Medicaid and CHIP managed care plans have been able to include the portion of

[174] We summarized and responded to public comments at pages 27776 through 27778 at *https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and.*

salaries and non-salary benefits that are part of a compensation package for staff performing QIAs that is attributable to QIAs in the MLR. The revision finalized at § 438.8(e)(3) does not change that, it only prohibits managed care plans from including as QIA fixed costs and other administrative costs that provide no benefit to enrollee health.

We understand that salary and benefit costs for staff who are performing the QIAs make up a substantial portion of QIA expenditures as these staff may spend all or part of their time working on QIA. However, such costs may only be included up to the amount that reflects the percentage of the employees' time actual spent on QIA. Managed care plans that report these costs as QIA should take care to both document and retain records supporting the amount(s) reported and the determination of what portion of these costs are a direct QIA expense. This question was also addressed for health insurance issuers subject to the private market MLR requirements in the HHS Notice of Benefit and Payment Parameters for 2023 (87 FR 27351).

Comment: One commenter noted that some administrative costs related to QIA implementation should be allowed because disallowing these types of costs could make plans less likely to implement QIAs.

Response: We disagree that prohibiting indirect or administrative costs in QIA will make managed care plans less likely to implement QIAs. We note that the proposed and finalized regulation prohibits managed care plans from allocating fixed costs that would, for the most part, exist even if the managed care plan did not engage in any QIA. That is, many administrative costs such as office space, human resources, and computer use would exist even if the managed care plan did not undertake QIA.

Comment: One commenter noted that undertaking QIA unavoidably adds administrative costs to the business or service line. The commenter noted that disallowing costs that are reasonably related or incidental to QIA could lead to understating the portion of the capitation rate for QIA. The commenter noted they believe that the QIA portion of the capitation rate may be set too low if most administrative costs were excluded from QIA, and therefore, managed care plans may have less incentive to perform QIA.

Response: We disagree with the commenter that implementing QIA requires incurring unavoidable administrative costs as many indirect costs such as office space and human resources would be incurred even if the managed care plan did not implement QIA. We disagree that prohibiting administrative costs such as office space or marketing, which do not provide direct benefit to enrollee health, in QIA would lead to incorrect QIA capitation rate setting. If costs that do not provide direct benefit to enrollee health are included in QIA rate setting, the portion of the capitation rate for QIA will be set too high and the resulting managed care capitation rates will be inappropriately inflated.

Comment: One commenter requested examples of computer software that would be considered indirect expenses, and therefore, would not qualify as QIA.

Response: Sections 438.8(e)(3)(iii) and 457.1203(c) provide that MCO, PIHP, or PAHP expenditures that meet the requirements related to Health Information Technology (HIT) in the private market MLR regulations at 45 CFR 158.151 would qualify as QIA expenditures. The proposed and finalized amendment to § 438.8(e)(2) does not modify the specification of HIT as outlined in 45 CFR 158.151. We affirm that HIT expenses that meet the applicable requirements in 45 CFR 158.151 are permissible costs that can be included as QIA expenses under §§ 438.8(e)(3)(iii) and 457.1203(c). For example, the cost of software designed and used primarily for QIA purposes such as Healthcare Effectiveness Data and Information Set (HEDIS) reporting, constitutes a direct expense related to activities that improve health care quality and can be included in QIA expenses for MLR reporting. In contrast, the costs of information technology infrastructure that primarily support regular business functions such as billing, enrollment, claims processing, financial analysis, and cost containment, do not constitute a direct expense related to activities that improve health care quality and cannot be included in QIA expenses for MLR reporting purposes. A similar comment was also addressed in the HHS Notice of Benefit and Payment Parameters for 2023 (87 FR 27351).

Comment: One commenter stated that the proposed QIA changes should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to QIA in the Medicaid MLR regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized QIA change will make it more difficult for States and managed care plans to implement VBP. As one goal of VBP is to reduce excessive health spending and growth by limiting administrative waste,[175] we believe that the changes finalized in this rule at §§ 438.3, and 457.1203 are very much aligned with the goals of VBP.

Comment: We received several comments related to including expenditures for activities related to social determinants of health (SDOH) and health-related social needs (HRSN) in the MLR. Commenters noted that these specific types of expenditures should be included in the numerator of the MLR, including community health worker quality improvement activities, activities related to SDOH, and managed care plan activities for the coordination of social services to address SDOH, as well as ILOSs at § 438.3(e)(2).

Response: We provided guidance related to the inclusion of expenses for activities to address SDOH in the MLR in a State Health Official Letter dated January 7, 2021,[176] that is also relevant for HRSN expenses. We provide a summary of the guidance here and encourage States and managed care plans to review the original guidance as it contains many examples of activities to address SDOH.

States may use incentive payments arrangements to reward managed care plans that make investments and/or improvements in SDOH. These payments must align with performance targets specified in the managed care plan contract, including implementation of a mandatory performance improvement project under § 438.330(d) that focuses on factors associated with SDOH, and comply with Federal requirements at § 438.6(b)(2). These incentive arrangements represent additional funds over and above the capitation rates. Managed care plan contract payments that incorporate incentive arrangements may not exceed 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. In the 2016 managed care rule (81 FR 27530), we specified that incentive arrangements made to the managed care plan in accordance with § 438.6(b)(2) should not be included in the denominator of the MLR as such payments are in addition to the capitation payments received under the contract.[177]

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[175] Value-Based Payment As A Tool To Address Excess US Health Spending, '' Health Affairs Research Brief, December 1, 2022.DOI: *10.1377/hpb20221014.526546.*

[176] *https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.*

[177] *https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.*

In the 2016 final rule (81 FR 27537), we clarified that services approved under a waiver (for example, sections 1915(b)(3), 1915(c), or 1115 of the Act) are considered State plan services for purposes of MLR requirements and are encompassed in the reference to State plan services in § 438.3(c). Therefore, if services to address SDOH are approved under these waiver authorities for the State Medicaid program, and the services are included in the managed care contract, then the covered services must necessarily be incorporated in the numerator of a plan's MLR. Additionally, States may develop and implement specific managed care plan procurement and contracting strategies to incentivize care coordination across medical and nonmedical contexts, including to address SDOH. Per recently issued guidance, Medicaid-covered HRSN services must be integrated with existing social services and housing services.[178] If managed care plans implement SDOH activities that meet the requirements in 45 CFR 158.150(b) and are not excluded under 45 CFR 158.150(c), managed care plans may include the costs associated with these activities in the numerator of the MLR as activities that improve health care quality under § 438.8(e)(3).[179]

Under the 2016 final rule (81 FR 27526), we also clarified that all services under § 438.3(e), including approved in lieu of services and settings, at § 438.3(e)(2), can be considered as incurred claims in the MLR numerator. Under § 438.3(e)(1), a managed care plan may voluntarily cover, for enrollees, services that are in addition to those covered under the State plan. These services are often referred to as value-added services, and the cost of these services may not be included in the capitation rate; however, as outlined in the 2016 final rule (81 FR 27526), value-added services can be considered as incurred claims in the numerator for the purposes of the MLR calculation if the services are activities that improve health care quality under 45 CFR 158.150 and are not excluded under 45 CFR 158.150(c).

After reviewing public comments, we are finalizing §§ 438.8(e)(3) and 457.1203(c) as proposed.

c. Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)(vii) and 457.1203(f))

As specified in current regulations at §§ 438.8(k)(1)(vii) and 457.1203(f) respectively, Medicaid and CHIP managed care plans must provide a report of the methodology or methodologies that they used to allocate certain types of expenditures for calculating their MLR. Examples of these types of expenditures include overhead expenses such as facility costs or direct expenses such as employee salaries. If a plan operates multiple lines of business, for example in both Medicaid and the private market, it must indicate in the Medicaid MLR report how the share of certain types of costs were attributed to the Medicaid line of business. However, the Medicaid MLR regulations in § 438.8(g) and (k)(1)(vii) do not require managed care plans to submit information about the types of expenditures allocated to the Medicaid line of business and do not require managed care plans to specify how each type of expenditure was allocated to the Medicaid MLR.

Recent CMS State-level Medicaid MLR reviews noted a lack of expense allocation information in managed care plans' MLR reports to States.[180] Specifically, CMS determined that several plans operated in multiple markets, for example, Medicaid and Medicare Advantage, and failed to adequately describe how certain costs that may apply across multiple lines of business were allocated to the Medicaid MLR report. Examples of these expenses include: quality improvement expenses, taxes, licensing or regulatory fees, and non-claims costs. The impact of this lack of transparency is that it may be impossible for a State to determine if the managed care plan's allocation of the applicable expenses to the Medicaid line of business was reasonable. For example, if a managed care plan operating in multiple markets does not provide information on how quality improvement activity expenses were allocated to the Medicaid MLR, the State will be unable to determine if the MLR numerator is accurately reported or inappropriately inflated.

The private market MLR regulations at 45 CFR 158.170(b) require significantly more detail for expense allocation in issuer's MLR reports. Specifically, § 158.170(b) requires a description of the types of expenditures that were allocated, how the expenses met the criteria for inclusion in the MLR, and the method(s) used to allocate these expenses. We proposed to require in § 438.8(k)(1)(vii) for Medicaid, which is included in CHIP regulations through an existing cross-reference at § 457.1203(f), that managed care plans must include information in the MLR report that they submit to the State that reflects the same information required under private market requirements at § 158.170(b). Specifically, in § 438.8(k)(1)(vii), we proposed to add to the existing text that plans' descriptions of their methodology must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described § 158.170(b). These proposed revisions would improve State MLR oversight by providing States with more detailed information to ensure the appropriateness of managed care plans' expense allocation. These proposed requirements would also align with private market regulations and reduce administrative burden for managed care plans operating across multiple markets. We proposed that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

We summarize and respond to public comments received on Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)(vii) and 457.1203(f)) below.

Comment: Several commenters supported the proposed changes to expense allocation methodology reporting. Commenters noted that these changes will clarify the underlying elements of MLR calculations to address potentially inaccurate or inflationary MLR calculations and produce more reliable reports.

Response: Given that a recent state-level Medicaid MLR review [181] found that many MLR reports from managed care health plans did not contain information about expense allocation methodologies, we believe the proposed and finalized changes to the regulation will improve expense allocation reporting from managed care plans.

Comment: One commenter noted that the proposed new reporting requirements imposed significant burdens on plans that serve dually

[178] *https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.*

[179] *https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.*

[180] See Completed MLR audit reports at: *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reports-guidance.*

[181] *https://www.cms.gov/files/document/oregon-medicaid-managed-care-medical-loss-ratio-report.pdf.*

eligible beneficiaries in fully integrated dual eligible special needs plans (FIDE SNPs).

Response: We do not believe that the proposed reporting requirements will impose new or significant burdens on managed care plans serving dually eligible beneficiaries as those types of managed care plans are currently required to allocate certain types of costs across lines of business as part of MLR reporting. The proposed change requires managed care plans to provide additional detail about how the plans allocate expenses across lines of business for MLR reporting; it does not require plans to report new types of expenses, nor does it change how costs should be allocated across lines of business.

Comment: One commenter noted that some managed care plans may have a ''delegated model'' where subcontractors are paid using capitated payment arrangements. The commenter noted they believe that managed care plans that use these types of arrangements will have significant difficulty with the proposed reporting requirements as medical and non-medical expenditures cannot be easily reported separately.

Response: We disagree that the proposed changes will burden managed care plans using a ''delegated model'' as Medicaid and CHIP requirements for delegation to subcontractors were finalized in the 2016 Managed Care rule at §§ 438.230(c)(1) and 457.1201(i) respectively and have been known to States and managed care plans since that time. We also published guidance in 2019 to assist States and managed care plans in MLR reporting when subcontractor arrangements were used by the managed care plan.[182] In this guidance, we noted that ''when a managed care plan subcontracts with a third-party vendor to administer, and potentially provide, a portion of Medicaid covered services to enrollees, the subcontractor must report to the managed care plan all of the underlying data needed for the Medicaid managed care plan to calculate and report the managed care plan's MLR.'' To correctly calculate the MLR, the required underlying data would need to separate medical and non-medical expenditures. Given that the subcontractor regulations and related guidance in this area have been available for several years, we would expect all managed care plans to be complying with MLR reporting requirements for subcontractor arrangements.

Comment: Several commenters requested that we provide preferred expense allocation methodologies for income taxes and other types of expenditures to promote more consistency in MLR calculations. One commenter noted that the Medicare Advantage MLR reporting instructions provide detail on income tax expense allocation methods unlike those for issuers offering group or individual health insurance coverage and Medicaid managed care plans.

Response: We respectfully disagree with the commenter that the Medicare Advantage MLR reporting instructions provide detail on income tax expense allocation methods. Neither the private market nor the Medicare MLR regulations provide methodologies for the allocation of specific types of expenditures, including income taxes. The private market MLR instructions reference to the National Association of Insurance Commissioners (NAIC) Statements of Statutory Accounting Principles (SSAP) and Supplemental Health Care Exhibit (SHCE) in effect for the MLR reporting year.[183] The instructions note that ''[t]hese references are solely for the convenience of the filer in identifying the information needed for this MLR form.'' [184] Similarly, the Medicare Advantage 2013 final rule references the use of Statutory Accounting Principles to align with the commercial MLR expense allocation requirements but does not specify methods for expense allocation; the preamble notes that MA organizations should ''allocate the expense to that particular activity'' or use ''a generally accepted accounting method that yields the most accurate results.'' (78 FR 31293) We decline to provide recommendations for specific expense allocation methodologies in regulation as neither the private market nor the Medicare regulations specify this detail. As noted in the preamble of the proposed rule, we aim to remain aligned with the private market MLR regulations to the extent possible (88 FR 28154). Specifying a method of allocating income taxes is also complicated by the fact that many issuers and managed care plans are affiliated, and taxes are filed at the holding company or parent level pursuant to an inter-company tax allocation agreement. Thus, prescribing the most accurate tax expense allocation methodology in the Medicaid regulation would be nearly impossible. In addition, as State Medicaid programs are unique, States are in the best position to develop oversight strategies and guidance for managed care plan financial reporting, including methods for income tax expense allocation.

Comment: One commenter stated that the proposed changes for expense allocation methodologies should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to the Medicaid MLR expense allocation regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized changes for expense allocation will make it more difficult for States and managed care plans to implement VBP. As one goal of VBP is to reduce excessive health spending and growth by limiting administrative waste,[185] we believe that the changes finalized in this rule at §§ 438.8, and 457.1203 are very much aligned with the goals of VBP.

Comment: A few commenters requested additional time for implementation and suggested that CMS not require managed care plans to comply with §§ 438.8(k)(1)(vii) and 457.1203(f) until the rating period beginning on or after 60 days after the effective date of the final rule.

Response: Although providing this level of detail related to expense allocation methods may be new for some managed care plans, we do not believe that it is particularly burdensome or that managed care plans need additional time for implementation. We point out that the effective date of the rule will be 60 days after publication in the **Federal Register**.

After reviewing the public comments, we are finalizing §§ 438.8(k)(1)(vii) and 457.1203(f) as proposed.

d. Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c))

Section 2718(c) of the Public Health Service Act charged the National Association of Insurance Commissioners (NAIC) with developing uniform methodologies for calculating measures of the expenditures that make up the calculation for the MLR applicable to the private market, and to address the special circumstances of smaller plans.

[182] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051519.pdf.*

[183] See, for example, *https://www.cms.gov/files/document/2022-mlr-form-instructions.pdf.*

[184] Ibid.

[185] Value-Based Payment As A Tool To Address Excess US Health Spending, '' Health Affairs Research Brief, December 1, 2022.DOI: *10.1377/hpb20221014.526546.*

The NAIC model regulation allows smaller plans in the private market to adjust their MLR calculations by applying a ''credibility adjustment.'' Under §§ 438.8(h) and 457.1203(c) respectively, Medicaid and CHIP managed care calculated MLRs may be adjusted using credibility factors to account for potential variability in claims due to random statistical variation. These factors are applied to plans with fewer enrollees to adjust for the higher impact of claims variability on smaller plans. As stated in § 438.8(h)(4), CMS is responsible for developing and publishing these factors annually for States and managed care plans to use when reporting MLRs for plans with fewer enrollees. In the 2015 Medicaid and CHIP managed care proposed rule (80 FR 31111), we proposed adopting a credibility adjustment methodology along with assurances to monitor and reevaluate credibility factors ''in light of developing experience with the Affordable Care Act reforms.'' In the 2015 proposed rule (80 FR 31111), we also proposed to update the credibility adjustment method within the parameters of the methodology in that proposed rule. We finalized this proposal without revision in the 2016 final rule (81 FR 27864). The Medicaid managed care credibility adjustment factors were published on July 31, 2017, at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib073117.pdf*.

Since this publication of the credibility adjustment factors in 2017, the factors have not changed. The factors were originally developed using a statistical model applying the Central Limit Theorem (80 FR 31111). This model produced credibility factors that were not expected to change annually. Therefore, we believe that annual updates to these factors are not required, and we proposed to modify § 438.8(h)(4) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to remove ''On an annual basis.'' If we determine that the factors need to be updated, we will use the methodology specified at § 438.8(h)(4)(i) through (vi). We did not propose any revisions to § 438.8(h)(4)(i) through (vi) in this rule. We proposed that these changes will be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable. We sought comment on this proposal.

We summarize and respond to public comments received on Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c)) below.

Comment: One commenter requested CMS to clarify if credibility factors will be reviewed on a regular basis even if they are not published annually.

Response: We understand the importance of credibility factors to smaller managed care plans' MLR calculations and commit to review them on a regular basis and publish updates if the factors change. If we determine that the factors need to be updated, we will use the methodology specified at § 438.8(h)(4)(i) through (vi).

After reviewing the public comments, we are finalizing § 438.8(h)(4) as proposed.

e. MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f))

Medicaid and CHIP managed care plans are required to resubmit MLR reports to States under certain circumstances. In the 2015 managed care proposed rule preamble, we noted that States may make retroactive changes to capitation rates that could affect the MLR calculation for a given MLR reporting year and that when that occurred, the MCO, PIHP, or PAHP will need to recalculate the MLR and provide a new report with the updated figures (80 FR 31113). We also indicated that ''In any instance where a State makes a retroactive change to the capitation payments for an MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.'' This regulation was finalized in 2016 without changes (81 FR 27864). However, the reference in the regulation to changes to capitation ''payments'' rather than ''rates'' has caused confusion about when managed care plans should resubmit MLR reports to the State and has contributed to additional administrative burden by requiring plans to resubmit MLR reports to the State and by requiring States to review multiple MLR report submissions from managed care plans.

As part of our Medicaid MLR report compliance reviews, we have heard from several States that MLR reports from MCOs, PIHPs, or PAHPs are often resubmitted to the State. These resubmissions usually resulted from payments the State made to the managed care plan as part of the retroactive eligibility review process. As part of this process in these States, the State reviews beneficiary eligibility records to determine if an individual qualifies for retroactive eligibility. If an enrollee qualifies for retroactive eligibility, the State modifies the number of capitation payments that were made to a plan; however, the State does not retroactively modify the capitation rate for a group of members.

We proposed to amend § 438.8(m) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(f), to specify that an MCO, PIHP, or PAHP will only be required to resubmit an MLR report to the State when the State makes a retroactive change to capitation rates. Specifically, we proposed to replace ''payments'' with ''rates'' and to insert ''retroactive rate'' before the word ''change.'' We proposed that these changes will be effective 60 days after the effective date of this final rule as we believe this timeframe was reasonable to alleviate State and plan administrative burden. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

We summarize and respond to public comments received on MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f)) below.

Comment: Several commenters opposed our proposal to modify § 438.8(m). These commenters opposed the proposed changes as they believed that retroactive eligibility determinations could have a significant impact on the MLR report calculation.

Response: After further consideration of these comments, as well as States' restarting of the eligibility redetermination process, we believe that the retroactive eligibility process that adjusts the number of capitation payments to plans may involve many individuals and could significantly affect the accuracy of the MLR calculations. After consideration of public comments and reconsideration of the impact of the restarting of the Medicaid and CHIP eligibility redetermination process, we have determined that by restricting managed care plan MLR resubmissions to when States make capitation rate changes, the MLRs may not be accurate. Therefore, we will not finalize proposed § 438.8(m).

f. Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e))

As specified in existing requirements at §§ 438.8(k) and 457.1203(f) respectively, Medicaid and CHIP managed care plans are required to submit detailed MLR reports to States,

and States, as required in § 438.74 for Medicaid and § 457.1203(e) for separate CHIP, must submit a summary description of those reports to CMS. In the preamble to the 2015 managed care proposed rule (80 FR 31113), we described the term ''summary'' as meaning an abbreviated version of the more detailed reports required from managed care plans in § 438.8(k) but did not refer to a Statewide aggregation of data across managed care plans. The proposed regulatory text for § 438.74 did not include the words ''for each'' and was finalized as proposed. In our compliance reviews of State summary MLR reports, several States provided MLR data aggregated over the entire State and neglected to provide the abbreviated MLR report for each plan. These submissions of MLR summary reports that omitted information by plan indicate States' confusion with what is required for these reports.

To correct this issue, we proposed to amend § 438.74(a) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(e), to note explicitly that State MLR summary reports must include the required elements for each MCO, PIHP, or PAHP that is contracted with the State. To specify that the MLR information will have to be reported for each managed care plan, we proposed in § 438.74(a)(1) to replace ''the'' with ''each'' before ''report(s).'' In addition, in § 438.74(a)(2), we proposed to add language to specify that the information listed as required in the summary description must be provided for each MCO, PIHP, or PAHP under contract with the State. These changes will specify that States must provide MLR information for each managed care plan in their annual summary reports to CMS. We proposed that States and managed care plans will be required to comply with these changes 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for MCO, PIHP and PAHP contracts beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

We summarize and respond to public comments received on Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e)) below.

Comment: Numerous commenters supported the proposed requirement for States to provide MLR reports at the managed care plan level, and CMS received no comments opposing the proposal. One commenter supported the proposed applicability date of 60 days after the effective date of the final rule, and we received no comments opposing the proposed timeline.

Response: We thank the commenters for their support of the proposed changes to specify the level of data aggregation required for State summary MLR reporting to CMS and the applicability date.

After reviewing the public comments, we are finalizing §§ 438.74 and 457.1203(e) as proposed.

g. Contract Requirements for Overpayments (§§ 438.608(a)(2) and (d)(3) and 457.1285)

In the 2016 final rule, we aimed to strengthen State and Medicaid and CHIP managed care plan responsibilities to protect against fraud and other overpayments in State Medicaid and CHIP programs, in part, by enhancing reporting requirements to support actuarial soundness payment provisions and program integrity efforts (81 FR 27606). Overpayments are defined in § 438.2 as any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled under Title XIX of the Act. These overpayments may be the result of fraud, waste, abuse, or other billing errors. Regardless of cause, overpayments should be excluded from the capitation rate because they do not represent reasonable, appropriate, or attainable costs.

The 2016 final rule also enhanced the integrity of capitation payments, in part, by requiring at § 438.608(d)(3) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, that State contracts with managed care plans include provisions specifying that managed care plans must report the recoveries of overpayments annually. This reporting to the State is critical to the actuarial soundness of capitation rates because managed care plans must exclude overpayments from their incurred claims, which is also a key element in the numerator of the MLR calculation. As required in § 438.5(b)(5), States must consider a Medicaid managed care plan's past reported MLR and the projected MLR in the development of capitation rates. If a managed care plan's MLR numerator does not exclude overpayments, the MLR may be inappropriately inflated. Section 438.608(d)(4) requires that the State use the results of the information and documentation collected under § 438.608(d)(3) for setting actuarially sound Medicaid capitation rates consistent with the requirements in § 438.4.

We proposed to modify § 438.608(a)(2), which requires managed care plan contracts to include a provision for the prompt reporting of all overpayments identified or recovered (specifying those due to potential fraud) to the State; and § 438.608(d)(3), which requires managed care plan contracts to include annual reports on plan recoveries of overpayments. Both proposed changes are included in separate CHIP regulations through an existing cross-reference at § 457.1285. The proposed changes aim to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to States in a timely manner, which will better position States to execute program integrity efforts and develop actuarially sound capitation rates.

Defining ''Prompt'' Reporting (§§ 438.608(a)(2) and 457.1285))

Current regulations at § 438.608(a)(2) require that States include a provision in their contracts with managed care plans for the prompt reporting to the State of all overpayments identified or recovered, specifying the overpayments due to potential fraud. However, the term ''prompt'' is not defined. Although a time period is not defined, prompt reporting of identified or recovered overpayments is important because it can enable a State to expeditiously take action against a provider to prevent further inappropriate activity, including potential fraud. With prompt reporting of managed care plan overpayments, the State is better equipped to identify similar overpayments and prevent future overpayments across its networks, managed care programs, and FFS.

CMS's oversight efforts and other program integrity reviews have revealed that States interpret the promptness requirement under § 438.608(a)(2) inconsistently. For example, some States do not define ''prompt'' in managed care plan contracts, instead deferring to managed care plans' interpretation of the timeframe to report overpayments; this lack of definition can result in inconsistent overpayment reporting among managed care plans and States. Our reviews also revealed that some States do not use a consistent timeframe across managed care plan contracts when requiring the reporting of overpayments. As a result, managed care plans may not report identified or recovered overpayments within a timeframe that enables States to

effectively and swiftly investigate and take appropriate administrative action against providers that may be committing fraudulent activities across networks and managed care programs.

We believe that establishing a uniform definition of the term ''prompt'' will provide clarity to States and managed care plans, thereby enhancing ongoing communication between managed care plans and States, particularly as it relates to program integrity practices. Therefore, we proposed to amend § 438.608(a)(2) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, to define ''prompt'' as within 10 business days of identifying or recovering an overpayment. We believed 10 business days would provide a managed care plan sufficient time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors, and also quickly provide the State with awareness to mitigate other potential overpayments across its networks and managed care programs. With a clear and consistent overpayment reporting requirement, States will be better equipped to: direct managed care plans to look for specific network provider issues, identify and recover managed care plan and FFS claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral.

We solicited public comments on the proposed 10 business day timeframe and whether reporting should be from date of identification or recovery, or instead on a routine basis, such as monthly. We proposed that States and managed care plans will be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We sought comment on this proposal.

Identifying Overpayment Reporting Requirements (§§ 438.608(d)(3) and 457.1285)

The overpayment reporting provisions in part 438, subpart H require managed care plans to recover the overpayments they identify, and in turn, report those identified overpayments to the State for purpose of setting actuarially sound capitation rates. In the 2015 proposed rule, we stated that ''MCOs, PIHPs, and PAHPs must report improper payments and recover overpayments they identify from network providers. States must take such recoveries into account when developing capitation rates. Therefore, capitation rates that include the amount of improper payments recovered by an MCO, PIHP, or PAHP as projected costs will not be considered actuarially sound.'' (80 FR 31119). It was our expectation that ''such recoveries'' include recoveries of all identified overpayments. This intent is also reflected in § 438.608(a)(2), which states that managed care plans must report both ''identified or recovered'' overpayments to the State. However, the words ''identified or'' were omitted from the related regulatory text at § 438.608(d)(3). Program integrity reviews and investigations conducted since the 2016 final rule have found that language in § 438.608(d)(3) providing that managed care plans only report ''recovered overpayments'' has created an unintentional effect of managed care plans' reporting partial overpayment data for capitation rate calculations. This omission may have also disincentivized managed care plans from investing in the resources necessary to recover identified overpayments in the interest of maintaining a higher MLR. For example, we have identified instances in which managed care plans identified an overpayment but did not recover the entire overpayment from the provider due to negotiating or settling the overpayment to a lesser amount. In other cases, managed care plans identified an overpayment that was resolved by applying an offset to future payments to the provider instead of recovering the full overpayment in the impacted rating period. These situations resulted in the managed care plans only reporting a relatively small or no overpayment recovery amount to the State in the impacted rating period, instead of the full amount of the identified overpayment. This inconsistent reporting does not reflect our original intent in imposing the current requirements in § 438.608(d)(3) and prevents the State from accounting for the full amount of the identified overpayment in the impacted rating period when developing capitation rates as required under § 438.608(d)(4).

To address these issues, in our May 3, 2023, proposed rule, we proposed to revise § 438.608(d)(3) for Medicaid and separate CHIP regulations through an existing cross-reference at § 457.1285, to specify our original intent that any overpayment (whether identified or recovered) must be reported by Medicaid or CHIP managed care plans to the State. Through this proposed change, we believe that managed care plans and States will have more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting to the State all overpayments, whether identified or recovered. By ensuring that both identified and recovered overpayments are reported, States and CMS will be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract. We proposed that States and managed care plans will be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule. We solicited comments on this proposal. We summarize and respond to public comments received on Contract Requirements for Overpayments (§§ 438.608(a)(2) and (d)(3), and 457.1285) below.

Comment: Several commenters opposed the proposal regarding the effective date of the proposed requirements at § 438.608(a)(2) and (d)(3). One commenter suggested delaying implementation of the rule to align with the next rate certification or contract submission date, instead of 60 days after the rule is finalized. Other commenters requested a minimum of 1 year, rather than 60 days.

Response: We considered these comments when finalizing the effective date of the new requirements for the prompt reporting of overpayments in § 438.608(a)(2) and (d)(3). We acknowledge that 60 days may not be long enough for CMS to provide any needed guidance to States, or for States to engage with managed care plans and update contract language. After considering the public comments, we are finalizing a revised effective date of the first rating period beginning on or after 1 year from the effective date of this final rule to provide States sufficient time to complete the necessary actions to come into compliance with these requirements.

Comment: One commenter supported our proposed 10 business days timeframe for ''promptly'' reporting overpayments under § 438.608(a)(2). However, many commenters recommended a longer timeframe for ''promptly'' reporting overpayments, indicating that 10 business days is not

enough time due to operational concerns. Several commenters suggested a 30-day or monthly cadence for ''prompt'' reporting to States, while other commenters suggested lengthier reporting timeframes, such as a 60-day, quarterly, or semi-annual cadence.

Response: We continue to believe that rapid reporting by managed care plans about identified or recovered overpayments is critical to enable States to effectively and swiftly investigate and take appropriate administrative action against providers that may be committing fraudulent activities across networks and managed care programs. However, after considering the public comments, we acknowledge that a slightly longer timeframe to report can still provide States with prompt awareness of overpayments while providing managed care plans additional time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors. Therefore, we are finalizing a revised proposal at § 438.608(a)(2) that States shall require managed care plans to report identified or recovered overpayments within 30 calendar days from the date of identification or recovery of an overpayment. We believe that 30 calendar days achieves the appropriate balance of addressing some commenters' concerns and maintaining the intent of ''prompt'' reporting of identified or recovered overpayments. While we are finalizing ''prompt'' reporting as within 30 calendar days, States still retain the flexibility to require managed care plans to report overpayments within a shorter timeframe.

Comment: Several commenters suggested aggregated or batched reporting instead of reporting each identified or recovered overpayment to the State. One commenter recommended reporting this on a routine basis, such as monthly or bimonthly, to avoid excessive notifications, as well as establish a cadence in which State could expect to receive reports. Another commenter recommended that the reporting be part of the managed care plan's and/or Risk Bearing Organization (RBO)'s normal quarterly financial reporting to the payer and/or regulator.

Response: We appreciate the comments on the allowable method of reporting. However, defining the method through which reporting of identified or recovered overpayment must be done, including the use of batched or other reporting mechanisms, is outside the scope of our proposal to define ''prompt'' reporting as within 10 business days. States maintain flexibility to determine the manner with which managed care plans report so long as it meets the finalized requirement that identified or recovered overpayment(s) be reported within 30 calendar days from the date it was identified or recovered.

Comment: One commenter suggested that while it might be reasonable to require reporting of an overpayment identified during an investigation to the State within 10 business days, it would not be feasible to require that investigation be completed within 10 days of identification.

Response: Our proposal does not include that an investigation must be completed in any amount of time. We stated in the proposed rule that our proposal of 10 business days would be sufficient time to begin an investigation and determine whether overpayments are due to potential fraud or other causes, such as billing errors. Also, as described above, after consideration of public comments, we are finalizing that States require managed care plans to report identified or recovered overpayments within 30 calendar days from the date of identification or recovery of an overpayment, specifying the overpayments due to potential fraud. This does not also require that an investigation be completed within that 30-calendar day timeframe.

Comment: Commenters sought clarification regarding the definition or interpretation of several terms within § 438.608(d)(3). Some commenters requested guidance to clearly define ''identified overpayment'' as compared to an allegation of fraud, waste, abuse, or other provider misconduct. Another commenter requested clarification about whether MCOs must separately report overpayments when they are both identified and when/if they are eventually recovered. One commenter supported the broad interpretation of ''overpayments,'' which may be the result of fraud, waste, abuse, or other billing errors, while other commenters suggested changes related to the reporting of any overpayments. One commenter suggested that an ''overpayment'' should not be considered ''identified'' until there is an actual claim paid and/or a final dollar value is determined. Another commenter suggested limiting reporting requirements to overpayments that rise above a de minimis percentage of the total claim amount to minimize administrative burden. Another commenter suggested either removing the word ''all'' from the language or allowing reporting of overpayments related to claim adjustments, Coordination of Benefits/Third Party Liability, error, and retroactive member disenrollment on a less frequent basis. One commenter suggested that CMS should allow managed care plans to apply direct costs for identifying, mitigating, and recovering overpayments in the MLR numerator.

Response: With regard to the commenters' request for clearly defined guidance on ''identified overpayment'' as compared to an allegation of fraud, waste, abuse, or other provider misconduct under revised § 438.608(d)(3), this is out of the scope of the proposed overpayment reporting requirements. States maintain flexibility to determine the scope of ''identified overpayments,'' and we encourage States to work with their managed care plans to ensure these terms are clearly and consistently defined in the contracts.

For the commenters' request for clarification about whether a managed care plan must separately report overpayments when the payments are both identified and when/if they are eventually recovered, these overpayments must be separately reported. As stated in the proposed rule, the omission of the words ''identified or'' from § 438.608(d)(3) created an unintentional effect of managed care plans reporting partial overpayment data for capitation rate calculations. This omission may have also disincentivized managed care plans from investing in the resources necessary to recover identified overpayments in the interest of maintaining a higher MLR. These situations resulted in the managed care plans only reporting a relatively small or no overpayment recovery amount to the State in the impacted rating period, instead of the full amount of the identified overpayment. The inconsistent reporting does not reflect our original intent in imposing the current requirements in § 438.608(d)(3) and prevents the State from accounting for the full amount of the identified overpayment in the impacted rating period when developing Medicaid capitation rates as required under § 438.608(d)(4). As such, our intent is that any overpayment (whether identified or recovered) must be separately reported by Medicaid or CHIP managed care plans to the State. Through this final rule, we believe that managed care plans and States would have more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting to the State of all overpayments, whether identified or recovered. By ensuring that both

identified and recovered overpayments are reported, States and CMS would be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the managed care plan contract.

With regard to the commenter's suggestion about limiting the reporting of overpayments to overpayments that rise above a de minimis percentage of the total claim amount to reduce administrative burden, we believe this is outside the scope of our proposal, as we did not propose a threshold for which overpayments must be reported under § 438.608(d)(3). The previous regulation at § 438.608(d)(3) required managed care plans to report recovered overpayments to the State and did not establish a certain threshold for such reporting. While our proposal specifically added the term ''all'' when referring to reported overpayments, our proposal sought to clarify what was previously implied, that all overpayments should be reported. As stated in the 2016 final rule, a requirement to report all overpayments is important to ensure actuarial soundness. For the commenter's comment about either removing the word ''all'' from the language or allowing reporting of overpayments related to claim adjustments, Coordination of Benefits/Third Party Liability, error, and retroactive member disenrollment on a less frequent basis, we also believe this is outside the scope of this proposal, as described above. Similarly, with regard to the commenter's suggestion that CMS should allow managed care plans to apply direct costs for identifying, mitigating, and recovering overpayments in the MLR numerator, this is outside the scope of this proposal.

Comment: Commenters requested that CMS confirm whether NEMT PAHPs are excluded from reporting overpayments.

Response: We appreciate the commenters' request for clarification. Requirements at §§ 438.9 and 457.1206 outline the provisions of 42 CFR part 438 subpart H and part 457 subpart L, respectively, that apply to NEMT PAHPs. Because the reporting of overpayments requirements at § 438.608 are not included in the provisions that apply to NEMT PAHPs, these provisions do not apply to NEMT PAHPs, and we are removing reference to NEMT PAHPs from these provisions in this final rule.

Comment: One commenter requested that CMS provide guidance regarding situations where a third-party should review overpayments.

Response: We believe this proposed clarifying guidance is outside the scope this final rule. We encourage managed care plans to work closely with States to gain a clear understanding of expectations and contractual requirements around identifying overpayments.

After consideration of public comments, we are finalizing our proposals for overpayments in revised § 438.608(a)(2) and (d)(3). However, we are modifying our proposal that States require managed care plans to define ''prompt'' as within 10 business days of identifying or recovering an overpayment. We are instead finalizing in revised § 438.608(a)(2) that States require managed care plans to define ''prompt'' as within 30 calendar days of identifying or recovery an overpayment. This revision is also applicable to separate CHIP via an existing cross-reference at § 457.1285. We believe 30 calendar days will provide a managed care plan sufficient time to investigate an overpayment and determine whether the overpayment is due to potential fraud or other causes, such as billing errors, and provide States with awareness to mitigate other potential overpayments across its networks, managed care programs, and FFS. With a clear and consistent overpayment reporting requirement, States will be better equipped to direct managed care plans to look for specific network provider issues, identify and recover managed care plan and FFS claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral. We reiterated that nothing in this final rule would prohibit a State from setting a shorter timeframe than 30 calendar days for reporting of overpayments.

We are also finalizing our proposal in § 438.608(d)(3) for Medicaid and separate CHIP managed care programs (through an existing cross-reference at § 457.1285), to clarify that all overpayments (identified or recovered) must be reported by Medicaid or CHIP managed care plans annually to the State. We believe this change will provide managed care plans and States with more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting of all overpayments, whether identified or recovered, to the States. By ensuring both identified and recovered overpayments are reported, States and CMS will be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract.

To address an error in the proposed rule, we are removing reference to the applicability of the overpayment reporting requirements at §§ 438.608(a)(2) and (d)(3) to NEMT PAHPs, as these plans are excluded from these regulatory provisions under existing §§ 438.9 and 457.1206.

Finally, we are modifying our proposals regarding the effective date of beginning on or after 60 days following the effective date of the final rule for both revisions to § 438.608(a)(2) and (d)(3). Instead, we are finalizing an effective date of the first rating period beginning on or after 1 year from the effective date of this final rule.

h. Reporting of SDPs in the Medical Loss Ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74, 457.1203(e) and 457.1203(f))

Many States with managed care programs are using the authority in § 438.6(c) to direct managed care plans' payments to certain providers. States' increasing use of these arrangements has been cited as a key area of oversight risk for CMS. Several oversight bodies, including OIG, and GAO, and other interested parties including MACPAC, have authored reports focused on CMS oversight of SDPs.[186] [187] [188] [189] Both GAO and MACPAC have recommended that we collect and make available provider-specific information about Medicaid payments to providers, including SDPs.

As discussed in section I.B.2. of this final rule, CMS's current review and approval process for SDPs is prospective; that is, we do not consistently nor systematically review the actual amounts that States provide to managed care plans for these arrangements [190] nor do we review the

[186] U.S. Department of Health and Human Services Office of the Inspector General, ''Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program,'' A–06–18–07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*

[187] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf.*

[188] U.S. Government Accountability Office, Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency,'' December 14, 2023, available at *https://www.gao.gov/products/gao-24-106202.*

[189] Medicaid and CHIP Payment and Access Commission, ''Oversight of Managed Care Directed Payments,'' June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf.*

[190] As CMS does not routinely perform this review, the current requirements for separate payment terms outlined in the Medicaid managed care rate guide requires States to (1) submit documentation to CMS that includes the total

Continued

actual amounts that managed care plans pay to providers. CMS requires States to provide an estimated total dollar amount that will be included in the capitation rates for the SDP arrangement.[191] However, States are not required to report to CMS on the actual expenditures associated with these arrangements in any separate or identifiable way after the rating period has closed and claims are adjudicated. On a limited basis, we perform in-depth State-level medical loss ratio (MLR) reviews and financial management reviews (FMRs) that include the actual amounts paid through SDPs. But without the systematic collection of actual payment amounts, we cannot determine exactly how much is being paid under these arrangements, to what extent actual expenditures differ from the estimated dollar amounts approved by CMS under a State's proposal, and whether Federal funds are at risk for impermissible or inappropriate payments.

We concur with the oversight bodies that it is important that we gain more information and insight into actual SDP spending to help us fulfill our oversight and monitoring obligations. We proposed two approaches, one near term and one longer term, for collecting both aggregate and provider-level information. The first proposal would use existing MLR reporting as a vehicle to collect actual expenditure data associated with SDPs. Specifically, in § 438.8(k), we proposed to require that managed care plans include SDPs and associated revenue as separate lines in their MLR reports to States; specifically, the amount of payments to providers made under SDPs that direct the managed care plan's expenditures as specified in § 438.6(c) and the payments from the State to the managed care plans for expenditures related to these SDPs. In turn, we proposed to require that managed care plan-level SDP expenditure reporting be explicitly reflected in States' annual summary MLR reporting to CMS, as required under § 438.74.

We believe these proposals and our responses to comments should be discussed in the context of the other proposed SDP reporting requirements to support oversight (see section I.B.2.o. of this final rule for comments and our proposed revisions to §§ 438.8(e)(2)(iii)(C) and (f)(2)(vii), 457.1203(e), 438.8(k)(1)(xiv) through (xvi), 438.74(a)(3) through (4)).

4. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.7, 438.16, 438.66, 457.1201 and 457.1207)

a. Overview of ILOS Requirements (§§ 438.2, 438.3(e), 438.16, 457.10, 457.1201(c) and 457.1201(e))

In the 2016 final rule, we finalized § 438.3(e) for Medicaid, which was included in separate CHIP regulations through cross-reference at § 457.1201(e), and specified in § 438.3(e)(2) that managed care plans have flexibility under risk contracts to provide a substitute service or setting for a service or setting covered under the State plan, when medically appropriate and cost effective, to enrollees at the managed care plan and enrollee option (81 FR 27538 and 27539). A substitute service or setting provided in lieu of a covered State plan service or setting under these parameters is known as an ''in lieu of service or setting'' (ILOS). In the 2015 proposed rule, we stated that, under risk contracts, managed care plans have historically had the flexibility to offer an ILOS that meets an enrollee's needs (80 FR 31116). Within the 2016 final rule, we clarified that this ILOS authority continues to exist for States and managed care plans, subject to § 438.3(e)(2). We believe ILOS authority is inherent in a risk contract in accordance with section 1903(m)(2)(A) of the Act which addresses risk-based capitation payments, which are defined in § 438.2. Additionally, we rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid for PIHPs and PAHPs. ILOSs are incorporated into the applicable States' contracts with its managed care plans and associated capitation rates and are subject to CMS review and approval in accordance with § 438.3(a) and § 438.7(a) respectively, and CMS will not approve contracts in accordance with § 438.3(a) that include an ILOSs that does not meet standards in regulatory requirements.

ILOSs are utilized by States and their managed care plans to strengthen access to, and availability of, covered services and settings, or reduce or prevent the need for covered services and settings. As outlined in the guidance issued on January 7, 2021,[192] January 4, 2023,[193] and November 16, 2023 [194] respectively, ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOH and HRSNs. The use of ILOSs can also improve population health, reduce health inequities, and lower overall health care costs in Medicaid and CHIP. We further believe that ILOSs can be used, at the option of the managed care plan and the enrollee, as immediate or longer-term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the State plan-covered services and settings. The investments and interventions implemented through ILOSs may also offset potential future acute and institutional care, and improve quality, health outcomes, and enrollee experience. For example, offering medically tailored meals (less than 3 meals per day) as an ILOS may improve health outcomes and facilitate greater access to HCBS, thereby preventing or delaying enrollees' need for nursing facility care. We encouraged managed care plans to leverage existing State and community level resources, including through contracting with community-based organizations and other providers that are already providing such services and settings and that have expertise working with Medicaid and CHIP enrollees. We believe there is a great deal of State and managed care plan interest in utilizing ILOSs to help address many of the unmet physical, behavioral, developmental, long-term care, and other needs of Medicaid and CHIP enrollees. We expected that States' and managed care plans' use of ILOSs, as well as associated Federal expenditures for these services and settings, will continue to increase. We acknowledged that ILOSs can offer many benefits for enrollees, but we also believe it is necessary to ensure adequate assessment of these substitute services and settings prior to approval, and ongoing monitoring for appropriate utilization of ILOSs and beneficiary protections. Additionally, we believe there must be appropriate fiscal protections and accountability of expenditures on these ILOSs which are alternative services and settings not covered in the State plan. Therefore, we proposed to revise the regulatory

amount of the payment into the rate certification's rate cells consistent with the distribution methodology included in the approved State directed payment preprint, as if the payment information had been known when the rates were initially developed; and (2) submit a rate amendment to CMS if the total amount of the payment or distribution methodology is changed from the initial rate certification.

[191] *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

[192] *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

[193] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.*

[194] *https://www.medicaid.gov/sites/default/files/2023-11/cib11162023.pdf.*

requirements for ILOSs to specify the nature of the ILOSs that can be offered and ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs.

To ensure clarity on the use of the term ''in lieu of service or setting'' and the associated acronym ''ILOS,'' we proposed to add a definition in § 438.2 for Medicaid to define an ''in lieu of service or setting (ILOS)'' as a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2) and acknowledge that an ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize State plan-covered service or setting. For separate CHIP, we proposed to align by adding ''In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter'' to the definitions at § 457.10. Given this proposed definition and associated acronym, we also proposed several conforming changes in § 438.3(e)(2). We proposed to revise § 438.3(e)(2) to remove ''services or settings that are in lieu of services or settings covered under the State plan'' and replace it with ''an ILOS.'' We proposed to revise § 438.3(e)(2)(i) and (ii) to remove ''alternative service or setting'' and replace it with ''ILOS.'' In § 438.3(e)(2)(iii), we proposed to remove ''in lieu of services'' and replace it with ''ILOS is,'' and remove the ''and'' at the end of this requirement given new requirements that will be proposed. We proposed to revise § 438.3(e)(2)(iv) to remove ''in lieu of services are'' and replace it with ''the ILOS is,'' and add the term ''and settings'' after ''covered State plan covered services'' to accurately reflect that ILOSs are substitute services and settings for State plan services and settings. Additionally, we added an ''and'' at the end of this requirement given a new proposed addition of § 438.3(e)(2)(v) that is described later in this section of this final rule. The proposed changes at § 438.3(e) are equally applicable to separate CHIP managed care plan contract requirements through the existing cross-reference at § 457.1201(e).

Because we made numerous proposals related to ILOSs, we believe adding a cross reference in § 438.3(e)(2)(v) to a new section will make it easier for readers to locate all of the provisions in one place and the designation flexibility of a new section will enable us to better organize the provisions for readability. To do this, we proposed to create a new § 438.16 titled *ILOS requirements* for Medicaid, and we proposed to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP. Our proposals in § 438.16 were based on several key principles, described in further detail in sections I.B.4.b. through I.B.4.h. of this final rule. These principles include that ILOSs would: (1) meet general parameters; (2) be provided in a manner that preserves enrollee rights and protections; (3) be medically appropriate and cost effective substitutes for State plan services and settings, (4) be subject to monitoring and oversight; and (5) undergo a retrospective evaluation, when applicable. We also proposed parameters and limitations for ILOSs, including our proposed requirements for ILOSs to be appropriately documented in managed care plan contracts and considered in the development of capitation rates, and our proposed risk-based approach for State documentation and evaluation requirements of any managed care plan contracts that include ILOSs. We proposed to continue our review of ILOSs as part of our review of the States' managed care plan contracts in accordance with § 438.3(a), and associated capitation rates in accordance with § 438.7(a). CMS has the authority in § 438.3(a) to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated Medicaid managed care plan contracts and capitation rates.

We acknowledged that one of the most commonly utilized ILOSs is inpatient mental health or substance use disorder treatment provided during a short term stay (no more than 15 days during the period of the monthly capitation payment) in an IMD. Due to the statutory limitation on coverage of services provided in an IMD in accordance with language in section 1905(a) of the Act following section 1905(a)(30) of the Act, our ability to permit States to make a monthly Medicaid capitation payment for an enrollee who receives services in an IMD is limited as outlined in § 438.6(e), and uniquely based on the nature of risk-based payment (see 80 FR 31116 for further details on this policy). Other than as an ILOS, in accordance with §§ 438.3(e)(2) and 438.6(e), FFP is not available for any medical assistance under Title XIX for services provided to an individual, ages 21 to 64, who is a patient in an IMD facility. We proposed no changes regarding the coverage of short term stays in an IMD as an ILOS, or payments to MCOs and PIHPs for enrollees who are a patient in an IMD in § 438.6(e) (see 81 FR 27555 through 27563 for further details on the existing policy). In acknowledgement of the unique parameters necessary for coverage of services provided in IMDs as an ILOS, given the statutory limitations, we did not believe § 438.16 should apply to a short term IMD stay as an ILOS. For example, a short term stay in an IMD as an ILOS was excluded from the calculation for an ILOS cost percentage, described in further detail in section I.B.4.b. of this final rule, as the costs of a short term IMD stay must not be used in rate development given the statutory limitation, and instead States must use the unit costs of providers delivering the same services included in the State plan as required in § 438.6(e). Additionally, as described in § 438.6(e), States may only make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21 to 64 receiving inpatient treatment in an IMD when the length of stay in an IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. Therefore, we proposed to add § 438.3(e)(2)(v) to explicitly provide an exception from the applicability of § 438.16 for short term stays, as specified in § 438.6(e), for inpatient mental health or substance use disorder treatment in an IMD. This proposal did not replace or alter existing Federal requirements and limitations regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for enrollees who utilize an IMD.

We did not propose to adopt the IMD exclusion for separate CHIP since there are no similar payment restrictions for stays in an IMD in separate CHIP. As long as a child is not applying for or renewing their separate CHIP coverage while a resident of an IMD, the child remains eligible for separate CHIP and any covered State plan services or ILOSs while in an IMD consistent with the requirements of § 457.310(c)(2)(ii). For this reason, we proposed to amend § 457.1201(e) to exclude references to IMDs in the cross-reference to § 438.3(e).

States and managed care plans continue to be obligated to comply with other applicable Federal requirements for all ILOS, including short term IMD stays. This includes, but is not limited to, those requirements outlined in §§ 438.3(e)(2), 438.6(e), and 438.66. As required in § 438.66(a) through (c),

States must establish a system to monitor performance of their managed care programs. When ILOSs are included in a managed care plan's contract, they too must be part of the State's monitoring activities. As part of such monitoring, States must ensure that all ILOSs, including short term stays in an IMD, are medically appropriate, cost effective, and at the option of the enrollee and managed care plan.

We summarize and respond to public comments received in this section on ILOSs (§§ 438.2, 438.3(e), 457.10, 457.1201(c) and (e)) below.

Comment: Many commenters offered widespread support for our proposed ILOS policies as they believe the proposed policy direction and the flexibility to offer expanded ILOSs supported States and managed care plans in their efforts to strengthen access to care, improve enrollee's health care outcomes, and lower overall health care costs in Medicaid and CHIP. Many commenters also supported the proposed definition of an ILOS and stated that this definition appropriately accounted for immediate or longer-term substitutes for a covered service or setting under the State plan, noting that it supports efforts to address enrollees' physical, behavioral, and health-related social needs, improve population health, and advance health equity.

Response: We appreciate the support for the proposed ILOS policies, including the proposed definition of an ILOS. Our goal is to strike the right balance to place appropriate guardrails on the use of ILOSs, to establish clarity and transparency on the use of ILOSs, ensure ILOSs advance the objectives of the Medicaid program, are an appropriate and efficient use of Medicaid and CHIP resources, and are in the best interests of Medicaid and CHIP enrollees while also incentivizing States and plans to use them to improve health outcomes and reduce health care costs.

Comment: Some commenters raised concerns that the additional guardrails and reporting requirements could increase State and plan burden and disincentivize them from expanding ILOSs. A few of these commenters recommended that CMS not finalize the proposed provisions, but rather focus additional oversight only on more novel or non-traditional ILOSs and allow approved ILOSs to continue without additional guardrails.

A few commenters requested additional protections for FQHCs to ensure that ILOSs could not be substituted for FQHC benefits, thereby causing a reduction in an FQHC's prospective payment system (PPS) or alternative payment methodology (APM) or otherwise reduce payment by other means such as restricting the definition of a billable encounter. Other commenters raised concerns that this definition could stifle managed care plans' ability to innovate and provide timely, person-centered, medically appropriate, and cost effective substitutes. One commenter raised concerns that the definition may require that the ILOS would need to be an immediate ''offset'' or substitute that reduces or prevents the use of the State plan-covered service or setting and recommended that CMS permit States and managed care plans additional latitude to expand ILOS coverage without a corresponding immediate offset in benefits elsewhere, such as if the plan demonstrates through documented experience or credible academic or other studies, a reasonable expectation that the ILOS will decrease cost and improve outcomes over time.

Response: While we recognize that defining an ILOS will add guardrails, we believe that finalizing a definition of ILOS is vital to ensuring clarity and transparency on the use of ILOSs to ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs. We also believe a definition will assist States in their efforts to determine that each ILOS is a medically appropriate and cost effective substitute for a covered service or setting under the State plan. The ILOS definition finalized in this rule provides flexibility to enable States to consider a longer-term substitute or when the ILOS is expected to reduce or prevent the future need for the State plan service or setting; therefore, an immediate offset or reduction in the State plan-covered service or setting would not always be necessary for a State to consider an ILOS to be medically appropriate and cost effective. We believe that the documentation of previous experience or credible academic studies could potentially be reasonable documentation for a State to consider as it makes its determination. We also do not believe specific protections are needed for FQHCs as the PPS rates are established in accordance with section 1902(bb) of the Act and approved in the State plan while ILOSs are substitutes for State plan-covered services and settings that are offered at the option of managed care plans and utilized by enrollees at their option. This inherent flexibility and unpredictability in the use of ILOSs is not a factor in the PPS rates approved in the State plan.

Comment: Some commenters requested clarification on what types of services or settings would qualify under the definition of an ILOS. Another commenter requested clarification on whether States would be permitted to offer multiple ILOSs as substitutes for the same State-plan covered service or setting.

Response: We provided several examples of possible ILOSs in the proposed rule, including sobering centers, housing transition navigation services, and medically tailored meals (less than 3 meals per day) (88 FR 28167). Other potential examples could include respite services, asthma remediation, environmental accessibility adaptations (that is, home modifications), and day habilitation programs. Each ILOS must be determined by the State to be a medically appropriate and cost effective substitute for a covered service or setting under the State plan and comply with all applicable Federal requirements. We also direct commenters to section I.B.4.b. of this final rule which has related comments regarding our proposal in § 438.16(b) (cross-referenced at § 457.1201(e) for separate CHIP) that an ILOS be approvable in the State plan or waiver under section 1915(c) of the Act. We also acknowledge that it would be permissible for multiple ILOSs to be substitutes for the same State-plan covered service or setting so long as each ILOS is determined by the State to be a medically appropriate and cost effective substitute for a covered service or setting under the State plan for an appropriate target population.

Comment: One commenter recommended that CMS revise § 438.3(e)(2)(i) to define specific parameters around the scope, duration, and intensity of quality for ILOSs.

Response: We agree with the commenter that as States determine whether an ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan, the scope and duration of an ILOS is a factor States may consider. We also direct commenters to section I.B.4.d. of this final rule where we indicated that States could consider using additional criteria for ILOSs, such as including a limit on the amount of an ILOS to ensure it is medically appropriate and cost effective. We are unclear what the commenter was referring to when they referred to ''intensity of quality.'' Generally, we agree that as States determine the medically appropriateness of an ILOS

that they consider whether an ILOS will improve quality of care and health outcomes. We decline to revise § 438.3(e)(2)(i) to define these specific terms as we believe States should have flexibility to make these determinations as they determine the ILOSs that are medically appropriate and cost effective substitutes for State plan-covered services and settings that best meet enrollees' needs and the target populations for ILOSs. ILOSs will also vary by managed care program given the differing populations and benefits offered, and the fact they are provided at plans' options. As such, we do not believe it is currently reasonable or appropriate for CMS to provide specific definitions for these terms to apply to all ILOSs.

Comment: Several commenters supported the proposed exclusion of inpatient mental health or substance use disorder treatment provided during a short term stay (no more than 15 days during the period of the monthly capitation payment) in an IMD from the proposed requirements in § 438.16. Commenters noted that this policy would lessen barriers for States to provide IMD coverage for those in need of these services, and in doing so, increase access to critical behavioral health care.

Response: We continue to believe, particularly with the support of commenters, that the exception of a short term stay in an IMD for inpatient mental health or substance use disorder treatment from the proposed requirements in § 438.16 is appropriate. As a reminder, this exclusion does not replace or alter existing Federal requirements and limitations regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for enrollees who utilize an IMD as outlined in §§ 438.3(e)(2) and 438.6(e) respectively.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.2, 438.3(e), 457.10 and 457.1201(c) and (e) as proposed with minor modifications to §§ 438.3(e)(2), (e)(2)(ii) and (e)(2)(iii) to add a comma between ''PIHP'' and ''or PAHP'' for consistency with current regulatory text.

b. ILOS General Parameters (§§ 438.16(a) Through (d), 457.1201(c), and (e), and 457.1203(b))

We believe ILOSs can give States and managed care plans opportunities to strengthen access to care, address unmet needs of Medicaid and CHIP enrollees, and improve the health of Medicaid and CHIP beneficiaries. However, we believe it is necessary to implement appropriate Federal protections to ensure the effective and efficient use of Medicaid and CHIP resources, particularly since these services and settings are not State plan-covered services and settings furnished under managed care plan contracts, and we rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively. Therefore, to ensure States and managed care plans utilize ILOSs effectively and in a manner that best meets the needs of the enrollees, as well as that related Federal expenditures are reasonable and appropriate, we proposed several key requirements in § 438.16.

We believe that a limitation on the types of substitute services or settings that could be offered as an ILOS was a key protection to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources, and we believe this is a reasonable method to ensure proper and effective operations in Medicaid and CHIP in accordance with authority in sections 1902(a)(4) and 2101(a) of the Act, respectively. We believe that the services and settings that could be provided as an ILOS should be consistent with the services and settings that could be authorized under the Medicaid or CHIP State plan or a program authorized through a waiver under section 1915(c) of the Act. As further described in section I.B.4.a. of this final rule, we believe the only Medicaid exception should be a short term stay in an IMD for the provision of inpatient mental health or substance use disorder treatment, which already has appropriate safeguards per requirements outlined in § 438.6(e). Therefore, we proposed to require in § 438.16(b) that an ILOS must be approvable as a service or setting through a State plan amendment, including sections 1905(a), 1915(i), or 1915(k) of the Act, or a waiver under section 1915(c) of the Act. For example, personal care homemaker services are approvable as a covered service in a waiver under section 1915(c) of the Act, and would be an approvable ILOS if the State determines it is a medically appropriate and cost effective substitute for a service or setting covered under the State plan.

For separate CHIP, we similarly proposed that ILOSs must be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act, as well as the services and settings identified in § 438.16(b). For this reason, we proposed to adopt the requirements proposed at § 438.16(b) by amending § 457.1201(e) to include a new cross-reference to § 438.16(b). We also reminded States that the use of an ILOS does not absolve States and managed care plans of their responsibility to comply with other Federal requirements. States must ensure that contracts with managed care plans comply with all applicable Federal and State laws and regulations in accordance with §§ 438.3(f) and 457.1201(f). For example, with the exception of short term IMD stays as described in section I.B.4.a. of this final rule, ILOSs must adhere to general prohibitions on payment for room and board under Title XIX of the Act. Additionally, States and managed care plans must ensure access to emergency services in accordance with the Emergency Medical Treatment and Labor Act and compliance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act. Moreover, consistent with § 438.208(c)(3), States must comply with person-centered planning requirements as applicable.

Because ILOSs are provided as substitutes for State plan-covered services and settings, we believe that we have an obligation to ensure appropriate fiscal protections for Medicaid and CHIP investments in ILOSs, and that there should be a limit on the amount of expenditures for ILOSs to increase accountability, reduce inequities in the services and settings available to beneficiaries across managed care and FFS delivery systems, and ensure enrollees receive State plan-covered services and settings. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid and section 2101(a) of the Act for establishing efficient and effective health assistance in CHIP. To determine a reasonable limit on expenditures for ILOSs, we proposed to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOS(s), hereinafter referred to as an ILOS cost percentage. States claim FFP for the capitation payments they make to managed care plans. Capitation payments are based on the actuarially sound capitation rates as defined in § 438.2, for Medicaid, and rates are developed with ''actuarially sound principles'' as required for separate CHIP at § 457.1203(a). The utilization and cost associated with ILOSs are accounted for in the development of Medicaid and separate CHIP capitation rates in accordance with §§ 438.3(e)(2)(iv) and 457.1201(e) respectively. Therefore, we proposed in § 438.16(c), that the ILOS cost

percentage must be calculated based on capitation rates and capitation payments as outlined in further detail in this section. In section I.B.2.l. of the proposed rule, we proposed requirements for State directed payments as a separate payment term, and proposed these costs should be accounted for in the denominator of the ILOS cost percentage as these are payments made by the State to the managed care plans. The reporting requirements in this proposal are authorized by sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

Given that actuarially sound capitation rates are developed prospectively based on historical utilization and cost experience, as further defined in § 438.5, we believe that an ILOS cost percentage and associated expenditure limit should be measured both on a projected basis when capitation rates are developed and on a final basis after capitation payments are made by States to the managed care plans. Therefore, we proposed to define both a ''projected ILOS cost percentage'' and ''final ILOS cost percentage'' in § 438.16(a) as the amounts for each managed care program that includes ILOS(s) using the calculations proposed in § 438.16(c)(2) and (3), respectively. Additional details on these percentages are provided later in this section. We also believe the projected ILOS cost percentage and final ILOS cost percentage should be measured distinctly for each managed care program as capitation rates are typically developed by program, ILOSs available may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We addressed managed care program variability within the 2016 final rule when we noted that ''This clarification in the regulatory text to reference ''managed care program'' in the regulatory text is to recognize that States may have more than one Medicaid managed care program—for example physical health and behavioral health . . .'' (81 FR 27571). Therefore, we did not believe it will be consistent with our intent to develop an ILOS cost percentage by aggregating data from more than one managed care program since that will be inconsistent with rate development, the unique elements of separate managed care programs, and the ILOSs elements (target populations, allowable provider types, etc.) that vary by managed care program. Developing the ILOS cost percentage by managed care program will further ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe 5 percent is a reasonable limit on ILOS expenditures because it is high enough to ensure that ILOSs will be used effectively to achieve their intended purpose, but still low enough to ensure appropriate fiscal safeguards. This proposed 5 percent limit would be similar to incentive arrangements at § 438.6(b), which limits total payment under contracts with incentive arrangements to 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. In § 438.6(b)(2), we note that total payments in excess of 105 percent will not be actuarially sound. We believe this existing limitation for incentive arrangements allows States to design and motivate quality and outcome-based initiatives while also maintaining fiscal integrity. We believe a similar threshold was necessary and appropriate for ILOSs. Therefore, we proposed, at § 438.16(c)(1)(i), to require that the projected ILOS cost percentage could not exceed 5 percent and the final ILOS cost percentage could not exceed 5 percent.

For separate CHIP, we require States at § 457.1203(a) to develop capitation rates consistent with actuarially sound principles, but at § 457.1203(b) we allow for States to establish higher capitation rates if necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. While we do not impose a similar limit for incentive arrangements in separate CHIP capitation rates as we do for Medicaid capitation rates, we wish to align with Medicaid in limiting projected and final ILOS cost percentages to 5 percent of capitation payments for separate CHIPs. For this reason, we proposed to amend § 457.1203(b) to adopt 5 percent ILOS cost percentage limits by amending § 457.1201(c) to include a new cross-reference to § 438.16(c)(1).

We also proposed, in § 438.16(c)(1)(ii), that the State's actuary will have to calculate the projected ILOS cost percentage and final ILOS cost percentage on an annual basis and recalculate these projections annually to ensure consistent application across all States and managed care programs. Furthermore, to ensure that the projected ILOS cost percentage and final ILOS cost percentage would be developed in a consistent manner with how the associated ILOS costs would be included in rate development, we proposed at § 438.16(c)(1)(iii) to require that the projected ILOS cost percentage and the final ILOS cost percentage would be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An ''actuary'' is defined in § 438.2 as an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates. Therefore, we believe that the actuary that will certify the projected and final ILOS cost percentages should be the same actuary that developed and certified the capitation rates that included ILOS(s). For separate CHIP, we do not require actuarial certification of capitation rates and are not adopting the requirement at § 438(c)(1)(iii). We proposed to amend § 457.1201(c) to exclude requirements for certification by an actuary. However, we reminded States that separate CHIP rates must be developed using ''actuarially sound principles'' in accordance with § 457.1203(a).

We proposed at § 438.16(c)(2), that the projected ILOS cost percentage would be calculated by dividing the portion of the total capitation payments that are attributable to all ILOSs, excluding short term stays in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the projected total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the projected total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We also proposed, at § 438.16(c)(3), that the final ILOS cost percentage would be calculated by dividing the portion of the total capitation payments that are attributable

to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the actual total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We believe these proposed numerators and denominators for the projected and final ILOS cost percentages would be an accurate measurement of the projected and final expenditures associated with ILOSs and total program costs in each managed care program in a risk-based contract. For separate CHIP, we proposed to align with the projected and final ILOS cost percentage calculations by amending § 457.1201(c) to include cross-references to § 438.16(c)(2) through (3). However, since pass-through payments and State directed payments are not applicable to separate CHIP, we proposed to exclude all references to pass-through payments and State directed payments at § 457.1201(c).

We considered proposing that the actual expenditures of the managed care plans for ILOSs and total managed care program costs, tied to actual paid amounts in encounter data, be the numerator and denominator for the final ILOS cost percentage. However, we determined this was inconsistent with how States claim FFP for capitation payments in a risk contract (based on the actuarially sound capitation rates as defined in § 438.2 for each managed care program, rather than on the actual plan costs for delivering ILOSs based on claims and encounter data submitted). Consistent with all services and settings covered under the terms of the managed care plans' contracts, we acknowledged that the actual plan experience would inform prospective rate development in the future, but it was an inconsistent measure for limiting ILOS expenditures associated with FFP retroactively. We believe expenditures for short term stays in an IMD should be excluded from the numerator of these calculations as they are excluded from the proposed requirements outlined in § 438.16. We also believe the denominator of these calculations should include all State directed payments and pass-through payments that are included into capitation rates as outlined in § 438.6(c) and (a) respectively. It is necessary to include these State directed payments and pass-through payments to ensure that the projected and final expenditures would accurately reflect total capitation payments.

We believe the projected ILOS cost percentage should be included in the rate certification for each managed care program that includes ILOS(s) and any subsequent revised rate certification (for example, rate amendment) as applicable, such as those that change the ILOSs offered, capitation rates, pass-through payments and/or State directed payments. As previously described in this section, we initially proposed at § 438.16(c)(1)(iii) that the actuary who certifies the projected ILOS cost percentage should be the same actuary who develops and certifies the associated Medicaid capitation rates and the State directed payments paid as a separate payment term (see section I.B.2.l. of the proposed rule for details on this proposal for separate payment terms). We also believe that including this percentage within the rate certification would reduce administrative burden for States and actuaries while also ensuring consistency between how this percentage would be calculated and how ILOS costs would be accounted for in rate development. Therefore, we proposed to require, at § 438.16(c)(5)(i), that States annually submit to CMS for review the projected ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a). For separate CHIP, we do not require actuarial certification of capitation rates or review by CMS, and for this reason we do not adopt the new requirement proposed at § 438.16(c)(5)(i) for separate CHIP.

Under the proposed rule, the proposed denominator for the final ILOS cost percentage, in § 438.16(c)(3)(i), would have been based on the actual total capitation payments and the State directed payments paid as a separate payment term (see section I.B.2.l. of the proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans. We recognized in the proposed rule that calculating the final ILOS cost percentage under this scenario would take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final capitation payments that are a component of the calculation. We also believe documentation of the final ILOS cost percentage is a vital component of our monitoring and oversight as it will ensure that the expenditures for ILOSs comply with the proposed 5 percent limit; and therefore, must be submitted timely. Given these factors, we believe that 2 years is an adequate amount of time to accurately perform the calculation. Therefore, we proposed, at § 438.16(c)(5)(ii), to require that States must submit the final ILOS cost percentage report to CMS with the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s). Under this proposal, for example, the final ILOS cost percentage report for a managed care program that uses a CY 2024 rating period will be submitted to CMS with the CY 2027 rate certification. For separate CHIP, we do not require review of capitation rates by CMS and did not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We considered requiring the final ILOS cost percentage be submitted to CMS within 1 year after the completion of the rating period that included ILOS(s) to receive this data in a timelier fashion. However, we were concerned this may not be adequate time for States and actuaries given the multitude of factors described previously in this section. We requested comment on whether our assumption that 1 year is inadequate is correct.

We also believe that it was appropriate for States' actuaries to develop a separate report to document the final ILOS cost percentage, rather than including it in a rate certification, because the final ILOS cost percentage may require alternate data compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). However, this final ILOS cost percentage could provide details that should inform prospective rate development, such as through an adjustment outlined in § 438.5(b)(4), so we believe it should be submitted along with the rate certification. We note that this proposal is similar to the concurrent submission necessary for the MLR reporting at § 438.74. We considered proposing that States submit this report separately to CMS upon completion. However, we believe there should be consistency across States for when this report is submitted to CMS for review, and we believe receiving this report and the rate certification at the same time will enable CMS to review them concurrently. For these reasons, we proposed, at § 438.16(c)(5)(ii), to require that States submit the final ILOS cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a). We intend to issue additional guidance on the standards and documentation requirements for this

report. For separate CHIP, we do not require review of capitation rates by CMS and did not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We believe there must be appropriate transparency on the managed care plan costs associated with delivering ILOSs to aid State oversight and monitoring of ILOSs, and to ensure proper and effective operations in Medicaid in accordance with authority in section 1902(a)(4) of the Act. Therefore, we proposed, in § 438.16(c)(4), that States provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to States. We also believe this summary report should be developed concurrently and consistently with the final ILOS cost percentage to ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe this summary report should be developed for each managed care program consistent with the rationale described in section I.B.4.b. of this final rule for developing the ILOS cost percentage for each managed care program. Therefore, in § 438.16(a), we proposed to define a ''summary report for actual MCO, PIHP, and PAHP ILOS costs'' and proposed that this summary report be calculated for each managed care program that includes ILOSs. We also proposed in § 438.16(c)(1)(ii) that this summary report be calculated on an annual basis and recalculated annually. We proposed in § 438.16(c)(1)(iii) that this summary report be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. Finally, we proposed in § 438.16(c)(5)(ii) that this summary report be submitted to CMS for review within the actuarial report that includes the final ILOS cost percentage. For separate CHIP, we do not require similar actuarial reports and did not propose to adopt the annual ILOS cost report requirements by excluding references to them at § 457.1201(c).

To balance States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs, we believe it will be appropriate to use a risk-based approach for States' documentation and evaluation requirements. This proposed reporting requirement is authorized by sections 1902(a)(6) and 2107(b)(1) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Therefore, we proposed that the ILOS documentation States would submit to CMS, as well as an evaluation States would complete, would vary based on a State's projected ILOS cost percentage for each managed care program. We believe the projected ILOS cost percentage would be a reasonable proxy for identifying States that offer a higher amount of ILOSs, in comparison to overall managed care program costs, and likely could have a corresponding higher impact to Federal expenditures. As we considered the types of State activities and documentation that could vary under this proposed risk-based approach, we considered which ones would be critical for all States to undertake for implementation and continual oversight of the use of ILOSs, but would not require our review unless issues arose that warranted additional scrutiny. We proposed that documentation requirements for States with a projected ILOS cost percentage that is less than or equal to 1.5 percent would undergo a streamlined review, while States with a higher projected ILOS cost percentage would have more robust documentation requirements. Additionally, we proposed States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS. These parameters are noted further in sections I.B.4.d. and I.B.4.g. of this final rule.

As we considered a reasonable percentage for this risk-based approach, we evaluated flexibilities currently offered in part 438 to assess if similar thresholds would be reasonable for this purpose. These flexibilities included the opportunity available to States to adjust rates without the requirement for a revised rate certification. Specifically, we are referring to the 1 percent flexibility for States that certify rate ranges in accordance with § 438.4(c)(2)(iii) and the 1.5 percent flexibility for States that certify capitation rates in accordance with § 438.7(c)(3). An additional flexibility currently available to States relates to incentive arrangements. In accordance with § 438.6(b)(2), total payment under States' managed care plan contracts with incentive arrangements are allowed to be no greater than 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. As we evaluated a reasonable and appropriate threshold to utilize for this risk-based approach, we explored utilizing similar flexibilities of 1 percent, 1.5 percent and 5 percent, and also considered 2.5 percent as a mid-point in this 5 percent range.

We did not believe 5 percent was a reasonable percentage for this risk-based approach as this is the proposed limit for the projected and final ILOS cost percentages described in this section. We believe a greater degree of State documentation, and CMS oversight, was necessary for States that offer ILOSs representing a higher share of overall managed care program costs, and likely have a corresponding higher impact on Federal expenditures. In the 2020 final rule, we finalized § 438.4(c)(2)(iii) to permit States that certify rate ranges to make rate adjustments up to 1 percent without submitting a revised rate certification. Our rationale was that States using rate ranges were already afforded additional flexibility given the certification of rate ranges, so it was not appropriate to utilize the same 1.5 percent flexibility that is offered to States that certify capitation rates (85 FR 72763). We did not believe a similar rationale is appropriate or relevant for this proposal, and thus, we did not believe 1 percent would be the most appropriate threshold. We are also concerned that utilizing 2.5 percent for a risk-based approach would result in inadequate Federal oversight to ensure program integrity, such as fiscal safeguards and enrollee protections related to ILOSs. We believe 1.5 percent, a *de minimis* amount, was appropriate to propose for utilization of a risk-based approach for States' documentation and evaluation requirements, and associated CMS review, as ILOS expenditures less than or equal to 1.5 percent would likely be a relatively minor portion of overall managed care program expenditures. Therefore, we proposed 1.5 percent for this risk-based approach in § 438.16(d)(2); States with a projected ILOS cost percentage that exceeds 1.5 percent would be required to adhere to additional requirements described in sections I.B.4.d. and I.B.4.g. of this final rule. For separate CHIP, we proposed to adopt the new documentation requirements for States with a cost percentage that exceeds 1.5 percent at § 438.16(d)(2) by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(2).

We summarize and respond to public comments received in this section on ILOSs (§§ 438.16(a) through (d), 457.1201(c) and (e), and 457.1203(b)) below.

Comment: Commenters generally supported the proposal that an ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i) or 1915(k) of the Act, as they believe it would implement ILOS guardrails and provide leeway under the proposed definition to include services

and supports to support SDOH and HRSN efforts.

Response: We appreciate comments in support of our proposal as we believe that ILOSs must be an appropriate and efficient use of Medicaid and CHIP resources and advance the objectives of these programs. We believe the proposal for an ILOS to be an approvable service or setting under the State plan or waiver under section 1915(c) of the Act will ensure an appropriate guardrail to meet these two aims.

Comment: Many commenters suggested revisions to the proposal that an ILOS must be approvable through another Medicaid authority or waiver. One commenter recommended revising § 438.16(b) to include services and settings approvable under Money Follows the Person while another commenter recommended using a similar set of eligibility criteria for Special Supplemental Benefits for the Chronically Ill (SSBCI) offered by Medicare Advantage plans. Some commenters stated that there should be no restriction on the types of services or settings that could be approved as an ILOS while another recommended creating an exception process for States that wanted to deviate from § 438.16(b). Another commenter recommended allowing room and board that is generally not allowed in Title XIX of the Act. Other commenters opposed this proposal and indicated it was too narrow, could limit States' use of ILOSs and chill innovation with one of these commenters indicating that any service or setting authorized in a demonstration under section 1115 of the Act should be allowable as an ILOS.

Response: We do not believe it is appropriate to include services and settings that are approvable in Money Follows the Person as it is a demonstration program with unique funding and eligibility criteria. SSBCI is a supplemental benefit option in Medicare Advantage specifically for the certain chronically ill SSBCI-eligible plan enrollees, so we do not believe it is relevant for ILOS policy as ILOSs are not limited to a target population of the chronically ill nor a supplemental benefit. We also do not believe authority under section 1115 of the Act is an adequate rationale to expand the scope of allowable ILOSs as this authority is utilized to approve experimental, pilot or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program, and this unique authority is separate and distinct from other traditional Medicaid authorities such as the State plan. We further believe that ensuring ILOSs comply with applicable Federal requirements, such as the general prohibitions on payment for room and board under Title XIX of the Act, is necessary and appropriate (see section I.B.4.a. of this final rule for further details on short-term IMD stays for inpatient mental health or substance use disorder treatment). ILOSs are not to be used as a mechanism to evade compliance with Federal statute and regulations. Therefore, we decline to adopt any of these suggestions in the finalized definition.

We recognize that requiring an ILOS to be approvable as a service or setting under the State plan or waiver under section 1915(c) of the Act will place restrictions on allowable ILOSs, but we believe the proposal strikes the right balance to encourage innovation while ensuring appropriate use of Medicaid and CHIP resources. We do not believe it is appropriate to consider an exception process for existing ILOSs that do not meet the proposed definition in § 438.3(b) as this would create inequity in the use of ILOSs and fail to ensure compliance with proposed Federal requirements, and we decline to revise the proposal to adopt such a process. We also remind managed care plans that if a service or setting they wish to provide does not meet ILOS requirements, the plans may always choose to voluntarily provide additional services in accordance with § 438.3(e)(1) although the cost of these services cannot be included when determining payment rates under § 438.3(c).

Comment: One commenter requested clarification on whether a service or setting must be approved in a State's Medicaid or CHIP State plan or waiver under section 1915(c) of the Act to be allowed as an ILOS.

Response: As specified in § 438.16(b), an ILOS must be approvable as a service or setting under the State plan or waiver under section 1915(c) of the Act to be eligible as an ILOS; however, it does not need to be approved in the State plan or waiver. For example, yoga is not a service that is approvable in the Medicaid or CHIP State plan, and therefore, it would not be eligible to be an ILOS. Additionally, any limitations in the coverage of a service or setting in the State plan or waiver under section 1915(c) of the Act must also be adhered to if the service or setting is covered as an ILOS, such as the limitations on room and board including that meals must be less than 3 meals per day and other limitations on allowable housing supports.[195]

Comment: One commenter recommended that CMS require more uniformity on allowable ILOSs by providing States with a menu of approved ILOSs that they can choose to implement within their Medicaid programs, with the option for States to include other ILOSs at their discretion. The commenter noted they believe that this uniformity could make it easier to evaluate the effectiveness of each ILOS. Other commenters opposed the proposal in § 438.16(b) as they noted it required unnecessary uniformity and decreased innovation.

Response: As required in § 438.3(e)(2)(1), States are required to determine that an ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan, and States have flexibility in §§ 438.3(e) and 438.16 to identify the ILOSs that they believe best meet enrollees' needs and the target population for an ILOS. Appropriate ILOSs will also vary by managed care program given the differing populations and benefits offered. As such, we do not believe it is currently reasonable or appropriate for CMS to provide a menu of approved ILOSs.

Comment: Some commenters requested clarification on whether nutritional supports, services provided by community health workers, or services provided through telehealth are allowable ILOSs while another commenter recommended that chronic pain management not traditionally covered by Medicaid or CHIP be considered approvable as an ILOS. Another commenter requested clarification on whether transportation to underlying services being provided as an ILOS would also be considered as a component of the ILOS.

Response: We continue to believe it is not appropriate to cover services or settings as an ILOS that are not approvable through the State plan or waiver under section 1915(c) of the Act to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources. As such, States must assess whether an ILOS being considered for inclusion in a managed care plan's contract is approvable in Medicaid and CHIP to evaluate if it is eligible as an ILOS. Similarly, transportation in conjunction with another service that is an ILOS could potentially be allowable as a component of that ILOS only if this is an allowable component of a service or setting that is approvable under the

[195] On November 16, 2023, CMS published a CMCS Informational Bulletin on coverage of services and supports to address HRSN needs in Medicaid and CHIP that included a table on allowable HRSN coverage and associated limitations: *https://www.medicaid.gov/sites/default/files/2023-11/cib11162023.pdf.*

State plan or waiver under section 1915(c) of the Act.

Comment: Generally, there was support for the proposed calculation and documentation of projected and final ILOS cost percentages, including the exclusion of short-term IMD stays that are ILOSs, and the summary report of managed care plans' ILOS costs. Many commenters also indicated that the definitions for the ILOS cost percentages were reasonable and appropriate. There were no specific comments on our proposals that these cost percentages be certified by State actuaries and reviewed by CMS. Another commenter supported our proposal to allow 2 years for submission of the final ILOS cost percentage as reasonable and indicated that the alternative of 1 year would be insufficient time for States to finalize this calculation. Some commenters supported the proposed 5 percent limit for the projected ILOS cost percentage and final ILOS cost percentage at § 438.16(c)(1), and indicated it was an appropriate upper threshold for ILOS expenditures as a component of total capitation payments.

Response: We believe these proposals are appropriate fiscal protections for Medicaid and CHIP investments in ILOSs. We also appreciate the feedback we received on the proposal in § 438.16(c)(5)(ii) regarding the timing to submit the final ILOS cost percentage. As the comments confirmed our concern that 1 year would be insufficient time for States and actuaries to develop this final calculation, we are finalizing this provision without revision.

Comment: Some commenters suggested revisions to the proposed calculations and documentation for ILOS cost percentages. One commenter recommended that CMS allow States with smaller programs to calculate the ILOS cost percentage across programs or require integrated programs to calculate ILOS cost percentages by major service types such as physical health, behavioral health, or LTSS within the single program (with a higher threshold limit for the ILOS cost percentage to offset the narrower denominator). Another commenter stated concern that the proposed definitions for the projected ILOS cost percentage and the final ILOS cost percentage were complex although no detail was provided by the commenter and indicated that the ILOS cost percentage calculations would create a new State administrative burden. Another commenter questioned the need for the calculation of both a projected ILOS cost percentage and a final ILOS cost percentage as the numerator for these calculations is consistent and only the denominator varies. This commenter requested clarification on why the final ILOS cost percentage was necessary given the proposal in § 438.16(c)(4) for States to submit to CMS a summary report of the managed care plans' actual ILOS costs for delivering ILOSs based on the claims and encounter data.

Response: We acknowledge that the calculation of projected ILOS cost percentages and final ILOS cost percentages will be a new State administrative burden; however, we believe it is a necessary tool to ensure appropriate Federal oversight. We accounted for this burden in the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details).

We continue to believe that an ILOS cost percentage should be calculated for each managed care program. We do not believe it is appropriate for this to be an aggregate calculation across multiple programs or broken down by major service category. This calculation should occur distinctly for each managed care program as ILOSs available may vary by program, each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types, and capitation rates are typically developed by program.

We agree that the numerator for the projected ILOS cost percentage and final ILOS cost percentage are identical, and it is the denominator that varies. As capitation rates are developed prospectively based on historical utilization and cost experience, the denominator for the projected ILOS cost percentage can only capture the projected total capitation payments. Conversely, the denominator of the final ILOS cost percentage captures the actual total capitation payments paid by the State to the managed care plans. As States claim FFP on these capitation payments and not managed care plans' actual expenditures, we believe it is necessary and appropriate to ensure compliance with the 5 percent limit proposed in § 438.16(c)(1) for both percentages. We also note that the final ILOS cost percentage is developed based on capitation payments while the summary report captures managed care plans' actual costs for delivering ILOSs based on claims and encounter data; these two are distinct reporting requirements to acknowledge the nature of risk-based rate development and how FFP is claimed for managed care expenditures.

Comment: One commenter recommended that CMS provide guidance on how costs associated with third party administrative management of ILOSs would be factored into the ILOS cost percentage. Another commenter recommended that CMS help States invest in infrastructure to support ILOS administration.

Response: We do not believe it is appropriate to include costs associated with third party management, operational costs, or infrastructure of ILOSs within any portion of ILOS costs. That is, these expenditures should not be included in any part of the ILOS cost percentage, ILOS benefit or non-benefit component, or any portion of Medicaid managed care capitation rates. For example, an ILOS cost percentage is focused on the portion of the total capitation payments that is attributable to the provision of ILOSs. In accordance with § 438.5(e), the non-benefit component of capitation rates includes reasonable, appropriate, and attainable expenses including those related to the managed care plan's operational costs associated with the provision of services identified in the § 438.3(c)(1)(ii) to the populations covered under the contract. While we are revising § 438.3(c)(1)(ii) to ensure that final capitation rates may be based on State plan, ILOSs and additional services deemed by the State to be necessary to comply with mental health parity, § 438.3(c)(1)(ii) also requires that this payment amount must be adequate to allow the managed care plan to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. As ILOSs are substitutes for State plan-covered services and settings that are provided at the option of the managed care plan, and not a contractual requirement, we do not believe it is appropriate to include associated costs for managed care plan operational costs, the third party administrative management of ILOSs or associated plan or provider infrastructure needs in the benefit or non-benefit component of capitation rates, or the associated ILOS cost percentage that is calculated based on capitation payments.

Comment: One commenter stated concern regarding the additional ILOS reporting proposed at § 438.16(c)(5)(ii) and suggested that CMS leverage existing reporting structures like the MCPAR.

Response: We agree with the commenter that we should leverage existing reporting, including the MCPAR for ILOSs; accordingly, we revised the requirement to include ILOSs in reporting related to availability

and accessibility of covered services in the MCPAR at § 438.66(e)(2)(vi). However, we do not believe capturing information on ILOSs in the MCPAR alone is sufficient to appropriately monitor and oversee the fiscal impact of ILOSs on managed care expenditures. ILOSs are included in capitation rates and, as outlined in this section of the preamble as well as section I.B.4.e. of this final rule, we believe it is appropriate for us to review the ILOS cost percentage and the summary report of managed care plans' actual ILOS costs as a component of our review of rate certifications. This helps us to review the calculation for the projected ILOS cost percentage and determine if it was developed in a manner consistent with how associated ILOS costs would be included in rate development and that the historical experience garnered from the final ILOS cost percentage and summary report of managed care plans' actual ILOS costs informs prospective rate development as appropriate.

Comment: Many commenters recommended revisions to the proposed 5 percent limit for the ILOS cost percentage or were in opposition to the limit. One commenter supported this limit, but raised concerns that the cost of a service should not be the principal or determinative criterion in findings of medical necessity for Medicaid coverage. Other commenters supported a 5 percent limit on ILOS expenditures but recommended other exceptions to this limit which varied by commenter or to focus the limit on novel ILOSs. Recommended exceptions included all approved ILOSs, ILOSs focused on HCBS, or ILOSs needed to ensure access to quality care such as HCBS and behavioral health. One commenter recommended that the proposed 5 percent limit be a general guideline while allowing States the flexibility to propose a modification to this limit by means of a waiver or exception process while another commenter recommended a process by which the 5 percent limit would be removed if a State met a pre-defined set of quality or cost outcomes. One commenter recommended that States should have the flexibility to set their own limit. Another commenter recommended this limit be increased to 10 to 15 percent for some programs, such as smaller behavioral health programs.

Other commenters opposed any limit of the projected ILOS cost percentage or final ILOS cost percentage. These commenters raised concerns that a fiscal limit could discourage utilization of ILOSs, reduce the use of existing ILOSs, remove State flexibility and create inequities in the ILOSs offered across States. One commenter stated concern that any fiscal limit could create hardships for smaller, limited benefit managed care programs while another stated similar concerns for nonintegrated programs. One commenter noted that the proposed CMS review of ILOSs and evaluation, as applicable, as well as the documentation of a projected ILOS cost percentage should be sufficient for demonstrating the reasonableness and appropriateness of ILOSs instead of requiring an overall fiscal limit. Another commenter noted that the cost effectiveness test for section 1915(b)(3) of the Act services should be sufficient and did not believe an additional limit was necessary for ILOSs. A few commenters requested clarification for CMS's rationale for selecting 5 percent and some of those commenters raised concerns that 5 percent was arbitrary. One commenter who opposed any fiscal limit did acknowledge that they were unaware of any States that actually spent more than 5 percent of total capitation payments on ILOSs.

Response: We believe that there must be appropriate and consistent fiscal guardrails on the use of ILOSs in every managed care program to ensure proper and efficient operations in Medicaid, and efficient and effective health assistance in CHIP. While we recognize that any limit imposed on ILOS expenditures in comparison to overall program expenditures will limit State and managed care plan use of ILOSs to some degree, we believe that we have an obligation to implement appropriate fiscal constraints for Medicaid and CHIP investments in ILOSs, and it is appropriate to set a limit for each managed care program so that ILOS expenditures do not grow unfettered. We continue to believe a fiscal limit would increase accountability, reduce inequities in the services and settings available to beneficiaries across managed care and FFS delivery systems, and ensure that enrollees receive State plan-covered services and settings. We believe a 5 percent limit on ILOS expenditures in comparison to total program expenditures is a reasonable limit for every managed care program, including smaller, limited benefit programs, because it is high enough to encourage the use of ILOSs, at the plan and enrollee option, but still low enough to maintain appropriate fiscal safeguards.

We do not believe it is reasonable or appropriate to include additional exceptions to the proposed fiscal limit as we believe this would exacerbate inequities in the coverage of ILOSs in State programs as well as create operational and oversight challenges. ILOSs are substitute services and settings provided in lieu of services or settings covered under the State plan. States have an obligation to ensure that all services covered under the State plan are available and accessible to managed care enrollees in a timely manner as required at §§ 438.206 and 457.1230(a) for Medicaid and separate CHIP, respectively, and that there is adequate capacity to serve the expected enrollment as required at §§ 438.207 and 457.1230(b), respectively. Therefore, we do not believe an exception process is reasonable based on access concerns. If States have concerns about compliance with this fiscal limit, States should explore transitioning to cover the services as Medicaid benefits through other pathways for coverage such as the State plan authority in section 1905(a), 1915(i) and 1915(k) or a waiver under section 1915(c) of the Act. For example, we are aware of one State that recently undertook an assessment of its historical ILOSs and determined that some historical ILOSs, or a component of an ILOS, were duplicative of services authorized in the Medicaid State plan. Once this State terminated these historical ILOSs prospectively, this eliminated the State's concern of exceeding the projected ILOS cost percentage for its applicable managed care program as the numerator of the ILOS cost percentage is the portion of the total capitation payments that is attributable to the provision of ILOSs and not services authorized in the Medicaid State plan as benefits.

The final rule does not stipulate that ILOS cost is the principal or determinative criterion in findings of medical necessity for Medicaid or CHIP coverage. In accordance with existing Federal requirements at § 438.3(e)(2)(i), States must determine each ILOS to be a medically appropriate and cost effective substitute for the covered service or setting under the State plan. Cost effectiveness of an ILOS is one factor in a State's determination, and medical appropriateness is an additional factor. CMS proposes to ensure clarity in the managed care plan contracts on the target population(s) for which each ILOS is determined to be medically appropriate and cost effective substitute for a State plan-covered service or setting (see section I.B.4.d. of this final rule for further details). We continue to believe that there should be an overall fiscal limit on ILOS expenditures to ensure appropriate use of ILOSs and to avoid creating a perverse incentive for States and plans

not to provide State plan-covered services and settings. For the reasons outlined above, we decline to revise the proposed 5 percent limit at § 438.16(c)(1).

We also remind commenters that section 1915(b)(3) of the Act services are separate and distinct services from ILOSs and have a separate and distinct cost effectiveness requirement. Under section 1915(b)(3) of the Act, States share cost savings resulting from the use of more cost effective medical care with enrollees by providing them with additional services, known as section 1915(b)(3) services. There is a specific cost effectiveness test that States must prospectively meet to request approval from CMS for section 1915(b)(3) services as a component of a section 1915(b) waiver application as well as retrospective cost effectiveness reporting.

Comment: One commenter stated concern about the administrative burden that the proposed ILOS rules will pose for smaller, more specialized CHIP managed care programs. In particular, the 5 percent limitation on ILOS as a proportion of overall capitated payments has a disproportionate impact on CHIP programs with a smaller enrollment population. The commenter stated the increased limitations on managed care programs do not align with the overall intent of managed care and restrict the flexibilities that make managed care a desirable model for children's services.

Response: We appreciate the commenter's concerns for the potential impact of new ILOS requirements on managed care programs that serve smaller separate CHIP populations. In our determinations throughout this final rule for which provisions would align separate CHIP with Medicaid, we sought to balance the burden on CHIP State agencies and separate CHIP managed care programs with the need for responsible Federal oversight and protections to CHIP beneficiaries. We believe requiring a 5 percent limit on ILOS expenditures in comparison to total program expenditures remains a reasonable limit even for managed care programs serving smaller populations. The 5 percent limit on ILOS expenditures ensures fiscal responsibility and additional transparency for State and Federal oversight of managed care programs. If separate CHIP managed care programs have concerns about exceeding this 5 percent limit for the ILOS cost percentage, we encourage States to evaluate services currently being provided as ILOSs that might alternately be coverable under the CHIP State plan through the service definitions at § 457.402—specifically ''home and community-based health care services and related supportive services.'' States also have the flexibility to cover SDOH and HRSN services through CHIP Health Services Initiatives.

Comment: One commenter requested that if CMS finalizes the 5 percent limit, that CMS should identify the affected States so interested parties can meaningfully understand the impacts of the proposed limits.

Response: We agree that States should engage with interested parties to ensure clarity on how the ILOS fiscal limit may impact particular managed care programs and we encourage the engagement of interested parties more broadly such as on ILOS development, evaluation and any necessary transition planning. We are unable to currently identify potentially affected States as ILOS offerings and enrollee utilization may vary year to year, and this will impact State calculations for the ILOS cost percentage. We encourage interested parties to engage directly with States.

Comment: One commenter recommended that CMS closely monitor this 5 percent limit after implementation to assess if the limit should be revisited in future rulemaking.

Response: We agree that it is imperative that CMS and States closely monitor implementation of this required limit to ensure compliance.

Comment: Several commenters supported the annual reporting of managed care plans' ILOS costs. One commenter indicated that ILOSs and the amounts paid by managed care plans should continue to be monitored at the State and national levels to drive Federal policy changes to the Medicaid program. Another commenter recommended that this spending data be made publicly available.

Response: We appreciate the support for this proposal to require annual reporting on managed care plans' actual ILOS costs and we believe this data should inform rate development and could be utilized to inform other policy changes. Managed care plans are required to provide all encounter data, including allowed and paid amounts, to the State per §§ 438.242(c)(3) and 457.1233(d) for Medicaid and separate CHIP respectively, and the State is required to submit this data to T–MSIS per §§ 438.818 and 457.1233(d), respectively. As encounter data will be generated when an ILOS is rendered, the data will be captured in T–MSIS and treated as other encounter data in the production of T–MSIS analytic files.[196] At this time, CMS does not plan to publicly release the annual reporting by managed care plans on actual ILOS costs, but we will take this into consideration in the future.

Comment: Some commenters supported the use of a risk-based approach for States' ILOS documentation and evaluation requirements as they believe the proposals struck the right balance between Federal oversight and State administrative burden.

Response: We appreciate the support for these proposals, and for the feedback that our proposals appropriately balanced States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs.

Comment: One commenter requested clarification on whether the proposed 1.5 percent threshold applied to each managed care plan contract or each individual ILOS.

Response: The threshold for the risk-based approach is by managed care program. The definitions for a projected ILOS cost percentage and final ILOS cost percentage proposed in § 438.16(a) indicate that these percentages are calculated for each managed care program that includes ILOSs, and these percentages are based on calculations proposed in §§ 438.16(c)(2) and (c)(3) which include all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e). See this section of the preamble, as well as sections I.B.4.d. and I.B.4.g. of this final rule for further details.

Comment: Other commenters were concerned with the State administrative burden associated with the proposed documentation and evaluation requirements, and either opposed any new requirements or recommended alternatives.

Response: As required in existing Federal requirements at § 438.3(e)(2)(1), States must determine each ILOS to be a medically appropriate and cost effective substitute for a State plan-covered service or setting. We expect that whenever a State is making such a determination that it has a clear process and protocol, and that it adequately maintains documentation of its decisions. Therefore, we do not believe the documentation requirements proposed in § 438.16(d)(2) should create substantially new burden for States as States should be readily able to provide a description of their evaluative

[196] *https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/t-msis-analytic-files/index.html.*

processes as these should already be maintained in States' records. The goal of this proposal was to reduce State administrative burden by only requiring that this documentation be submitted to CMS when the projected ILOS cost percentage exceeded a 1.5 percent as opposed to always providing it.

We recognize that the proposed evaluation requirement outlined in § 438.16(e)(1) is a new State requirement and will increase administrative burden. We believe this is a necessary requirement to ensure that States appropriately evaluate whether ILOSs meet their intended purposes and truly are medically appropriate and cost effective, and for CMS to receive these evaluations to inform our determination of continued approval of these ILOSs in managed care plan contracts or to consider termination as appropriate. We did account for this burden in the associated Collection of Information for § 438.16 (see section II.B.7. of this final rule for further details).

Comment: A few commenters recommended alternatives to the 1.5 percent threshold. The recommended alternative varied by commenter and included utilizing a 2.5 or 3 percent threshold, allowing the State's actuary to determine a threshold, and only requiring these requirements when the ILOS cost percentage had shifted noticeably. Some commenters also recommended exempting currently approved ILOSs from any additional documentation and evaluation requirements. Other commenters recommended CMS consider setting a minimum threshold for each ILOS so that the documentation and/or evaluation requirements only apply to individual ILOSs of material size. A few commenters recommended using the 1.5 percent threshold for each ILOS while several of the commenters indicated they thought a threshold of 0.1 percent of the capitation rates for each ILOS was a reasonable threshold.

Response: Commenters provided several alternatives to the proposed 1.5 percent threshold which we have reviewed and considered. We do not believe the alternative to consider an ILOS cost percentage threshold that exceeds 3 percent for additional documentation and evaluation requirements is appropriate to consider for this risk-based approach. We believe that this alternative, which is twice as high as the 1.5 percent threshold proposed, is not sufficent to appropriately ensure appropriate Federal oversight that ILOSs are medically appropriate and cost effective substitutes for State-plan covered services and settings and in the best interests of the Medicaid and CHIP programs.

We continue to believe that there should be a consistent Federal standard utilized across all managed care programs that include ILOSs to appropriately monitor and oversee the use of ILOSs, and therefore, we do not believe it is reasonable and appropriate to consider allowing a State's actuary to have the discretion to determine a varying threshold for each program or to allow currently approved ILOSs to be excluded from this risk-based approach. We also note that the commenters who recommended the alternative to allow a State's actuary to have the discretion to determine a threshold for this risk-based approach did not provide a rationale for this alternative for us to reconsider our position. Therefore, at this time, we do not believe allowing States and their actuaries to identify a reasonable threshold for submitting to CMS additional documentation and evaluation requirements is a reasonable alternative to consider further.

We are also concerned that applying a risk-based approach threshold for documentation and evaluation requirements by each ILOS, rather than for all non-IMD ILOSs across a given managed care program, could actually increase State administrative burden based on the potential volume of ILOSs that could exceed the proposed 1.5 percent ILOS cost percentage threshold. We also have concerns that the proposed alternative to consider a threshold of 0.1 percent would be far too low to meaningfully ensure appropriate Federal oversight of ILOSs. We are also concerned that any threshold that is required for each ILOS, rather than at the aggregate across a managed care program, could increase administrative burden and the complexity for States and CMS to operationally implement and oversee this proposed requirement as some States have a significant volume of ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(a) through (d), 457.1201(c) and (e) and 457.1203(b) as proposed with the following modifications. As outlined in section I.B.2. of this final rule, we are prohibiting the use of separate payment terms for State directed payments. We will modify § 438.16(c)(2)(ii) to remove the word ''including'' before ''all State directed payments,'' and the following language: ''and the projected total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6)'' and the comma that preceded this statement as well as add a comma before ''and pass-through payments.'' We will also modify § 438.16(c)(3)(ii) to remove the word ''including'' before ''all State directed payments,'' and the following language: ''and the actual total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6)'' and the comma that preceded this statement as well as add a comma before ''and pass-through payments.'' We will also modify §§ 438.16(c)(4) and (c)(5) to add a comma before ''and PAHP'' for consistency.

c. Enrollee Rights and Protections (§§ 438.3(e), 438.10(g), 457.1201(e) and 457.1207)

Consistent with the ILOS definition proposed in § 438.2, ILOSs are immediate or longer-term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the covered services and settings under the State plan. They can be utilized to improve enrollees' health care outcomes, experience, and overall care; however, ILOSs are an option and not a requirement for managed care plans. While ILOSs are offered to Medicaid and CHIP enrollees at the option of the managed care plan, the provision of an ILOS is also dependent on the enrollees' willingness to use the ILOS instead of the State plan-covered service or setting. Medicaid managed care enrollees are entitled to receive covered services and settings under the State plan consistent with section 1902(a)(10) of the Act. As ILOSs can be offered as substitutes for covered State plan services and settings that Medicaid enrollees are otherwise entitled to, we believe that it is of the utmost importance that we identify the enrollee rights and managed care protections for individuals who are offered or opt to use an ILOS instead of receiving State plan-covered service or setting. To ensure clarity for States, managed care plans, and enrollees on the rights and protections afforded to enrollees who are eligible for, offered, or receive an ILOS, we proposed to add new § 438.3(e)(2)(ii)(A) and (B) under § 438.3(e)(2)(ii) to specify our meaning of enrollee rights and protections that are not explicitly stated elsewhere in part 438. We believe it will be appropriate to add this clarity to § 438.3(e)(2)(ii) as these are not new rights or protections, but rather, existing rights and protections that we believe should be more explicitly stated for all ILOSs, including short-term IMD stays.

We proposed to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS will retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they will retain their right to receive the service or setting covered under the State plan on the same terms as will apply if an ILOS was not an option. We believe this proposed addition would ensure clarity that the rights and protections guaranteed to Medicaid managed care enrollees under Federal regulations remain in full effect when an enrollee is eligible to be offered or elects to receive an ILOS. For example, enrollees retain the right to make informed decisions about their health care and to receive information on available treatment options and alternatives as required in § 438.100(b)(2)(iii). To ensure that enrollee rights and protections would be clearly and consistently provided to enrollees, we proposed to revise § 438.10(g)(2)(ix) to explicitly require that the rights and protections in § 438.3(e)(2)(ii) be included in enrollee handbooks if ILOSs are added to a managed care plan's contract. For separate CHIP, enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457. To acknowledge these differences, we proposed to amend § 457.1207, (which includes an existing cross-reference to § 438.10) to reference instead to the separate CHIP enrollee rights and protections under subparts K and L of part 457. Protections to ensure that managed care enrollees have the ability to participate in decisions regarding their health care and have avenues to raise concerns including their right to appeals related to adverse benefit determinations and grievances are critical to ensure that ILOSs are utilized in a reasonable, appropriate, and effective manner.

We believe safeguards and protections for enrollees that elect to use an ILOS should be specified, particularly since ILOS costs can vary compared to costs for the State plan service or setting for which it is a substitute. Specifically, we wanted to make clear that the provision or offer of an ILOS may not be used coercively or with the intent to interfere with the provision or availability of State plan-covered service and setting that an enrollee would otherwise be eligible to receive. Therefore, we proposed to add § 438.3(e)(2)(ii)(B) to ensure that an ILOS would not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and a managed care plan could not deny an enrollee access to a service or setting covered under the State plan on the basis that an enrollee has been offered an ILOS as a substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past. While ILOSs can be effective substitutes for services and settings covered under the State plan, we wanted to ensure consistent and clear understanding for enrollees, States, and managed care plans on how ILOSs can be appropriately utilized to meet an enrollee's needs.

For separate CHIP, we proposed to adopt the enrollee rights and protections at § 438.3(e)(2)(ii)(A) and (B) through an existing cross-reference at § 457.1201(e). However, separate CHIP enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457. To acknowledge these differences, we proposed to amend § 457.1201(e), which already includes a cross-reference to § 438.3(e) to state, ''An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with § 438.3(e) . . . of this chapter . . . except . . . that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part.''

We believe that a strong foundation built on these enrollee rights and protections would also ensure that ILOSs could have a positive impact on enrollees' access to care, health outcomes, experience, and overall care. As such, we believe these enrollee rights and protections must be clearly documented in States' managed care plan contracts. Therefore, we proposed this documentation requirement in § 438.16(d)(1)(v). For separate CHIP, we proposed to adopt the requirement for enrollee rights and protections for ILOSs to be documented in managed care plan contracts by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(1)(v).

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.3(e), 438.10(g), 457.1201(e), 457.1207) below.

Comment: Many commenters supported the proposed enrollee rights and protections and the inclusion of these in managed care plan contracts and enrollee handbooks if ILOSs are authorized and identified in managed care plan contracts as commenters noted they believe these were reasonable and appropriate guardrails.

Response: We appreciate the support for these proposals, and we continue to believe that outlining the existing enrollee rights and protections in regulation is a critical safeguard to ensure that the delivery of ILOSs is in the best interest of beneficiaries and advances the objectives of the Medicaid and CHIP programs.

Comment: A few commenters recommended that CMS require States to develop a public list of available ILOSs, related targeting criteria and the managed care plans who offer them, and to conduct outreach to providers and enrollees, so that providers and enrollees understand what ILOS options may be available.

Response: Information on ILOSs authorized by the State that their managed care plans may elect to offer and that enrollee may choose at their option to utilize will be in the managed care plan contracts which, as required in §§ 438.602(g)(1) and 457.1285 for Medicaid and separate CHIP respectively, must be posted on their websites. We are aware that many States conduct education and outreach efforts to raise awareness of authorized ILOSs, including web postings, provider outreach, enrollee handbooks, and other interested parties engagement. We do not believe it is necessary for CMS to further mandate the use of specific education and outreach mechanisms as States are in the best position to determine what efforts are appropriate for the target population for each ILOS.

Comment: One commenter recommended that CMS implement an appeals process, using existing State and managed care plan infrastructure, for ILOSs.

Response: We appreciate these comments as they allow CMS to clarify existing policy guidance. On January 4, 2023, we published ILOS guidance [197] which clarified that ''The rights and protections guaranteed to Medicaid managed care enrollees under Federal regulations remain in full effect when an enrollee is eligible to be offered or elects to receive any ILOS.'' Enrollees retain all rights afforded to them in part 438. As we further noted in this ILOS guidance published on January 4, 2023, managed care plans' contracts must, pursuant to § 438.228, require each managed care plan to have a grievance and appeal system in place that meets the requirements of subpart F of part 438. States are required to provide State fair hearings, as described in subpart E

[197] *https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf.*

of part 431, to enrollees who request one after an adverse benefit determination is upheld on appeal (see § 438.402(c)(1)(i)). The grievance, appeal, and State fair hearing provisions in part 438, subpart F, apply to enrollees and ILOSs to the same extent and in the same manner as all other services covered by the managed care plans' contracts. As with all services in managed care, enrollees can request a State fair hearing before the Medicaid agency in accordance with § 431.220(a)(4). As further noted in the January 4, 2023, guidance, ''The offer or coverage of ILOS(s) by a managed care plan in no way alters or diminishes an enrollee's rights under subpart F of part 438. For example, at § 438.404, managed care plans are expected to provide notice of an adverse determination to enrollees if ILOS(s) offered by their Medicaid managed care plan are not authorized for an enrollee because of a determination that it was not medically appropriate. Additionally, consistent with § 438.402, Medicaid enrollees also retain the right to file appeals and/or grievances with regard to the denial or receipt of an ILOS.'' For separate CHIP, we amended § 457.1201(e) to apply separate CHIP enrollee rights and protections at subparts K and L of part 457 for ILOSs. Subpart L of part 457 applies separate CHIP managed care grievance system requirements to ILOSs and subpart K of part 457 applies all separate CHIP external review requirements to ILOSs. We are finalizing the proposal to clarify this existing guidance in §§ 438.3(e)(2)(ii)(A) and 457.1201(e) for Medicaid and separate CHIP, respectively.

Comment: One commenter requested clarification on whether ILOSs could be offered retroactively, and if so, how the managed care plan would ensure enrollee rights and protections.

Response: ILOSs must be provided at the option of the enrollee and the managed care plan, as well as authorized and identified in the managed care contract as required in § 438.3(e)(2). As such, it is not appropriate to retroactively implement an ILOS. For example, it is not possible to retroactively offer an enrollee the option to receive an ILOS rather than the State plan service.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(e), 438.10(g), 457.1201(e) and 457.1207 as proposed with a minor modification to § 438.3(e)(2)(B) to add a comma between ''PIHP'' and ''or PAHP'' for consistency.

d. Medically Appropriate and Cost Effective (§§ 438.16(d) and 457.1201(e))

In § 438.3(e)(2)(i), managed care plans may cover an ILOS if the State determines the ILOS is medically appropriate and cost effective substitute for a covered State plan service or setting. This policy is consistent with authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid, as well as the nature of capitation payments based on risk-based capitation rates recognized in section 1903(m)(2)(A) of the Act. We interpreted medically appropriate and cost effective substitute to mean that an ILOS may serve as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan. We believe this was a reasonable interpretation in acknowledgement that health outcomes from any health care services and settings may also not be immediate. We offered the following examples to illustrate the difference between an ILOS that is an immediate versus longer-term substitute for a State plan service or setting, or when the ILOS could be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan.

For example, transportation to and services provided at a sobering center could be offered as a medically appropriate and cost effective immediate substitute for target populations for specific State plan services or settings, such as an emergency room visit or hospital inpatient stay. Alternatively, we could envision target populations for which an ILOS, such as housing transition navigation services, might serve as a longer-term substitute for a covered State plan service or setting, or when the ILOS could be expected to reduce or prevent the need to utilize the covered service or setting under the State plan, such as populations with chronic health conditions and who were determined to be at risk of experiencing homelessness. The managed care plan might choose to offer medically tailored meals to individuals with a diabetes diagnosis and poorly managed A1C levels within the allowable limit of less than 3 meals per day. While not an immediate substitute for a State plan-covered service such as emergency room visits or inpatient hospital stays, medically tailored meals consistently provided to the individual over a period of time could contribute to improved management of the diabetes. In the long term, improved management might lead to fewer complications related to diabetes and consequentially, fewer emergency room visits and inpatient stays thereby demonstrating the ILOS was both medically appropriate and cost effective for the individual.

We believe it was important to ensure appropriate documentation to support a State's determination that an ILOS is a medically appropriate and cost effective substitute, either long or short term, for a State plan-covered service or setting. ILOS documentation requirements for States would permit CMS and the State to better monitor the use of ILOSs, safeguard enrollee rights, facilitate fiscal accountability, and promote transparency to ensure the efficient and appropriate use of Medicaid and CHIP resources. Therefore, we proposed to expand the documentation requirements for ILOSs through the addition of requirements in § 438.16. Specifically, we proposed at § 438.16(d)(1), elements that must be included in any managed care plan contract that includes ILOS(s) in order to obtain CMS approval consistent with § 438.3(a). In accordance with § 438.3(e)(2)(iii), States are already required to authorize and identify ILOSs in each managed care plan contract and such ILOSs are offered at the option of the managed care plan. Therefore, we believe it was consistent with a risk contract to require States to provide sufficient detail regarding any ILOSs covered under the contract and accounted for in the capitation rates per § 438.3(e)(2)(iv).

In our experience reviewing managed care plan contracts, States have not always provided sufficient detail in their managed care plan contracts for Federal review. For example, some contracts have included only general language that ILOSs are provided at the option of the managed care plan and have not clearly identified each ILOS that the State has authorized in sufficient detail. We believe clarity was needed to ensure accountability and transparency in managed care plan contracts. Therefore, we proposed § 438.16(d)(1)(i) and (ii) to require that States would include within each managed care plan contract that includes ILOS(s), the name and definition for each ILOS and clearly identify the State plan-covered service or setting for which each ILOS was determined to be a medically appropriate and cost effective substitute by the State. For separate CHIP, we proposed to adopt the new documentation requirements at § 438.16(d)(1)(i) and (ii) by amending § 457.1201(e) to include the cross-reference. By requiring that this

information be clearly identified in the contract, we believe that managed care plans would have sufficient detail on the ILOSs to be able to utilize ILOSs appropriately while enabling States and CMS to more effectively monitor each ILOS over time. We also believe including this level of detail in the contract would be an appropriate fiscal protection to ensure that capitation rates are developed in an actuarially sound manner in accordance with § 438.4 for Medicaid, and developed with actuarially sound principles in accordance with § 457.1203(a) for separate CHIP. Actuarially sound capitation rates, as defined in § 438.4(a) for Medicaid, and actuarially sound principles as defined at § 457.10 for CHIP, are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. Additionally, for Medicaid, such capitation rates must be developed in accordance with the requirements in § 438.4(b), including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2).

The existing regulation § 438.3(e)(2)(i) indicates that a managed care plan may offer an ILOS if the State determines that the ILOS is a medically appropriate and cost effective substitute for a covered service or setting under the State plan. As noted in section I.B.4.a. of this final rule, we proposed a definition of ILOS in § 438.2 to specify that ILOSs may be determined to be cost effective and medically appropriate as immediate or longer-term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize State plan-covered services and settings. Current regulations do not require States or managed care plans to document any details related to the determination of medical appropriateness and cost effectiveness, either broadly or for a specific enrollee who is offered an ILOS. For managed care plans to appropriately offer ILOSs to enrollees consistent with the State's determination of medical appropriateness and cost effectiveness, States will have to identify the target populations for each ILOS using clear clinical criteria. Prospective identification of the target population for an ILOS is necessary to ensure capitation rates are developed in an actuarially sound manner in accordance with § 438.4, including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2) and meet the applicable requirements of part 438, including ILOS requirements as required in § 438.4(b)(6). For these reasons, we proposed a new requirement at § 438.16(d)(1)(iii) to require States to document within each managed care plan contract the clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost effective substitute. For separate CHIP, we proposed to adopt the new documentation requirements at § 438.16(d)(1)(iii) by amending § 457.1201(e) to include the cross-reference. We proposed the phrase ''clinically defined target populations'' as we believe that States would have to identify a target population for each ILOS that would be based on clinical criteria. This would not preclude States from using additional criteria to further target certain clinically defined populations for ILOSs.

While States may establish target population(s) for which an ILOS is medically appropriate, we believe that the actual determination of medical appropriateness should be completed by a provider, for each enrollee, using their professional judgement, and assessing the enrollee's presenting medical condition, preferred course of treatment, and current or past medical treatment to determine if an ILOS is medically appropriate for that specific enrollee. Therefore, we proposed, at § 438.16(d)(1)(iv), to require that the managed care plan contract document a process by which a licensed network or managed care plan staff provider would determine that an ILOS is medically appropriate for a specific enrollee before it was provided. Under this proposal, this determination and documentation could be done by either a licensed network provider or a managed care plan staff provider to ensure States and managed care plans have capacity to implement this requirement, consistent with State standards. For separate CHIP, we proposed to adopt the new documentation requirements at § 438.16(d)(1)(iv) by amending § 457.1201(e) to include the cross-reference. The provider would document the determination of medical appropriateness within the enrollee's records, which could include the enrollee's plan of care, medical record (paper or electronic), or another record that details the enrollee's care needs. This documentation would include how each ILOS is expected to address those needs.

As discussed in section I.B.4.b. of this final rule, we proposed a risk-based approach based on a State's projected ILOS cost percentage, for State documentation and evaluation requirements of ILOSs that would require standard streamlined documentation to CMS for States with a projected ILOS cost percentage less than or equal to 1.5 percent while States with a projected ILOS cost percentage that exceeds 1.5 percent will be required to submit additional documentation. To specify the proposed additional documentation requirements for a State with a projected ILOS cost percentage that exceeds 1.5 percent, we proposed, at § 438.16(d)(2), the documentation requirements in paragraphs § 438.16(d)(2)(i) and (ii), and that this documentation would be submitted to CMS concurrent with the managed care plan contract that includes the ILOS(s), for review and approval by CMS under § 438.3(a). We believe concurrent submission is the most efficient, since each ILOS must be authorized and identified in States' contracts with a managed care plan as required in § 438.3(e)(2)(ii). In § 438.16(d)(2)(i), we proposed that the State submit a description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with proposed § 438.16(d)(1)(iii). As ILOSs are often substitutes for State plan-covered services and settings that have already been determined medically appropriate, we expected States to use evidence-based guidelines, peer reviewed research, randomized control trials, preliminary evaluation results from pilots or demonstrations, or other forms of sound evidence to support the State's determination of an ILOS' medical appropriateness. Lastly, in § 438.16(d)(2)(ii), we proposed that the State provide a description of the process and supporting data that the State used to determine that each ILOS is a cost effective substitute for a State plan-covered service or setting for the clinically defined target population(s), consistent with the proposed § 438.16(d)(1)(iii). CMS has the authority in § 438.3(a) to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated

Medicaid managed care plan contracts and capitation rates. For separate CHIP, we proposed to adopt the new documentation requirements at § 438.16(d)(2) by amending § 457.1201(e) to include the cross-reference.

While we believe that a risk-based approach for States' ILOS documentation and evaluation requirements is a reasonable and appropriate balance of administrative burden and fiscal safeguards, we always reserve the right to ask for additional documentation from a State as part of our review and approval of the managed care plan contracts and rate certifications as required respectively in §§ 438.3(a) and 438.7(a), and we are not precluded from doing so by our proposal to add § 438.16(d)(2)(i) through (ii). Therefore, we proposed to require at § 438.16(d)(3) that any State must provide additional documentation, whether part of the managed care plan contract, rate certification, or supplemental materials, if we determined that the requested information was pertinent to the review and approval of a contract that includes ILOS(s). For separate CHIP, we proposed to adopt the new documentation requirements at § 438.16(d)(3) by amending § 457.1201(e) to include the cross-reference, except that references to rate certifications do not apply.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(d), 457.1201(e)) below.

Comment: Many commenters supported our documentation requirements proposed in this section of the preamble and indicated the proposals were reasonable to ensure that ILOSs are an appropriate Medicaid investment and serve to meet beneficiaries' health care needs and ensure enrollees' health and safety.

Response: We appreciate the support we received for these documentation proposals to ensure proper and efficient operations for the use of ILOSs in Medicaid and CHIP managed care.

Comment: Some commenters recommended allowing States flexibility to only update managed care plan contracts every 3 to 5 years rather than when the level of detail on ILOSs changes as the commenters indicated that the level of detail rarely changes. Other commenters recommended to grandfather in existing ILOSs and not require additional contract documentation for these existing ILOSs. A few of these commenters raised concerns that the proposed documentation requirements could create administrative burden, inhibit use of these ILOSs in the future or not allow flexibility including individualized planning to meet enrollees' needs. A few of these commenters requested flexibility to revise the ILOSs outside the managed care contracts when such care otherwise meets the criteria for ILOSs, and one such commenter recommended all the necessary detail be included in the rate certification rather than the contract.

Response: As managed care plan contracts are the critical vehicle by which States outline their expectations to the managed care plans and are used to enforce plans' contractual obligations, we have historically believed and continue to believe that the contracts are the appropriate mechanism to document the ILOSs that the State had determined to be medically appropriate and cost effective substitutes for State plan-covered services and settings, as well as the administrative and operational processes necessary to monitor these ILOSs. The proposals in § 438.16(d) also build upon existing Federal requirements in § 438.3(e)(2)(iii) that the ILOSs approved by the State are identified in the managed care plan contracts. In alignment with this existing requirement, as well as the new proposed requirements, we expect States to revise managed care plan contracts anytime the ILOSs that the State has determined to be medically appropriate and cost effective substitutes change, as well as any time the associated administrative and operational processes for these ILOS change. We do not believe it would be appropriate to outline the proposed documentation outlined in § 438.16(d) within a rate certification in lieu of a managed care plan contract as a rate certification is the documentation a State's actuary develops as it certifies actuarially sound Medicaid capitation rates. States may find it administratively less burdensome to revise an appendix to the managed care contract, though we remind States that any appendix to the contract or other document included as reference in the contract is a component of the contract that requires CMS review and approval. We also remind commenters that ILOSs are required to be medically appropriate and cost effective substitute services for clinically defined target populations. We remind managed care plans that if a service or setting they wish to provide does not meet ILOS requirements, the plans may always choose to voluntarily provide additional services in accordance with § 438.3(e)(1) although the cost of these services cannot be included when determining payment rates under § 438.3(c).

Comment: Some commenters sought revisions or clarifications on the processes in § 438.16(d)(iii) and (iv). One commenter recommended revising the term ''clinically defined target population'' to include functional and HRSNs of enrollees in addition to medically appropriateness of an ILOS. Another commenter requested confirmation that the State should identify the clinically defined target populations for ILOSs and not managed care plans. Other commenters recommended that CMS require States and managed care plans to document the safety and efficacy of each ILOS in the enrollee's records or require that only the enrollee's primary care provider be allowed to make the determination that an ILOS is medically appropriate.

Response: We agree that States should consider the safety and efficacy of an ILOS when they are determining a potential ILOS is medically appropriate, as well as when a network provider or staff provider for the managed care plan determines and documents in the enrollee's records that an ILOS is medically appropriate for a specific enrollee.

We are not entirely clear what the commenter meant by functional need, but we believe the commenter may be referring to functional assessment tools that collect information on an individual's health conditions and functional needs. We agree that evaluating the functional needs and HRSNs of enrollees can be critical components for care coordination and determining medically appropriate services; however, these factors cannot be the sole rationale for the determination that an ILOS is medically appropriate, as an ILOS is a substitute for a State plan-covered service or setting.

We appreciate the commenter who requested confirmation that the State should identify the clinically defined target populations for ILOSs and not managed care plans. As States are required to determine, subject to CMS review, each ILOS is a medically appropriate and cost effective substitute for a State plan-covered service or setting as required in § 438.3(e)(2)(i), the State is also responsible for determining the clinically defined target population for which each ILOS is determined to be a medically appropriate and cost effective substitute. We are finalizing § 438.16(d)(1)(iii) with a modification to add language after ''medically appropriate and cost effective'' to add

''substitute by the State'' to ensure clarity on this issue.

As a reminder, when authorizing an ILOS, a State is required to determine the clinically defined target population(s) for which each ILOS is determined to be a medically appropriate and cost effective substitute for a State plan covered service or setting, and the State must document this clinically defined target population(s) in the managed care plan contract in accordance with § 438.16(d)(iii). For example, it would not be sufficient to indicate that the target population is any individual at risk for any chronic condition as clinical criteria must be utilized to document a specific clinical condition that is predictive of adverse health outcomes, and that is not itself a social determinant of health. For example, a State may determine that asthma remediation (*e.g.,* air filters) is a medically appropriate and cost effective substitute in lieu of the covered State plan services of emergency department services, inpatient services, and outpatient services for a target population of individuals with poorly controlled asthma (as determined by a score of 25 or lower on the Asthma Control Test).

Additionally, in accordance with § 438.16(d)(iv), the State must ensure that there is the process by which a licensed network or plan staff provider determines and documents in the enrollee's records that an identified ILOS is medically appropriate for a specific enrollee, and this process must be documented in the State's contracts with its managed care plans. We agree than an enrollee's primary care provider may be an appropriate provider to determine and document that an ILOS is medically appropriate for a specific enrollee; however, we believe States should have flexibility to allow other licensed network or staff providers to make this determination, as they deem appropriate.

Comment: One commenter recommended that managed care plans be able to provide ILOSs without State and provider determination that the ILOS is medically appropriate. One additional commenter requested that CMS remove managed care plans' control over access to ILOSs and require standardized availability of ILOSs across managed care plans.

Response: ILOSs must be determined by States to be medically appropriate and cost effective substitutes for State plan-covered services and settings in accordance with § 438.3(e)(2)(i). We continue to believe that there must be appropriate documentation in managed care plan contracts to ensure managed care plans appropriately offer ILOSs consistent with the State's determination. We also remind commenters that in accordance with existing Federal requirements at § 438.3(e)(2)(iii), an ILOS is always provided at the option of a managed care plan as an ILOS is a substitute for a State plan-covered service or setting. An ILOS is not a Medicaid benefit, but rather a medically appropriate and cost effective substitute for one. CMS or States cannot remove managed care plans' option to provide ILOSs; however, States must ensure standardization in the name, definition, clinically defined target population, and other critical components necessary to properly oversee that ILOSs are medically appropriate and cost effective substitutes for specific State plan-covered services and settings that also comply with all applicable Federal requirements.

Comment: One commenter requested clarification on whether a licensed social worker could be an allowable provider under the proposed requirement at § 438.16(d)(1)(iv).

Response: We agree that a licensed social worker could potentially be a provider that States and managed care plans consider as they develop the process outlined in § 438.16(d)(1)(iv).

Comment: A few commenters recommended that the ILOS documentation requirements be posted on the State's website or otherwise made publicly available in addition to documented in the managed care plan contracts.

Response: We remind commenters that information on ILOSs authorized by the State that their managed care plans may elect to provide, and that enrollee may choose at their option to utilize will be in the managed care plan contracts, and these contracts are required in § 438.602(g)(1) to be posted on States' websites.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(d) and 457.1201(e) as proposed with four minor corrections to replace ''cost-effective'' with ''cost effective'' in §§ 438.16(d)(1)(ii) and 438.16(d)(2)(ii) to utilize consistent language with existing regulatory terminology in § 438.3(e)(2)(i), modify § 438.16(d)(1)(iii) to add ''substitute by the State'' after ''medically appropriate and cost effective,'' and add a comma before ''or PAHP'' for consistency.

e. Payment and Rate Development (§§ 438.3(c), 438.7 and 457.1201(c))

In accordance with existing regulations at § 438.3(e)(2)(iv), States are required to ensure the utilization and actual cost of ILOSs are taken into account in developing the benefit component of the capitation rates that represents covered State plan services, unless a statute or regulation explicitly requires otherwise. Additionally, through existing regulations at § 438.4(b)(6), States' actuaries are required to certify that Medicaid capitation rates have been developed in accordance with the ILOS requirements outlined in § 438.3(e). We relied on authority in section 1903(m)(2)(A)(iii) of the Act and regulations based on our authority under section 1902(a)(4) of the Act, to establish actuarially sound capitation rates. While ILOS utilization and actual costs, when allowed, are included in rate development, the existing regulations at § 438.3(c)(1)(ii) do not clearly acknowledge the inclusion of ILOSs in the final capitation rates and related capitation payments. Existing regulations at § 438.3(c)(1)(ii) require that the final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of subpart K of part 438 (Parity in Mental Health and Substance Use Disorder Benefits), and represent a payment amount that is adequate to allow the managed care plan to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. As an ILOS is not a managed care plan requirement, but rather offered at the option of the managed care plan, it will not be included within the requirement in § 438.3(c)(2)(ii) related to contractual requirements. We proposed to revise § 438.3(c)(1)(ii) to include ''ILOS'' to ensure clarity on this matter. This technical change would be included in separate CHIP regulations through an existing cross-reference at § 457.1201(c).

Additionally, we proposed to revise § 438.7(b)(6) and the proposed § 438.7(c)(4) (see section I.B.2.l. of this final rule) to add ''ILOS in § 438.3(e)(2)'' to ensure any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval. We believe this is necessary to ensure compliance with proposed new regulatory requirements in § 438.16(c)(1)(i) and (5)(i), described in section I.B.4.b. of this final rule, to ensure that the projected ILOS cost percentage documented in the rate

certification would not exceed the proposed 5 percent limit. This is a similar approach to the current requirements in § 438.7(b)(6) which require a revised rate certification for any change to contract provisions related to payment in § 438.6, including incentive arrangements that have a similar 5 percent limit in accordance with § 438.6(b)(2). We signaled our intent to issue additional guidance in the Medicaid Managed Care Rate Development Guide, in accordance with § 438.7(e), on the Federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications. For separate CHIP, we did not plan to adopt the proposed change at § 438.7(b)(6) since rate certifications are not applicable to separate CHIP.

As risk-based capitation rates are developed prospectively, States' actuaries would make initial assumptions regarding managed care plan and enrollee utilization of ILOSs and associated costs. Since ILOS are offered at the option of the managed care plan and Medicaid enrollee, States and their actuaries should closely monitor whether managed care plans elect to offer these ILOSs and enrollees utilize these ILOSs. States' actuaries should assess if adjustments to the actuarially sound capitation rates are necessary in accordance with §§ 438.4 and, 438.7(a) and (c)(2). For example, a rate adjustment may be necessary if a managed care plan's actual uptake of ILOSs varies from what is initially assumed for rate development and results in an impact to actuarial soundness.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.3(c), 438.7 and 457.1201(c)) below.

Comment: Many commenters supported the proposed changes to §§ 438.3(c) and 438.7 to clarify that ILOSs, when authorized by a State and offered by a managed care plan(s), should be appropriately included in the final capitation rates and rate certifications.

Response: We appreciate the confirmation that these proposals provide clarity to States and their actuaries on how ILOS costs can be incorporated into managed care capitation rates and should be appropriately documented in rate certifications.

Comment: Some commenters requested that CMS clarify that capitation rates must be sufficient to account for ILOSs and State plan services, and one commenter raised concerns that this is not occurring today in a particular State.

Response: As required at § 438.5(b), when setting actuarially sound capitation rates, States and their actuaries must identify and develop base utilization and price data and make appropriate and reasonable adjustments to account for programmatic changes. The base data should include historical utilization and costs for State plan-covered services and settings, as well as associated ILOSs as applicable, and actuaries should make adjustments for programmatic changes to ILOSs and State plan services. Additionally, as required at § 438.4(b)(6), States' actuaries must certify that Medicaid capitation rates were developed in accordance with the ILOS requirements outlined in § 438.3(e). We believe these existing Federal requirements ensure that State plan services and settings and associated ILOSs are accounted for in the development of actuarially sound capitation rates; and we believe the proposed change at § 438.3(c) will clarify that ILOSs should be included in the final capitation rates and related capitation payments when ILOSs are offered by managed care plans. We also direct commenters to section I.B.4.b. of this final rule for our response to a commenter's inquiry on the inclusion of costs associated for managed care plan operational costs, the third party management of ILOSs, or associated plan or provider infrastructure needs for ILOSs within the ILOS cost percentage and the benefit or non-benefit components of Medicaid managed care capitation rates.

Comment: One commenter requested that CMS outline specific Federal guidelines for actuarial rate setting for ILOSs that are longer-term substitutes for State plan-covered services and settings under the State plan.

Response: We believe that States and their actuaries have responsibility under § 438.5(b)(4) to include appropriate and reasonable adjustments to account for ILOSs that are longer-term substitutes for State plan-covered services and settings in rate development. We encourage States to work with their actuaries on how best to incorporate ILOSs into capitation rates which may vary based on States' determinations on the medically appropriateness and cost effectiveness of the ILOS and the clinically defined target population(s). At this time, we do not believe additional Federal guidelines are necessary on this matter. CMS will continue to monitor this issue and may consider guidance within the annual Medicaid Managed Care Rate Development Guide in accordance with § 438.7(e) if deemed necessary.

Comment: One commenter requested that CMS consider revising its proposal at § 438.7(c)(4). The commenter opposed this proposal as they believe the proposal would increase State administrative expenses and not result in any improved oversight.

Response: We disagree with the commenter that the proposal at § 438.7(c)(4) would not improve oversight. As described in section I.B.4.b. of this final rule, we proposed in § 438.16(c)(2) and (c)(3) to require the calculation of a projected and final ILOS cost percentage based on capitation payments, and we proposed in § 438.16(c)(1) that this percentage, on both a projected and final basis, may not exceed 5 percent. We also proposed in § 438.16(c)(5)(i) to require that documentation for the projected ILOS cost percentage should be included in the rate certification. When States amend capitation rates, we believe this should require the calculation of a revised projected ILOS cost percentage, and this revised calculation should be accurately accounted for in the revised rate certification to ensure continued compliance with the proposed regulatory requirements in § 438.16, including the 5 percent limit for the projected ILOS cost percentage. We agree with the commenter that this proposal could increase State administrative burden, and we accordingly have revised the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details).

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(c), 438.7 and 457.1201(c) as proposed.

f. State Monitoring (§§ 438.16(d) and (e), 438.66(e) and 457.1201(e))

In the 2016 final rule, we clarified the term ''monitoring'' to include oversight responsibilities, and we required standard data elements that a State's monitoring system must collect to inform performance improvement efforts for its managed care program(s). We wish to continue to strengthen State and CMS oversight of each Medicaid managed care program with the addition of proposed text to explicitly address States' monitoring of ILOSs. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid.

Currently, § 438.66 requires that States establish a system to monitor performance of managed care programs broadly, § 438.66(b) outlines the data elements that a State's system must collect, § 438.66(c) establishes expectations for State use of such data

for performance improvement, and § 438.66(e) requires States to provide a report on and assessment of each managed care program. When ILOSs are included in a managed care plan's contract, they too must be included in the State's monitoring activities required in § 438.66(b) and (c). We believe States must ensure appropriate monitoring, evaluation, and oversight of ILOSs. We believe additional protections are necessary to ensure the delivery of ILOSs. In the 2015 proposed rule, we proposed expanded State monitoring requirements in § 438.66 and noted that our experience since the 2002 final rule has shown that strong State management and oversight of managed care is important throughout a program's evolution, but is particularly critical when States transition large numbers of beneficiaries from FFS to managed care or when new managed care plans are contracted (see 80 FR 31158). We subsequently finalized these requirements in the 2016 final rule. We believe that this logic is also applicable when a State expands the use of ILOSs as we have seen in recent years. Therefore, our proposals in this section further strengthened these existing Federal requirements related to States' monitoring activities for each managed care program.

As with all covered services and settings, States and their managed care plans must comply with all enrollee encounter data requirements in §§ 438.242 and 438.818. We rely on authority in section 1903(m)(2) of the Act to require sufficient encounter data and a level of detail specified by the Secretary. Complete, accurate, and validated encounter data will also support the evaluation and oversight of ILOS proposals described in sections I.B.4.g. and section I.B.4.h. of this final rule, and ensure appropriate rate development, as described in section I.B.4.e. of this final rule. In § 438.242(c)(2), we require that contracts between a State and its managed care plans provide for the submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight, and program integrity needs. Further, at § 438.242(d), States must review and validate that encounter data collected, maintained, and submitted to the State by the managed care plan is a complete and accurate representation of the services and settings provided to enrollees. Because ILOSs may not be easily identifiable in CPT® and HCPCS, we believe it is imperative that States identify specific codes and modifiers, if needed, for each ILOS and provide that information to its managed care plans to ensure consistent use. For example, the use of a modifier is useful when a State needs to separately identify an ILOS from a State plan-covered service or setting that may utilize the same HCPCS code. We proposed in § 438.16(d)(1)(vi), to require that States include a contractual requirement that managed care plans utilize the specific codes established by the State to identify each ILOS in enrollee encounter data. States could require the use of specific HCPCS or CPT codes and modifiers, if needed, that identify each ILOS. To the extent possible, we encouraged States to work towards the development of standard CPT® and HCPCS codes for ILOSs, and we noted that States may wish to collaborate with appropriate interested groups. For separate CHIP, while the provisions at § 438.66 are not applicable, we proposed to adopt the new coding requirements at § 438.16(d)(1)(vi) by amending § 457.1201(e) to include the cross-reference.

We considered allowing States to include this level of data outside of the managed care plan contract, such as in a provider manual or similar documents; however, those documents are frequently not readily available to interested parties and some are not made publicly available. We believe requiring specific codes to be in the managed care plan contracts would ensure that we can easily identify ILOSs in T–MSIS data, support program integrity activities, and ensure that the information is publicly available as required at § 438.602(g)(1). For these reasons, we believe requiring the codes for ILOSs in the managed care plan contract would be the most appropriate and efficient option. We also believe this proposal would ensure that ILOSs are easily identifiable in the base data utilized for development of capitation rates in accordance with rate development standards described in § 438.5(c), and the associated development of the projected and final ILOS cost percentage which are built off of capitation rates and capitation payments as proposed in section I.B.4.b. of this final rule.

States are required to submit an annual performance report to CMS for each Medicaid managed care program administered by the State in accordance with § 438.66(e)(1), known as the MCPAR. In § 438.66(e)(2), we specify the content of the MCPAR, including § 438.66(b)(11) that specifies accessibility and availability of covered services in the managed care plan contract. As ILOSs are substitutes for State plan-covered services and settings, we believe States should already be reporting on ILOSs in MCPAR, but to improve clarity for States, we proposed to add an explicit reference. Therefore, we proposed a minor revision to § 438.66(e)(2)(vi) to add the phrase ''including any ILOS.'' To facilitate States' reporting of their monitoring activities and findings for ILOSs in MCPAR, we intend to update the MCPAR report template to enable States to easily and clearly include ILOS data throughout the report. We believe that it is important for States to monitor trends related to the availability and accessibility of ILOSs given the unique and innovative nature of some ILOSs, and we believe using MCPAR will be an efficient way for States to report their activities.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(d), 438.66(e), 457.1201(e)) below.

Comment: Commenters generally supported the proposal to require States to identify and document in managed care plan contracts the specific codes and modifiers for ILOSs to utilize for encounter data. Commenters indicated that this proposal would make ILOS data more easily available in T–MSIS, support program integrity and provide transparency. One commenter also indicated that this proposal would provide plans, States and researchers more opportunities to assess and build the evidence base about which specific interventions work best as ILOSs and are medically appropriate and cost effective for specific clinically defined target populations.

Response: We agree that including ILOSs in encounter data is a critical component for appropriate program operations, oversight, and evaluation.

Comment: A few commenters suggested that CMS define and require specific ILOS codes for States to use for ILOS services to ensure uniformity and comparability of services across States, and one of those commenters also recommended that CMS provide States, managed care plans and providers with resources and technical assistance to educate providers on ILOS coding practices. Similarly, another commenter stated concerns that some ILOS providers, such as community-based organizations, have limited billing and coding experience and will need to build expertise and could benefit from necessary training and support. One commenter encouraged the use of Z codes to help identify SDOH factors.

Response: We encourage States to collaboratively work towards the development of standard CPT® and

HCPCS codes and modifiers for ILOSs, and we noted that States may wish to collaborate with appropriate interested groups in this section of the preamble. As the ILOSs utilized in States may vary and we do not want to stifle State innovation, at this time, we believe that States should continue to lead efforts to identify ILOS codes and modifiers that work best in their programs and provide necessary resources, training, and technical assistance to providers (although we remind States costs associated with these activities cannot be included within the capitation rates or ILOS cost percentage). CMS will continue to monitor States ILOS encounter data requirements to identify best practices and evaluate if CMS should consider further standardization in the future.

Comment: Commenters supported the proposal at § 438.66(e)(2)(vi) to include ILOSs in the MCPAR when States report on the availability and accessibility of covered services. One commenter noted it is unclear how ILOSs should be reported in the MCPAR.

Response: We appreciate the comments supporting our proposal to clarify that ILOSs are reported in the MCPAR in § 438.66(e)(2)(vi). As ILOSs are substitutes for State-plan covered services and settings, we believe States should already be reporting ILOSs in the MCPAR and we appreciate the support to clarify this issue. We intend to update the MCPAR template to enable States to easily, clearly, and separately include ILOS data in the report from State plan-covered services and settings. We also clarify that for separate CHIP, the provisions at § 438.66 are not applicable so we did not propose to adopt the additional reporting requirements through MCPAR.

Comment: One commenter requested clarification on how network adequacy standards will be applied to ILOSs given that MCOs provide ILOSs on an optional basis.

Response: We encourage States and managed care plans ensure appropriate access to ILOSs that States authorize, and managed care plans choose to offer so that enrollees have appropriate access to those ILOSs if they choose. As ILOSs are substitutes for State plan-covered services and settings, the access standards, such as the network adequacy standards outlined in § 438.68, are not required for ILOSs.

Comment: One commenter requested CMS provide additional guidance and discussion related to monitoring and reporting for ILOSs versus the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.

Response: We are unsure what specific guidance the commenter requires as they did not provide additional detail in their comment. Medicaid's EPSDT benefit for children and youth under age 21 provides a comprehensive array of preventive, diagnostic, and treatment services, as specified in section 1905(r) of the Act. Through EPSDT, States are required to provide comprehensive services and furnish all medically necessary services listed in section 1905(a) of the Act that are needed to correct or ameliorate health conditions, based on certain Federal guidelines. We direct the commenter to *Medicaid.gov* which provides more details on EPSDT requirements and related monitoring and reporting, including the annual EPSDT performance information required annually on Form CMS–416.[198] On the other hand, ILOSs are substitutes for State-plan covered services and settings that a managed care plan may provide at their option, and the related monitoring and reporting is outlined in the preamble of this final rule. We encourage States to request technical assistance from CMS if they have further questions on the monitoring and reporting for the EPSDT benefit and ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at (§§ 438.16(d), 438.66(e), 457.1201(e) as proposed.

g. Retrospective Evaluation (§§ 438.16(e) and 457.1201(e))

As part of Federal monitoring and oversight of Medicaid and CHIP programs, we regularly require States to submit evaluations to CMS that analyze cost or cost savings, enrollee health outcomes, or enrollee experiences for a specific Medicaid or CHIP benefit, demonstration, or managed care program. For example, as set forth in an SMDL[199] published on December 22, 1998, States with a program authorized by a waiver of section 1915(b) of the Act must conduct two independent assessments of the quality of care, access to care, cost effectiveness, and impact on the State's Medicaid program to ensure compliance with § 431.55(b)(2)(i) through (iii). There are also quality requirements at §§ 438.340 and 457.1240(e) for States contracting with a managed care plan to develop and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the plan. We also believe that States should evaluate and demonstrate that ILOSs are cost effective, medically appropriate, and an appropriate and efficient use of Medicaid and CHIP resources, and that such a requirement will be consistent with those existing requirements and the proposals outlined in sections I.B.4. of this final rule. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. To reduce State and Federal administrative burden, where possible, we again proposed a risk-based approach to the State documentation requirement that will be proportional to a State's ILOS cost percentage. We proposed, in § 438.16(e)(1) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to submit a retrospective evaluation to CMS of ILOSs, if the final ILOS cost percentage exceeds 1.5 percent, though we do encourage all States that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs. As a State could authorize multiple ILOSs in one managed care program, we believe that this evaluation should evaluate each ILOS in order to clearly assess the impact and effectiveness of each ILOS.

With § 438.16(e)(1)(i) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed that an evaluation be completed separately for each managed care program that includes an ILOS. We considered allowing States to evaluate ILOSs across multiple managed care programs to reduce State administrative burden and alleviate potential concerns regarding sample size for the evaluation. We further considered permitting States to self-select the appropriate level at which to evaluate ILOSs including for each managed care program, across managed care programs, or by managed care plan contract. However, in our experience, a State with multiple managed care programs (for example, behavioral health, physical health, etc.) could have differing enrollee eligibility criteria, populations, covered benefits, managed care plan types, delivery models, geographic regions, or rating periods among the separate managed care programs. Including more than one managed care program in an evaluation

[198] *https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html.*

[199] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd122298.pdf.*

will likely impact evaluation rigor and could dilute or even alter evaluation results due to the variability among managed care programs. As States will be required to provide the ILOS cost percentage for each managed care program, we believe that it is necessary for the evaluation to also be conducted at the individual program level as it is one measure to aid in evaluating the overall impact of the ILOSs. For these reasons, we believe it would be critical for States to provide separate evaluations for each managed care program that includes ILOSs. We sought public comment on whether the evaluation should be completed for each managed care program, across multiple managed care programs, each managed care plan contract, or at a level selected by the State.

Since these proposed retrospective evaluations will utilize complete encounter data, we considered several options for the length of the evaluation period. Often, evaluation reports are required on an annual basis, such as MCPAR in § 438.66(e) or the NAAAR in §§ 438.207(d) and 457.1230(b) for Medicaid and separate CHIP, respectively. We considered requiring an annual submission for the report required in § 438.16(e)(1) but believe that encounter data would be insufficient to result in meaningful analysis. We also considered a 3-year evaluation period, which may be sufficient for ILOSs that are immediate substitutes, but enrollees may need to receive longer-term substitutes for a period of several years in order for a State to have robust data. We also considered a 10-year period, but we concluded that seemed to be an unreasonably long time to obtain information on the efficient and effective use of these unique services and settings. We concluded that a 5-year period will provide sufficient time to collect complete data. Therefore, we proposed in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that a State's retrospective evaluation would use the 5 most recent years of accurate and validated data for the ILOSs. We believe the 5-year period will allow managed care plans and enrollees to become comfortable with the available ILOSs and opt to provide or receive them, thus generating the necessary data for the evaluation. Even for ILOSs that are longer-term substitutes, we believe a 5-year period will be sufficient to permit robust data collection for cost effectiveness and medical appropriateness. We requested comment on the appropriate length of the evaluation period. As described in section I.B.4.h. of this final rule, we also proposed in § 438.16(e)(2)(ii) that CMS may require the State to terminate the use of an ILOS if it determines the State is out of compliance with any ILOS requirement which includes if the evaluation does not show favorable results such as those consistent with those proposed in § 438.16(e)(1).

By proposing that retrospective evaluations be completed using the five most recent years of accurate and validated data for the ILOS(s), we recognized we needed to also propose the scope of the evaluation. We considered permitting States to identify an appropriate 5-year evaluation period, but ultimately decided against this as it could create a perverse incentive to identify a favorable evaluation period for each ILOS in order to circumvent the termination process proposed in § 438.16(e)(2)(iii) and described in section I.B.4.h. of this final rule. We also considered if the evaluation period should begin with the first year that a State exceeds the 1.5 percent final ILOS cost percentage threshold, but decided against this option as we believe it is necessary for evaluation rigor to establish an early or ideally, pre-intervention, baseline from which to evaluate the impact of a new ILOS over time. We concluded that States' evaluations should be retroactive to the first complete rating period following the effective date of this provision in which the ILOS was included in the managed care plan contracts and capitation rates; we proposed this in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP. We believe that our proposed approach is aligned with identified best practices for evaluation. We encouraged States to consider developing a preliminary evaluation plan for each ILOS as part of the implementation process for a new ILOS, and any time States significantly modify an existing ILOS. We requested comment on the appropriate timing of an ILOS evaluation period.

To ensure some consistency and completeness in the retrospective evaluations, we believe there should be a minimum set of required topics to be included. First, in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed to require that States must utilize data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS. Similar elements are required in evaluations for programs authorized by waivers approved under sections 1915(b) and 1915(c) of the Act and demonstrations under section 1115(a) of the Act. We believe these five proposed elements would permit CMS and States to accurately measure the impact and programmatic integrity of the use of ILOSs. We expanded upon these elements in § 438.16(e)(1)(iii) wherein we proposed the minimum elements that a State, if required to conduct an evaluation, would evaluate and include in an ILOS retrospective evaluation. We proposed, in § 438.16(e)(1)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate the impact each ILOS had on utilization of State plan-covered services and settings, including any associated savings. As an intended substitute for a State plan-covered service or setting, that is cost effective and medically appropriate as required in § 438.3(e)(2)(i), we believe that it is important to understand the impact of each ILOS on these State plan-covered services and settings and any cost savings that result from reduced utilization of such specific services and settings. We believe that this evaluation element would also require the State to evaluate potentially adverse trends in State plan services and settings utilization, such as underutilization of adult preventive health care. Per § 438.3(e)(2)(i), the State must determine that an ILOS is a cost effective substitute; therefore, we believe that it will be appropriate for a State to evaluate any cost savings related to utilization of ILOSs in place of State plan-covered services and settings. CMS will monitor the results of the evaluations to ensure the results are reasonable and CMS may request additional evaluations per § 438.16(e)(1)(v) as necessary. As described in section I.B.4.h. of this final rule, we also proposed in § 438.16(e)(2)(ii) that CMS may require the State to terminate the use of an ILOS if it determines the State is out of compliance with any ILOS requirement which includes if the evaluation does not show favorable results such as those consistent with those proposed in § 438.16(e)(1).

Similarly, we proposed in § 438.16(e)(1)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States evaluate trends in managed care plan and enrollee use of each ILOS. We believe that it is necessary to understand actual utilization of each ILOS in order to evaluate enrollee access to ILOSs and related trends that occur over time.

Trends in enrollee utilization of ILOSs could also be compared to data related to State plan services and settings utilization to determine if there is a correlation between utilization of certain ILOSs, and decreased or increased utilization of certain State plan services and settings. Trends in utilization of ILOSs may also help identify when enrollees choose not to utilize an ILOS to help States and managed care plans assess future changes in authorized ILOSs. We believe this is a key evaluation element necessary to determine if the ILOS was cost effective.

Critical to the authority for the allowable provision of ILOSs, is a State determination that an ILOS is a cost effective and medically appropriate substitute for a covered service or setting under the State plan as required in § 438.3(e)(2)(i). Therefore, we believe States should evaluate whether, after 5 years, its determinations are still accurate given actual enrollee utilization and experience for the clinically defined target population. To achieve this, we proposed § 438.16(e)(1)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which will require that States use encounter data to evaluate if each ILOS is a medically appropriate and cost effective substitute for the identified covered service or setting under the State plan or a medically appropriate and cost effective measure to reduce or prevent the future need to utilize the identified covered service or setting under the State plan. We have included the following example to identify how a State could use encounter data to evaluate the medical appropriateness and cost effectiveness of an ILOS. A State may initially determine that the provision of air filters as an ILOS is a medically appropriate and cost effective substitute service for a target population of individuals with poorly controlled asthma (as determined by a score of 25 or lower on the Asthma Control Test) in lieu of the covered State plan services of emergency department services, inpatient services and outpatient services. After analyzing the actual encounter data, the State may discover that the provision of air filters to this clinically defined target population did not result in decreased utilization of a State plan service such as emergency department services, inpatient services and outpatient services. In this instance, the evaluation results would demonstrate that the ILOS as currently defined was not a medically appropriate and cost effective substitute for the target population of individuals as currently defined.

As ILOSs are services and settings provided to Medicaid and CHIP managed care enrollees in lieu of State plan-covered services and settings, we believe that it is important for States to evaluate the quality of care provided to enrollees who utilized ILOSs to ensure that the ILOS(s) are held to the same quality standards as the State plan services and settings enrollees would otherwise receive. Quality of care is also a standard domain within evaluations of Medicaid and CHIP services, Medicaid and CHIP managed care plans, and Medicaid and CHIP programs as demonstrated by the ubiquitous use of the National Committee for Quality Assurance (NCQA) CAHPS survey, and HEDIS measure set which includes standardized and validated quality of care measures for use by States and managed care plans operating within Medicaid and CHIP managed care environments. Accordingly, in § 438.16(e)(1)(iii)(D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed that States evaluate the impact of each ILOS on quality of care. We believe that States should use validated measure sets, when possible, to evaluate the quality of care of ILOSs, though we do not want to stifle State innovation in this area, so we did not propose to require it. We considered proposing to require that States procure an independent evaluator for ILOS evaluations. In consideration of the myriad of new proposed requirements within this final rule, we weighed the value of independent evaluation with increased State burden. We were concerned that it would be overly burdensome for States to procure independent evaluators for ILOS(s) due, in part, to the timing of the final ILOS cost percentage submission. In section I.B.4.b. of this final rule, we proposed that the final ILOS cost percentage be submitted 2 years following completion of the applicable rating period, and we proposed here that if the final ILOS cost percentage exceeds the 1.5 percent, States would be required to submit an evaluation. While States should conduct some evaluation planning efforts, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the ILOS evaluation since States would not know definitely whether an evaluation is required until 2 years following the rating period. We solicited comment on whether we should consider a requirement that States use an independent evaluator for ILOS evaluations.

We believe that States should, to the extent possible, leverage existing quality improvement and evaluation processes for the retrospective ILOS evaluation. Through §§ 438.364(a) and 457.1250(a), we require States to partner with an EQRO to produce an annual technical report that summarizes findings related to each MCO's, PIHP's, PAHP's, or PCCM entity's performance relative to quality, timeliness, and access to health care services furnished to Medicaid and CHIP enrollees. Through these existing EQR activities at § 438.364(b), and, if finalized, the newly proposed optional activity at § 438.64(c)(7), discussed in more detail in section I.B.5.c. of this final rule, we believe States could leverage the CMS-developed protocol or their EQRO to assist with evaluating the impact of ILOSs on quality of care. We believe this new optional activity could reduce burden associated with these new evaluation requirements for ILOSs.

The elements we proposed in the evaluation should communicate a complete narrative about the State, managed care plans, and enrollees' experience with ILOSs. As key thresholds and limits on ILOSs, the final ILOS cost percentages would be another element that CMS would consider as part of the overall mosaic to understand the impact that an ILOS might have on each managed care program. Although the final ILOS cost percentage is proposed to be submitted with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after each rating period that includes ILOS(s), we believe it was important to the completeness of the retrospective evaluation, that all final ILOS cost percentages available be included. Therefore, we proposed in § 438.16(e)(1)(iii)(E) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that States provide the final ILOS cost percentage for each year in their retrospective evaluation, consistent with the report proposed in § 438.16(c)(5)(ii), (described in section I.B.4.b. of this final rule) with a declaration of compliance with the allowable 5 percent threshold proposed in § 438.16(c)(1)(i). We believe this necessary documentation of State compliance would be appropriate to document in the evaluation alongside the other data we proposed to ensure a fulsome evaluation that accurately demonstrates whether the ILOS(s) are an appropriate and efficient use of Medicaid and CHIP resources.

In section I.B.4.c. of this final rule, we proposed to identify enrollee rights and protections for individuals who are

offered or who receive an ILOS, and in section I.B.4.f. of this final rule we outlined requirements for States' monitoring of enrollee rights and protections. To determine if States have appropriately safeguarded and adequately monitored enrollee rights and protections, we proposed in § 438.16(e)(1)(iii)(F) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate appeals, grievances, and State fair hearings data, reported separately for each ILOS, including volume, reason, resolution status, and trends. As ILOSs are substitutes for covered State plan services and settings and are offered at the option of the managed care plan, we believe it will be important to evaluate appeals, grievances, and State fair hearing trends to ensure that enrollees' experience with ILOSs was not inconsistent or inequitable compared to the provision of State plan services and settings. We acknowledged that we already require for Medicaid, through § 438.66(e)(2)(v), that States include an assessment of the grievances, appeals, and State fair hearings annually in MCPAR. But the information we proposed that States submit with the ILOS retrospective evaluation was different as it would be specific to each ILOS compared to the summary level information required by MCPAR. We believe collecting these data by ILOS will help evaluate the quality of care and enrollee experience related to the provision of each ILOS.

Finally, we believe an evaluation of the impact ILOSs have on health equity efforts is a critical component to measure enrollee experience, health outcomes, and whether ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. As ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOHs and HRSNs, we also believe it was critical to measure their impact on improving population health and reducing health disparities. We proposed in § 438.16(e)(1)(iii)(G) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate the impact of each ILOS on health equity efforts undertaken by the State to mitigate health disparities. To do this, managed care plans should submit enrollee encounter data, to the extent possible, that includes comprehensive data on sex (including sexual orientation and gender identity), race, ethnicity, disability status, rurality, and language spoken. We reminded managed care plans of their obligations in §§ 438.242(c)(3) and 457.1233(d) to submit all enrollee encounter data that States are required to report to CMS under § 438.818; currently, T–MSIS provides fields for sex, race, ethnicity, disability status, and language spoken.

To allow adequate time for claims run-out and the evaluation to be conducted, we proposed in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States submit a retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included the ILOS following the effective date of this provision, if finalized. This 2-year timeframe is similar to the timeframe utilized for independent assessments to evaluate programs authorized by waivers approved under section 1915(b) of the Act.

While we believe many ILOSs can be sufficiently validated as medically appropriate and cost effective substitutes within 5 years, we know that some may not. To fulfill our program monitoring obligations, we believe we must be able to require additional evaluations if the initial evaluation demonstrates deficiencies. We proposed in § 438.16(e)(1)(v) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to explicitly assert our right to require States to provide additional 5-year retrospective evaluations. We believe that this could be a necessary flexibility when additional evaluation time might be needed, such as to demonstrate that an ILOS acting as a longer-term substitute for a covered State plan service or setting is cost effective and medically appropriate. We also believe we may need to utilize this flexibility when a State substantially revises the ILOSs that are options within a managed care program.

For CHIP, our typical mechanism for retrospective managed care cost evaluation is through the CHIP Annual Report Template System (CARTS). We recognized that CARTS is completed annually by States and that our proposed timeframe for the retrospective evaluation is for a period of 5 years, but we considered whether it would be less burdensome to States to incorporate the separate CHIP ILOS retrospective evaluation into CARTS rather than as a stand-alone report. We sought public comment on whether or not the proposed retrospective evaluation should be incorporated into CARTS for separate CHIP ILOSs.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(e) and 457.1201(e)) below.

Comment: Many commenters supported the proposed ILOS evaluations in §§ 438.16(e) and 457.1201(e) as they stated it was an appropriate guardrail to ensure ILOSs are in the best interests of the Medicaid and CHIP programs and would ensure appropriate assessment of whether ILOS are medically appropriate, cost effective, as well as improve access to care, ensure enrollee rights and protections, and advance health equity efforts. Commenters stated support for requiring these evaluations be conducted for each applicable managed care program, and all ILOSs in that program as they believe it would ensure robust evaluations. Commenters also supported the evaluation elements, as they believe this would ensure a fulsome, broad-based evaluation.

Response: We believe an evaluation of ILOSs is a reasonable component of a State's monitoring and oversight activities. States should be actively monitoring their ILOSs on a continual basis to ensure that each ILOS is an appropriate substitute for a State-plan covered service or setting that an enrollee is entitled to, including monitoring trends in the utilization of ILOSs, data related to appeals, grievances, and State fair hearings for each ILOS to ensure there are no concerns with beneficiary rights and protections, and that each ILOS continues to be medically appropriate and cost effective.

As we reviewed these comments, we recognized a revision to the technical text in § 438.16(e)(1)(i) was needed. In the proposed rule, we outlined our intent to require that a retrospective evaluation, when required, must include all ILOSs in that managed care program (see 88 FR 28171). Therefore, we are revising § 438.16(e)(1)(i) to include ''and include all ILOSs in that managed care program'' after ''be completed separately for each managed care program that includes an ILOS.'' The finalized revision to § 438.16(e)(1)(i) is also applicable to separate CHIP through a cross-reference at § 457.1201(e).

Comment: Some commenters supported revisions to the ILOS evaluation proposals. One commenter recommended that rather than requiring States conduct ILOS evaluations that CMS should assume this responsibility to reduce State administrative burden. Other commenters indicated the CMS should require States to conduct ILOS evaluations from all managed care programs to ensure that clinical learning and improvement can be derived from

those programs going forward. One commenter recommended that an evaluation be done for each managed care plan contract rather than by program though the commenter did not provide a substantive rationale for this alternative. Some commenters opposed this proposed evaluation requirement and raised concerns regarding the associated State administrative burden, possibility that it may inhibit State and managed care plan use of ILOSs, and/or did not find the evaluation necessary.

Response: We continue to believe that ILOSs evaluations are a reasonable and appropriate oversight mechanism to ensure ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. We also believe it is appropriate for States rather than CMS to conduct ILOS evaluations at this time. We also believe that evaluations should be done for each managed care program rather than across managed care programs or by managed care plan contract, as in our experience, the ILOSs in managed care programs may have differing enrollee eligibility criteria, populations, covered benefits, managed care plan types, delivery models, and geographic regions. While we encourage States to evaluate all ILOSs, we will maintain our proposed risk-based approach for providing evaluations to CMS to balance State administrative burden.

Comment: One commenter requested clarification on whether CMS's intent is for States to continuously submit a rolling 5-year evaluation. This commenter also suggested CMS consider requiring that States update ILOS evaluations within a certain number of years, similar to CMS's proposal for evaluations of State directed payments described in section I.B.2.j. of the proposed rule. Another commenter noted their belief that clarity was needed on the timing for when ILOS evaluations would first be expected.

Response: We appreciate these comments. Upon further review, we acknowledge that the preamble was inconsistent for this proposal as to when an evaluation would be required and for what 5-year period. We utilized both ''5 most recent years of accurate and validated data for ILOS'' in preamble (85 FR 28171) and proposed regulatory text at § 438.16(e)(1)(ii) (85 FR 28242), as well as ''the first 5 rating periods that included the ILOS'' in preamble (85 FR 28173) and proposed regulatory text at § 438.16(e)(1)(iv) (see 85 FR 28242).

We believe an evaluation is a helpful tool to ensure that ILOSs that have been in place for some time, as well as new ILOSs, such as those to address HRSNs, are reasonable and appropriate for Medicaid and CHIP enrollees. However, we also strive to balance State administrative burden; therefore, we are utilizing a risk-based approach to only require States submit an evaluation when the final ILOS cost percentage exceeds 1.5 percent as outlined in section I.B.2.b. of this final rule. Additionally, we do not believe it is necessary to have a ''rolling'' evaluation requirement as there are other monitoring and oversight tools that will continue to evaluate ILOSs, including the MCPAR required in § 438.66(e)(2), ILOS cost percentage and required State notification for identified issues at § 438.16(e)(2)(i) (see sections I.B.4.f., I.B.4.b. and I.B.4.h. of this final rule respectively). CMS also has the option to request an additional evaluation in § 438.16(e)(2)(v), such as if the ILOS is a longer term substitute and additional evaluation time is needed to determine whether an ILOS is a cost effective and medically appropriate substitute for a covered State plan service or setting (see 85 FR 28173).

As such, our intent was to require a retrospective evaluation of existing ILOSs typically only for a specified period of time (that is, 5 years) following the publication of the final rule unless new ILOSs are authorized by the State and offered by the plans. We also intend to utilize a risk-based approach to require States submit this evaluation to CMS if the final ILOS cost percentage for one of these 5 years exceeds 1.5 percent, unless CMS determines another evaluation is warranted. This intent is also consistent with the SMDL published on January 4, 2023,[200] which indicated that the evaluation would be completed for ''the first five contract years that include ILOS(s)'' following the effective date of the guidance.

We also recognize that some ILOSs have been used for many years and other ILOSs will begin to be new, and we acknowledge both circumstances as we determine an appropriate timeframe for States to submit the evaluation to CMS. Therefore, we intend to require this evaluation be submitted to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that include ILOSs or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent. We believe 2 years is a sufficient period of time as all States are encouraged to develop a preliminary evaluation plan for each ILOS as part of the implementation process for a new ILOS, and any time States significantly modify an existing ILOS (88 FR 28171), and States should actively be monitoring their ILOSs to ensure they are medically appropriate, cost effective and in compliance with other Federal requirements. States will also project an ILOS cost percentage each year, should be closely monitoring this percentage throughout the rating period and will reasonably know if the final ILOS cost percentage will exceed 1.5 percent during the rating period and 6 months following the rating period when most claims data are finalized. Therefore, we believe it is unnecessary to require the evaluation to be submitted 2 years after the State submits this final ILOS cost percentage to CMS as we believe this would create unnecessary delays.

Therefore, we replace the proposed language in the first sentence at § 438.16(e)(1) after the section title of ''Retrospective evaluation'' of ''A State with a final ILOS cost percentage that exceeds 1.5 percent, is required to submit at least one retrospective evaluation of ILOS to CMS'' with ''A State is required to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) following the applicability date in paragraph (f), or as required in paragraph (v).'' And finalize the second sentence in this subsection as proposed. Additionally, we replace language at § 438.16(e)(1)(iv) of ''The State must submit the retrospective evaluation to CMS no later than 2 years after the first 5 rating periods that included ILOS'' with ''The State must submit the retrospective evaluation to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent.'' The revisions to §§ 438.16(e)(1) and (1)(iv) are equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

We believe it would be helpful to provide a few illustrative examples of when an evaluation would be required, as well as the timeframe to be evaluated and the required timeline for submission of the ILOS evaluation to CMS. As one illustrative example, a State's managed care program that has 3 ILOSs that were first authorized by the State and documented in the managed care plan contracts for the CY 2027

[200] *https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf.*

rating period would be required to submit an evaluation of all 3 ILOSs to CMS if the final ILOS cost percentage for CYs 2027, 2028, 2029, 2030, or 2031 exceeds 1.5 percent. CMS also reserves the right to require the State to submit additional retrospective evaluations to CMS at § 438.16(e)(1)(v). If the final ILOS cost percentage for any of these 5 rating periods exceeds 1.5 percent, the State must submit an evaluation to CMS no later than 2 years after the completion of this 5-year period which in this example would be December 31, 2033, as this is 2 years following the completion of the first five rating periods that include the ILOSs. As a second illustrative example, a State's managed care program has 5 ILOSs that were first authorized by the State and documented in the managed care plan contracts in CY 2022. In CY 2027, the final ILOS cost percentage is 2 percent. The State is required to conduct an evaluation as the final ILOS cost percentage exceeds 1.5 percent. And this evaluation would be due to CMS by December 31, 2029, as this is 2 years following the completion of the CY 2027 rating period that had a final ILOS cost percentage that exceeded 1.5 percent. As a third illustrative example, a State's managed care program has 2 ILOSs that were first authorized by the State and documented in the managed care plan contracts in CY 2026. In CY 2040, the final ILOS cost percentage is 1.7 percent. Since CY 2040 is not the first 5 years following the applicability date in § 438.16(f), CMS would make a determination as to whether the State would be required to submit a retrospective evaluation per § 438.16(e)(1)(v).

Comment: Some commenters stated the 5-year evaluation period was appropriate while others recommended that CMS reconsider the 5-year look back period for evaluations and these commenters varied in their recommended timeframe, including 3 years or a longer evaluation period than 5 years. One commenter recommended 7 years while another commenter just indicated a timeframe greater than 5 years without specifying a specific timeframe. A few commenters indicated that many ILOSs are cost effective in the first year they are offered and indicated that in those circumstances reporting 5 years of data would be an unnecessary burden to apply unilaterally. One of these commenters recommended that CMS revise § 438.16(e)(1)(ii) to acknowledge that the evaluation would ''be completed using either the most recent year or 5 most recent years'' of accurate and validated data for the ILOS, and the commenter noted they believe this flexibility would allow States to evaluate the ILOS using data for either one or 5 years of data and that this constraint, as opposed to a revision of ''5 or fewer years'' would preclude States from cherry-picking the most favorable set of years.

Response: We continue to believe that 5 years of ILOS data is an appropriate time period as it would allow managed care plans and enrollees to become comfortable with the available ILOSs and opt to provide or receive them, thus generating the necessary data to evaluate. The commenters who recommended 3 years did not provide a substantive rationale for us to evaluate this recommendation further. We also agree with commenters that a longer evaluation period than 5 years may be needed in some circumstances which is why CMS will finalize § 438.16(e)(v) which allows CMS to require the State to submit additional retrospective evaluations to CMS when warranted.

In line with the revisions at § 438.16(e)(1) and (e)(1)(iv) that we are finalizing, we are also replacing the first sentence proposed at § 438.16(e)(1)(ii) of ''Be completed using the 5 most recent years of accurate and validated data for the ILOS'' with ''Be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii).'' In addition, we are finalizing the second sentence in this subsection as proposed. The revision to § 438.16(e)(1)(ii) is equally applicable to separate CHIP through the cross-reference at § 457.1201(e). Given inconsistency in the proposed rule discussed in the previous comment and response, this revision clarifies our intent, which is that the ILOS evaluation be completed using ILOS data from the first 5 rating periods that the ILOS is authorized by the State and offered by the managed care plan. Using the first illustrative example described in the previous comment, the ILOS evaluation would be required to utilize ILOS data from CYs 2027, 2028, 2029, 2030, and 2031. Additionally, using the second illustrative example described above, the evaluation would be required to utilize ILOS data from CYs 2022, 2023, 2024, 2025, and 2026.

Comment: We received some comments on ILOS data and its use in evaluations. A few commenters requested flexibility on data used for ILOS evaluations and raised concerns with requiring ILOS encounter data to be utilized for evaluations. Another commenter stated concern that States and plans would not utilize standard codes for ILOSs and there would then be little insight into the exact service provided. Other commenters recommended that CMS require specific data frameworks be utilized by States and plans for the ILOS evaluation, such as standardized social care data frameworks to report ILOS impact on health equity. A few commenters recommended that States work with managed care plans to encourage that ILOS data be stratified by various factors, including pregnancy status, as this provides useful insights in addressing health disparities and advancing health equity. One commenter also recommended the evaluation elements outlined in 438.16(e)(1)(ii) be expanded to include how many ILOSs were utilized with demographic data on age, disability, race, and ethnicity.

Response: As we further outline in section I.B.4.f. of this final rule, we believe that requiring managed care plans and their providers to utilize specific codes established by the State to identify each ILOS in encounter data is critical for appropriate monitoring, oversight, and evaluation; as such, we will not grant flexibility on this matter. The ILOS evaluation will include data on ILOS utilization as specified in § 438.16(e)(1)(iii)(A). Additionally, we continue to believe encounter data, when possible, must include data necessary for the State to stratify ILOS utilization by sex (including sexual orientation and gender identity), race, ethnicity, disability status, and language spoken to inform health equity initiatives and efforts to mitigate health disparities; and this type of data stratification can be utilized by States in many contexts beyond ILOSs. While we encourage States to stratify encounter data, when possible, we are not requiring it at this time given the data limitations that we recognize some States have, such as the data that enrollees choose to share. We are unclear what specific data the commenter is referring to when they indicated that data stratification by pregnancy status may also be useful. We agree that, when possible, States, plans and evaluators should stratify applicable data by pregnancy status to inform program development, oversight, and evaluation efforts. To aid these efforts, we remind commenters that we released a previous resource that may be helpful. As pregnant women are a critical subgroup of Medicaid beneficiaries and their identification in many administrative data files, such as the T–MSIS Analytic Files (TAF), is not

straightforward, CMS previously developed a set of specifications and programming code to help researchers who wish to use administrative data to analyze this population.[201] At this time, we are not requiring States to use a standardized social care data framework to evaluate the impact of the ILOS. As we monitor the use of ILOSs and State evaluations of ILOSs, we will continue to assess how various frameworks and standardization may be useful to States, managed care plans and CMS.

Comment: One commenter requested clarification on whether for purposes of the evaluation, the ILOS cost percentage will be calculated annually or as an average of the 5-year period of the evaluation.

Response: An ILOS evaluation will document the final ILOS cost percentage for each year of the respective evaluation as this percentage is an annual calculation. See section I.B.4.b. of this final rule for further details on the final ILOS cost percentage.

Comment: One commenter urged CMS to clarify how the proposed evaluation requirements would apply to MCOs serving dually eligible enrollees and account for data limitations on Medicare cost data.

Response: The evaluation proposed in § 438.16(e)(1) is critical to ensuring that ILOSs are used in an effective and efficient manner and achieve their intended purpose. CMS makes available a variety of Medicare claims data to States for dually eligible beneficiaries. As such, we believe States have sufficient relevant data on dually eligible enrollees to produce a robust evaluation.

Comment: A few commenters recommended that CMS create additional guidance or standardized templates for data collection and reporting associated with evaluations to make it easier for States to evaluate the effectiveness of ILOSs, and another recommended that CMS have final approval of the quality measures a State utilizes in an evaluation if it is not a validated measure set.

Response: We appreciate the recommendation regarding associated templates for data collection and reporting, and we will take this under advisement as we consider developing subregulatory guidance on ILOS evaluations. We recommend that States use validated measure sets, when possible, to evaluate the quality of care of ILOSs. At this time, we will not require CMS to approve States' measure sets as we do not want to stifle States' evaluation efforts including those of novel ILOSs. We will take this into consideration for future rulemaking as needed.

Comment: One commenter recommended that CMS consider tracking mechanisms to ensure States are on track to submit necessary evaluations while another recommended that ILOSs and associated costs be monitored at the State and national levels to inform future policymaking. One additional commenter also encouraged CMS to require that ILOS evaluations be publicly available.

Response: We agree with commenters that CMS and States should closely monitor the evaluation efforts for ILOSs, and that these efforts may inform future policy efforts. States should consider developing a preliminary evaluation plan for each ILOS as part of the implementation process for a new ILOS and any time States significantly modify an existing ILOS to ensure they are adequately prepared to conduct an ILOS evaluation when required. We also encourage States to post publicly on their websites all ILOS evaluations that they conduct, including those not required by CMS; however, we are not requiring this in Federal regulation at this time as this would cause additional State administrative burden than initially proposed in the proposed rule.

Comment: One commenter requested clarification on whether the proposed ILOS evaluation requirements would supersede any prior written requirements for an ILOS evaluation included in approved Standard Terms and Conditions for existing waivers and demonstrations under section 1915(b) and section 1115 respectively.

Response: Any approved Special Terms and Conditions in an approved waiver or demonstration, such as those under section 1915(b) or section 1115 of the Act, are additional requirements that are conditions of CMS's approval of the associated Medicaid authority.

Comment: We received some comments regarding our proposal to encourage, but not require States to utilize an independent evaluator for ILOS evaluations. Most commenters supported not requiring the use of an independent evaluator. One of these commenters indicated than an independent evaluator would be costly and administrative burdensome. A few commenters recommended that CMS require States use an independent evaluator.

Response: We appreciate this feedback from commenters. Given the majority of commenters supported our proposal, we plan to move forward with our proposal to encourage, but not require an independent evaluator for ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(e) and 457.1201(e) as proposed with a few changes. First, as discussed in this section, we will modify the text of § 438.16(e)(1), (1)(i), (1)(ii), and (1)(iv). Additionally, we will replace ''cost-effective'' with ''cost effective'' in § 438.16(e)(1)(iii)(C) to utilize consistent language with existing regulatory terminology in § 438.3(e)(2)(i).

h. State and CMS Oversight (§§ 438.16(e) and 457.1201(e))

If a State determines that an ILOS is no longer a medically appropriate or cost effective substitute or the State identifies another area of noncompliance in the provision of ILOSs, we believe CMS must be promptly notified. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. We proposed, in § 438.16(e)(2) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to establish processes and timelines for State and CMS oversight of ILOSs. In § 438.16(e)(2)(i)(A) and (B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed to require that States notify CMS within 30 calendar days if the State determines that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance in this proposed section. Issues of noncompliance that would require State notification to CMS included, but was not limited to, contravening statutory requirements (for example, the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, or the absence of the proposed provider documentation necessary to establish that an ILOS is medically appropriate for a specific enrollee. We believe that 30 days was a reasonable period of time for a State to identify and confirm an area of noncompliance. We considered a 60-day notification period, but believe that States should notify CMS in a more

[201] *https://www.medicaid.gov/medicaid/data-systems/macbis/medicaid-chip-research-files/transformed-medicaid-statistical-information-system-t-msis-analytic-files-taf/index.html.*

expeditious manner so that CMS may assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We sought comment on the time period for State notification to CMS to ensure it is reasonable and appropriate.

We believe a termination process for ILOSs was critical to properly safeguard the health and safety of Medicaid and CHIP enrollees. Therefore, we proposed a Federal oversight process at § 438.16(e)(2)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would permit CMS to terminate the use of an ILOS, if we determined noncompliance or receive State notification of noncompliance as proposed in § 438.16(e)(2)(i). In § 438.16(e)(2)(iii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed a process for termination of an ILOS that will apply when a State terminates an ILOS, a managed care plan elects to no longer offer an ILOS to its enrollees, or CMS notifies the State that it must terminate an ILOS. In any of these events, we proposed that the State will be required to submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision by the State to terminate an ILOS, a managed care plan notifying the State it will no longer offer an ILOS, or receipt of notice from CMS to terminate. In addition to 15 calendar days, we also considered 30, 60, and 90 calendar days, but ultimately decided on the former option. We recognize that 15 calendar days is a rapid submission timeline, but we firmly believe that such a transition plan would need to be implemented immediately following an ILOS termination to safeguard enrollee health and safety, and to maintain the integrity and efficient operation of the Medicaid program in accordance with sections 1902(a)(4) and 2101(a) of the Act. Given the submission timeline and that ILOSs are provided at the option of the managed care plan, we believe States should prepare an ILOS transition plan as part of the implementation process for any new ILOSs. The process for termination proposed at § 438.16(e)(2)(iii) is the same, regardless of whether the State, managed care plan, or CMS terminates the ILOS as the potential risks to enrollees are the same irrespective of which entity directs termination of the ILOS.

In § 438.16(e)(2)(iii)(A) through (D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed the elements States should include in the transition plan for the ILOS. We believe that a transition plan is necessary to protect the health and well-being of Medicaid and CHIP enrollees for whom the sudden termination of an ILOS, without an adequate transition plan, could have a significant negative impact. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. In § 438.16(e)(2)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we proposed to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditously as the enrollee's health condition requires. We also proposed, in § 438.16(e)(2)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States create and make publicly available a transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to the care for any enrollees receiving an ILOS at the time of termination. From the period of notification onward, we would expect that a State and its managed care plans cease provision of the ILOS to any new enrollees. Together, we believe that these two actions will ensure adequate beneficiary protections, including adequate beneficiary notice and access to medically appropriate State plan-covered services and settings in a timely fashion.

In addition to enrollee focused activities, we proposed that the transition plan also include administrative actions that States would take to remove a terminated ILOS from the applicable managed care plan contract(s) and capitation rates. ILOSs must be authorized and identified in the managed care plan contract consistent with § 438.3(e)(2)(iii) and § 457.1201(e), and we believe it was equally important to ensure any terminated ILOS is removed from the managed care plan contract (and rate certification if necessary) to ensure clarity on contractual obligations and appropriate program integrity. We proposed, in § 438.16(e)(2)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to direct States to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval as required for Medicaid in § 438.3(a). Similarly, we permitted States, through §§ 438.3(e)(2)(iv) and § 457.1201(e), to account for the utilization and actual cost of ILOSs in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly required otherwise. As part of the transition plan, States would be required to provide an assurance that it will submit the necessary contract amendment and outline a reasonable timeline for submitting the contract amendment to CMS for review and approval. In the event that an ILOS is terminated from the managed care plan contract, the State and its actuary, would evaluate if an adjustment(s) to the capitation rates is necessary to ensure Medicaid capitation rates continue to be actuarially sound, such as if the programmatic change will have a material impact to the rate development. As outlined in § 438.4 for Medicaid, actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the managed care plan contract, and the State's actuary must ensure that the capitation rates continue to be actuarially sound given any change to the contract. Therefore, we proposed in § 438.16(e)(2)(iii)(D) to direct States to adjust the actuarially sound capitation rate(s), as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2). As part of the transition plan, States would be required to provide an assurance that it will submit an adjustment to the capitation rates, as needed, and outline a reasonable timeline for submitting the revised rate certification to CMS for review and approval.

For separate CHIPs, States must develop capitation rates consistent with actuarially sound principles as required at § 457.1203(a). We also believe that in the event a separate CHIP ILOS is terminated, a State should evaluate if an adjustment to the capitation rate is needed to account for the removal of ILOS utilization and cost from the managed care plan contract. For this reason, we proposed to adopt § 438.16(e)(2)(iii)(D) for separate CHIP through a new cross-reference at § 457.1201(e). However, we note that the requirements at § 438.7 are not applicable for part 457.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(e) and 457.1201(e)) below.

Comment: Some commenters supported the proposed State notification requirements when a State determines that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance. The commenters stated the proposal ensured adequate notice and transparency. Many commenters also supported a required transition plan for terminated ILOS and prompt enrollee notification when an ILOS is terminated, and indicated it was appropriate oversight and transparency.

Response: We appreciate the support for these provisions which we believe are critical to ensure appropriate Federal oversight of ILOSs to ensure they advance the objectives of the Medicaid and CHIP programs, and properly safeguard the health and safety of Medicaid and CHIP enrollees. We take this opportunity to note that both States and CMS can determine that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting. Further, both States and CMS can identify other areas of noncompliance.

Comment: One commenter supported a 60-day time period for this notification rather than our proposed 30-day timeframe as the commenter indicated that additional time was necessary to provide this notification to CMS. This commenter also requested clarification on the format and process for this proposed notification. Another commenter opposed the State notification requirement.

Response: We continue to believe that requiring States to notify CMS within 30 calendar days is necessary to ensure appropriate oversight. We believe this is critically important in circumstances where enrollee's health or well-being may be impacted. We are concerned that 60 calendar days is not an adequate timeframe to ensure CMS can assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We also believe that States have existing experience on required notifications to CMS such as those required in § 438.610(d)(1) for prohibited affiliations and in § 438.742 for sanctions, as well as notifications related to the termination of waivers under section 1915(b) of the Act. Therefore, we do not believe additional guidance on the notification process is necesary, but we will provide technical assistance to States as necessary, and continue to evaluate if further guidance is necessary on this process for State notification.

As we reviewed these comments, we recognized a technical correction to the regulatory text in § 438.16. As outlined in this section of the preamble for the proposed rule (88 FR 28174), our intent was to require State notification of noncompliance with part 438 as evident by the examples to contravening statutory requirements (such as the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, etc. The proposed regulatory text utilized the term ''in this section'' which could be construed to reference only § 438.16. Therefore, we believe a technical correction is needed. While we are finalizing the notification timeframe as proposed, we are revising § 438.16(e)(2)(i)(B) to acknowledge that identified noncompliance relates to part 438, and not just § 438.16. The revision to § 438.16(e)(2)(i)(B) is equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

Comment: Some commenters raised concerns with our proposal that States must submit a transition plan to CMS within 15 calendar days. Several commenters indicated that 15 calendar days is not a reasonable timeframe to develop and submit a transition plan because States would struggle to collect necessary data from their managed plans, and analyze it quickly enough to develop a meaningful transition plan for the specific ILOS. Commenters stated that transition plans should ensure that enrollees experience minimal disruption to services when an ILOS is no longer available to them and developing a robust plan specific to each ILOS takes time and should include input from interested parties. These commenters noted they believe this is likely not feasible within 15 calendar days and recommended alternative timeframes of 45 days, 60 days, and 12 months. Further, commenters pointed out that this 15-day timeframe does not align with the 30-day timeframe for a State to notify CMS as proposed in § 438.16(e)(2)(i)(A) and (B). These commenters stated that this misalignment makes the requirements on States unclear which could lead to confusion and disruption for enrollees. One commenter also noted that in some instances, States may choose to terminate ILOSs at a future date, but the requirement to submit a transition plan is based on the decision to terminate and not the termination date; the commenter requested clarification on the which action the timeframe is tied to.

Response: We concur with commenters that smooth transitions with minimal disruption for enrollees is our goal. We proposed that an ILOS transition plan be submitted within 15 calendar days of the decision by a State, managed care plan or CMS to terminate an ILOS believing that to be the most appropriate timeframe to address potential health and safety concerns. However, we realize that monitoring for and addressing health and saftey concerns is a routine part of managed care plan operations and is done through multiple methods such as grievance monitoring, encounter data analysis, and utilization management. While identifying these issues must inform the development of a transition plan, we know that managed care plans will continue to prioritize addressing health and safety issues as expeditiously as necessary. We acknowledge that we may have focused on those issues too narrowly leading us to propose 15 calendar days, but we agree with commenters that transition plans have to be meaningful and address many aspects in order to be effective. After consideration of the comments, we are finalizing § 438.16(e)(2)(iii) to allow States up to 30 calendar days to submit an ILOS transition plan to CMS for review and approval to align with the State notification process so both of these activiites, when pertinent, could occur concurrently within the same 30-day timeframe. The revision to § 438.16(e)(2)(iii) is equally applicable to separte CHIP through the cross-reference at § 457.1201(e). We remind States that this 30-day timeframe to submit an ILOS transition plan is a maximum time period and States must always ensure that any health and safety issues for enrollees are mitigated as expeditiously as possible. We also continue to believe that the submission of a transition plan should be tied to the decision date and not the termination date to ensure adequate timing for enrollee notification and operational planning, as well as allow CMS time to review and approve the transition plan.

Additionally, as we reviewed these comments, we recognized that our intent in § 438.16(e)(2)(iii) would be clearer if we restructured the proposed language. In response to commenters' requests, we believe it would be helpful to clarify the specific actions that require an ILOS transiton plan to be submitted to CMS as the term ''decision'' appears to have caused confusion. Consistent with the intent outlined in this section of the proposed rule preamble, upon receipt of a notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS, an MCO, PIHP, or PAHP provides to the State of its decision to cease

offering an ILOS to its enrollees, or CMS provides to the State of its decison to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval. Therefore, we are finalizing § 438.16(e)(2)(iii) by replacing ''When a State decides to terminate an ILOS, an MCO, PIHP or PAHP decides to cease offering an ILOS to its enrollees, or CMS makes the decision to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision'' with ''Within 30 calendar days of receipt of a notice described in paragraph(e)(2)(iii)(A), (B) or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval: (A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS; (B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees; or (C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS.'' Additionally, we are redesignating requirements for an ILOS transition plan originally proposed in § 438.16(e)(2)(iii) to § 438.16(e)(2)(iv). The revisions to § 438.16(e)(2)(iii) and (iv) are equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

Comment: Some commenters recommended revisions to § 438.16(e)(iii) to require a termination process for ILOSs. One commenter requested that CMS outline a specific process, including timelines and parameters for notifying enrollees about the termination of an ILOS while another commenter requested that CMS outline the requirements for the termination process, but leave the management of the process to individual States. Another commenter recommended that in addition to a notification process for impacted enrollees, States should also notify providers and family caregivers. One commenter opposed the proposed requirement for States to notify enrollees of a terminated ILOS.

Response: We appreciate commenters' requests for further details on the activities related to ILOS terminations, including notifications to enrollees, providers, and family caregivers. We believe States should follow their standard practices for termination of services. For example, some States provide enrollees (and their authorized representatives, if applicable) a notice, such as a postcard and web posting, announcing an update to the enrollee handbook as required in § 438.10(g) and § 457.1207 for Medicaid and CHIP, respectively. We believe using a consistent process for ILOSs is reasonable and makes it easier for enrollees. Managed care plans should also provide notice to providers in accordance with their usual protocols.

Comment: One commenter stated that managed care plans should not have the ability to reverse their decision to cover ILOSs and suggested that a different termination process should apply in this situation. Specifically, the commenter recommended that CMS prohibit managed care plans from terminating coverage of an ILOS within a contract year, and that if a plan chooses to terminate an ILOS at the end of a rating period, the plan should be required to provide a 6-month transition period after enrollee and provider notice. This same commenter raised concerns with the proposed transition of care policy only pertaining to enrollees currently receiving the ILOS that will be terminated, and the commenter recommended that new enrollees be able to receive the ILOS during the transition period.

Response: We do not agree with the commenter than CMS should place requirements on managed care plans regarding how long a managed care plan must provide an ILOS before it can choose to no longer offer it. We believe ILOS authority is inherent in a risk contract in accordance with section 1903(m)(2)(A) of the Act which addresses risk-based capitation payments (88 FR 28161), and this is reflected in § 438.3(e)(2)(iii) which specifies that an ILOS is a substitute for a State-plan covered service or setting that will be offered to enrollees at the option of the managed care plan. As such, it is not appropriate for CMS to place limits on when a managed care plan can decide to no longer offer an ILOS to its enrollees. However, plans are obligated to ensure that enrollees have timely access to State-plan covered services and settings and should provide enrollees notice if they intend to change their coverage of an ILOS.

As we acknowledged in the proposed rule (85 FR 28174), we have concerns with enrollees being able to begin receiving an ILOS after the decision has been made that it is being terminated. We recognize that enrollees currently receiving an ILOS that will be terminated require time to transition to State plan services and settings and managed care plans must ensure that they are provided such services timely and with minimal disruption to care. However, we are concerned that allowing additional enrollees to receive an ILOS that is being terminated is inappropriate particularly when an ILOS is being terminated because it is no longer medically appropriate or has triggered health and safety concerns. Therefore, we decline to adopt the commenter's suggestion and will only require transition plans to be implemented for enrollees who are currently receiving an ILOS that will be terminated, and not allow terminating ILOSs to be provided to new enrollees during the transition period.

Comment: A few commenters submitted comments related to the administrative steps associated with terminating an ILOS, namely the proposed requirements to amend the managed care plan contracts and any necessay revised rate certification to amend capitation rates. One commenter recommended that States be required to notify CMS through a different reporting mechanism, such as the MCPAR, instead of amending a managed care plan's contract. Another commenter opposed a requirement to amend managed care plan contracts and amend capitation rates, as necessary.

Response: While we recognize that there is additional State burden to revise managed care plan contracts and revise rate certifications, as applicable, we continue to believe that these actions are necessary in circumstances when a State or CMS requires, or a managed care plan chooses to terminate an ILOS. As currently required in § 438.3(e)(2)(iii), ILOSs must be identified in the managed care plan contracts, which necessitates amending them to reflect the termination of an ILOS. Additionally, ILOSs are considered in the developement of actuarially sound capitation rates; therefore, if an ILOS is terminated from the managed care plan contract, the State and its actuary must evaluate if an adjustment(s) to the capitation rates is necessary to ensure Medicaid capitation rates continue to be actuarially sound. This is consistent with any programmatic change that may have a material impact to rate development.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(e) and 457.1201(e) as proposed with the following modifications:

- At § 438.16(e)(2)(i)(B), remove ''this section'' and replace it with ''this part.''
- At § 438.16(e)(2)(iii), modify text as discussed in this section.
- At § 438.16(e)(2)(iv), renumber text proposed at § 438.16(e)(2)(iii) within this new section entitled ''Requirements for an ILOS Transition Plan'' as discussed in this section.

i. Applicability Dates (§§ 438.3(e), 438.7(g), 438.10(g)(2)(ix), 438.16(f) and 457.1200(d))

We proposed that States and managed care plans would be required to comply with the provisions outlined in §§ 438.2, 438.3(c)(1)(ii) and (e)(2)(i) through (iv), 438.10(g)(2)(ix), 438.66(e)(2)(vi), and applicable cross-references for separate CHIP at §§ 457.10, 457.1201(c) and (e), and 457.1207 no later than the effective date of the final rule. We believe this is appropriate as these proposals are technical corrections or clarifications of existing requirements. Additionally, we proposed that States and managed care plans would comply with §§ 438.3(e)(2)(v), 438.16, and 438.7(b)(6) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We proposed to revise § 438.3(v) to add this proposed date, remove ''July 1, 2017,'' and update ''2015'' and referenced citations; and add §§ 438.7(g)(1) and 438.16(f). We proposed to adopt the applicability date at § 438.16(f) for separate CHIP by adding § 457.1200(d).

We summarize and respond to public comments received in this section related to ILOS applicability dates (§§ 438.3(e), 438.7(g), 438.16(f), 438.10(g), 457.1200(d)) below.

Comment: Some commenters requested that CMS delay the proposed applicability dates for ILOS provisions as they noted additional time was needed to make necessary contractual and operational changes. A few of these commenters requested delay of all ILOS provisions, one commenter requested delay of §§ 438.16(d) and 438.16(e), another recommended delay of § 438.66(c)(1), and one commenter recommended delay of § 438.66(e)(2)(vi). Other commenters were unclear which ILOS provisions they recommended be delayed. Additionally, we received commenters who requested CMS delay enforcement of the associated guidance published on January 4, 2023 until the effective date of the final rule.

There was also variability in the recommended revisions to applicability dates. One commenter recommended delaying all ILOS requirements to take effective with the next rate certification or contract submission. Another commenter recommended delaying ILOS provisions until the contract rating period beginning on or after 1 year following the effective date of the final rule. Other commenters did not provide specific recommendations on applicability dates. The commenter who specifically requested to delay the documentation, monitoring, evaluation, and oversight in § 438.16(d) and (e) recommended allowing States until September 1, 2024. This commenter noted additional time was needed to finalize necessary contract amendments with managed care plans. This commenter indicated these contract amendments typically take at least 90 days, and managed care plans typically need 60 to 90 days after these contractual changes to update their member handbooks and related processes. The commenter who requested a delay for MCPAR changes in § 438.66(e)(2)(vi) recommended a 2-year delay to allow time for States to make necessary changes to contracting, reporting templates, and systems. The commenter who requested a delay for the ILOS cost percentage limit in § 438.66(c)(1) recommended a 5-year delay to allow States sufficient time for necessary ILOS implementation changes.

Response: We continue to believe that the proposed applicability dates give States ample time to comply with the proposed regulatory changes for ILOSs. On January 4, 2023, we published guidance [202] to clarify the existing option for States to pursue efforts to address enrollees' unmet HRSNs, strengthen access to care, improve population health, reduce health inequities, and lower overall health care costs in Medicaid through the use of ILOSs. This guidance outlined our expectations for such ILOSs and provided a policy framework for States and managed care plans to ensure appropriate and efficient use of Medicaid resources. This guidance was effective with the date of publication; however, we acknowledged that States with existing ILOSs would need a glidepath to conform to the guidance given necessary procedural and contractual changes. Therefore, we allowed States with existing ILOSs to have until the contract rating period, beginning on or after January 1, 2024, to conform with the guidance for existing ILOSs. If States elected to add any new ILOSs, they were required to conform to this guidance for new ILOSs as of the publication of the SMDL. As the regulatory changes are generally consistent with the ILOS guidance, we believe States have had ample notice and should actively be making the necessary contractual and procedural changes. As such, we are finalizing the applicability dates as proposed.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(e), 438.7(g), 438.10(g)(2)(ix), 438.16(f), 457.1200(d) as proposed.

5. Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review (§§ 438.330, 438.340, 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240 and 457.1250)

a. Quality Assessment and Performance Improvement Program (§ 438.330)

Regulations at § 438.330 establish the Quality Assessment and Performance Improvement (QAPI) programs that States must require of Medicaid managed care plans (that is, MCOs, PIHPs, and PAHPs). Section 438.330(d) describes the performance improvement projects (PIPs) that States must require of Medicaid managed care plans as part of the QAPI program. MA plans are subject to similar (but not identical) requirements at § 422.152. In the proposed rule, we noted that § 422.152 outlines the quality improvement program requirements for MA organizations, including the development and implementation of a Chronic Care Improvement Program (CCIP) (88 FR 28175). We noted that CMS had previously required MA organizations to develop and implement Quality Improvement Project (QIPs), which were an organization's initiatives focusing on specified clinical and nonclinical areas and were expected to have a favorable effect on health outcomes and enrollee satisfaction. However, CMS found the implementation of the QIP and CCIP requirements had become burdensome and complex, and removed the requirements for the QIP. We removed the QIP requirement in the 2019 Final Rule (83 FR 16440). Accordingly, we proposed to update our regulations at § 438.330(d)(4) which still referenced a QIP as a substitute for a PIP in managed care plans exclusively serving dually eligible individuals.

In the 2016 final rule (81 FR 27682), we implemented a policy, at § 438.330(d)(4), to allow States to permit Medicaid managed care plans exclusively serving dually eligible individuals to substitute an MA plan's QIP conducted under § 422.152(d) in the place of a Medicaid PIP, to prevent unnecessary duplication and increase flexibility for plans and States. Subsequently, in the final rule ''Medicare Programs; Contract Year 2019 Policy and Technical Changes to

[202] *https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf.*

the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program,'' we removed the QIP from the requirements for MA organizations at § 422.152, because we determined that they did not add significant value and many were duplicative of existing activities, such as the CCIP (83 FR 16669). As we noted in the proposed rule, we neglected to remove a reference to the QIP from § 438.330(d)(4) to conform with the changes at § 422.152. We proposed to replace the outdated reference at § 438.330(d)(4) to § 422.152(d) (which previously described the now-removed QIP), with a reference to the CCIP requirements for MA organizations in § 422.152(c). Under our proposal, States could permit a Medicaid managed care plan exclusively serving dually eligible individuals to substitute an MA organization CCIP, conducted in accordance with the requirements at § 422.152(c), for one or more of the PIPs required under § 438.330(d). We noted our belief that the CCIP meets the same intent of the current regulation as an appropriate substitute for a PIP, based on the quality improvement standards in a CCIP, including the identification of intervention goals and objectives, the collection and analysis of valid and reliable data, the assessment of performance and outcomes using quality indicators and measures, systematic and ongoing follow-up for increasing or sustaining improvement, and the reporting of results to CMS. We noted our belief that permitting such a substitution would also maintain the intent of the current regulation to prevent unnecessary duplication and increase flexibility for plans and States, while allowing Medicaid managed care plans to maintain robust health improvement initiatives for dually enrolled individuals. Since the change to remove QIPs has been in place since 2019, we stated that we expected some States to already have CCIPs in place of QIPs, and therefore, we proposed that States must comply with this update in § 438.330(d)(4) no later than the rating period for contracts beginning after the effective date of the final rule in the applicability date provision at § 438.310(d)(1). We noted that this proposed change does not apply to separate CHIP because we did not apply § 438.330(d)(4) to separate CHIP in the 2016 final rule, and because § 457.310(b)(2) does not allow for concurrent health coverage in separate CHIP.

We summarize and respond to public comments received on our proposal to allow States to permit plans exclusively serving dually eligible individuals to substitute an MA organization CCIP, conducted in accordance with the requirements at § 422.152(c), for one or more of the PIPs required under § 438.330(d), below.

Comment: Several commenters supported our proposal to replace the outdated reference at § 438.330(d)(4) to § 422.152(d) (which previously described the now-removed QIP), with a reference to the CCIP requirements for MA organizations in § 422.152(c). A few commenters requested CMS provide clarification on the definition of the term ''exclusively'' and how CMS intends to define MCOs ''exclusively'' serving dually eligible individuals.

Response: For the comments regarding the definition of the term ''exclusively,'' our proposal would not change the intent of the previous policy that allowed States to permit Medicaid managed care plans that exclusively serve dually eligible individuals to substitute a quality plan required for their MA organization for a PIP required for the Medicaid managed care plan. It only replaces the reference to a QIP (which are no longer in use) with a CCIP. Under this final rule, like the previous policy, ''exclusively serving dually eligible individuals'' means the policy would only apply to Medicaid managed care plans whose enrollees are all dually eligible for Medicare and Medicaid.

After reviewing the public comments, and for the reasons described in the proposed rule, we are finalizing the change to § 438.330(d)(4) as proposed. We note that we are modifying the effective date of this provision to allow States with Medicaid managed care plans that exclusively serve dually eligible individuals to substitute an MA plan's CCIP conducted under § 422.152(c) in the place of a Medicaid PIP effective with the effective date of this final rule. The proposed applicability date would have required States to comply with this update in § 438.330(d)(4) no later than the rating period for contracts beginning after the effective date of the final rule in the applicability date provision at § 438.310(d)(1) (88 FR 28175); however, this was an error. Since the change is optional for plans, we are not finalizing the applicability date proposed at § 438.310(d)(1), since separate applicability dates are only required if the effective date is different from that of the final rule.

b. Managed Care State Quality Strategies (§§ 438.340 and 457.1240)

Current regulations at § 438.340, which are included in separate CHIP regulations through an existing cross-reference at § 457.1240(e), set forth requirements for States to draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, or PAHP. The requirement also applies to a PCCM entity whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). The quality strategy is intended to serve as a foundational tool for States to set goals and objectives related to quality of care and access for their managed care programs. Regulations at § 438.340(c) require States to make their quality strategy available for public comment when drafting or revising it and require States to submit their initial quality strategy to CMS for feedback prior to adopting in final. These regulations also stipulate that States must review and update their quality strategy as needed, but no less than once every 3 years and submit the strategy to CMS whenever significant changes are made to the document or whenever significant changes occur within the State's Medicaid program. Building upon these requirements, we proposed several changes to increase transparency and opportunity for meaningful ongoing public engagement around States' managed care quality strategies. We proposed that States must comply with these updates in § 438.340 no later than 1 year from the effective date of the final rule and proposed to codify this applicability date at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

First, we proposed to increase the opportunity that interested parties have to provide input into States' managed care quality strategy. Regulations at § 438.340(c)(1) require that States make their quality strategy available for public comment when it is first adopted and when revisions are made. However, the regulations did not require that the quality strategy be posted for public comment at the three-year renewal mark if significant changes had not been made. We proposed to revise § 438.340(c)(1) to require that States make their quality strategy available for public comment at the 3-year renewal, regardless of whether or not the State intends to make significant changes, as well as whenever significant changes

are made. The proposed change would promote transparency and give interested parties an opportunity to provide input on changes they believe should be made to the quality strategy, even if the State itself is not proposing significant changes. We noted that States would retain discretion under the proposed rule to define the public comment process. We proposed this change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

Second, we proposed to revise § 438.340(c)(2)(ii) to clarify that the State Medicaid agency must post on its website the results of its 3-year review. The regulations clarify at § 438.340(c)(2) that the review must include an evaluation, conducted within the previous 3 years, of the effectiveness of the quality strategy and that the results of the review must be made available on the State's website, but do not specifically state that the full evaluation must be posted on the website. We proposed revisions at § 438.340(c)(2)(ii) to make clear that the evaluation, as part of the review, must be posted. We noted that § 438.340(c) allows for States to post the evaluation on the website as a standalone document or to include the evaluation in the State's updated and finalized quality strategy, which is required to be posted under § 438.340(d). We proposed this change at § 438.340(c)(2)(ii) would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e). For additional information on the components and purpose of the managed care quality strategy, see the Quality Strategy Toolkit, available at *https://www.medicaid.gov/medicaid/downloads/managed-care-quality-strategy-toolkit.pdf*.

Third, we proposed to clarify when States must submit a copy of their quality strategy to CMS. Regulations at § 438.340(c)(3) require that States submit to CMS a copy of their initial quality strategy for feedback and a copy of the revised quality strategy whenever significant changes are made. The regulations did not require States to submit to CMS subsequent versions of their quality strategy unless the State has made significant changes to the document or to their Medicaid program. We proposed to modify § 438.340(c)(3)(ii) to require that States, prior to finalizing a revised or renewed quality strategy as final, submit a copy of the revised strategy to CMS at minimum every 3 years, following the review and evaluation of the strategy described at § 438.340(c)(2), in addition to when significant changes are made. These changes would allow CMS the opportunity to provide feedback periodically to help States strengthen their managed care quality strategies before they are finalized, whether or not significant changes are made to a State's strategy or to their Medicaid program. We proposed to include this requirement into the provision at § 438.340(c)(3)(ii) for Medicaid by adding paragraphs (c)(3)(ii)(A) through (C), which applies to separate CHIP through an existing cross-reference at § 457.1240(e). We proposed at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with updates to § 438.340 no later than 1 year from the effective date of the final rule, which we believed would give States time to update internal processes accordingly.

Finally, we proposed a technical correction to § 438.340(c)(3)(ii) to correct an internal citation related to State-defined significant changes. Currently, § 438.340(c)(3)(ii) references significant changes ''as defined in the State's quality strategy per paragraph (b)(11) of this section[.]'' However, § 438.340(b)(10) contains the information on a State's definition of a significant change. Therefore, we proposed to replace ''paragraph (b)(11)'' with ''paragraph (b)(10)'' in § 438.340(c)(3)(ii). This proposed change will apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

We summarize and respond to public comments received on Managed Care State Quality Strategies (§§ 438.340, 457.1240) below.

Comment: Several commenters supported our proposals to increase the opportunity for public comment, clarify the requirements for posting the quality strategy evaluation on the State Medicaid website, and submit the quality strategy to CMS every 3 years regardless of whether significant changes were made. One commenter opposed the publication of the State's quality strategy for public comment every 3 years regardless of whether a significant change was made, and one commenter opposed the proposal to submit the quality strategy to CMS regardless of whether a significant change was made. The commenter opposing the provision requiring public comment noted that the requirement would be burdensome for States and that the current requirements are sufficient. Some commenters requested CMS impose more requirements on the State public comment process, such as requiring a certain amount of lead time for the public to make comments, and requiring States to publicly document the actions they took in response to the public feedback, or the rationale for not taking actions requested by the public. One commenter requested clarification on what is considered a significant change.

Response: We disagree with commenters who thought the current requirements were sufficient. Under § 438.340(b)(10), it is up to the State to define what is considered a significant change, and to include that definition in their quality strategy. Without finalizing these changes, States may make revisions that do not rise to the level of ''significant change,'' as defined by the State, and would not be required to post the quality strategy for public comment or submit the strategy to CMS for feedback. We believe these new requirements bring the regulations closer to the original intent—for the quality strategy to evolve over time with the shifting needs of the managed care population, and for the public and CMS to weigh in on the strategy every 3 years.

We also appreciate the comments recommending additional requirements on how States administer the public comment process. In the proposed rule, we stated that States would retain discretion to define the public comment process. We clarify that States are currently required under § 438.340(c)(1) to obtain input from the Medical Care Advisory Committee, beneficiaries and interested parties, as well as consult with Tribes, if appliable, during the public comment process. We did not propose additional requirements on the public comment process for the quality strategy, and are therefore, not finalizing any additional requirements at this time.

Comment: One commenter noted that the timeframe we proposed to implement these changes to the quality strategy requirements (1 year from the effective date of the final rule) was reasonable, and one commenter requested we consider a longer timeframe, such as 2 years, for compliance with these new requirements to help States manage the process.

Response: We continue to believe the timeframe we proposed is reasonable given that many States are already implementing the policies we proposed based on our review and feedback provided on quality strategies to date. Therefore, we are finalizing the implementation date as proposed.

We did not receive any comments on the proposed technical correction to replace ''paragraph (b)(11)'' with

''paragraph (b)(10)'' in § 438.340(c)(3)(ii), and are therefore finalizing this provision as proposed.

After reviewing the public comments, we are finalizing the rules for the quality strategy as proposed. We note that the applicability date, though unchanged, will be finalized at § 438.310(d)(1), not § 438.310(d)(2) as proposed.

c. External Quality Review (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240 and 457.1250)

Current regulations at §§ 438.350, 438.354, 438.358, 438.360, 438.364, and 457.1250 provide requirements for the annual External Quality Review (EQR) on quality, timeliness, and access to the health care services furnished to Medicaid and CHIP beneficiaries enrolled in managed care. The regulations set forth the EQR-related activities that States or a qualified EQR organization (EQRO) must perform, and the information that must be produced from an EQR and included in an annual detailed EQR technical report. States must submit to CMS an annual EQR technical report, which must include, among other things, a description of data, including validated performance measurement data for certain mandatory EQR-related activities. The regulations also delineate the circumstances in which States may use the results from a Medicare or private accreditation review in lieu of conducting an EQR for a given managed care entity. The EQR requirements in subpart E of part 438 apply to each MCO, PIHP, and PAHP that has a contract with a State Medicaid or CHIP agency, as well as certain PCCM entities whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). We proposed several changes to the EQR regulations that seek to accomplish two overarching goals: (1) eliminate unnecessary burdensome requirements; and (2) make EQR more meaningful for driving quality improvement.

(1) Removal of PCCM Entities From Scope of Mandatory External Quality Review

In the final 2016 final rule, we added a definition of ''primary care case management entity'' in §§ 438.2 and 457.10 to recognize a new type of primary care case management system in Medicaid and CHIP. Previously, the regulations recognized, and continue to recognize, a primary care case manager (PCCM) as a physician or a physician group practice or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife that contracts with the State to furnish case management services to Medicaid beneficiaries. The 2016 final rule added the term ''PCCM entity,'' which is defined in §§ 438.2 and 457.10 as an organization that provides one or more additional specified functions in addition to primary care case management services, for example, intensive case management, development of care plans, execution of contracts with and/or oversight responsibilities for other FFS providers, and review of provider claims, utilization and practice patterns, among others. We further recognized in the 2016 final rule that some PCCM entities have contracts with the State that provide financial incentives for improved quality outcomes. Per current § 438.310(c)(2), such PCCM entities are subject to a number of the requirements in part 438, subpart E (relating to Quality Measurement and Improvement and External Quality Review) to which PCCMs are not similarly subject.

Of particular relevance to this final rule, the regulations have long provided that States are not required to perform an annual EQR of the State's PCCMs. However, in the 2016 final rule, we provided at §§ 438.350 and 457.1250(a) that States are required to conduct an annual EQR of PCCM entities operating under a risk-bearing contract described in § 438.310(c)(2). We reasoned at the time that, while PCCMs traditionally are paid a per capita fee to provide case management services for Medicaid beneficiaries and otherwise are reimbursed for services rendered on a FFS basis, such PCCM entities function more like a managed care entity because their contracts include shared financial risk, and thus should be subject to the EQR requirements.

The 2016 final rule also provided for CMS review of States' contracts with their PCCM entities under § 438.3(r). Our reviews of these contracts have led us to reevaluate the policy to require an annual EQR of PCCM entities described in § 438.310(c)(2), as these contracts exhibit wide variability in the size, structure, and scope of case management and other services provided by risk-bearing PCCM entities. This variation called into question the appropriateness of EQR as an oversight tool for many of the PCCM entities. For example, the scope of services for some of these PCCM entities may yield little to no data for EQR. In addition, some PCCM entities are a single provider or a small provider group, and we believe the cost and burden imposed by the EQR process may disincentivize them from entering into risk-bearing contracts with States aimed at improving quality and outcomes in the FFS delivery system. We do not believe the EQR requirement should be a barrier for these types of PCCM entities to establish arrangements aimed at quality improvement when States have additional quality monitoring and oversight tools that may be sufficient (for example, QAPI program reviews described at § 438.330(e)).

Therefore, we proposed to remove PCCM entities described in § 438.310(c)(2) from the managed care entities subject to EQR under § 438.350. Other requirements in part 438, subpart E that currently apply to risk-bearing PCCM entities described at § 438.310(c)(2) are not impacted by this final rule.[203] We noted that States may perform additional oversight and monitoring activities that are similar to mandatory external quality reviews for PCCM providers (and other providers not subject to EQR such as non-emergency medical transportation providers) at their discretion, and may choose to use an entity that is also an EQRO for these activities, however these activities will not be subject to EQR regulations at part 438. Further, we believe that the removal of all PCCM entities from the mandatory scope of EQR would alleviate burden on States and PCCM entities while retaining appropriate tools for quality monitoring and oversight.

We proposed conforming amendments to remove reference to PCCM entities described in § 438.310(c)(2) at §§ 438.310(b)(5), 438.358(a)(1), 438.364(a)(3) through (6), and 438.364(c)(2)(ii), and to remove the reference to § 438.350 from § 438.310(c)(2). We also proposed removing the current provision at § 438.358(b)(2) that applies risk-bearing PCCM entities to the mandatory EQR activities, to conform with the proposed changes at § 438.350, and reserve this provision for future use. We maintain that EQROs must be independent from any PCCM entities they review at the State's discretion, as currently required under § 438.354(c), and proposed a modification at § 438.354(c)(2)(iii) to clarify this. We note that these changes,

[203] States are currently required to include their PCCM entities in CMS contract review under § 438.3(r), and for PCCM entities described at § 438.310(c)(2), States must include them in aspects of their quality assessment and performance improvement programs (QAPI) including an annual utilization and program reviews (§ 438.330(b)(2), (b)(3), (c), and (e)), and their quality strategy (§ 438.340), which includes a quality strategy effectiveness evaluation. States have the discretion under § 438.358(d) to use their EQRO to provide technical assistance to PCCM entities described at § 438.310(c)(2).

if finalized, would be effective as of the effective date of the final rule. For separate CHIP, we likewise proposed to exclude all PCCM entities from EQR requirements by removing the cross-reference to § 438.350 at § 457.1201(n)(2), by removing the reference to PCCM entities entirely from § 457.1250(a), and removing the cross-reference to § 457.1250(a) for quality requirements applicable to PCCM entities at § 457.1240(f).

We summarize and respond to public comments received on Removal of PCCM entities from scope of mandatory External Quality Review below.

Comment: Several commenters supported our proposal to remove the EQR requirements for PCCM entities described at § 438.310(c)(2). Some commenters noted that States will continue to exercise optional participation for PCCM entities in the performance measure validation activity, especially where performance measures are not otherwise evaluated by an independent auditor.

Response: As we noted in the proposed rule, we intended to allow flexibility for States to continue to monitor PCCM entities at their discretion, including through EQR. Therefore, we are finalizing these changes largely as proposed, with one revision to more explicitly allow validation of performance measures and performance improvement projects conducted by PCCM entities described at § 438.310(c)(2) at the discretion of States, which was supported by public comments. Specifically, we proposed to remove § 438.358(b)(2) to implement our proposal to exclude PCCM-entities described at § 438.310(c)(2) from EQR. Instead, we are finalizing a modification to this provision to remove the word ''must'' and replace it with ''may.'' It now reads ''For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section *may* be performed'' (emphasis added). This change will allow States that choose to conduct these activities to continue to access FFP at the 50 percent rate in accordance with § 438.370(b). We are also finalizing a technical change to remove the references to PCCM entities described at § 438.310(c)(2) within the optional activities at § 438.358(c)(3) and (4) since they are no longer included in the required activities referenced at § 438.358(b)(1)(i) and (ii) but are included in the list of plans for which States can exercise optional activities at § 438.358(c).

After reviewing the public comments, we are finalizing the rules for the removing EQR requirements for PCCM entity (described in § 438.310(c)(2)) with modifications at § 438.358(b)(2), and at § 438.358(c)(3) and (4).

(2) EQR Review Period

In the proposed rule, we noted that the regulations provided that most EQR activities are performed using information derived from the preceding 12 months, but did not clearly indicate to which 12-month period the activity should pertain. Specifically, the regulations at § 438.358(b)(1) (which apply to separate CHIP through an existing cross-reference at § 457.1250(a)) required validation of information collected or calculated during ''the preceding 12 months'' for three of the mandatory EQR activities (validation of performance improvement projects, validation of performance measurement data, and validation of network adequacy activities). The optional EQR activities described in § 438.358(c) were also required to use information derived ''during the preceding 12 months.'' In addition, we did not previously specify in the regulations when the EQR activity must take place relative to the finalization and posting of the annual report. The result was a lack of uniformity in the review periods included in States' annual EQR technical reports each year. In some cases, for example, States reported on the results of EQR activities conducted 3 or more years ago, while other States reported on the results of EQR activities conducted relatively close to the completion of the report. To support States' and CMS's ability to use the reports for quality improvement and oversight, we proposed modifications to ensure consistency and align the data in the annual reports with the most recently available information used to conduct the EQR activities.

We proposed to add paragraph (a)(3) in § 438.358 to define the 12-month review period for all but one of the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). The one exception is the activity described in § 438.350(b)(1)(iii), which requires a review within the previous 3 years. We proposed at § 438.358(a)(3) that the 12-month review period for the applicable EQR activities begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity.

We understand that most performance measures run on a calendar year, while performance improvement projects and network adequacy assessments typically align with the contract year. We proposed that the 12-month review period for EQR activities does not have to be the same. For example, if an EQRO begins the performance measurement validation activity in July of 2022, and the State calculates performance measures on the calendar year, the review period for the performance measurement validation activity will be January 1 through December 31, 2021. Similarly, if the EQRO validates PIPs in November 2021 and the most recent contract year ended in March 2021, the review period for the EQRO will be March 2020–March 2021.

We also proposed to require at § 438.358(b)(1) and (c) that the EQR-related activities must be performed in the 12 months preceding the finalization and publication of the annual report. We believe these two proposed changes would result in more recent data being publicly posted in the annual EQR technical reports and would create more consistency among States regarding the time period represented by the data. Consistency in what data are reported could help make the EQR technical reports a more meaningful tool for monitoring quality between plans within and among States.

We proposed the 12-month review period for the applicable EQR-related activities described in § 438.350(b)(1) and (c) would be effectuated at proposed § 438.358(a)(3). We proposed conforming changes to § 438.358(b)(1)(i), (ii) and (iv), and (c) to reference the EQR review period proposed at § 438.358(a)(3). We proposed to modify the language at § 438.350(b)(1) and (c) to indicate that the EQR-related activities must be performed in the 12 months preceding the finalization of the annual reports. We proposed changes would apply equally to separate CHIP EQR requirements for MCOs, PIHPs, and PAHPS through an existing cross-reference to Medicaid's EQR-related activities in § 438.358 at § 457.1250(a). We proposed that States must comply with these updates to § 438.358 no later than December 31, 2025, and proposed to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. We believed this timeline would allow States the time to make any contractual or operational updates following the final rule.

We summarize and respond to public comments received on EQR review period below.

Comment: Several commenters supported the proposed changes to the EQR review period, noting the importance of using the most recent

available data and creating more uniformity across State EQR reports. One commenter encouraged us to consider further standardizing the reporting periods along the calendar year. Another commenter supported the alignment of review periods but noted that some EQR activities may not be completed in the 12-month timeframe proposed.

Response: After reviewing the public comments, we are finalizing these provisions as proposed for EQR mandatory activities and, based on comments received about how some EQR activities are not completed in a 12-month timeframe, revising how the review period is applied to EQR optional activities. We considered the commenter's suggestion to align all review periods on the calendar year, but decided against this since many States use the contract year as a review period which may be more appropriate in some circumstances. In response to the commenter's concern about the EQR activities taking more than 12 months, we continue to believe applying these timeframes will result in the most recent available data for the three applicable mandatory activities at § 438.358(b)(1) (which apply to separate CHIP through an existing cross-reference at § 457.1250(a)). We encourage States to request technical assistance if they experience challenges with these new timeframes and anticipate that with our decision (discussed in section I.B.5.c.5. of this final rule) not to move up the EQR report deadline to December 31 will help States implement these changes. However, the commenter's concern about EQR activities taking more than 12 months did make us reconsider how the review periods apply to EQR optional activities, particularly with the finalization of the new optional activity at § 438.358(c)(7) for evaluations (discussed in section I.B.5.c.3. of the final rule). Based on comments received, we no longer believe the review period proposed applies equally between mandatory and optional EQR activities. If we finalized our proposed review period timeline for optional activities, the data and information used for optional activities would be limited to a 12-month period, which conflicts with the 3–5 year time periods required to be evaluated for quality strategies, SDPs and ILOSs. Therefore, we are finalizing the regulations at § 438.358(c) to remove the reference to a review period from the optional activities, and to remove the reference to the optional activities in the new review period regulation at § 438.358(a)(3). We believe this modification will provide flexibility for States to determine the appropriate time periods for the optional activities they implement based on the intended use of the data obtained from these activities.

Based on our review of public comments, we are finalizing this provision with modifications at § 438.358(c) and finalizing the applicability at § 438.310(d)(2) for Medicaid (not § 438.310(d)(3) as proposed), and at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

(3) Using an Optional EQR Activity To Support Current and Proposed Managed Care Evaluation Requirements

We proposed to add a new optional EQR activity to support States in their evaluations to learn more about quality outcomes and timeliness of and access to care in managed care plans and programs. Specifically, we believe the existing or proposed evaluation requirements included in this final rule for quality strategies at § 438.340(c)(2)(i), State Directed Payments (SDPs) at § 438.6(c)(2)(iv) and (v), and In Lieu of Services or Settings (ILOSs) at § 438.16(e)(1) may be implemented using this new EQR activity. We currently require at § 438.340(c)(2)(i) that States review their quality strategy at a minimum every 3 years, and that this review include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years. In this final rule, we finalize new requirements related to the evaluation of SDPs at § 438.6(c)(2)(iv) and (v) and ILOSs at § 438.16(e)(1), described in more detail in sections I.B.2.j. and I.B.4.g. of this final rule. We discussed at length the challenges States have demonstrated regarding the SDP evaluation plans and results in the proposed rule, which indicated to us that States will likely benefit from additional technical assistance and support in conducting evaluations under the new SDP and ILOS requirements. Additionally, we described how CMS's reviews of State quality strategy evaluations revealed many challenges for States and a similar need for greater technical assistance. For this reason, we proposed to add a new optional EQR activity at § 438.358(c)(7) to assist in evaluations of quality strategies, SDPs, and ILOSs, that pertain to outcomes, quality, or access to health care services. We focused the scope of the EQR optional activity to activities permissible under the statutory authority at section 1932(c)(2) of the Act, which requires external review of the quality outcomes and timeliness of, and access to, the items and services for which the organization is responsible under the contract. We believe by adding this optional activity, States, their agent, or an EQRO could use the accompanying protocol that CMS will develop (in coordination with the National Governors Association in accordance with § 438.352) to assist with evaluation activities related to quality strategies, SDPs, and ILOS, that are within the scope of EQR. We also believe EQROs may be well positioned to help with evaluations since their qualifications, as required under § 438.354(b), include research design and methodology, statistical analysis, and quality assessment and improvement methods. We believe this optional activity will provide States critical technical assistance via a CMS-developed protocol that will enable more robust evaluations, which could lead to greater transparency and quality improvement in States' implementation of their quality strategy, SDPs and ILOSs. It could also reduce burden by allowing States to receive an enhanced match for activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

For separate CHIP, we did not adopt the proposed evaluation of SDPs at § 438.6(c)(2)(iv) and (v) (see sections I.B.2.a. and I.B.2.j. of this final rule). For this reason, we proposed to amend separate CHIP EQR requirements at § 457.1250(a) to exclude references to § 438.6. However, we proposed to adopt the new ILOS retrospective evaluation requirements at § 438.16(e)(1) through our proposed cross-reference at § 457.1201(e) (see section I.B.4.g. of this final rule). Since section 2103(f)(3) of the Act requires external review of CHIP managed care plans, we also believe that CHIP EQROs are well positioned to assist with the proposed ILOSs evaluations and believe it would be beneficial to States to have this optional EQR activity. We proposed to adopt the new EQR optional activity for separate CHIP through an existing cross-reference to § 438.358 at § 457.1250(a). We intended this optional activity to be available to States as of the effective date of the final rule.

We summarize and respond to public comments received on using an optional EQR activity to support current and proposed managed care evaluation requirements below.

Comment: Several commenters supported our proposal to allow States to use an optional EQR activity to support the new evaluation requirements in the proposed rule. Some commenters noted that States would appreciate the flexibility to

conduct the evaluations themselves. One commenter noted concerns about whether the current EQRO vendors have the capabilities, staffing and expertise to support these activities. Commenters also noted that if a State Medicaid agency does use an EQRO, CMS should not require a new competitive procurement to amend the scope of an EQRO contract or other contract vehicle.

Response: In response to the comment about State flexibility, we clarify that States are allowed to conduct the evaluation themselves for their quality strategy, SDPs and ILOSs under these final rules. As we described in the proposed rule, we continue to believe the competencies of an EQRO required under § 438.354(b), including research design and methodology, statistical analysis, and quality assessment and improvement methods, could be leveraged for these activities. However, States have the discretion under § 438.358(a)(1) to conduct EQR activities themselves or use an agent that does not qualify as an EQRO, so long as it is not a managed care plan (the EQRO is, however, required to compile and write the final EQR reports). Regarding the comment about procuring a new EQRO contract, we note that § 438.356(e) currently requires States to follow an open, competitive procurement process for each contract with an EQRO that is in accordance with State law and regulation and requires State to comply with 45 CFR part 75 as it applies to State procurement of Medicaid services. We acknowledge, however, that state procurement laws may vary relative to what actions prompt a new competitive procurement process. We also note that under § 438.370(c) States, would need to obtain CMS approval of the EQRO contract or contract amendment including this optional activity prior to claiming a 75 percent FFP match for the activity. We intend to update the EQR protocols to provide guidance on this new activity in accordance with § 438.352, and once published, States can begin claiming FFP match for this activity.

After reviewing the public comments, we are finalizing the changes EQR optional activities at § 438.358(c) as proposed.

(4) Non-Duplication of Mandatory EQR Activities With Medicare or Accreditation Review

Current § 438.360 provides an option for States to exempt MCOs, PIHPs, or PAHPs from EQR-related activities that will duplicate activities conducted as a part of either a Medicare review of a MA plan or a private accreditation review. Section 438.360(a)(1) required that, in order for a State to exercise this option for private accreditation, the plan accreditation must be from a private accrediting organization recognized by CMS ''as applying standards at least as stringent as Medicare under the procedures in § 422.158 of this chapter[.]'' Section 422.158 describes the procedures for private, national accreditation organizations (PAOs) to apply for approval of accreditation as a basis for deeming compliance with Medicare requirements, also referred to as ''deeming authority.'' Sections 422.156 and 422.157 discuss conditions and applications of the deeming authority, under which a PAO may accredit MA plans for the purposes of deeming compliance with one or more specific areas of the MA program. The implementation of this requirement at § 438.360(a)(1) meant that PAOs had to obtain deeming authority from CMS as a prerequisite for the States to use the PAO's plan accreditation review for the purposes of nonduplication of mandatory EQR activities. This meant the PAO had to obtain and periodically renew their MA deeming authority from CMS even if it is solely for the purpose of providing States the opportunity to use their reviews of a Medicaid managed care plans in lieu of conducting a similar EQR-related activity.

We believe this regulation created an unnecessary administrative burden on both CMS and PAOs and restricted the availability of the EQR nonduplication option for States. We also do not believe that the requirement is compelled under the statute. The statutory basis for the nonduplication provision, found at section 1932(c)(2)(B) of the Act, states: a State may provide that, in the case of a Medicaid managed care organization that is accredited by a private independent entity (such as those described in section 1852(e)(4) of the Act) or that has an external review conducted under section 1852(e)(3) of the Act, the external review activities conducted under subparagraph (A) for the organization shall not be duplicative of review activities conducted as part of the accreditation process or the external review conducted under such section (*emphasis added*). Section 1852(e)(4) of the Act is the statutory basis for PAOs to obtain MA deeming authority from CMS. We do not interpret this provision as requiring every private independent entity to be described under section 1852(e)(4) of the Act in order for a State to exercise the nonduplication provision. Rather, we read section 1932(c)(2)(B) of the Act as describing in general terms the types of organizations that will be eligible to participate in nonduplication, and providing organizations described in section 1852(e)(4) of the Act as an example.

Therefore, we proposed at § 438.360(a)(1) to remove the requirement that PAOs must apply for MA deeming authority from CMS in order for States to rely on PAO accreditation reviews in lieu of EQR activities. We proposed conforming changes to the title of § 438.362(b)(2) to remove language specific to Medicare Advantage deeming. Additionally, we proposed to remove the requirements for PAOs related to MA deeming authority at § 438.362(b)(2)(i). This proposal removed paragraph (b)(2)(i)(B) and modified paragraph (b)(2)(i) to include current § 438.362(b)(2)(i)(A). We believe this proposed change would reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We noted that under § 438.360(a)(2) States are required to ensure the review standards used by any PAO are comparable to standards established through the EQR protocols under § 438.352, and pursuant to § 438.360(c), and need to explain the rationale for the State's determination that the activity is comparable in their quality strategy at § 438.340. We proposed these changes would be effective as of the effective date of the final rule.

We summarize and respond to public comments received on non-duplication of mandatory EQR activities with Medicare or accreditation review below.

Comment: We received several comments on this proposal to remove the requirements on PAOs to obtain MA deeming authority. The two commenters that supported the proposal noted how the revisions would reduce burden, make data more accessible, and streamline EQRs by facilitating the use of accreditation data. Two commenters opposed the proposal. One commenter did not specify their objection; the second commenter stated concerns about States having to ensure that private accreditation standards are comparable to standards established through EQR protocols and consistent with a State's quality strategy. This commenter stated that private accreditation should not substitute for Federal or State monitoring and noted that it is more efficient for CMS to make one determination regarding an accreditation organization rather than each State making its own determination.

Response: After reviewing the public comments, we are finalizing this rule as

proposed. We agree with commenters that this change will reduce burden and streamline the EQR process for States by removing barriers to using accreditation data. States may leverage the non-duplication option for EQR-related activities that would otherwise be performed by the State, the State's entity or an EQRO. In response to the concerns about the use of accreditation data for monitoring and State responsibilities for ensuring accreditation standards are comparable to those in EQR protocols, we note that the current regulations at § 438.360(a) already allow States to use information from a private accreditation review of an MCO, PIHP, or PAHP for the annual EQR, and at § 438.360(a)(2) already require each State to determine that the accreditation review standards are comparable to the standards established in the EQR protocols and include the rationale for this determination in its quality strategy. Furthermore, under § 438.360(c) the State must identify in its quality strategy under § 438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the State's determination that the Medicare review or private accreditation activity is comparable to such EQR activities. The removal of the requirement for PAOs to obtain Medicare deeming authority does not affect those existing requirements. Regarding the comment about efficiencies, the current regulations at § 438.360(b), already require the State to furnish all the data obtained from an accreditation review to the EQRO for analysis and inclusion in the annual EQR technical reports. Removing the requirement for PAOs to obtain Medicare deeming authority does not impact this requirement but would create efficiencies for the State by reducing barriers to obtaining data for the annual EQR. In addition, as noted in the proposed rule, we do not believe the requirement for PAOs to obtain Medicare deeming authority is compelled under the statute, and we do not believe the process has added value to a PAO's ability to conduct accreditation reviews that could be used for EQRs.

After reviewing the public comments, we are finalizing the changes to non-duplication at § 438.360(a)(1) as proposed.

(5) External Quality Review Results (§ 438.364)

(a) Data Included in EQR Technical Reports

The current regulations at § 438.364, included in separate CHIPs through an existing cross-reference at § 457.1250(a), describe what information must be included in the annual EQR technical reports, as well as the public availability of the reports. While the information currently provided in the EQR technical reports is useful to CMS in our work with States to improve beneficiary access to and quality of care provided through a managed care delivery system, we believe these reports could and should provide additional information useful to both CMS and the public.

Regulations at § 438.364(a)(2) describe the information the State must include in the annual EQR technical report for each EQR-related activity. Under § 438.364(a)(2)(iii), the EQR technical reports must include a description of data obtained, including validated performance measurement data for each PIP validation and performance measurement validation activity at § 438.358(b)(1)(i) and (ii), respectively. The regulations, however, limited the data included in the reports to performance measurement data; the regulations did not require other types of data used to measure the outcomes associated with a PIP, such as percentages of enrollees that participated in the PIP or data on patient satisfaction based on services received from the plan, be included in the annual reports. The result was that reports often focused on whether the methods used to implement or evaluate the PIP were validated, but did not include the measurable data reflecting the outcomes of the PIP. Additionally, the regulations did not require the reports to include any data obtained from the mandatory network adequacy validation activity.

We believe validation alone was insufficient to provide CMS and interested parties with insight into plan performance on PIPs or States' effectiveness in driving quality improvement through PIPs. We also believe data on network adequacy validation was critical to understanding plan performance regarding timeliness and access to care. Therefore, we proposed to revise § 438.364(a)(2)(iii) in two ways: (1) to require that the EQR technical reports include ''any outcomes data and results from quantitative assessments'' for the applicable EQR activities in addition to whether the data has been validated, and (2) to require this type of data from the mandatory network adequacy validation activity to also be included the EQR technical report. We believe this change would result in more meaningful EQR technical reports because they would include, in addition to validation information, the data demonstrating the outcome of PIPs and the results of quantitative assessments that determined plan compliance with network adequacy standards. This, in turn, would make the EQR technical reports a more effective tool to support quality improvement and oversight in managed care. We proposed that the revisions to § 438.364(a)(2)(iii) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We proposed at § 438.310(d)(4) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with these updates to the type of data in the EQR technical report no later 1 year from the issuance of the associated protocol, which we believe will provide the guidance and time for States and EQROs need to update their processes.

In addition to the proposed regulations in this section, we sought comment on adding guidance in the EQR protocols, described under § 483.352, for States to stratify performance measures collected and reported in the EQR technical reports under the performance measure validation activity. We noted that stratification of performance measure data in EQR technical reports could support States' efforts to monitor disparities and address equity gaps. Stratifying performance measure data also aligns with requirements for the mandatory reporting of Medicaid and CHIP Core Sets and requirements in the MAC QRS proposed under new 42 CFR part 438 subpart G. We sought comment on how CMS could best support States in these efforts using future guidance we develop in the EQR protocols.

We summarize and respond to public comments received on Data included in EQR technical reports below.

Comment: Several commenters supported our proposal to expand the scope of data included in the EQR technical reports. Commenters in general supported these changes, noting that they would make the data more accessible and result in more meaningful reports that can be used to support quality improvement, oversight in managed care, and stronger managed care plan performance for beneficiaries. Commenters agreed that some States have limited their technical reports to include only information about the validation of quality data, while not including the results of performance measures or performance improvement projects. One commenter questioned whether we plan to require the secret shopper survey results be included in

the EQR Protocol 4 Technical Report. MACPAC noted that this proposal may help to address the concern that the reports do not focus on changes in performance and outcomes over time, and interested parties would like EQR process and findings to place more emphasis on outcomes and comparability.

Response: We agree with commenters about how this change will make reports more meaningful to support quality improvement. In response to the question about secret shopper survey results, we will include guidance in the updated EQR protocols on what the EQR technical reports must include, including guidance on results from quantitative assessments related to the network adequacy validation activity.

Comment: Several commenters supported the future addition of guidance in the EQR protocols for States to stratify performance measures collected and reported in the EQR technical reports under the performance measure validation activity. Commenters noted that additional guidance would facilitate monitoring health disparities and would promote alignment of the EQR technical report with the mandatory reporting of Medicaid and CHIP Core Sets and requirements we proposed for the MAC QRS. Some commenters noted concerns about data reliability and indicated that State Medicaid agencies would need significant time to develop their data infrastructure. Another commenter recommended that CMS use a phased approach with pre-validated subsets of the measures.

Response: We agree with commenters that adding guidance for the stratification of performance measure data in the EQR technical reports would support States in monitoring health disparities and addressing equity gaps. We appreciate the comments to align the guidance with the Core Sets and MAC QRS stratification requirements, as well as the concerns noted about State implementation time and data infrastructure and using a phased approach. We will consider these concerns and recommendations from commenters as we develop future EQR protocol guidance.

After reviewing the public comments, we are finalizing the changes to the data included in EQR reports at § 438.364(2)(iii) as proposed. As noted in the proposed rule, we intend to release an updated EQR protocol in accordance with § 438.352 to implement the changes finalized at § 438.364(a)(2)(iii). This applicability date, though unchanged, will be finalized at § 438.310(d)(3).

(b) Revising the Date Annual EQR Technical Reports Must Be Finalized and Posted

We currently require at § 438.364(c) that EQR technical reports be completed and available on the State's website required under § 438.10(c)(3) no later than April 30th of each year. However, we understand that most States with managed care programs use HEDIS measures. HEDIS measures represent the majority of measures included in the performance measure validation EQR activity. Data on these measures from the previous calendar year are audited and finalized in June annually. Therefore, we proposed to revise § 438.364(c)(1) and (c)(2)(i) to change the April 30th date to December 31st. We believe this proposed change would align better with the HEDIS timeframes because the EQR performance measurement activity could then follow the HEDIS audit. We considered aligning the EQR technical report posting date with the end of the Federal fiscal year on September 30th. However, we believe States and EQROs needed more time to complete the EQR activities after receiving audited HEDIS data. We also believe December 31st is most appropriate because performance measurement data are most often calculated on a calendar year, so the December 31st date would result in data being at most one-year old at the time the reports are posted on the State's website. We believe this change, coupled with those discussed in section I.B.5.c.2. of this final rule regarding changes to the EQR review period, would have improved the utility of the technical reports for States, CMS and interested parties by making the data reported in them more current. We proposed changes at § 438.364(c)(1) and (c)(2)(i) for Medicaid that would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We solicited comments on changing the posting date to December 31st annually. We also solicited comments on whether additional time beyond December 31st is needed by States, and if so, how much time and why, or whether the posting date should remain at April 30th of each year, or a date between April 30th and December 31st and why. We proposed at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States come into compliance with this new due date by December 31, 2025, which we believe will provide enough time for contractual and operational updates.

We summarize and respond to public comments received on revising the annual due date for EQR technical reports below.

Comment: Commenters both opposed and supported the proposal the change the annual due date from April 30 to December 31 each year. Some commenters requested to clarify whether the change represents more or less time to complete the reports. Commenters who supported the proposal noted that the change would better align with the availability of finalized HEDIS performance measures in the EQR technical reports, leading to more recent data and better comparability across States. Other commenters supported the change to make the reports more actionable but noted that the change would result in States incurring additional costs, and could result in data reporting lags as some measures would not make the ''cut-off'' date to be included in that year's report if it was due December 31. Commenters who opposed the change noted that it would be extremely challenging to complete the mandatory EQR activities under the new proposed due date, citing the burden and time constraints associated with this change. Some commenters detailed the timelines of their internal processes to conduct the EQR activities, for the EQRO to analyze and compile the report, and for State officials to review and approve the report before it is posted online. One commenter noted that the EQR activities typically occur in the second half of the calendar year, and the December 31 date would not allow enough time to complete all the individual activities to be incorporated into the annual report. Another commenter noted that the last step of the State officials reviewing and approving the report usually starts in February, and the December 31 date would be very difficult to meet.

Response: After reviewing the public comments, we are not finalizing this proposed change to the annual due date for EQR technical reports and are maintaining the current requirement for posting annually by April 30. We clarify for commenters that we did intend to reduce the time allowed to finalize the reports by 4 months in our proposal by moving the due date from April 30 to December 31. Based on comments received, we no longer believe the benefit of the EQR technical reports being posted 4 months earlier outweighs the current burden of changing State and EQRO processes for conducting annual EQR activities and compiling the EQR technical reports. Though the April 30 due date does create a considerable

lag time between the data and information included in the reports and when that data becomes available to the public, we believe our new provisions regarding the EQR review period is a sufficient step to making reports more current. We will consider where there may be efficiencies to be gained through standardization or electronic reporting that could help States post their EQR reports earlier to reduce this lag time and make the reports more timely and actionable. With this change we are also not finalizing the corresponding change at § 438.364(c)(2)(i), as well as the proposed applicability date of December 31, 2025, and the reference to § 438.364(c)(2)(iii) was removed from § 438.310(2).

After reviewing the public comments, we are not finalizing the changes proposed to the EQR report due date at § 438.364(c)(1).

(c) Notifying CMS When Annual EQR Technical Reports Are Posted

Current regulations do not require States to notify CMS that their EQR technical report has been completed and posted on the State's website. We proposed to revise § 438.364(c)(2)(i) to require that States notify CMS within 14 calendar days of posting their EQR technical reports on their website, for example, by providing CMS with a link to the report. Section 401 of the Children's Health Insurance Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3, February 4, 2009) and section 2701 of the ACA require that CMS review and aggregate data from these reports in an annual report to the Secretary by September 30th. We described that this change would facilitate our review and aggregation of the required data and ensure that all States' data are included in the annual report. We proposed that the notice to CMS be provided ''in a form and manner determined by CMS.'' However, we sought comment on whether we should require that this notice be provided via email or some other mode of communication. The proposed revisions at § 438.364(c)(2)(i) will apply to separate CHIP through an existing cross-reference at § 457.1250(a). We note that this requirement be effective as of the effective date of the final rule, which we did not believe will impose a great burden on States since most States already notify CMS when their EQR technical reports are posted by email.

We summarize and respond to public comments received on Notifying CMS when annual EQR technical reports are posted below.

Comment: One commenter supported our proposal to require that States notify CMS within 14 calendar days of posting their EQR technical reports on their website, noting that the State already notifies CMS once the State's EQR technical report is posted.

Response: After reviewing the public comments, we are finalizing the change to require States to notify CMS when their EQR reports are posted as proposed, but we are not finalizing the proposed change to the due date, which we are keeping as April 30 (per our discussion in section 5.c.5.b. of this final rule).

(d) Revising Website Requirements for Historical EQR Technical Reports

Currently, States are encouraged, but not required, to retain EQR technical reports from previous years on their websites. We proposed to require States maintain at least the previous 5 years of EQR technical reports on their website. Retaining at least 5 years of past EQR technical reports will provide administrative efficiencies and additional transparency by allowing CMS to use historical data and information within the annual EQR technical reports for the purposes of reviewing States' managed care program and plan performance during contract renewals and waiver renewals. In addition, having archived reports will provide other interested parties insight into historical plan performance. We noted that section 1915(b) waivers can be approved for up to 5 years, and section 1115 demonstrations are often approved for 5 years, providing additional support for 5 years being an appropriate timeframe for this requirement.

We understand that almost half of States already retain at least 2 years' worth of EQR technical reports based on a review of State websites in 2022, and we sought comment on whether archiving 5 years of reports will pose a significant burden on States. We proposed to add this provision to the requirements at § 438.364(c)(2) for Medicaid, which will apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We proposed that States must comply with this update to § 438.364(c)(2)(iii) no later than December 31, 2025, and proposed to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. We believe this applicability date would provide the time needed to update websites accordingly.

We summarize and respond to public comments received on revising website requirements for historical EQR technical reports below.

Comment: Several commenters supported our proposal to require States to maintain at least the previous 5 years of EQR technical reports on their website. Commenters in general supported this revision, noting there is little additional burden to keep technical reports available to the public over an extended period, and that having an archive of EQR technical reports would make it easier to track responses to recommendations, evaluate progress on performance improvement projects, and monitor changes in quality performance. Three commenters requested that we consider extending this requirement for States to maintain at least 10 years of EQR technical reports on their website and two comments requesting CMS provide clarification on how State agencies are expected to display this data.

Response: In response to commenters requesting the requirement be extended to at least 10 years, we encourage States to maintain a publicly available archive of EQR technical reports dating back as long as feasible, however we are not requiring more than 5 years of reports to be posted at this time. We understand that EQR technical reports can be lengthy and vary greatly from State to State, so at this time we are not specifying how the data must be displayed. We will consider developing technical assistance resources to help States make the EQR data more accessible and usable for interested parties.

After reviewing the public comments, we are finalizing this change to the website posting requirements for EQR at § 438.364(c)(2)(iii) as proposed.

(6) Technical Changes

We proposed a technical change at § 438.352 to eliminate the apostrophe from National Governors Association to align with the correct name of the organization.

We did not receive any comments in response to our proposed technical change. Therefore, we are finalizing this provision as proposed.

6. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240)

We proposed significant revisions to the requirements for the Medicaid and CHIP managed care quality rating system, including revisions to existing regulations and the adoption of a new subpart in part 438 for regulations governing the rating system. In response to supportive comments we received and for the reasons outlined in this

rulemaking, we are finalizing most provisions related to the mandatory measure list, the flexibility for States to request to implement an alternative MAC QRS, the proposed subregulatory process to make updates to the mandatory measure list in the future, and the ability for States to include additional measures in their MAC QRS. We are finalizing several modifications from our proposal to clarify the scope of the alternative QRS and to reduce the implementation resources States need for their MAC QRS, including when, or if, a State chooses to adopt an alternative QRS.

Specifically, many comments we received on our alternative quality rating system proposal suggested that commenters did not understand what changes to the MAC QRS developed by CMS would require CMS approval as a State alternative MAC QRS. The current regulations at § 438.334(b)(1) identify two components of the MAC QRS framework: (1) The quality measures used to assess plan performance and (2) the methodology for calculating quality ratings based on the measure data reported for each plan rated by the QRS. Current § 438.334(c) establishes a process by which States may request CMS approval to display different performance measures or apply a different methodology to generate quality ratings in their MAC QRS after requesting and receiving CMS approval. As described in more detail in section I.B.6.h. of the proposed rule, we proposed to narrow the scope of actions that require CMS approval under the alternative quality rating system flexibility to only modifications to the MAC QRS methodology. We also proposed that States could display additional measures in their MAC QRS without requiring CMS approval if they requested input from a broad range of interested parties and documented the input received and the state's response. Therefore, we proposed to change the existing QRS rule (reflected in the regulation at § 438.334(c)), to allow States to include *additional* measures, meaning that States would include these measures in addition to the CMS-identified mandatory measures for the QRS. Upon review of the comments, we realized that this was misinterpreted, and that commenters thought that our proposal was intended to allow States to implement alternative mandatory measures to replace CMS-identified selected measures as opposed to being in addition to those measures.

A number of commenters also misunderstood our proposal and thought that we proposed to allow States to request alternatives to the website display features proposed in § 438.520 as a third MAC QRS framework component. Although the proposed rule anticipated that States could add *additional* website display features, we did not propose to allow States to eliminate or use alternatives to the QRS website design features included in the proposed MAC QRS rules. To summarize, the proposed rule included that States would no longer need CMS approval to add measures that are in addition to those identified as mandatory measures by CMS; would be able to implement website display features in addition to those newly proposed in § 438.520 (also without CMS approval); and would continue to have the option to use an alternative methodology (meaning an alternative to the rating methodology described in § 438.515(b)), for calculating quality ratings for mandatory measures identified by CMS, subject to CMS review and approval).

To address these issues, we are finalizing the provision enabling States to request an alternative QRS as part of the section of the regulation governing the QRS methodology with changes to more clearly and accurately reflect the State flexibility option to apply an alternative QRS rating methodology. We believe this makes clear that States must request CMS approval to apply an alternative methodology but need not seek CMS approval to include additional measures or website display features in their MAC QRS. We stress that these changes in the final rule compared to the proposed rule are merely organizational. Under this final rule, States will have the flexibility to display additional measures not included in the mandatory measure set, as well as to develop additional QRS website display features, as proposed. States also retain flexibility currently available under § 438.334, and finalized in this final rule at § 438.515(c) to use an alternative QRS methodology, if they request and receive CMS approval to do so, subject to fewer procedural requirements.

We also are finalizing changes compared to the proposed rule to reduce State burden in implementing a QRS. As discussed throughout the proposed rule, our proposals were meant to minimize burden on States, managed care plans, and other interested parties, such as providers, and to maximize access to the information that beneficiaries identified as useful and desirable in selecting a plan. However, while commenters were overwhelmingly supportive of the MAC QRS, many commenters stated concern that the overall administrative complexity of implementing the MAC QRS, including the time and resources needed to do so, would be substantial. Based on feedback received from commenters, we are finalizing five modifications to our proposal that we believe will further reduce QRS implementation burden with minimal impact on beneficiaries' access to the information it is important for them to have.

First, as discussed in additional detail in section I.B.6.d of this final rule, we are finalizing an option for States to request a one-time, one-year extension to fully comply with one or more of the requirements of the MAC QRS rating methodology under § 438.515(b) and certain website display requirements under § 438.520(a), if the State, despite a good faith effort, would be unable to fully implement the requirements in § 438.515(b) or § 438.520(a)(2)(v) and (a)(6) by the implementation deadline specified for CMS in subpart G. As discussed in section I.B.6.g. of the proposed rule, we proposed that States will implement a MAC QRS in two phases and we are finalizing that approach. In the first phase of implementation, States must fully comply with all MAC QRS requirements, except for requirements under § 438.520(a)(6), by the implementation date specified in § 438.505(a)(2) (by the end of the fourth calendar year following July 9, 2024. This rule is being finalized July 9, 2024, which means States must implement a MAC QRS by December 31, 2028. States granted an extension for eligible first phase requirements—those under § 438.515(b) or § 438.520(a)(2)(v)—will have until December 31, 2029 to fully comply with these requirement(s). Requirements under § 438.520(a)(6) will be implemented in a second phase. CMS will specify the implementation date of the second phase in the future, but this date must be no earlier than 2 years after implementation of the first phase as per § 438.520(a)(6). Therefore, States will be required to implement the requirements under § 438.520(a)(6) no earlier than calendar year 2030, and States granted an extension for requirements under § 438.520(a)(6) will have until at least until calendar year 2031 to fully comply with the requirement.

Second, under the proposed rule, States would have been required to display a quality rating for all MAC QRS mandatory measures. As discussed in section I.B.6.e. of this rule, this final rule narrows the scope of mandatory measures for which a quality rating must be displayed in a State's MAC QRS to only those that are applicable to the managed care program(s) established by the State (meaning those MAC QRS

mandatory measures that assess a service or action covered by one or more of the State's managed care contracts). As a result of this change, the scope of data that States must collect and validate to calculate quality ratings for mandatory measures will be narrowed—to only data for measures that are applicable to a State's managed care program(s). Third, as described in section I.B.6.h. of this final rule, we are removing the requirement (proposed to be redesignated from current § 438.334(c)(2) to proposed § 438.525(b)(1) and (2)) that requires States to obtain input from the State's Medical Care Advisory Committee and provide an opportunity for public comment of at least 30 days on a request for, or modification of a previously approved, alternative Medicaid managed care quality rating system. Fourth, we proposed at § 438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan's network. In this final rule we are narrowing the scope of these proposed MAC QRS requirements to apply only to managed care plans that participate in managed care programs with two or more participating plans; this change is discussed in section I.B.6.g.2 of this final rule.

Finally, under the proposed rule States would be required to collect the data necessary to calculate quality ratings for each MAC QRS mandatory measure from Medicaid FFS, Medicare, or both if all data necessary to calculate a measure could not be provided by Medicaid managed care plans. Furthermore, States would be required to ensure that the collected data are validated and then used to calculate performance rates for MAC QRS measures. In the proposed rule, we acknowledged that challenges currently exist to the collection and use of Medicare data and, to some extent, Medicaid FFS data that may be necessary to calculate quality ratings for Medicaid plans. We therefore proposed an undue burden standard under which States would be required to collect necessary Medicare and Medicaid FFS data when such data are available for collection by the State *without undue burden.* We are largely finalizing these requirements as proposed, but with modifications throughout § 438.515(a) and (b) to clarify that the scope of the undue burden standard extends beyond the collection of Medicaid FFS and Medicare data and may be applied also to the validation of collected data and the use of validated data to calculate quality ratings for MAC QRS mandatory measures for Medicaid managed care plans. As finalized, States will be required to collect Medicaid FFS and Medicare data, validate the collected data, and use the validated data to calculate quality ratings for managed care plans for MAC QRS mandatory measures *the extent feasible without undue burden.* This change is discussed in section I.B.6.f of this final rule.

a. Background

In the 2016 final rule we established the authority to require States to operate a Medicaid managed care quality rating system (QRS) at § 438.334 and adopted the requirement for this provision, excluding provisions regarding consultation with the Medical Care Advisory Committee, to apply to separate CHIP at § 457.1240(d). We use the term ''Medicaid and CHIP Managed Care Quality Rating System'' (''MAC QRS'') for this final rule in line with the terminology used in the 2020 final managed care rule (85 FR 72754). The MAC QRS requirements currently include public posting of quality ratings on the State's website, which is intended to provide beneficiaries and their caregivers with a web-based interface to compare Medicaid and CHIP managed care plans based on assigned performance indicators and ratings. As described in previous rulemaking, the policy objectives of the MAC QRS are threefold: (1) to hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries; (2) to empower beneficiaries with useful information about the plans available to them; and (3) to provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs. Managed care is the dominant delivery system in the Medicaid program; of the 80.8 million individuals covered by Medicaid as of July 1, 2020, 67.8 million (84 percent) were enrolled in a type of managed care, with most beneficiaries offered a choice of plans.[204]

Numerous States have implemented rating systems for Medicaid and CHIP managed care plans, but the MAC QRS represents the first time that States will be held to a minimum Federal standard for their rating systems and that Medicaid and CHIP beneficiaries in every State contracting with a managed care plan could access quality and other performance data at the plan level, supporting the ability of Medicaid and CHIP beneficiaries to select plans that meet their needs. The MAC QRS is intended to be a one-stop-shop where beneficiaries can access information about Medicaid and CHIP eligibility and managed care; compare plans based on quality and other factors key to beneficiary decision making, such as the plan's drug formulary and provider network; and select a plan that meets their needs.

Current requirements at § 438.334(b)(1) for Medicaid, which are adopted by cross-reference at § 457.1240(d) for separate CHIP, provide that CMS, in consultation with States and other interested parties, including beneficiaries, managed care plans, external quality review organizations (EQROs), tribal organizations, and beneficiary advocates (hereafter referred to as ''interested parties''), will develop a MAC QRS framework that includes quality measures and a methodology for calculating quality ratings. The current regulations also provide States the option to either use the CMS-developed framework or establish an alternative QRS that produces substantially comparable information about plan performance, subject to our approval. Furthermore, the current regulations require that we develop a minimum set of mandatory quality measures that must be used, regardless of whether a State chooses to implement the CMS-developed QRS or an alternative QRS; this supports the goal of State-to-State comparisons of plan performance while reducing plan burden through standardization. The current regulations also require the MAC QRS framework to align, where appropriate, with other CMS managed care rating approaches (such as the Medicaid Scorecard initiative, the Medicare Advantage (MA) and Part D 5-star, and the Qualified Health Plan (QHP) quality rating systems) as a way to reduce State and plan burden across quality reporting systems.

Since the previous regulations were issued, we have used a variety of forums to engage in robust consultation with interested parties to develop the framework of the MAC QRS to fulfill our obligation under § 438.334(b)(1) for Medicaid and under § 457.1240(d) for separate CHIP. These forums included beneficiary interviews, workgroup meetings, listening sessions, user testing of a MAC QRS prototype, and in-depth interviews with participants from State Medicaid programs, managed care plans, and EQROs. Through these extensive consultations, which took

[204] *https://www.medicaid.gov/medicaid/managed-care/downloads/2020-medicaid-managed-care-enrollment-report.pdf.*

place between 2018 and 2022 and are summarized in section I.B.6.a of the proposed rule, we learned about current State quality measure collection and reporting efforts and beneficiary needs and preferences related to the selection of a health plan. What we learned informed the MAC QRS framework set forth in the proposed rule.

Based on this consultation, we proposed a MAC QRS framework that includes mandatory measures, a rating methodology (either the CMS-developed methodology or an alternate methodology approved by CMS), and a mandatory website display format; the website display will be an additional third component of the MAC QRS framework. We proposed that States must include the mandatory measures under the MAC QRS framework, but that States may also include additional measures without implementing an alternative QRS methodology. This would represent a change from the current regulations that include both mandatory and non-mandatory measures in the CMS-developed framework. We proposed the initial mandatory measure set that States must use regardless of whether they use the MAC QRS CMS methodology or a CMS-approved alternative QRS methodology, as well as a subregulatory process under which CMS will engage regularly with interested parties to update the mandatory measure set over time.

Additionally, after consulting with prospective MAC QRS users, we came to understand that displaying quality ratings alone would not be useful in selecting a health plan without additional context about Medicaid and CHIP, as well as other information about health plans. Therefore, we proposed website display requirements as a new component of the overall framework, and that the MAC QRS website include information that draws from existing State data and information to ensure a State's MAC QRS is a meaningful and usable tool for beneficiaries. Finally, considering the diverse starting points from which States will begin to implement their MAC QRS, we proposed to delay the deadline by which States must come into compliance with several of the requirements of the proposed MAC QRS framework to provide States with more time to implement the more complex requirements, including certain interactive website display features. Importantly, States can use the optional EQR activity at § 438.358(c)(6) to assist with the quality rating of MCOs, PIHPs, and PAHPs, though enhanced FFP would only be available in the case of MCOs. This could reduce burden by allowing States to receive an enhanced match for certain, limited activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

The MAC QRS proposals in the proposed rule were made under our authority to implement and interpret sections 1932(c)(1), 1932(a)(5)(C) and 2103(f)(3) of the Act, which provide that States that contract with MCOs for Medicaid managed care and CHIP, respectively, must develop and implement a quality assessment and improvement strategy that examines standards for access to care, as well as other aspects of care and services directly related to the improvement of quality of care (including grievance procedures and information standards) and must provide comparative information on available plans related to health plan benefits and cost-sharing, service area, and available quality and performance indicators. As with most other requirements for managed care plans, we relied on section 1902(a)(4) of the Act to extend the same requirements to PIHPs and PAHPs that apply to MCOs in a Medicaid managed care program and on section 2103(f)(3) of the Act to extend the same requirements that apply to MCOs in CHIP to PIHPs and PAHPs. Throughout the proposed rule, we noted how the proposed Medicaid managed care regulations in part 438, subpart G (related to the MAC QRS) would apply equally to separate CHIP by a proposed cross-referenced added to § 457.1240(d).

The proposed set of minimum quality measures were intended to evaluate performance on quality of care, access to services, and outcomes. By measuring performance annually on specific quality measures (that is, mandatory measures adopted by us and any additional measures elected by the State), States would have information and data to monitor and evaluate performance of their managed care plans.

In exercising our authority under sections 1932(c)(1) and 2103(f)(3) of the Act, CMS may not implement standards for the implementation of a quality assessment or improvement strategies unless the Secretary implements such standards in consultation with the States. To fulfill this requirement, we have engaged in robust consultation with States, as described in section I.B.6.a. of the proposed rule and of this final rule, on the design of the MAC QRS, including the mandatory measure set, methodology, and display requirements. Under this final rule, we will continue to engage in consultation prior to making updates to the three components of the MAC QRS framework. In section I.B.6.e.3. of this final rule (regarding § 438.510(b)(1)), we are finalizing a subregulatory process through which we will continue to consult with States and interested parties to update the mandatory measure set; in section I.B.6.f. of this final rule (regarding § 438.515(e)), we are finalizing our proposal to propose new rules to implement domain-level quality ratings after consulting with States and interested parties to update the MAC QRS methodology; and in section I.B.6.g. of this final rule (regarding § 438.520(d)), we are finalizing our proposal to periodically consult with States and interested parties (including Medicaid managed care quality rating system users) to evaluate the website display requirements for continued alignment with beneficiary preferences and values.

b. Provisions of the Proposed Rule (§§ 438.334, 438 Subpart G and 457.1240(d))

We proposed to create a new subpart G in 42 CFR part 438 to implement the MAC QRS framework required under § 438.334 of the current regulations and establish the standards which States must meet for CMS to approve adoption of an alternative QRS and related requirements. We proposed to redesignate and revise existing regulations at § 438.334 to newly created proposed sections in Subpart G with proposed revisions, discussed in detail in section I.B.6 in this final rule. For separate CHIP, we proposed to adopt the new provisions of subpart G in part 438 by cross-reference through an amendment at § 457.1240(d). We did not receive any comments on this general approach and are moving the QRS provisions to subpart G, as proposed.

c. Definitions (§§ 438.334, 438.500 and 457.1240(d))

We proposed definitions for several technical and other terms at § 438.500 for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Additional definitions are discussed in more detail later in this final rule in connection with specific proposals for which the definitions are relevant.

- *Measurement period* means the period for which data are collected for a measure or the performance period that a measure covers.
- *Measurement year* means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

• *Medicaid managed care quality rating system framework* (*QRS framewor*k) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

• *Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system)* means the rating system described in subpart D of parts 422 and 423 of this chapter.

• *Qualified health plan quality rating system (QHP quality rating system)* means the health plan quality rating system developed in accordance with 45 CFR 156.1120. We inadvertently used the term ''Qualified health plan rating system (QHP quality rating system)'' in the proposed rule and are updating the terminology here by adding the word quality after ''Qualified health plan'' and before ''rating system.''

• *Quality rating* means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

• *Technical resource manual* means the guidance described in § 438.530.

• *Validation* means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

We did not receive any public comments on these proposed definitions (§§ 438.334, 438.500, and 457.1240(d)). We are finalizing these definitions as proposed, with the minor correction outlined above regarding the term ''Qualified health plan rating system (QHP quality rating system),'' and use the terms consistent with the definitions throughout part 438, subpart G. We are also finalizing our approach that CHIP managed care programs be subject to the same quality rating system rules, except where otherwise explicitly noted, by using a cross-reference in § 457.1240(d) to the Medicaid rules.

d. General Rule and Applicability (§§ 438.334(a), 438.505(a) and 457.1240(d))

Currently, § 438.334(a) lays out the general rule for the MAC QRS, including general requirements for States contracting with MCOs, PIHPs and/or PAHPs to furnish services to Medicaid beneficiaries. These requirements also apply to separate CHIP through a cross-reference to § 438.334 at § 457.1240(d). Specifically, § 438.334(a) requires States to adopt a quality rating system using the CMS framework or an alternative quality rating system and to implement such quality rating system within 3 years of the date of the final rule published in the **Federal Register**. We proposed at § 438.505(a)(2) for Medicaid, and for separate CHIP by cross-reference to part 438, subpart G at § 457.1240(d), to require States to implement their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of the final rule (meaning the fourth calendar year following issuance of the final rule). This proposed change from the current 3-year implementation date currently in § 438.334(a)(3) would provide States more time to make the operational and contractual changes needed to meet the requirements in this final rule and give States flexibility to determine what time of year to publish their quality ratings.

To illustrate the proposed timeline change, we provided the following example: if the final rule were effective on April 1, 2024, States would be required to implement their MAC QRS no later than December 31, 2028, and the data displayed in 2028 would be from the measurement year between January 1, 2026, and December 31, 2026. The timeline for future measurement and display years is discussed in detail in section I.B.6.e.7. of this final rule. The proposal at § 438.520(a)(6) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), would require implementation of some website display requirements, discussed in section I.B.6.g. of this final rule, after the proposed implementation date. We also discuss, in section I.B.6.g. of this final rule, how several of the proposed display requirements build upon existing information and data States either already have or are currently required to report publicly or to CMS. We sought comment on whether these proposed policies, all together, would give States sufficient time to implement their MAC QRS on a timeline that meets their operational needs.

We also proposed for Medicaid, as a general rule, that States provide a support system for beneficiaries or users of a State's MAC QRS, leveraging existing State resources. In our user testing, described in greater detail in section I.B.6.g. of the proposed rule, users responded positively to the availability of live consumer assistance through telephone or online chat, which 83 percent of participants found useful as it helped them navigate the MAC QRS website and get the information they were looking for right away. Per § 438.71, States are currently required to develop and implement a beneficiary support system. The elements of the beneficiary support system are identified at § 438.71(b)(1) as including choice counseling for all beneficiaries in § 438.71(b)(1)(i), assistance for enrollees in understanding managed care in § 438.71(b)(1)(ii), and assistance related to the receipt of long-term services and supports at § 438.71(b)(1)(iii).

Currently, § 438.2 provides that choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions and includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP. We noted in the proposed rule that we believe that this existing support is an appropriate system for States to build upon to assist beneficiaries in using and understanding the information in the MAC QRS to select a managed care plan. Therefore, we proposed at § 438.505(a)(3), for Medicaid, that States would be required to use the beneficiary support system implemented under current § 438.71 to provide choice counseling to all beneficiaries, and assistance for enrollees on understanding how to use the managed care quality rating system to select a managed care plan, including the receipt of long-term services and supports. With the support system already in place, we believe States could leverage existing resources by developing new scripts and training existing staff. We discussed the importance of providing this assistance in section I.B.6.g. of the proposed rule where we provide an overview of the input we received from beneficiaries. However, since a beneficiary support system is not required for separate CHIP, we did not propose to adopt this provision for subpart L of part 457.

The current regulations at § 438.334(b)(1) for Medicaid and applied by cross-reference at § 457.1240(d) for separate CHIP, require the MAC QRS framework to align, where appropriate, with the QHP quality rating system, the MA and Part D quality rating system and other related CMS quality rating approaches to reduce State burden across Federal quality reporting systems. We believe this requirement should continue to apply broadly to the MAC QRS framework, and therefore, proposed to require this alignment, to the extent appropriate, as part of CMS's updates to the MAC QRS mandatory measures and

methodology. We proposed to redesignate this requirement for alignment in § 438.334(b)(1) to its own provision at § 438.505(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). The importance of alignment of the MAC QRS with the MA and Part D and QHP quality rating systems was shared by States, managed care plans, and other interested parties during our pre-rulemaking consultations, which informed the policy reflected in our current regulations that, to the extent possible, the MAC QRS should be aligned with the MA and Part D and QHP quality ratings systems, the Medicaid and CHIP Child Core Set, the Medicaid Adult Core Set, and other similar CMS initiatives such as the Medicaid and CHIP Scorecard and the CMS Universal Foundation.[205] We also proposed, at § 438.505(c), that in maintaining the MAC QRS mandatory measure set and rating methodology, CMS would align with these other similar CMS programs and approaches when appropriate.

Finally, current regulations at § 438.334(a) for Medicaid managed care programs (applied to separate CHIP through a cross-reference in § 457.1240(d)) apply the requirements for the MAC QRS to each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid or CHIP beneficiaries. We proposed to revise this to refer to ''an applicable managed care plan as described in paragraph (b) of this section'' in proposed § 438.505(a), and add an applicability provision at new § 438.505(b) stating that the provisions of newly proposed subpart G apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The proposed provisions at § 438.505(a) and (b) were also proposed to apply to separate CHIP through a cross-reference at § 457.1240(d) but excluded all references to beneficiary support systems. We noted that the current and proposed regulations in Subpart G do not apply to PCCM entities, consistent with current regulations at §§ 438.10(c)(2) and 457.1207; non-emergency medical transport PAHPs are also not included in the MAC QRS, in accordance with §§ 438.9 and 457.1206(b). In addition, our proposal for the MAC QRS framework excluded contracts between States and MA dual eligible special needs plans (D–SNP) where the contract is only for the D–SNP to provide Medicaid coverage of Medicare cost sharing for the D–SNP enrollees; this is reflected in proposed § 438.505(b).

We summarize and respond below to public comments received on the general rule and applicability provisions (§§ 438.334(a), 438.505(a) and 457.1240(d)).

Comment: Most commenters supported our proposal to extend the implementation date for the MAC QRS another year, from 3 years to the end of the fourth calendar year following the publication of the final rule. Commenters who supported the timeline stated that the proposal balances the burden on States, health plans, and providers with the needs of beneficiaries. Some commenters urged CMS to accelerate the initial implementation so users could access the information sooner. Several commenters requested that CMS consider further extending the implementation timeline beyond the proposed additional year, with many suggesting that CMS provide another additional year to implement, giving States 5 calendar years to implement a MAC QRS following the publication of the final rule. A couple of commenters encouraged CMS to consider implementing a voluntary performance year prior to mandating full implementation of the proposed MAC QRS, effectively requesting an additional year to implement a MAC QRS. Several commenters suggested that CMS consider an extension process for MAC QRS requirements (especially for States with a small number of managed care plans) to allow States additional time to implement MAC QRS requirements. States noted several challenges to meeting the implementation dates, including collecting the data necessary to calculate measures for certain beneficiaries, such as those who are dually eligible, and collecting data needed to stratify quality ratings. A couple of commenters requested that CMS phase in the proposed mandatory measures, starting with a subset of mandatory measures, such as ten, required for the first year, and moving toward display of the full measure set over time.

Response: We agree that States may be challenged to implement all MAC QRS requirements by the proposed implementation date despite a good faith effort. We considered but are declining the suggestion to further extend the implementation dates as a whole by an additional year or to phase in use of the full mandatory measure set over time. We believe that the additional year that was proposed (extending the current 3-year timeframe under the current regulation to 4 years), as well as our proposal to implement the MAC QRS website requirements in two phases, giving additional time to implement the search tools and display of measures stratified by beneficiary characteristics required under § 438.520(a)(6) that may require more advanced technological capabilities or more challenging data collection, is sufficient to implement the MAC QRS, particularly since many of our requirements build upon existing information and data States either already have or are currently required to report publicly or to CMS. We note that the deadline specified in § 438.505(a)(2) as finalized is the end of the fourth calendar year after the effective date of this final rule (meaning the fourth calendar year after July 9, 2024 2024), unless otherwise specified in the part 438, subpart G regulations.

Nonetheless, we recognize that some States may need additional time to fully comply with all MAC QRS requirements and we are adding new provisions at §§ 438.515(d) and 438.520(b) to this final rule to allow States to request a one-time, one-year extension for certain MAC QRS requirements for which commenters identified specific concerns and barriers to implementation. These include the methodology requirements established at § 438.515(b)(1) and (2), as well as the website display requirements established at § 438.520(a)(2)(v) and (6). We discuss additional details related to extensions for methodology requirements in section I.B.6.f. and related to extensions for website display requirements in section I.B.6.g but address here the overall elements common to both types of extensions.

States may submit a request for an extension under either §§ 438.515(d) or 438.520(b) of the final rule by submitting an extension request to CMS that includes the information and by the deadline(s) identified in these respective sections. We are finalizing identical content requirements for requests for both types of extensions. First, the State must identify the specific requirement for which the extension is requested. Second, the State must describe the steps the State has taken to meet the requirement as well as the anticipated steps that remain to implement the requirement. Third, the State must explain why it will be unable to comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement by its implementation date. Finally, the

[205] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

State must include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, the operational steps the State will take to address identified implementation barriers by the end of the extension year as the extension is for only one-year, and it is a one-time extension. If a State wishes to request an extension for multiple requirements, the State need not submit multiple extension requests, but must provide the required information for each individual requirement identified in its single extension request. We discuss the types of information a State could provide to meet these requirements for each type of extension in more detail in sections I.B.6.f. and I.B.6.g of this final rule.

We are also finalizing the same standard for approving extension requests for implementation of the methodology (§ 438.515(d)(3)) and the website display requirements (§ 438.520(b)(3)). CMS will approve a State's request for an extension if CMS determines that the request: (1) includes the information required for the extension request; (2) demonstrates that the State has made a good-faith effort to identify and begin executing an implementation strategy for the requirement but is unable to comply with the specified requirement by the implementation date specified in the regulations in part 438 subpart G; and (3) demonstrates the State has an actionable plan to implement the requirements by the end of the one-year extension. If a State requests an extension for multiple requirements, CMS will review each request separately against these standards and will the provide the State with an individual determination for each requirement for which the State has requested an extension.

We believe that providing States with an opportunity to request an extension for these individual MAC QRS requirements, if needed, best balances the important policy goals and burdens associated with implementation of the MAC QRS requirements adopted in this final rule and addresses the various policy discussions in the comments to accelerate or postpone MAC QRS implementation. We discuss the implementation extension for rating methodology requirements in additional detail in section I.B.6.f of this final rule and the implementation extension for website display requirements in additional detail in section I.B.6.g. of this final rule.

Comment: Many commenters supported our proposal to require States to provide support to beneficiaries, enrollees, or both, seeking assistance as to how to use the MAC QRS through the State's existing beneficiary support system. Most of these commenters agreed that this would require additional training and financial resources and requested that CMS ensure that States have access to an enhanced Federal match (FFP funding) to provide these services. A couple of commenters noted the importance of ensuring that any choice counseling provided include information and resources related to Medicare coverage for people who are dually eligible. One commenter recommended that CMS issue guidance or best practices for communicating with dually eligible beneficiaries about the differences between the MAC QRS ratings and Medicare and Part D quality rating system ratings.

Response: We appreciate commenters' support for our proposal to require States to use their beneficiary support system to assist beneficiaries, enrollees, or both, using the MAC QRS implemented by the State. We agree that this requirement will necessitate additional training and resources for call center staff, and we acknowledge that the MAC QRS requirements may be more complex than information currently provided through the beneficiary support system. To address this concern, we will consider developing technical assistance resources to support States in training call center staff, including how to best address the unique needs of dually eligible individuals, and differences between the MAC QRS ratings and the MA and Part D quality rating system ratings.

In response to the commenters that requested increased FFP funding to support States in the design and development of their MAC QRS, we clarify that there are existing pathways States can use to receive enhanced FFP related to the implementation of the MAC QRS. As was discussed in the proposed rule and reiterated in section I.B.6.f. of this final rule, under the EQR optional activity at § 438.358(c)(6), States may use their EQRO to assist with quality ratings, which could include the collection of data, validation of data, and calculation of performance rates. States may be eligible for a 75 percent FFP for such EQRO services in the case of an MCO, as provided in § 438.370. We appreciate commenters requesting clarity on FFP regarding the other aspects of the MAC QRS implementation. If the requirements for the enhanced match are met, a State may be eligible for enhanced FFP as part of the State's Medicaid Enterprise System (MES) for the design, development, and implementation of a new public facing website—and the data infrastructure that supports it—when necessary to comply with the new MAC QRS website requirements we are finalizing in § 438.520. We refer States to SMDL #22–001[206] for more information and encourage States to meet with their MES State Officer for technical assistance on which operational elements of their MAC QRS implementation may be eligible for enhanced FFP. We will also consider developing more specific guidance on FFP availability for MAC QRS to help States plan their implementation.

We also agree with commenters that information developed by the State that is related to the MAC QRS, including choice counseling, should also address the unique needs of dually eligible individuals. We will consider using the information and perspectives gathered during our pre-rulemaking engagement with beneficiaries, described in section I.B.6.a. of the proposed rule, to inform future guidance on best practices for how to assist MAC QRS users, including dually eligible beneficiaries, and how to explain the differences between the MAC QRS ratings and the MA and Part D rating system ratings.

Comment: Commenters overwhelmingly supported alignment of the MAC QRS with existing CMS quality measurement and rating initiatives, when appropriate, and encouraged continued focus on alignment to reduce burden on both States and plans. Many cited the QHP quality rating system and MA and Part D quality ratings system, specifically, as well as the Adult and Child Core Sets and the Universal Foundation as particularly important initiatives with which to align.

Response: We agree with commenters that alignment of the MAC QRS with existing CMS quality measurement and rating initiatives is an important way to reduce burden on States and plans and we appreciate the support for our proposal at § 438.505(c) to continue alignment between the MAC QRS and existing CMS quality measurement and rating initiatives for other markets and programs to the extent appropriate.

After consideration of the public comments and for the reasons outlined in the proposed rule and this final rule, we are finalizing § 438.505 largely as proposed, with some modifications. As finalized, § 438.505(a)(1) reflects changes to clarify the scope of flexibility for States regarding the methodology

[206] See State Medicaid Director Letter #22–001, *https://www.medicaid.gov/sites/default/files/2023-06/smd22001.pdf.*

used in the QRS and to clarify that States may display additional quality measures and website features in addition to the mandatory minimum measures specified by CMS and the mandatory minimum content of the MAC QRS website identified in § 438.520(a). In addition, we are finalizing minor changes throughout paragraph (a) to improve the readability of the provision. We are also finalizing the cross-reference in § 457.1240(d) to part 438, subpart G to require CHIP managed care programs to comply with implementing their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of this final rule as proposed. We note that although the MAC QRS changes in this rule are intended to work harmoniously to achieve a set of goals and further specific policies, they are not so interdependent that they will not work as intended even if a provision is held invalid. Many of the MAC QRS provisions may operate independently of each other. For example, quality ratings for mandatory measures can be displayed in accordance with the requirements of phase one of the website display implementation even if website display requirements in phase two are successfully challenged. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements). We intend that if any amendment or new provision regarding the MAC QRS adopted in this rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from the remaining provisions.

e. Establishing and Modifying a Mandatory Measure Set for MAC QRS (§§ 438.334(b), 438.510 and 457.1240(d))

The current regulations at § 438.334(b)(1) direct CMS, after consulting with States and other interested parties, to identify a mandatory set of QRS quality measures that align, where appropriate, with the MA and Part D and QHP quality rating systems and other related CMS quality rating approaches, and to provide an opportunity for public notice and comment on such mandatory measures. In section I.B.6.e.1. of the proposed rule, we discussed the standards that guided CMS in identifying the initial mandatory measures and proposed an initial mandatory measure set. We sought comment on our proposed initial mandatory measure set, which we are finalizing in this final rule. We noted that we would not duplicate the list of the mandatory measures and specifications in regulation text considering the regular updates and revisions that would occur under the subregulatory process at least every other year to include the addition, removal, or update of the mandatory measure set proposed in § 438.510(b). We also proposed to codify both the standards that guided development of the initial mandatory measure set and the standards for a subregulatory process to modify the mandatory measure set over time.

(1) Standards for Including Measures in Mandatory Measure Set (§§ 438.510(c) and 457.1240(d))

Three distinct considerations guided the process of selecting individual measures to establish a concise proposed initial mandatory measure set. We proposed at § 438.510(c)(1) through (3) to codify these three considerations as standards that we would apply in subsequent years in adding measures to the mandatory measure set, making substantive updates to an existing mandatory measure, and in some circumstances when removing measures from the mandatory measure set. Specifically, a measure was only included in our proposed initial mandatory measure set if: (1) it met five of six measure inclusion criteria proposed in § 438.510(c)(1); (2) it will contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas in the mandatory measure set; and (3) the burdens associated with including the measure will not outweigh the benefits to the overall quality rating system framework of including the new measure based on the measure inclusion criteria we proposed. Performance areas are domains of care, such as preventive health and long-term services and supports. We discussed in section I.B.6.e.4. of the proposed rule that these same standards will be applied in determining whether a measure may be added to or removed from the mandatory set.

As discussed in section I.B.6.e.1. of the proposed rule (and reflected in proposed § 438.510(c)(1)), during our pre-rulemaking discussions with States and other interested parties, we identified six measure criteria for determining whether a given measure is a good candidate for including in the mandatory MAC QRS measure set: (1) Usefulness: is the measure meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan; (2) Alignment: is the measure currently used by States and other Federal programs and does it align with other CMS rating programs described in § 438.505(c) of this chapter; (3) Relevance: does the measure assess health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity; (4) Actionability: does the measure provide an opportunity for managed care plans to influence their performance on the measure; (5) Feasibility: is the measure based on data that are readily available, or available without undue burden on States and plans, such that it is feasible to report by most States and managed care plans; and (6) Scientific Acceptability: does the measure demonstrate scientific acceptability, meaning that the measure, as specified, produces consistent and credible results.

We provided the following explanation in the proposed rule of each of these criteria and how we assessed (and, if finalized, how we will assess) whether a given measure met it for inclusion in the initial mandatory measure set.

- *Usefulness:* For the initial mandatory set, we assessed whether a measure meets this criterion by seeking beneficiaries' feedback on which measures of health plan performance are most relevant to them and determined that measures that assess the quality of care or services most identified by beneficiaries as relevant to selection of a health plan. We noted that when adding, updating, or removing measures through the proposed process, we would rely on the continued engagement with beneficiaries proposed in § 438.520(c) and discussed in section I.B.6.g.4. of the proposed rule to determine whether a measure meets this criterion of being meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan. We noted that input from beneficiaries or beneficiary advocates with experience assisting beneficiaries was particularly important in evaluating this criterion, but input from other interested parties was also considered.
- *Alignment:* For measures in the initial mandatory measure set, we assessed whether a measure met this criterion by identifying the extent to which States and other Federal programs (such as the Medicaid and CHIP Scorecard, the MA and Part D quality rating system, and the QHP quality rating system) currently collect or report the measure. We considered feedback on measures commonly used to assess health plan performance, as well as the challenges and concerns

with these measures. If the measure is not currently in use, we assessed whether it overlaps with an existing, widely used measure. This approach reflects the continuing evolution of quality measurement and allowed for consideration of new, better measures.

- *Relevance:* For each measure under consideration, we determined, using measure information and technical specifications, whether the measure evaluated or measured at least one of these areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity. If it was determined that the measure evaluated or measured at least one of these areas, it was considered to meet the criteria.
- *Actionability:* For the proposed measure set, we assessed whether a measure met this criterion by considering input from States, plans, and other interested parties on what actions managed care plans may take to improve or maintain measure performance and the extent to which the plans control, or are capable of influencing, what is being measured. We also considered whether the measure is currently specified at the plan level, meaning that measure specifications are available to calculate the measure at the plan (as opposed to provider or State) level because individual plans cannot effectively impact performance of all plans aggregated across the state.
- *Feasibility:* For the proposed measure set, we assessed whether a measure meets this criterion by considering the accessibility of the data required to calculate the measures and the proportion of plans or States that currently collect data for the measure.
- *Scientific Acceptability:* For the proposed measure set, we assessed whether the intervention included in the measure directly correlates to the quality of care provided and provides consistent and credible results by reviewing evidence that the measure can be used to draw reasonable conclusions about care in a given domain.[207]

Using feedback throughout our consultations related to the mandatory measure list, we assessed our list of suggested measures to identify the extent to which each measure met these inclusion criteria. During the consultations, we received feedback confirming our assessment that, while each of the six criteria were important to consider, it would be difficult for a measure to meet all six criteria. For instance, we found that requiring all six criteria could prevent the inclusion of either measures that are extremely meaningful to beneficiaries but not commonly used by States, or measures aligned with State priorities for managed care quality and plan performance, but less useful to beneficiaries. Therefore, we proposed in § 438.510(c)(1) that a measure must meet at least five of the six measure inclusion criteria to be considered against our other standards and included in the mandatory measure set in the future. We sought comment on the six criteria we proposed to evaluate prospective measures for the mandatory measure set, and whether there are additional objective measure inclusion criteria that we should use to evaluate quality measures for inclusion as mandatory measures. Additionally, we sought comment on our proposal to require measures to meet five out of the six proposed criteria, and whether that threshold produces enough measures to consider for the MAC QRS. Finally, we sought comment on the extent to which the measures in our proposed measure set met the proposed measure inclusion criteria, including the reasons and/or supporting data for why the measure meets or does not meet the criteria.

Through our work to develop the proposed mandatory measure set, we found that many measures met at least five of the six measure inclusion criteria and came to understand that additional standards would be needed to narrow the initial mandatory measure set to a manageable size and to prevent future measure sets from becoming too large. States and managed care plans recommended limiting the mandatory set to between 10 and 30 measures to ensure that plans can improve on selected measures, that States will be able to report all measures, and that implementing a QRS would not overwhelm State and plan resources. Furthermore, our website prototype user testing showed that beneficiaries were evenly split between those with high informational needs who preferred detailed information from a lot of measures, and those who valued clear and concise information on the big picture using fewer measures.

The first standard which a measure must meet for inclusion in the mandatory measure set, under the proposed rule, reflected at § 438.510(c)(1), is to satisfy at least five of the six criteria discussed above. The two additional standards that we proposed to codify in § 438.510(c)(2) and (3) reflect the feedback we received for a concise mandatory measure list and allow us to consider how a measure would contribute to the measure set as a whole. First, in § 438.510(c)(2), we proposed that a measure must contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas that are assessed within a concise mandatory measure set since we included as part of our standard proposed in § 438.510(c)(2) that the overall measure set should be ''concise.'' We stated our intent to maintain a goal of no more than 20 measures for the initial mandatory measure set, but proposed to allow flexibility for the number of measures to increase as the mandatory set is updated over time. We stated that we would consider each suggested measure in relation to other suggested measures, as well as the measures already in the mandatory measure set to identify those that are very similar or duplicative, keeping in mind the need for a mandatory measure set that is both representative and concise.

The second standard, proposed in § 438.510(c)(3), is that a measure would be added to the mandatory measure set when the burdens of adding the measure do not outweigh the benefits. To make this assessment, the extent to which the measure meets the six criteria proposed at § 438.510(c)(1)(i) through (vi) would be considered. If several similar measures are suggested for inclusion (that is, those that measure performance within similar subpopulations of beneficiaries, health conditions, services, and performance areas), we would assess the extent to which each suggested measure meets the criteria listed in proposed paragraph (c)(1), to assess the benefits and burdens of including each measure in the mandatory measure set and identify a measure that best balances burdens and benefits. We proposed to include a measure when all three of the standards proposed in § 438.510(c) are met. We also proposed that CMS would use the subregulatory process proposed in § 438.510(b) and discussed in section 1.B.6.e.3. of the proposed rule, to determine which measures meet the proposed standards.

We sought comment on the standards proposed at § 438.510(c)(2) and (3) and how measures should be assessed using these standards. We sought comment on the appropriate balance of representation (of populations and performance areas) in the mandatory measure set and any additional considerations that may be missing from our proposed paragraph (c)(2). Further, we sought comment on whether there are additional considerations that CMS

[207] CMS Measures Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/overview.*

should consider in the weighing of burdens and benefits of a measure under proposed § 438.510(c)(3).

We summarize and respond to public comments received on standards for including and adding mandatory measures for the MAC QRS (§§ 438.334(b), 438.510(c) and 457.1240(d)) below.

Comment: We received many comments supporting our standards for measure selection, including our proposed measure selection criteria. One commenter supported our proposed measure selection criteria but recommended that we revise the feasibility criterion to consider burden on providers. Another commenter recommended that we consider the burden of chart review abstraction in data collection and reporting when weighing the benefits and burdens of a measure.

Response: We agree with the commenter that recommended that we revise the feasibility criterion to consider provider burden and we are modifying the proposed feasibility measure selection criterion at § 438.510(c)(1)(v) to add ''providers'' to ensure that provider burden, as well as State and plan burden, is considered when assessing whether data collection associated with the measure is feasible. This means that feasibility of a measure will be determined by whether data are available without undue burden on States, plans, or providers such that it is feasible to report by many States, managed care plans, and providers. We believe that this change also addresses the commenter that requested that we specifically consider the burden of chart review abstraction on providers in data collection and reporting when assessing the burdens and benefits of a measure. In § 438.510(c)(3), we proposed that the benefit and burden assessment would be made based on the six criteria listed at § 438.510(c)(1). By finalizing our feasibility criteria at § 438.510(c)(1)(v) with modifications to include the feasibility and potential burden of data reporting for providers, CMS may consider the extent to which chart review abstraction may burden providers when assessing a measure for inclusion in the mandatory measure set.

Comment: One commenter requested additional clarification on how CMS intends to assess the administrative burden associated with a potential measure and evaluate the reasonableness of that burden, as well as the relative benefit to the larger quality rating system, noting that CMS's determination of burdens associated with data collection and reporting and whether they are reasonable is not always consistent with States' views or experiences.

Response: In section I.B.6.e.1 of the proposed rule, we provided an overview of the process by which we identified the three standards for adding mandatory measures, finalized in this final rule at § 438.510(c)(1)–(3). We emphasize here that we did not develop the standards for including a measure without input and do not intend to apply them without an opportunity for input from interested parties. Rather, the standards proposed and finalized in this rule reflect the thought process and concerns discussed by and among interested parties, including States, over several years of engagement.

Furthermore, as discussed in section I.B.6.e.3 of the proposed rule and finalized in § 438.510(b), before adding a measure to the mandatory set, we must engage in a subregulatory process through which States and other interested parties evaluate the current mandatory measure set, make recommendations to add mandatory measures, and provide comment on modifications to the mandatory measure set. When a measure meets all three of the standards finalized at § 438.510(c)(1)–(3), per § 438.510(c), we will add the measure to the mandatory set—an assessment that must be based on available relevant information, including the input received during the subregulatory process. Following the engagement required under § 438.515(b)(1), as proposed and finalized at § 438.510(b)(2), we must provide public notice and opportunity to comment through a call letter or similar subregulatory process using written guidance on any planned modifications to the mandatory measure set. During this second phase of engagement, we will gather additional input from the public on any mandatory measures identified by us as meeting the three standards for adding a measure, which will be reviewed and considered prior to finalizing the measure in the technical resource manual.

In combination, the subregulatory process, finalized at § 438.510(b), and the requirement, finalized at § 438.515(c), that we base the decision to add a measure on available relevant information (which would include the input received during the subregulatory process) ensures that assessment of whether a measure meets the standards, including that the benefits of a given measure outweigh the burdens, will take into account the input that we receive through the subregulatory process. This process will allow us to assess each proposed measure based on—among other things—the identified benefits and burdens of a given measure and how those benefits and burdens are perceived and weighed across the health care system, the existence of alternative measures that may better balance burdens with benefits, and the extent to which CMS can provide support that addresses the challenges that create burdens for a given quality measure, such as through technical assistance or reasonable implementation timelines.

After considering the commenter's concerns, we do, however, believe that additional clarity on how CMS will assess a measure under the balancing standards in §§ 438.510(c)(2) and (3) is warranted to ensure that, when providing their own perspective on how they would assess the measure under these two balancing standards, those who provide measure input through the subregulatory process finalized in § 438.510(b) have a clear understanding of the types of CMS's considerations. As noted, in section I.B.6.e, the proposed rule detailed many of the factors and considerations considered by participants in our pre-rulemaking engagement. We are finalizing a new (c)(4) at § 438.510 to reflect these considerations by establishing that, when making the determination required under § 438.510(c)(1) through (3), to add, remove, or update a measure, CMS may consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas when assessing the measure under the balancing standards in § 438.510(c)(2) and (3). This modification reflects what we observed during pre-rulemaking discussions among interested parties about potential MAC QRS measures. Participants in these discussions did not just assess each measure in a vacuum, but assessed measures on their own merits and also engaged in robust discussion on both how a measure would work together with other measures considered for inclusion in the MAC QRS mandatory set and whether other, similar measures exist that may be more appropriate for inclusion. As finalized, our intent in adding new § 438.510(c)(4) is to encourage participants in the subregulatory process to include these considerations when providing their perspective on how they would assess a measure under § 438.510(c)(2) and (c)(3) through the subregulatory process so that CMS can may use input from across the healthcare system to assess the measure against the measure standards, including the balancing standards in § 438.510(c)(2) and (3). We note that we

are not including a reference to § 438.510(c)(1) in new (c)(4) as whether a measure meets a given measure selection criterion is not impacted by whether any other measure does so as well.

Comment: Several commenters suggested additional criteria including those that would require the measure to advance health equity; be an outcomes-based measure (as opposed to a process measure); be endorsed by the National Quality Foundation (NQF); and be validated, audited, and publicly reported.

Response: We considered commenters' requests to finalize additional measure selection criteria, but we are declining to add to our existing list of criteria. We agree with commenters that a measure's potential impact on improving health equity is an important consideration in assessing a measure for inclusion in the mandatory measure set. We considered adding a selection criterion related exclusively to health equity but concluded that advancing health equity is already considered during measure selection as it is a consideration under the relevance criteria in § 438.510(c)(1)(iii), which assesses whether a proposed measure evaluates health plan performance in at least one area specified by CMS including customer experience, access to services, health outcomes, quality of care, and health equity. We recognize that the relevance criteria does not require that a measure evaluate performance in health equity to be considered for addition to the mandatory set. However, when providing perspective on whether a measure meets the standards in § 438.510(c)(2) and (c)(3), participants in the subregulatory process could provide input on whether a measure that evaluates health equity alone, or in addition to other priority topics, would result in a better balance of representation, provide more benefits to the overall quality rating system framework, or both, as compared to those measures that do not evaluate health equity, which CMS may then consider when assessing the measure under the standards in § 438.510(c).

After consideration, we have decided not to add a criterion that would require measures to be outcomes-based measures (instead of process measures). While outcomes-based measures are considered by many to be the ''gold standard'' of quality measures, the outcomes addressed by these measures are often influenced by multiple factors, including those outside the control of a health plan. In many cases, a process measure may be a better way to determine the degree of access a health plan's enrollees have to important services, such as preventive care. Furthermore, beneficiaries often find certain process measures informative and desirable. Therefore, we do not want to exclude process measures from inclusion in the MAC QRS measure set.

We considered the suggestion to require NQF endorsement, however we are declining to add endorsement as a measure selection criterion because the criteria used for NQF endorsement overlap with the MAC QRS measure selection criteria in § 438.510(c) as finalized in this rule and would therefore be redundant.[208] Likewise, while we agree that whether a measure rating is validated and audited, and whether the measure is publicly reported, are also important considerations, we decline to add these suggestions as additional selection criteria. Validation and auditing are sufficiently addressed through our requirement in § 438.515(a)(3) that States validate data used to calculate quality ratings for mandatory measures.

Finally, our alignment measure criterion considers the extent to which a measure is publicly reported as it assesses the extent to which a measure aligns with other CMS rating programs, that is, the measure is already reported to CMS. To the extent that managed care plans or States already report a measure, that would also have bearing on the criterion at § 438.510(c)(1)(v), which addresses the level of burden of reporting a measure such that it is feasible to report.

Comment: A few commenters suggested that we make certain measure selection criteria, or combinations of measure criteria, mandatory including usefulness to beneficiaries, feasibility, actionability, and scientific acceptability. One commenter recommended that CMS make the actionability and feasibility criteria mandatory, noting that these criteria are essential to ensuring that all measures included in the MAC QRS meet the goals described by CMS in section I.B.6.a. of the proposed rule. The commenter noted that if CMS only requires measures to meet five of six inclusion criteria, the mandatory measure set could include measures that managed care plans cannot reasonably be expected to impact, or that are not feasible to report. Another commenter recommended that a measure should only be included in the MAC QRS mandatory measure set if it meets the usefulness to beneficiary's standard given the stated role of the MAC QRS. Another commenter suggested that CMS make the usefulness, feasibility, and scientific acceptability criteria mandatory to better align with the measure evaluation criteria that is widely accepted by the quality measurement ecosystem and used by the CMS consensus-based entity.

Response: We considered but are declining commenters' suggestions to make certain measure selection criteria, or certain combinations of selection criteria, mandatory. In section I.B.6.e.1 of the proposed rule, we discussed how we considered each of the six measure selection criteria to be important, but that our own process of identifying the initial mandatory measure set showed that requiring a measure to meet all six criteria severely limited the measures that could be included in the MAC QRS. Similarly, we believe that requiring certain measure selection criteria to be mandatory could prevent flexibility to include important measures in the future. Additionally, there was no consensus among those who commented on this aspect of the proposed rule about which criteria should be made mandatory, highlighting the difficulty of establishing this additional designation. Instead of identifying a subset of mandatory criteria, we believe that the subregulatory process for adding measures finalized at § 438.510(b) and described in the proposed rule in section I.B.6.e.4 will allow CMS to gather for consideration varying viewpoints on whether a measure does or does not meet certain measure selection criteria and on the relative importance of a criterion and other considerations specified in § 438.510(c), which CMS may use when assessing the overall benefits and burdens of adding the measure in applying § 438.510(c)(2) through (4). Furthermore, we are finalizing in new § 438.510(c)(4) that when assessing whether a measure meets the measure standards in § 438.520(c)(2) and (3), CMS may consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas. This provision will allow CMS to consider input gathered through the subregulatory process on how interested parties balance and weigh the importance of the measure standards, including the measure selection criteria when assessing measures for inclusion in the mandatory set.

Comment: One commenter suggested that new measures undergo a 2-year

[208] *https://www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx* (includes criteria: important to measure, scientifically acceptable, useable, relevant, and feasible to collect.)

pilot period to allow States and CMS to collect benchmark data before implementing in the QRS. The commenter did not identify the perceived benefits of adopting this approach. Furthermore, the commenter did not specify what they would consider to be ''new'' measures—whether these would include any measure newly added to the mandatory measure set or only measures added to the mandatory set that are ''new'' in that they were recently developed or adopted by a measure steward.

Response: After consideration, we are declining the commenter's suggestion to implement a pilot period prior to implementing new measures in the MAC QRS, both when a measure is newly added to the mandatory measure set or when a measure is added that is recently developed. Benchmarks for a given quality measure help health plans to assess how well they are currently performing on a given quality measures, identify any need for improvement, and make educated decisions on how to assign finite resources towards quality improvement. We believe that our established selection criteria, which include scientific acceptability and alignment with other CMS programs such as the QHP quality rating system and MA and Part D quality rating system, the Adult and Child Core Sets, and other programs identified at § 438.505(c), will make it likely that measures added to the measure set are well-established and already in use. As such, we believe that States and health plans will have a sense of both State and plan performance on the measures added to the mandatory measure set as well as the feasibility of reporting the measure. However, we noted in the proposed rule at I.B.6.e.1 that when considering whether a measure that is not currently in use (such as a newly developed measure) meets the alignment criterion we would assess whether it overlaps with an existing, widely used measure. As such, we recognize that our current policy accepts the possibility that a newly developed measure (including one that may not have data from which benchmarks could be developed) could be added to the mandatory measure set. We continue to believe that this approach is appropriate as it reflects the continuing evolution of quality measurement, allows for consideration of new, better measures, and the measure would still need to meet at least 5 of the 6 measure selection criteria.

If a newly developed measure is added to the mandatory measure set (following the subregulatory process requiring extensive public engagement and application of the measure selection standard finalized in § 438.510), this final rule provides CMS with flexibility to determine the implementation date for such a measure, which could allow something like the pilot period recommended by the commenter prior to mandatory implementation. As finalized in § 438.510(f), States will have at least 2 calendar years after a measure is added to the mandatory measure set to display the measure in its MAC QRS. The flexibility to give States more than 2 years to implement a mandatory measure newly added to the measure set would allow CMS to implement a voluntary implementation period or pilot program. Furthermore, the extensive subregulatory engagement process would provide CMS with many opportunities to gather input on an appropriate implementation timeline and any additional steps that may be desirable prior to mandatory implementation. We recognize that other programs may use pilot periods similar to what the commenter generally described but believe that the specific policy goals and implementation structure for the MAC QRS means that setting mandatory pilot periods as part of adopting or changing the mandatory minimum measure set is not necessary.

Comment: One commenter expressed concern that the alignment measure selection criteria in § 438.510(c)(1)(ii) could make it harder for new HCBS measures to be included as HCBS measures will never align with the QHP quality rating system or the MA and Part D quality rating system since neither Medicare nor QHPs provide coverage for HCBS.

Response: We agree with the commenter that HCBS measures will likely not align perfectly with MA and Part D quality rating system or QHP quality rating system measures because those quality rating systems do not include measures specifically developed to assess HCBS plans. While we do not believe that our current alignment requirement would hinder the inclusion of HCBS measures in the MAC QRS mandatory measure set, we are finalizing modifications to paragraph (c)(1)(ii) to require alignment, t*o the extent appropriate,* with other CMS programs described in § 438.505(c), which include the MA and Part D quality rating system and QHP quality rating system and other similar CMS quality measurement and rating initiatives. Under finalized § 438.510(c)(1)(ii), it would not be appropriate to require measures developed specifically for HCBS to align with either the MA and Part D or QHP quality rating system, but it would be appropriate to look to whether the measure is aligned with other similar CMS quality measurement and rating initiatives, such as the HCBS Quality Measure Set. If a measure is proposed for which there is no existing CMS program with which it would be considered appropriate for the measure to align, CMS would consider the proposed measure to meet the alignment criterion.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.510(c) as proposed except for revisions to § 438.510(c)(1)(ii) and (v). We are finalizing paragraph (c)(1)(ii) with the additional phrase ''to the extent appropriate'' to clarify that if alignment is appropriate, it should be considered when determining whether a measure meets this criterion. We are finalizing § 438.510(c)(1)(v), with a modification to include provider burden when considering whether a measure meets the feasibility criterion established in § 438.510(c)(1) of the final rule.

(2) Mandatory Measure Set (§§ 438.510(a) and 457.1240(d))

We proposed in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that the quality rating system for managed care plans implemented by the State for Medicaid and CHIP managed care programs must include the measures in a mandatory measure set, which would be identified by CMS in the technical resource manual as proposed in § 438.530(a)(1). We note that proposed § 438.520(b), discussed in section I.B.6.g.5. of the proposed rule and this final rule, would allow States to include other, additional measures outside the mandatory measure set. We received input through our pre-rulemaking consultations with interested parties, detailed in section I.B.6.a. of the proposed rule, on the mandatory measure set for the MAC QRS, including the number of measures, measure inclusion criteria, and performance areas and populations represented by the measures. After considering the priorities and other information gleaned through the several years of pre-rulemaking consultations described in section I.B.6.a. of the proposed rule, and applying the standards discussed in section I.B.6.e.1. of the proposed rule, we proposed for public comment an initial set of 18 mandatory measures. The proposed mandatory measures reflected a wide range of preventive and

chronic care measures representative of Medicaid and CHIP beneficiaries. The proposed list of measures included:

1. Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics;
2. Initiation and Engagement of Substance Use Disorder (SUD) Treatment;
3. Preventive Care and Screening: Screening for Depression and Follow-Up Plan;
4. Follow-Up After Hospitalization for Mental Illness;
5. Well-Child Visits in the First 30 Months of Life;
6. Child and Adolescent Well-Care Visits;
7. Breast Cancer Screening;
8. Cervical Cancer Screening;
9. Colorectal Cancer Screening;
10. Oral Evaluation, Dental Services;
11. Contraceptive Care—Postpartum Women;
12. Prenatal and Postpartum Care;
13. Hemoglobin A1c Control for Patients with Diabetes;
14. Asthma Medication Ratio;
15. Controlling High Blood Pressure;
16. CAHPS survey measures: how people rated their health plan, getting care quickly, getting needed care, how well doctors communicate, and health plan customer service;
17. MLTSS–1: LTSS Comprehensive Assessment and Update; and
18. MLTSS–7: LTSS Minimizing Institutional Length of Stay.

See also 88 FR 28187 through 21891 for additional details on the proposed measures.

At the time the proposed rule was published, 15 of the 18 measures were commonly reported by States,[209] 16 of the 18 measures overlapped with the 2023 and 2024 Core Set measures, 11 with the QHP quality ratings system, 13 with the 2021 Medicaid and CHIP Scorecard, 5 with the MA and Part D quality rating system, and 2 with the HCBS Quality Measure Set.

In the proposed rule, we also provided an overview of several measures that we considered but decided not to include in the proposed initial mandatory set. We noted that these other measures were not included because they did not meet one or more of the standards proposed at § 438.510(c). We also identified these other measures and the reasons we did not include them in the measure set in the proposed rule as follows:

- *Contraceptive Care—All Women Ages 15 to 44 (CCW) and Person-Centered Contraceptive Counseling (PCCC):* During our pre-rulemaking engagement, States and other interested parties stated a desire for the MAC QRS to include a quality measure involving contraceptive services that will be relevant for all women, but many noted that there is not yet a measure they would recommend that meets this description. Beneficiaries did not specifically speak to the importance of a contraceptive measure, but consistently noted the desire to be involved in their care decisions and for providers to respect their health goals and needs when providing counseling on health care options. We considered various contraceptive measures in addition to CCP, the measure we proposed. The additional measures that we considered on this topic included Contraceptive Care—All Women Ages 15 to 44 (CCW) and a new survey-based measure, Person-Centered Contraceptive Counseling (PCCC), that uses patient provided responses to assess the person-centeredness of contraceptive counseling.

While we believe the PCCC measure aligns well with beneficiary preferences stated during beneficiary consultations, it is an emerging measure that fails to meet two of the six measure inclusion criteria and is not currently used in any other CMS quality measurement and rating initiatives. First, PCCC does not currently meet our measure inclusion requirement of feasibility as we did not find evidence that plans are currently collecting the data necessary to produce this measure and some interested parties stated concern about the perceived burden of reporting PCCC. Second, we believe the measure does not meet the scientific acceptability criterion as it is currently specified only at the provider level, so it is unknown whether it produces consistent and credible results at the plan level. We note, however, that emerging measures would still be assessed based on the criteria and standards proposed at § 438.510(c), and it could take time for emerging measures to meet the proposed regulatory standards.

Both CCW and CCP meet at least five of the six inclusion criteria and both measure access to contraception that reduces unintended pregnancy in a defined population. Therefore, each would contribute to balanced representation of beneficiaries by providing insight into the accessibility of contraceptive care among beneficiaries who may become pregnant. However, we believe the benefits of including CCP are greater than those of including CCW because CCP is more actionable than CCW due to the larger proportion of individuals who are enrolled in a health plan during the postpartum period (the focus of CCP) as opposed to the preconception period (the focus of CCW). CCP focuses on measuring access to effective contraceptive care during the postpartum period, which can improve birth spacing and timing and improve the health outcomes of women and children.

- *Follow-up after Emergency Department Visit for Mental Illness (FUM) versus Follow-up After Hospitalization for Mental Illness (FUH):* States and other interested parties supported including FUM, as well as Follow-up After Hospitalization for Mental Illness (FUH) in the initial mandatory measure list. Both measures met the measure inclusion criteria and had similar benefits and burdens, and including both would give a fuller picture of the percentage of emergency department and inpatient hospital discharges for which beneficiaries received follow-up services. The two measures assessed important, but very similar services. We concluded that including both would not add sufficiently to the goal of achieving balanced representation given the need also to select a concise overall mandatory set. Upon balancing benefits and burdens associated with each measure, we proposed to include FUH because it was more commonly collected and reported by States and other Federal programs and more frequently used by States to assess plan performance. We provide a detailed analysis of our review of the FUH and FUM measures in section I.B.6.e.4. of the proposed rule in the Table 2-Example Inclusion Criteria Assessment.
- *Childhood Immunization Status (CIS):* We considered including the CIS measure; however, we included the well-child visit measures (Well-Child Visits in the First 30 Months of Life (W30) and Child and Adolescent Well-Care Visits (WCV)) instead. All three measures met at least five of the six inclusion criteria, and each could contribute to balanced representation within the overall mandatory set. However, when reviewing the burdens and benefits to the overall MAC QRS, we concluded the well-child visit measures will have greater benefit to beneficiaries based on our beneficiary testing, which showed that parents cared a lot about whether their children can get appointments (reflected in the well-child visit measure), but no beneficiary commented specifically on childhood immunizations.
- *Postpartum Depression Screening:* We considered this measure based on recommendations from the 2019

[209] As reported by States for the 2020–2021 EQR reporting cycle.

Measure Workgroup. However, we did not include this measure because it did not meet two of our six inclusion criteria, including the feasibility and alignment criteria, at the time of our evaluation.

We also note that we are retaining flexibility in the final rule for States to display quality ratings for additional measures not included in the mandatory measure set after following the process described in § 438.520(c). We encourage States to work with plans and providers regarding the selection of additional measures.

We summarize and respond to public comments received on the MAC QRS mandatory measure set (§§ 438.510(a), (b), and 457.1240(d)) below.

Comment: Many commenters supported the use of a mandatory measure set for the MAC QRS, stating that a unified reporting structure of mandatory measures would bring a level of discipline and consistency that would foster more reliable data across the Medicaid program. Commenters also agreed that the uniformity in tracking plan quality will enable CMS to determine if certain States or managed care plans across States are underperforming.

Response: We appreciate the support and agree that using a minimum mandatory measure set will facilitate comparisons of managed care plan and program performance nationwide. To ensure that our use of a mandatory measure set for the MAC QRS maximizes the uniformity and consistency supported by commenters, we are finalizing § 438.510(a) with modifications to clarify that the mandatory minimum measure set includes only measures calculated using the technical specifications identified and specified by CMS in the technical resource manual. As discussed in section I.B.6.h of the proposed rule, when quality ratings calculated for a mandatory measure do not use the technical specifications approved by the measure steward, we consider those to be ratings for a different measure (that is, an additional measure that may be displayed only once the requirements in finalized § 438.520(c)(2) are met); therefore, display of a measure calculated or used with different specifications than those identified in the technical resource manual would not meet the requirement in § 438.510(a)(1)(i). To the extent that the technical resource manual identifies flexibilities for calculating ratings for MA (either explicitly or through reference to flexibilities approved by the measure steward), calculating the mandatory measure using those flexibilities complies with § 422.510(a)(1). We intend to provide additional guidance on what modifications or flexibilities we would consider to be approved by the measure steward in the technical resource manual. For example, as discussed in the proposed rule, steward-approved modifications could include allowable adjustments to a measure's specifications published by the measure steward or measure specification adjustments requested from and approved by the measure's steward. This approach supports consistency in the use of the measures and ensures comparability by clearly establishing that quality ratings for such measures must be produced using specifications approved by the measure steward, which have been reviewed and subjected to the measure steward's own process to ensure that modified specifications allow for comparisons across health plans.

Comment: Many commenters supported the proposed MAC QRS mandatory measure set, with several suggesting prioritization of certain types of measures such as those that assess health outcomes, promote health equity, or present opportunities for quality improvement in the Medicaid and CHIP populations and incorporation of stronger assessments of the services provided under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.

Response: We agree with the measure topics identified by commenters as priorities and believe our measure selection criteria addresses them sufficiently. Specifically, whether a measure addresses health plan performance for health equity and health outcomes is considered under the relevance measure selection criteria in § 438.510(c)(1)(iii), and whether a measure presents an opportunity for plans to influence performance on the measure is considered under the actionability criteria in § 438.510(c)(1)(iv). We agree with commenters on the importance of measuring quality of care and services delivered to children, including those eligible children under the ESPDT benefit, and believe that the MAC QRS will supplement ongoing efforts we are making to strengthen quality reporting in this area. For example, current ongoing efforts to monitor services provided under the EPSDT benefit include the CMS collection of information on the delivery of EPSDT services at the State level annually through the Annual EPSDT Participation Report (Form CMS–416) and the Child Core Set, which will be mandatory for States to report in 2024. We believe the measures included in our initial mandatory measure set for the MAC QRS will supplement the State level data received from the CMS–416 and Child Core Set by enabling interested parties to view the MAC QRS measures for children at the health plan level within a State. The MAC QRS mandatory measures that are focused on children include measures that help to assess whether eligible children are receiving EPSDT services, such as the Well-Child Visits in the First 30 Months of Life. The rating for this measure will indicate the percentage of children who received this preventive health service for each plan that is responsible for delivering those services. The MAC QRS measures for children will also help parents select a health plan that meets their child's needs, which is one of the objectives of the MAC QRS.

Comment: Many commenters suggested either specific measures or types of measures to add to the initial mandatory measure set. Specific measure recommendations included HIV Viral Load Suppression, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, Kidney Health Evaluation for Patients with Diabetes, and Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure. Measure topics recommended for inclusion included Cesarean deliveries, child lead screening, adult immunization status, and measures that support patient-primary care team relationships such as child and adolescent well-care visits, prenatal and postpartum care visits, and adults' access to preventive/ambulatory health services. We also received several comments that advocated for the inclusion of a measure of social determinants of health (SDOH) and measures that reflect quality of care for people with rare disorders. One commenter recommended that we include measures that cover a wide array of potentially avoidable events, and another commenter suggested that we include a metric related to newborn screening that benchmarks health plan performance to the Recommended Uniform Screening Panel (RUSP), but the commenters did not suggest a specific measure.

We received comments in response to our request for feedback on our decision to exclude the following measures: Childhood Immunization Status, Contraceptive Care—All Women Ages 15–14 (CCW), Person-Centered Contraceptive Counseling (PCCC), and Postpartum Depression Screening. Some commenters provided feedback in support of including the CCW measure

because measuring contraceptive access for all individuals, regardless of pregnancy status, is important to improve health outcomes and effectively compare access to contraception from State to State. One commenter encouraged CMS to consider mandating the use of various measures that exist for contraceptive need screening such as Pregnancy Intention Screening Question (PISQ) and Self Identified Need for Contraception (SINC). Some commenters recommended inclusion of the Childhood Immunization Status measure to ensure that the MAC QRS assesses not only access to care, but also quality of care, and commitment to the health of members and the community. Other commenters provided feedback indicating that while they understood the rationale for not including the Postpartum Depression Screening measure at this time, they requested this metric to be included in the future due to the short-term and long-term consequences if left untreated.

Response: We thank those who suggested additional measures for inclusion in the initial mandatory measure set. We reviewed the comments for each additional measure suggestion and, based on our assessment of the measures according to our measure selection criteria in § 438.510(c), we are declining to add additional measures at this time. Regarding the suggestions to add HIV Viral Load Suppression, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, Kidney Health Evaluation for Patients with Diabetes and Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure, we appreciate these suggestions and believe they meet many (but not all) of the measure criteria. However, to keep the initial mandatory measure list concise, we are not adding them at this time. Furthermore, while we agree with the importance of these measures and that they show promise in meeting our measure standards, we believe that it is important to gather additional input through the public and notice comment process finalized in § 438.510(b), and we do not believe it is appropriate to bypass that process by adopting an additional measure without providing a clear opportunity for comment on the specific measure. Additional rationale for not including these measures in the initial mandatory measure set is indicated below.

We are declining to include the HIV Viral Load Suppression measure because the measure does not meet two of the measure selection criteria described in § 438.510(c)(1). It does not meet the feasibility criterion in paragraph (c)(1)(v) because the data required to calculate the measure is not consistently available to health plans and it does not meet the actionability criterion in paragraph (c)(1)(iv) for plan-level reporting because it has only been used at the provider and State level and the data are not consistently available at the plan level. We are declining to add the Adherence to Antipsychotic Medications measure for Individuals with Schizophrenia as we have concluded after analysis that the benefits of the measure would be outweighed by the burdens given that many health plans are likely to be unable to display this measure due to small denominator sizes.

While the Kidney Health Evaluation for Patients with Diabetes measure and the Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure meets at least five of six measure selection criteria in § 438.510(c)(1), we are excluding them, and measures of Cesarean birth, child lead screening, and adult immunization status, from the initial mandatory measure set for two reasons. First, the proposed mandatory measure set already includes preventive health measures for both adults and children and reproductive health measures and, to maintain a balanced and concise set of measures as required under § 438.510(c)(2), we believe that we would need to remove an existing measure in these performance areas to add the suggested measures. Second, using the standard at § 438.510(c)(3), we carefully considered the burdens and benefits of the suggested measures against those from our current list and believe that the benefits of our current measures outweigh those of the suggested measures. Specifically, our current measure for Prenatal and Postpartum Care represents a larger proportion of pregnant individuals than the Cesarean birth measures.

Regarding the comment to include measures that support patient-primary care team relationships such as child and adolescent well-care visits, prenatal and postpartum care visits, and adults' access to preventive/ambulatory health services, we agree with the importance of these measures and several of these types of measures are included in the initial mandatory measure set, including, for example, the Child and Adolescent Well-Care Visits measure which is described as the percentage of members who had at least one comprehensive well-care visit with a primary care practitioner or an obstetrician/gynecologist during the measurement year.

We agree with the importance of measures that address social determinants of health (SDOH) and support measure development in this area. In our consultations, beneficiaries stated preferences for measures that reflect critical upstream services that impact health, which could include the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) Social Needs Screening and Intervention (SNS–E) measure. However, no existing SDOH measure has yet been widely publicly reported at a plan-level so we are not convinced that they are appropriate for inclusion in the initial mandatory measure set. We will consider adopting SDOH measures in the future through the subregulatory process set forth in § 438.510(b). Regarding the suggestion to add measures for rare diseases, due to the limited number of beneficiaries with rare diseases, we have concerns that these measures would ultimately not be included in a State's QRS website due to low denominator sizes despite State efforts to collect, validate, and use these data to calculate such measures. We understand the importance of capturing information about quality and experience of care among individuals with rare diseases and will look for ways to address this within our other quality focused Medicaid and CHIP efforts. Regarding the recommendation to add measures that cover a wide array of potentially avoidable events and metrics related to newborn screenings under RUSP, we will obtain input from interested parties through the subregulatory process to determine whether these types of measures would be a good fit for inclusion in the mandatory measure set.

Regarding the measures not included in the initial list and for which we requested feedback, we reviewed the public comments and have concluded that our original rationale for not including these measures on the initial mandatory measure set, set forth in section I.B.6.e.2. of the proposed rule, still holds. We agree with commenters that Childhood Immunization Status is an important measure. However, as discussed in I.B.6.e.2 of the proposed rule, when reviewing the burdens and benefits to the overall MAC QRS, we concluded the well-child visit measures will have greater benefit to beneficiaries based on our beneficiary testing, which showed that parents cared a lot about whether their children can get appointments (reflected in the well-child visit measure), but no beneficiary

commented specifically on childhood immunizations. We also agree with commenters about the importance of CCW but our original rationale for not including CCW as set forth in section I.B.6.e.2 of the proposed rule still holds, and we note that both the Adult and Child Core Sets include the CCW measure to enable comparisons among States.

Regarding the request to include a contraceptive need screening measure, we appreciate the commenter's suggestion to include a measure that assesses contraceptive need. While the commenter suggested a couple screening tools (Pregnancy Intention Screening Question (PISQ) and Self-Identified Need for Contraception (SINC)), they did not recommend, and we are unaware of, quality measures related to contraceptive needs assessment that meet the measure inclusion criteria. We will monitor measure development in this area and consider additional contraceptive measures through our subregulatory process. We agree with commenters that PCCC, as well as other contraceptive needs screening measures are promising given their focus on measuring person-centered care, which was frequently identified as highly desirable in our conversations with beneficiaries. Furthermore, we also agree with commenters on the importance of including a postpartum depression screening measure in a future mandatory measure set. However, as we previously noted, we believe that measure additions should occur through the subregulatory process to update the mandatory measure set finalized in this rule to allow for public notice and comment prior to any decision to add or not add a measure to the mandatory set. We will continue to monitor the evolution of these suggested measures, their ability to meet our measure selection criteria, and input on these measures from those who participate in our subregulatory process.

Comment: Several commenters requested that specific measures be removed from the initial mandatory measure set and replaced with alternative measures. A few commenters suggested the removal of the Asthma Medication Ratio (AMR) because they do not believe it includes an accurate depiction of asthma control for the pediatric population. These commenters recommended replacement with an alternative measure that would better capture asthma outcomes for children, but they did not suggest a specific alternative measure. Two commenters suggested removal of the Initiation and Engagement of Substance Use Disorder Treatment (IET) because it captures a minimum number of encounters but does not assess the effectiveness of the treatment or clinical outcome. One of these commenters suggested replacing IET with other NCQA measures related to alcohol use screening, such as Unhealthy Alcohol Use Screening and Follow-up. We received two comments regarding the Prenatal and Postpartum Care (PPC) measure. One commenter supported the inclusion of PPC in the initial mandatory measure set, while the other commenter suggested removal of PPC and replacement with another maternity measure such as Cesarean birth. Another commenter suggested that we remove the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF) measure and replace it with the NCQA HEDIS Depression Screening and Follow-Up for Adolescents and Adults (DSF) measure because CDF is no longer endorsed by NQF and has measure specifications that differ from a similar measure included in HEDIS. We received a couple of comments regarding our proposal to include the Dental Quality Alliance's (DQA) Oral Evaluation, Dental Services (OEV) measure into the initial mandatory measure set. One comment was in support of including OEV, and the other suggested the removal of OEV and replacement with the NCQA HEDIS measure Oral Evaluation, Dental Services (OED). The commenter who suggested replacement of DQA's OEV with NCQA's HEDIS OED indicated that HEDIS measures are audited and certified by an NCQA auditor, and that using OED would reduce the administrative burden for State agencies and their external quality review office by eliminating the need to perform separate measure audits and would ensure that the rates published in the QRS were calculated the same way across all managed care plans.

We did not receive support for inclusion of the two MLTSS measures that were proposed. Several commenters requested the removal of MLTSS–1: LTSS Comprehensive Assessment and Update because it is not endorsed and requires case management and record review, which would be burdensome to collect. Several commenters requested the removal of MLTSS–7: LTSS Minimizing Institutional Length of Stay because it is not endorsed. Two commenters suggested removal of MLTSS–7 because MLTSS plans are limited in their ability to influence the length of the institutional stay within the first 100 days for dually eligible beneficiaries. These commenters recommended that we engage with States, plans, and other interested parties to determine the best two MLTSS measures to incorporate, and suggested MLTSS–8: LTSS Transition after Long-Term Facility Stay [210] or other measures as options to replace MLTSS–7. Commenters also recommended that the MAC QRS MLTSS measures align with the initial HCBS core measure set as part of CMS's proposals in the Medicaid Program; Ensuring Access to Medicaid Services proposed rule (88 FR 27960 (May 3, 2023)).

Response: Regarding the suggestion to remove AMR and replace it with an alternative measure, since there was not an alternative asthma measure suggestion, and since we are unaware of a better replacement measure, we continue to believe that AMR is the appropriate measure to include in the initial mandatory measure set because of its alignment with CMS programs and initiatives such as the Core Sets, Scorecard, and QHP quality rating system. Regarding the suggestion to remove Initiation and Engagement of SUD Treatment (IET) and replace it with an NCQA measure related to alcohol use screening, we continue to believe that IET is the appropriate measure to include in the initial mandatory measure set because it includes both alcohol and drug abuse or dependence, which will contribute to balanced representation of beneficiary subpopulations and health conditions. Additionally, we are including IET because of its alignment with CMS programs such as the Adult Core Set, Scorecard, and QHP quality rating system. Regarding the suggestion to remove PPC and replace it with another maternity measure such as Cesarean Birth, we continue to believe that PPC is the appropriate measure to include because it applies to a broader set of beneficiaries than the Cesarean Birth measure, and because of its alignment with CMS programs such as the Core Sets, Scorecard, and QHP quality rating system. We will continue to monitor the evolution of asthma and substance use measures to identify a better replacement measure, should one be developed in the future, through the subregulatory process set forth in § 438.510(b) to update the mandatory measure set address inclusion in the MAC QRS mandatory measure set. Regarding the suggestion to remove CDF because it is not endorsed and replace it with NCQA's DSF, endorsement by a consensus-based entity is not a

[210] *Centers for Medicare and Medicaid Services Measures Inventory Tool (cms.gov).*

requirement for the MAC QRS mandatory measures. We included CDF in the initial mandatory measure set over DSF because, while both measure similar care, when balancing the benefits and burdens of these two, similar measure under § 438.510(c)(3), we believe CDF would result in a smaller burden to report (and therefore more feasible) because CDF is aligned with the Core Set and States are already collecting, calculating, and reporting this measure at the State level for the Core Sets. Regarding replacement of the OEV measure with OED, we agree with the commenter on the importance of reducing burden and ensuring consistency in measure calculation across health plans. Like our rationale with CDF, we included OEV in the initial mandatory measure set because OEV aligned with the Child Core Set and alignment with mandatory Child Core Set measures increases feasibility and reduces burden on States. Further, to ensure quality ratings remain comparable within and among States, we note that validation of all data collected is required under § 438.515(a)(2).

Regarding the request to remove MLTSS measures because they are not endorsed, endorsement by a consensus-based entity is not a requirement for MAC QRS mandatory measures. We reassessed our proposal to include MLTSS–1 based on comments that the case management and record review required for reporting on MLTSS–1 would be burdensome for providers and plans. Additionally, we reassessed MLTSS–7 based on the comments received about implications for dually eligible individuals. Based on the comment suggesting that we replace MLTSS–7 with MLTSS–8, we also considered MLTSS–8, but we did not include MLTSS–8 because we have concerns that this measure could not be displayed in the QRS due to low denominator sizes and potential privacy concerns.

Based on our reassessment of MLTSS–1 and MLTSS–7, we are not finalizing the proposal to include these two MLTSS measures in the initial mandatory measure set adopted in this final rule, but we intend to continue evaluating them and other available MLTSS measures for inclusion as future additions to the mandatory measure set. Because of the concerns about potential burden for reporting MLTSS–1, we believe it would not be appropriate to finalize the inclusion of MTLSS–1 without additional feedback from States and other interested parties that will allow CMS to evaluate it more fully against both the feasibility criterion in § 438.510(c)(1)(v) and under § 438.510(c)(3) (weighing the burdens and benefits of including the measure). As we are finalizing paragraph § 438.510(c)(1)(v) with a modification to consider provider burden (in addition to State and plan burden) when considering whether a measure is based on data available without undue burden, we believe that it is appropriate to gather additional thought and consideration through the subregulatory process to identify whether there is a more appropriate MLTSS measure than MLTSS–1 to include. (See § 438.510(c)(4) as finalized.) As for MTLSS–7, we intend to use the subregulatory process to gain additional feedback to determine whether it is a better measure for influencing plan performance (the criterion in § 438.510(c)(1)(iv)) than other available measures and whether it will contribute meaningfully to a balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set (the standard in § 438.510(c)(2)). We believe that it is important to finalize measures that are a good fit with the standards we are adopting at § 438.510(c) to ensure that the MAC QRS provides useful information about managed care plan performance in this important area.

Inclusion of these or other MLTSS measures in a future mandatory set will be assessed during the subregulatory process set forth in § 438.510(b), both through the process finalized in § 438.510(b)(1), through which we will obtain input from interested parties to determine whether there are MLTSS measures that meet our standards for inclusion in the mandatory measure set, and the process finalized in § 438.510(b)(2), through which we will provide notice and an opportunity for comment on any MLTSS measures identified by CMS for addition to the mandatory set following the process in paragraph (b)(1). Specifically, through the subregulatory process States and other interested parties will have the opportunity to provide additional information and input on MLTSS measures not finalized here for CMS to consider for future updates to the mandatory set. States and interested parties also could propose and consider other MLTSS measures that may better align with our measure selection criteria. We believe that these MLTSS measures could include MLTSS–6: LTSS Admission to an Institution from the Community (which, like MLTSS–7, is a rebalancing measure) or the NCQA HEDIS Long-Term Services and Supports Comprehensive Care Plan and Update (CPU–AD) measure, which meets all six of the measure selection criteria in § 438.510(c)(1), and, like MLTSS–1, assesses person-centered planning. Further, though CPU–AD requires case management and record review, it is on the Adult Core Set and the alignment between programs could address the concerns about potential burden. We considered these measures as alternatives to MLTSS–1 and 7 but chose not to finalize here to allow consideration through the subregulatory process. Feedback on MLTSS measures that we receive through the initial subregulatory process in 438.510(b)(1) will be used, in addition to other relevant information, to conduct a preliminary analysis under § 438.510(c)(1), (2) and (3) to prepare the call letter (or other mechanism for public notice and comment) required by § 438.510(b)(2), CMS would evaluate the respective potential burden of including MLTSS 1 versus CPU–AD or MLTSS–7 versus MLTSS–6 (and other measures proposed for consideration through the subregulatory process) . For example, we believe that CPU–AD combined with MLTSS–6 could contribute to a balanced representation of beneficiary subpopulations who receive MLTSS services.

Although we are not including either of the proposed MLTSS measures (that is, MTLSS–1 and MTLSS–7) in the initial mandatory measure set, States may display quality ratings for additional measures after following the process described in § 438.520(c)(2). Additional measures are discussed further in this section and in section I.B.6.g.5 of the final rule. Regarding the recommendations that the MAC QRS MLTSS measures align with the initial HCBS quality measure set, alignment is one of the measure selection criteria that will be used to evaluate these and other MLTSS measures for addition to the MAC QRS measure set through the subregulatory process.

Comment: Several comments pertained to electronic clinical data systems (ECDS) measures. One commenter supported our proposal to include ECDS measures like Colorectal Cancer Screening that can be collected using administrative or electronic means while another commenter requested confirmation that the administrative specification is an acceptable data collection method for the Breast Cancer Screening (BCS) measure. Another commenter cautioned against using electronic clinical data measures because they require significant resources for implementation

of more robust interoperability between provider EMR and MCOs. One commenter requested the addition of NCQA's Healthcare Effectiveness Data and Information Set (HEDIS) Depression Remission or Response for Adolescents and Adults ECDS measure (DRR–E) to the mandatory measure set and for CMS to provide support to States seeking to improve capabilities for reporting ECDS measures. Another commenter cautioned against using the ECDS version of DSF (DSF–E) because DSF–E has first-year status for measurement year 2023, and therefore, NCQA has not yet completed its validation process.

Response: Regarding the comments cautioning against using electronic clinical data measures, we understand that States and plans are in different stages of utilization of digital measures, including ECDS, and that some experience significant challenges in reporting HEDIS ECDS measures. As discussed in section I.B.6.f., we are requiring States to calculate MAC QRS quality ratings using approved measure steward technical specifications, which would require States to calculate ratings as ECDS-only specified as such by a measure steward's technical specifications. CMS will provide technical assistance to States and plans to ensure adherence to measure steward technical specifications for these measures.

Comment: We received several comments supporting our proposal to include Agency for Healthcare Research and Quality (AHRQ) Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures in the initial mandatory measure set. Several commenters relayed concerns with the industry-wide challenge of declining response rates to the CAHPS survey. These commenters encouraged CMS to allow for greater flexibility in how the CAHPS survey is fielded to increase response rates, for example, by allowing web-based and mixed-mode surveying, testing the use of interactive voice response (IVR) technologies, and use of proxy respondents. One commenter encouraged CMS to consider using the current AHRQ database directly to report out the CAHPS measures and suggested that CMS could populate the templates using the CAHPS data and States could link to the templated page to reduce burden and promote consistency in the display of these data across States. One commenter stated CMS should align patient experience survey questions across Medicaid and Medicare such as the CAHPS for Merit-based Incentive Payment System (MIPS) Survey but did not specify how they should be aligned. One commenter requested clarification on how States should handle situations where there are fewer than 100 responses for specific plans for the CAHPS measures included in the mandatory measure set. One commenter stated that the proposed rule does not clarify the relationship between the enrollee experience survey required under § 438.66, the required MAC QRS enrollee experience measures, and other enrollee experience survey efforts.

Response: We appreciate the comments in support of our proposal. We acknowledge the concerns about CAHPS and will consider commenters' suggestions as we continue to work in partnership with AHRQ to identify longer-term solutions to improve CAHPS response rates and streamline CAHPS reporting. Regarding the comment to align patient experience survey questions across Medicaid and Medicare, such as MIPS CAHPS survey questions, we highlight that both the CAHPS health plan survey used by the Medicaid and CHIP programs as required in the MAC QRS and the MIPS CAHPS survey contain questions regarding getting care quickly and how well doctors communicate. Regarding the comment requesting clarification on situations where there are fewer than 100 responses for CAHPS survey questions, we will include guidance on how to handle these situations in accordance with measure steward specifications and, as applicable, existing CMS guidance such as the CMS Cell Suppression Policy [211] in the technical resource manual and will also provide links to additional resources from AHRQ on administering the CAHPS Health Plan Survey. We note that the minimum enrollment threshold established in § 438.515(a)(1)(i) requiring States to collect data necessary to calculate quality ratings for MAC QRS measures from the State's contracted managed care plans that have 500 or more enrollees does not provide a standard for the public display of CAHPS survey responses but is about data collection, meaning that managed care plans with less enrollment would not be required under these Federal rules to provide this data to the State (State contract requirements or regulations may impose additional survey or data collection obligations). Regarding the request to clarify the relationship between the different enrollee experience survey requirements in this final rule, we note that the five CAHPS measures included in the mandatory measure set make up the CAHPS health plan survey. By including all of these CAHPS measures in their MAC QRS, States could also meet the enrollee experience survey requirements in § 438.66, but may be sufficient for monitoring, oversight, and quality improvement activities of some, but not all, programs, such as those with a narrow set of populations or benefits. For instance, the requirements are different in that § 438.66 applies to all managed care plans (regardless of enrollment), whereas the MAC QRS requirement for CAHPS is only applicable to a portion of a State's managed plans (that is, those with more than 500 enrollees, per § 438.515(a)(i) of this final rule).

Comment: Many commenters supported our proposal that States may include additional measures in their MAC QRS. Commenters recommended that States should have flexibility to use additional measures specific to their population needs and that the use of additional measures by States is critical to local health initiatives. Several commenters suggested that CMS should limit the number of additional measures that State Medicaid and CHIP agencies can include in their MAC QRS. These suggestions included limiting the number of additional measures States can add by requiring them to select from a small menu of additional measures and prohibiting States from adding more than five additional measures. One commenter requested CMS to provide detailed guidance on the appropriate use of additional measures.

Response: We continue to believe it is preferable for States to have the flexibility to display additional measures that align with State priorities and are representative of beneficiary subpopulations. Therefore, we are not limiting the number or type of additional measures that a State may use in its MAC QRS. However, based on the feedback we received from beneficiaries and other interested parties during our pre-rulemaking consultation process, we encourage States to limit their QRS measure list to under 30 measures. We will take the request for detailed guidance on the appropriate use of additional measures into consideration when developing the design guide. Further discussion on the use of additional measures in a State's MAC QRS and the steps a State must take prior to their display can be found in section I.B.6.g.5. of this final rule.

Comment: Several commenters suggested that CMS should not permit States to create their own custom measures, and stated concern that allowing States to create their own

[211] See CMS Cell Suppression Policy, January 1, 2020, *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.*

measures when there are multiple measures to choose from will only confuse providers, create misalignment, and increase costs. Another commenter recommended that CMS further incentivize States to continue to develop new, innovative measures, and that CMS should continue to act as a conduit to share measures across States to promote collaboration so that multiple States can report new measures for possible future inclusion in a national data set. Other commenters were concerned about State variation in the use of additional measures, and recommended CMS limit this variation by providing States a list of vetted measures that are nationally recognized or requiring that States use the CMS measure selection criteria described in § 438.510(c), and that CMS should develop a process for States to submit potential measures for inclusion in the list of vetted measures. One commenter suggested that we prohibit States from displaying any measure removed from the MAC QRS mandatory minimum measure set because of a lack of validity.

Response: As to State use of custom measures, we understand that custom measures can be challenging for health plans and providers. However, we want to preserve State flexibility and encourage States to work with health plans and providers regarding the selection and use of additional measures, including custom measures. As described in § 438.520(c)(2) of the final rule (proposed at § 438.520(b)), we note that if the State chooses to display quality ratings for additional measures not included in the mandatory measure set described in § 438.510(a)(2) for Medicaid, which applies to separate CHIP through a proposed revision to § 457.1240(d), the State must first obtain input on the additional measures from prospective users, including beneficiaries, caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy. We encourage States to also work with plans and providers regarding the selection of additional measures. Additionally, we appreciate the suggestion to share measures across States to promote collaboration and will take this into consideration when providing technical assistance to States and establishing the workgroup process to update the mandatory measure set. We will use State reporting to monitor the use of additional measures, including measures that a measure steward no longer considers valid, and to inform whether any limitations are necessary in future rulemaking.

After considering all comments on the measure list, we are finalizing 16 measures for inclusion in the mandatory measure set of the 18 measures that were proposed. We are not finalizing inclusion of MLTSS–1: LTSS Comprehensive Assessment and Update, and MLTSS–7: LTSS Minimizing Institutional Length of Stay in the initial mandatory measure set based on considerations raised by public comment received as discussed previously in this section. Under this final rule and subject to the process adopted in § 438.510, we retain flexibility for the number of measures to increase as we update the mandatory measure set over time. We are finalizing flexibility for States to display quality ratings for additional measures not included in the mandatory measure set after following the process described in § 438.520(c)(2), (proposed at § 438.520(b)). We encourage States to work with plans and providers regarding the selection of additional measures.

Table 2 includes a list of the measures in the initial mandatory measure set for the MAC QRS finalized in this rule, which maintains a high level of alignment with CMS programs and initiatives.[212] The table of finalized measures incorporates necessary, non-substantive changes to align with updates implemented by the measure steward to the proposed measures that occurred after the proposed rule was published and to address a handful of non-substantives errors in the measure descriptions that were included in the proposed initial measure table. Specifically, the non-substantive measure steward updates include changes to a proposed measure's description, acronym or data sources, incorporation of gender-affirming terminology within the measure description,[213] and, in the case of Hemoglobin A1c Control for Patients with Diabetes (HBD), a measure name change (to Glycemic Status Assessment for Patients with Diabetes (GSD)) and conforming edits to the measure's description.[214] The finalized measure table also corrects the non-substantive errors in the proposed measure table measure descriptions. We are updating the measure description for FUH (which inadvertently included the description of the FUM measure) as well as the measure descriptions for FUH, COL, and CAHPS—Health plan customer service (which each identified the incorrect age range).

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[212] Table 2 includes updates to use the CMIT identifiers instead of NQF identifiers for the measures.

[213] Table 2 includes updates to measure steward descriptions for APP, IET, CDF, FUH, WCV, BCS, CCS, CCP, PPC, AMR.

[214] See HEDIS MY 2024: What's New, What's Changed, What's Retired, August 1, 2023, *https://www.ncqa.org/blog/hedis-my-2024-whats-new-whats-changed-whats-retired/*. The measure title for HBD. was updated in NCQA HEDIS's measure year 2024 along with conforming changes to the measure description to include a glucose management indicator with hemoglobin A1c.

TABLE 2: Initial MAC QRS Mandatory Measure Set

CMIT #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
743	NCQA	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP)	The percentage of members who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment. Ages: 1 to 17	Administrative**
394	NCQA	Initiation and Engagement of Substance Use Disorder Treatment (IET)	The percentage of new substance use disorder (SUD) episodes that result in treatment initiation and engagement. Two rates are reported: • Initiation of SUD Treatment. The percentage of new SUD episodes that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth, or medication treatment within 14 days. • Engagement of SUD Treatment. The percentage of new SUD episodes that have evidence of treatment engagement within 34 days of initiation. Ages: 13 and older	Administrative or EHR
672	CMS	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	The percentage of members screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of the qualifying encounter. Ages: 12 and older	Administrative or EHR
268	NCQA	Follow-Up After Hospitalization for Mental Illness (FUH)	The percentage of discharges for members who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are reported: • The percentage of discharges for which the member received follow-up within 30 days after discharge. • The percentage of discharges for which the member received follow-up within 7 days after discharge. Ages: 6 and older	Administrative
761	NCQA	Well-Child Visits in the First 30 Months of Life (W30)	The percentage of members who had the following number of well-child visits with a primary care practitioner (PCP) during the last 15 months. The following rates are reported: • Well-Child Visits in the First 15 Months. Children who turned age 15 months during the measurement year: Six or more well-child visits. • Well-Child Visits for Age 15 Months to 30 Months. Children who turned age 30 months during the measurement year: Two or more well-child visits. Ages: 0 to 15 months | 15 to 30 months	Administrative
123	NCQA	Child and Adolescent Well-Care Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year.	Administrative

CMIT #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			Ages: 3 to 21	
93	NCQA	Breast Cancer Screening (BCS-E)	The percentage of members who were recommended for routine breast cancer screening and had a mammogram to screen for breast cancer. Ages: 50 to 74	Electronic Clinical Data System (ECDS)◆
118	NCQA	Cervical Cancer Screening (CCS, CCS-E)	The percentage of members who were recommended for routine cervical cancer screening who were screened for cervical cancer using any of the following criteria: • Members 21 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology performed within the last 3 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years. Ages: 21 to 64	Administrative, hybrid, EHR, or ECDS
139	NCQA	Colorectal Cancer Screening (COL-E)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 45 to 75	ECDS
897	DQA	Oral Evaluation, Dental Services (OEV)	The percentage of members who received a comprehensive or periodic oral evaluation within the reporting year. Ages: 0 to 20	Administrative
166	OPA	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: 1. Were provided a most effective or moderately effective method of contraception within 3 days of delivery and 90 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 days of delivery and 90 days of delivery. Ages: 15 to 44	Administrative
581	NCQA	Prenatal and Postpartum Care (PPC)	Percentage of deliveries of live births on or between October 8 of the year prior to the measurement year and October 7 of the measurement year. For these members, the measure assesses the following facets of prenatal and postpartum care: 1. Timeliness of Prenatal Care. The percentage of deliveries that received a prenatal care visit in the first trimester, on or before the enrollment start date, or within 42 days of enrollment in the organization. 2. Postpartum Care Rate. The percentage of deliveries that had a postpartum visit on or between 7 and 84 days after delivery. Ages: All Ages	Administrative or hybrid

CMIT #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
148	NCQA	Glycemic Status Assessment for Patients with Diabetes (GSD)	The percentage of members with diabetes (types 1 and 2) whose most recent glycemic status (hemoglobin A1c [HbA1c] was at the following levels during the measurement year: • Glycemic Status <8.0%. • Glycemic Status >9.0%. Ages: 18 to 75	Administrative or hybrid
80	NCQA	Asthma Medication Ratio (AMR)	The percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Ages: 5 to 64	Administrative
167	NCQA	Controlling High Blood Pressure (CBP)	The percentage of members who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85	Administrative, hybrid, or EHR
151/152	AHRQ[v]	CAHPS – How people rated their health plan	The percentage of members who rated their health plan a 9 or 10, where 0 is the worst health plan possible and 10 is the best health plan possible. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ[v]	CAHPS – Getting care quickly	Composite of the following items: • The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. • The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ[v]	CAHPS – Getting needed care	Composite of the following items: • The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months. • The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ[v]	CAHPS – How well doctors communicate	Composite of the following items: • The percentage of members who indicated that their doctor always noted things in a way that was easy to understand. • The percentage of members who indicated that their doctor always listened carefully to enrollee. • The percentage of members who indicated that their doctor always showed respect for what enrollee had to say. • The percentage of members who indicated that their doctor always spent enough time with enrollee. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ[v]	CAHPS – Health plan customer service	Composite of the following items:	Consumer survey

CMIT #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• The percentage of members who indicated that customer service always gave necessary information or help, in the last six months. • The percentage of members who indicated that customer service always was courteous and respectful, in the last six months. Ages: 0 to 17 | 18 and older	

*The CMS Measures Inventory Tool (CMIT) is the repository of record for information about the measures that CMS uses in various quality, reporting, and payment programs. More information is available at https://www.cms.gov/medicare/quality/measures/cms-measures-inventory. A public access quick start guide for CMIT is available at *https://cmit.cms.gov/cmit/assets/CMIT-QuickStartPublicAccess.pdf*.

**Examples of administrative data collection methods are claims, encounters, vital records, and registries.

[v] AHRQ is the measure steward for the survey instrument (CMIT 151/152) and NCQA is the developer of the survey administration protocol.

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After reviewing the public comments and for the reasons outlined in the proposed rule and in response to comments, we are finalizing § 438.510(a), including the cross-reference at § 457.1240(d) to apply the mandatory minimum measure set to CHIP, as proposed.

(3) Subregulatory Process To Update Mandatory Measure Set (§§ 438.510(b) and 457.1240(d))

The current regulations at § 438.334(b)(2) establish that CMS may, after consulting with States and other interested parties and providing public notice and opportunity to comment, periodically update the Medicaid managed care QRS framework developed under current § 438.334(b)(1). We noted in the proposed rule that we remain dedicated to the policy, currently reflected in § 438.334(b)(1) and (b)(2), that requires engagement with interested parties for continuous improvement of the MAC QRS. Continued engagement with States is consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. Our proposal reflected that commitment and our understanding of our obligations under these statutory provisions.

We noted that we believe that requiring rulemaking to add new measures that may better meet beneficiaries' and States' needs or to remove measures whose utility has been surpassed by other measures would be overly restrictive and would undermine our ability to adapt the mandatory set to keep pace with changes in the quality field and user preferences. A robust subregulatory process involving extensive input from interested parties would ensure that any changes the mandatory measure set are consistent with the regulatory standards established in the final rule. Therefore, we proposed to revise § 438.334(b)(2), redesignated at new proposed § 438.510(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we would use a subregulatory process to engage with States and other interested parties, to obtain expert and public input and recommendations prior to modifying the mandatory measure set. Under our proposal, we would adopt the initial mandatory measure set in the final rule (see section I.B.6.e.) and subsequent, periodic updates to add, remove, or update measures would occur through a subregulatory process. To ensure that the mandatory measure set stays current to changes in the quality field, we proposed to engage in this subregulatory process to make any needed modifications at least every other year (biennially).

With exceptions for removing measures for specific reasons proposed at § 438.510(d) and non-substantive updates to existing measures as proposed at § 438.510(e)(1), we proposed in new § 438.510(b) that we will engage in a two-step subregulatory process to obtain input and recommendations from States and other interested parties prior to finalizing certain types of changes to the mandatory measure set in the future. This proposed engagement with States is like the public notice and comment process currently required by § 438.334(b) and consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. Proposed § 438.510(b) would apply to separate CHIP by cross-reference through a proposed revision to § 457.1240(d).

As the first step in the process, we proposed at § 438.510(b)(1) that CMS will engage with States and interested parties (such as State officials, measure experts, health plans, beneficiaries and beneficiary advocates or organizations, tribal organizations, health plan associations, health care providers, external quality review organizations and other organizations that assist States with MAC QRS ratings) to evaluate the current mandatory measure set and make recommendations to add, remove, or update existing measures. The purpose of this evaluation will be to ensure the mandatory measures continue to meet the standards proposed in § 438.510(c). We noted our vision that this engagement could take several forms. For example, a workgroup could be convened to hold public meetings where the workgroup attendees will make recommendations to CMS to add and remove measures. Alternatively, a smaller series of meetings with interested parties could be held, or a request for information could be published to solicit recommendations from experts. In either case, we proposed that recommendations would be based on the standards proposed in § 438.510(c) and discussed in section I.B.6.e.1. of the proposed rule.

At § 438.510(b)(2), we proposed that the second step in the process would be for CMS to provide public notice and

opportunity to comment through a call letter (or similar subregulatory process using written guidance) that sets forth the mandatory measures identified for addition, removal or updating and that this second step would provide an opportunity for interested parties to provide comments. Following this public notice and opportunity for comment, we proposed at § 438.510(f) that we would publish the modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual proposed at § 438.530. Section § 438.510(f) is discussed in section I.B.6.e.7. of this final rule. The technical resource manual is discussed in more detail in section I.B.6.i. of the final rule.

This subregulatory process is like the process used by the QHP quality rating system, which uses a call letter to communicate changes and gather feedback on proposed measure updates and refinements to the QHP quality rating system. It also aligns with how the Core Sets are updated annually. As part of the Core Set annual review and selection process, a workgroup made up of Medicaid and CHIP interested parties and measurement experts convenes annually, in a public meeting, and develops a set of recommendations for changes to the Core Sets. These recommendations are posted in a draft report for public comment, and the final report that is submitted to CMS includes both the workgroup recommendations and public comments. The annual updates to the Core Sets are based on the workgroup recommendations and comments, and using input from States and Federal partners, CMS decides whether to accept the input in the final, updated Core Sets (see 88 FR 60280). Details on this process are available at *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf*. We noted that while we are aligning the MAC QRS workgroup processes, as noted above, with the QHP quality rating system and Core Set processes as appropriate, the MAC QRS is independent and the process for changes to the MAC QRS measure set would be conducted separately.

We provided an example of when the measure set might be updated using this subregulatory process as follows. Assuming that the proposal was finalized with an effective date in 2024, the implementation deadline for each State's MAC QRS per proposed § 438.505(b) (which provides for implementation to be no later than the fourth calendar year following publication of the final rule) would be December 31, 2028, and the first measurement year would be 2026. Since we proposed to finalize our initial measure set in this rulemaking, any updates to the initial mandatory measure list made pursuant to the subregulatory process proposed at § 438.510(b) would be effective no earlier than the year after the implementation of States' MAC QRS. We noted our belief that it would be appropriate to initiate the proposed subregulatory process for the second display year (for example, 2029 if the rule is finalized in 2024) because the mandatory measure list would be 5 years old by then, and at least biennially thereafter (in line with proposed § 438.510(b)(2)).

We solicited comments on whether we should instead initiate the subregulatory process to update the mandatory measure list for the third display year (for example, 2030 if the rule was finalized in 2024). We also solicited comments on the types of engagement that would be important under the proposed subregulatory process (for example, workgroups, smaller meetings, requests for information), the types of experts that CMS should include in the engagement, and the use of a call letter or similar guidance to obtain public input.

We summarize and respond to public comments received on subregulatory process to update mandatory measure set (§§ 438.510(b) and 457.1240(d)) below.

Comment: Many commenters supported our proposal to use a subregulatory process to update the mandatory measure set, and several of these commenters indicated that using a rulemaking process would be too cumbersome and slow. One commenter was opposed to creating a separate MAC QRS subregulatory process and suggested that we use the Medicaid and CHIP Child and Adult Core Sets Annual Review Workgroup process instead. Several commenters suggested that we use CMS's consensus-based entity (CBE) and existing pre-rulemaking process to obtain input on the proposed MAC QRS mandatory measure set and future updates to the mandatory measure set.

Response: We believe that the proposed subregulatory process—the use of an engagement process to evaluate the current measure set and gather potential changes for consideration and the public notice and comment process before changes are finalized—is sufficiently flexible to address the underlying policy goals described by the commenters.

Regarding the comment to use the Medicaid and CHIP Child and Adult Core Sets Annual Workgroup process to determine inclusion of measures in the MAC QRS mandatory measure set, we believe that the MAC QRS should have its own process to determine mandatory measures because the Core Sets and MAC QRS have different purposes. The measures on the Core Sets are collected and reported on the State level and are intended to serve as a set of measures which, taken together, can be used to estimate the overall national quality of health care for Medicaid and CHIP beneficiaries. The MAC QRS measures are collected and reported at the plan level and are intended to provide beneficiaries and their caregivers with information to compare Medicaid and CHIP managed care plans, to hold States and plans accountable for care provided through its managed care program, and to provide a tool for States to measure and drive improvement of plan performance and quality of care. Each program has similar, but different, measure selection criteria based on the program's scope and purpose. Having separate processes will allow us and interested parties to focus on the specific standards and goals in each program.

Regarding the suggestion to use CMS's CBE review process to obtain interested party input on the mandatory measure set, that process is not used in Medicaid programs or for the Core Sets and we do not believe using that process for public input on updates to the mandatory measure set for the MAC QRS would be most appropriate or fitting. However, we may use available relevant information from the CBE process when we consider measures for inclusion in the MAC QRS. For example, to the extent that an MA quality measure is evaluated under the CBE review process, and we consider that measure for inclusion in the MAC QRS against the criteria we proposed and are finalizing at § 438.510(c), information from the public CBE process may be considered by CMS in making the necessary determinations whether to add that measure to the MAC QRS mandatory measure set. We proposed (and are finalizing at § 438.505(c)) that the MAC QRS be aligned with the MA and Part D and QHP quality ratings systems and the Core Sets to the extent possible, and we maintain this guiding principle in the final rule. Therefore, information and perspectives gathered as part of the processes for adopting quality measures for those other programs may be used, as relevant and appropriate, by CMS in applying § 438.510(b) and (c) to make changes to the minimum mandatory measure set adopted in this final rule.

Comment: Most commenters supported the proposed schedule to

conduct the subregulatory process to modify the mandatory measure set at least biennially. One commenter recommended that we update the mandatory measure set more frequently than biennially to ensure that consumers will receive data in a transparent and timely manner. Regarding future modifications of the mandatory measure set, several commenters recommended that we provide consistent schedules for when we plan to provide public notice and the opportunity to comment and that we give adequate time for health plans to review and respond to proposed changes to the MAC QRS measures.

Response: Regarding the comment that we shorten the two-year timeline, our proposal was to review the measures in the QRS mandatory measure set *at least* biennially, meaning we may conduct the subregulatory process to update the mandatory measure set more frequently if there is a need to keep pace with changes in the quality field and user preferences. We intend to regularly assess whether there are changes in the quality field and user preferences (such as a public health emergency, the availability of a new or improved quality measure, or a technology improvement) that would necessitate conducting the subregulatory process more frequently than biennially. Establishing the biennial minimum timeframe avoids imposing an unnecessary burden on us and interested parties to identify, evaluate, and make changes when it might not be necessary. Upon further consideration, we are modifying § 438.510(b) to make clear that, while we are required to engage in the subregulatory process described in § 438.510(b)(1) at least every other year, we are not *required* to update the mandatory measure set at least every other year after completing the subregulatory process, per § 438.510(b). As proposed, our requirement would have required us to make at least one update to the mandatory measure set, whether by adding, removing, or making a substantive update to an existing measure, at least every other year. Finalizing this change recognizes the real possibility that no updates are identified or necessary after we go through the process described in § 438.510(b)(1).

We agree with commenters on the importance of consistent schedules for providing public notice and the opportunity to comment with adequate time for health plans to respond to proposed changes to the MAC QRS measures and are finalizing these provisions as proposed. A robust subregulatory process will ensure that any changes to the mandatory measure set will reflect input from interested parties to take it into consideration when we establish the workgroup process. We expect and hope for extensive input from interested parties based on the level of public comments on this proposal and on scope of the MAC QRS goals and use. Having varied and diverse viewpoints on whether any measure meets five of the six criteria specified in § 438.510(c)(1) and on how to apply the standards in § 438.510(c)(2) and (3) would help ensure that the minimum measure set for the MAC QRS reflects important quality metrics and provides an accurate and reliable picture of quality in the Medicaid and CHIP managed care programs.

Comment: Most commenters supported our proposal that we engage with States and other interested parties (such as State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations) as the first step of the subregulatory process for changing the minimum measure set and commenters supported the examples of engagement that we provided. Several commenters suggested additional types of engagement as part of the subregulatory process. One commenter suggested that we convene listening sessions with health plans in addition to a formalized workgroup of experts and interested parties. One commenter recommended that we engage the existing Core Sets Annual Workgroup in the subregulatory process. Another commenter suggested that CMS establish a quality measure workgroup to develop and test quality measure sets before requiring mandatory reporting.

Response: We appreciate commenters suggestions on the types of interested parties we should engage and the forms of engagement we should use. Throughout the development of the MAC QRS, we engaged with a broad spectrum of interested parties through numerous workgroups, listening sessions, and other means of obtaining input on the MAC QRS mandatory measures set and other parts of the MAC QRS framework. As discussed in section I.B.6.e.3 of the proposed rule, our continued dedication to engagement with interested parties to ensure continuous improvement of the MAC QRS is the basis for the requirement at § 438.510(b)(1), which sets a minimum level of engagement with at least States and other interested parties including, but not limited to, State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations. We believe that the subregulatory process will allow for robust input from interested parties to ensure varied and diverse viewpoints and that the types of engagement recommended by commenters are permissible under the regulation we proposed and are finalizing at § 438.510(b). Therefore, we do not believe that establishing a specific set of procedures (for example, workgroups, public hearings, listening sessions with specific interested groups) in the regulation is necessary or appropriate.

We appreciate the recommendation from a commenter that we establish a quality measure workgroup to develop and test the mandatory measure set before requiring mandatory reporting, but are declining to implement this suggestion. We agree with the commenter that such engagement is important and a useful way to gather information and viewpoints, however, as described in section I.B.6.a of the proposed rule, we have already participated in several years of engagement to identify the MAC QRS mandatory measure set identified in this final rule, including a measure set workgroup through which an initial mandatory measure set was identified and refined over the years through our engagement with States, health plans, potential MAC QRS users, and other interested parties. As described in section I.B.6.g of the proposed rule, this engagement included several years of testing with potential MAC QRS users to gain additional feedback and insight of the MAC QRS measure set. Furthermore, as part of our mandatory measure set development, we engaged in extensive research to identify quality measures already collected or reported by States. Requiring the same level of engagement for all potential modifications to the MAC QRS measure set would be unnecessarily burdensome, especially when some years will only require minimal or routine updates to the measure set.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.510(b) and 457.1240(d) related to the subregulatory process to update the mandatory measure set as proposed.

(4) Adding Mandatory Measures (§§ 438.510 and 457.1240(d))

Under proposed § 438.510(c), CMS would add a measure to the mandatory measure set if all three standards proposed at § 438.510(c)(1) through (3) are met, based on available information,

including input from the subregulatory process. We proposed that, at least biennially, we would use the subregulatory process proposed in § 438.510(b) to gather input that would be used to determine if a measure meets the proposed standards to be added to the mandatory measure set. CMS could request an assessment from the engaged interested parties of the whether each of the measures suggested for addition (from the interested parties, CMS, or both) meets each of the three proposed standards at § 438.510(c)—that is, (1) whether it satisfies at least five of the criteria set forth at proposed § 438.510(c)(1); (2) whether it contributes to balanced representation of measures across the mandatory measure set as a whole per proposed § 438.510(c)(2); and (3) whether the benefits outweigh the burden of adopting the measure per proposed § 438.510(c)(3). Under our proposal CMS would use this input and could identify a subset of measures from the list of potential suggested additional measures that meets all three standards. This subset of measures would then be considered eligible to add to the mandatory measure set and described in a call letter or similar written guidance, which would explain how standards in § 438.510(c) were applied using input from prior engagement activities and CMS's own research and evaluation. Through the call letter process, CMS would gather public comment to obtain additional evidence, explanations, and perspectives to make a final determination of which measures meet the standards in proposed § 438.510(c). Measures that meet these standards would be added to future iterations of the mandatory measure set.

To further illustrate how we intended for the standards proposed in § 438.510(c) to be applied using the subregulatory process, we provided more specific detail of our assessment of two measures (Follow-Up After ED Visit for Mental Illness (FUM) and the Follow-Up After Hospitalization for Mental Illness (FUH)) which were considered for inclusion in the proposed mandatory measure set. We intended for the proposed subregulatory process for adding measures to follow that same approach.

In discussions prior to developing the proposed rule, States and other interested parties had recommended both the Follow-Up After ED Visit for Mental Illness (FUM) and the Follow-Up After Hospitalization for Mental Illness (FUH) as potential measures to include in our preliminary measure set. As a first step in considering these measures, we used our own research and input from various consultations to assess the measures against the measure inclusion criteria that we proposed as our first standard under § 438.510(c)(1) and concluded that both measures meet each of the six proposed criteria (see Table 3).

TABLE 3: Example Inclusion Criteria Assessment

Criteria	FUM	FUH
Alignment	• Identified by 16 States as a measure collected from managed care plans in the '20-'21 EQR reporting cycle. • Reported publicly as a measure of plan performance in 2 States. • Core Set measure.	• Identified by 19 States as a measure collected from managed care plans in the '20-'21 EQR reporting cycle. • Reported publicly as a measure of plan performance in 4 States. • Core Set and QHP quality rating system measure.
Usefulness to Beneficiaries	• The importance of timely access to mental health services were consistently identified in our conversations with Medicaid beneficiaries.	
Relevance	• Both measures address access to services.	
Actionability	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health.	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health. • Used by 3 States to assess plan performance as part of the State's quality strategy
Feasibility	• Relies on administrative data from claims that plans already have or are available to plans but will require coordination between plans in States that offer behavioral services through a separate managed care program.	
Scientific Acceptability	• Generally regarded as reliable and valid measure in our listening sessions. • Endorsed by the National Quality Forum (former CBE).	

Second, we considered the two measures in light of our goals for balanced representation within a concise measure set. Given our goal to limit the initial mandatory measure set to fewer than 20 measures and the fact that both measures focus on assessing follow-up care for mental illness, we determined that including one of the two measures would best maintain balanced representation both within the overall measure set and within the behavioral health performance area. We then weighed the benefits and burdens of including each measure using our

assessment of the extent to which each measure's benefits compared to the burden associated with reporting it. As represented in Table 3, we found that both measures had similar benefits and burdens, but the FUH measure imposed less burden and had more benefits, as it was more commonly collected or reported at both the State and Federal level and more frequently used by States to assess plan performance. Therefore, we chose to include the FUH measure in the proposed mandatory set.

We did not receive any comments in response to our proposal related to adding mandatory measures using the proposed subregulatory process and proposed criteria and standards in § 438.510. For the reasons outlined in the proposed rule and our responses to comments in other sections of this final rule on § 438.510(b) and (c), we are finalizing these provisions as proposed.

(5) Removing Existing Mandatory Measures (§§ 438.510(d) and 457.1240(d))

We proposed at § 438.510(d)(1) that we may remove existing mandatory measures from the mandatory measure set if, after following the subregulatory process proposed at § 438.510(b), we determine that the measure no longer meets the standards for the mandatory measure set proposed at § 438.510(c). We proposed to use the same approach we described in section I.B.6.e.2. of the proposed rule (relating to selection of the selection of the initial mandatory measure set) and stated that the discussion of how we selected the FUH measure (in section I.B.6.e.4. of the proposed rule) illustrated how we would assess whether a measure continues to meet our measure inclusion criteria to remain in the mandatory measure set. We also proposed at § 438.510(d)(2) through (4) to provide CMS the authority to remove mandatory measures outside of the subregulatory process proposed in § 438.510(b) in three circumstances that would indicate that a measure would no longer be an appropriate indicator of health plan performance: (1) if the measure steward (other than CMS) retires or stops maintaining a measure (proposed § 438.510(d)(2)); (2) if CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes (proposed § 438.510(d)(3)); or (3) if CMS determines that a measure shows low statistical reliability under the standard identified in 42 CFR 422.164(e) (proposed § 438.510(d)(4)).

When a measure steward such as NCQA or PQA retires a measure, the steward goes through a process that includes extensive review by experts and solicitation of public comments from a variety of interested parties, including health plans, purchasers, consumers, and other interested parties. The proposal to allow CMS to remove a measure if an external measure steward retires or stops maintaining a mandatory measure would allow us flexibility to ensure that measures included in the QRS mandatory measure set are maintained by the measure steward and consistent with the measure steward's underlying standards of clinical meaningfulness, reliability, and appropriateness for measures. When there is a change in clinical guidelines such that measure specifications no longer align with or promote positive health outcomes or when a measure is shown to have low statistical reliability (that is, how much variation between measure values that is due to real differences in quality versus random variation), we believe and thus proposed that it would be appropriate to remove the measure. The proposed criteria for removing measures outside the subregulatory process align with similar criteria in the current regulations at §§ 422.164(e) and 423.184(e) governing the MA and Part D quality rating system.[215] Under the proposed rule, we would use the same standard for statistical reliability as applied for the MA and Part D quality rating system under §§ 422.164(e) and 423.184(e). Any measures removed under any of the three circumstances proposed at § 438.510(d)(2) through (4) would be announced in the annual technical resource manual proposed at § 438.530. We sought comments on the proposal, including specifically on whether there are additional circumstances in which we should be able to remove a mandatory measure without engaging in the subregulatory process proposed at § 438.510(b).

We summarize and respond to public comments received on the proposed regulations for removing existing mandatory measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d)) below.

Comment: Overall, commenters supported our proposal for removing existing mandatory measures for the specified reasons. Two commenters recommended that a measure no longer endorsed by the consensus-based entity (CBE) should no longer be included in the MAC QRS.

Response: Regarding the comment to develop criteria to remove a measure, we believe that the standards we proposed in § 438.510(d) are sufficient to determine whether a measure should be removed from the mandatory measure set. Sections § 438.510(b)(1) and (2) describe the subregulatory process we will use at least biennially to determine whether measures should be added, removed, or updated and § 438.510(d)(1) specifies that CMS will use that subregulatory process and the criteria and standards in § 438.510(c) to identify measures that CMS may remove if and when a measure that is in the mandatory measure set no longer meets the regulatory requirements to be required for the MAC QRS. This approach sufficiently preserves the integrity of the mandatory minimum measure set by using the same standards to add and remove measures. In addition, § 438.510(d)(2) through (4) provide that a measure will be removed without use of the subregulatory process (and without public input) if the measure steward retires or stops maintaining a measure, if the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes, or if CMS determines that the measure shows low statistical reliability. When one of these things happen, we believe that a measure is no longer suitable to be mandated for State use in the MAC QRS. When a measure steward retires a measure, when a measure is no longer aligned with clinical guidelines, or when the measure shows low statistical reliability, the measure would not provide the type of information we believe is most useful for evaluating managed care plan or program performance. This is like the process that the MA and Part D quality rating system (§§ 422.164(e) and 423.184(e)) uses to determine removal of measures; those regulations also provide for removal of measures by CMS when a measure steward other than CMS retires a measure.

Related to the commenters' recommendation that we remove measures that are no longer endorsed by the CBE, as discussed in section I.B.6.e.3 of this final rule, we do not require CBE endorsement for MAC QRS mandatory measures and therefore do not believe that it would be appropriate to modify § 438.510(d)(2) to allow CMS to unilaterally remove a mandatory

[215] See also ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' (CMS–4201–F).), which appears in the April 12, 2023, **Federal Register** (88 FR 22120). Available online at *https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf.*

measure due to loss of CBE endorsement. However, we noted in section I.B.6.e.3 of this final rule that available relevant information from the CBE process could be considered when assessing a measure for inclusion in the MAC QRS measure set. Similarly, we believe that information from the CBE process could be considered to determine whether a measure meets the criteria for removal by CMS under § 438.510(d) and may also be considered during the process described in § 438.510(b) to determine whether a measure should be recommended for removal from the MAC QRS mandatory measure set. For example, to the extent that an MA quality measure is evaluated under the CBE review process and lost endorsement for any of the reasons identified at § 438.510(d)(2) through (4), we could rely on information identified through the CBE process showing that the measure meets any of the removal criteria in paragraph (d)(2) through (4) to choose to remove the measure from the MAC QRS mandatory measure set.

Comment: One commenter recommended that CMS set a transparent, robust reliability standard of no less than .75, which is generally the minimum standard for high statistical validity, to assess whether the measure meets the scientific acceptability criterion in § 438.510(b)(vi). The commenter also noted that they have consistently voiced their concern that CMS' statistical validity minimums for other quality programs are much too low and undermine the integrity of the data.

Response: We appreciate commenter's recommendation on how to assess whether a measure is statistically reliable and will consider this recommendation as we continue to reflect on our data reliability standards. We did not propose and are not adopting a new CMS standard that would apply across CMS program here. For the MAC QRS, we intend to align with existing CMS policy in this area. For instance, the MA and Part D Quality Rating System uses the HEDIS reliability standard for HEDIS measures for contracts with low enrollment (those with at least 500 but less than 1,000 enrollees), which are included only if the measure score reliability is equal to or greater than 0.7.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.510(d) and 457.1240(d) as proposed.

(6) Updating Mandatory Measure Technical Specifications (§§ 438.510(e) and 457.1240(d))

In addition to adding and removing measures, we also proposed rules at § 438.510(e) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), governing how we would handle updates to mandatory measures in the MAC QRS that are a result of changes made by a measure steward to an existing mandatory measure's technical specifications. These are updates that measure stewards routinely make to quality measures and can be non-substantive (such as changes that clarify instructions to identify services or procedures) or substantive in nature (for example, major changes to how the measures are calculated). We proposed different subregulatory processes by which non-substantive and substantive updates to existing technical specifications for mandatory measures would be made. First, in paragraph § 438.510(e)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that we would update the technical resource manual to revise descriptions of the existing mandatory measures that undergo non-substantive measure technical specification changes. In alignment with current practices in the MA and Part D quality rating system, we did not propose to use the subregulatory notice and comment process proposed in § 438.510(b) for non-substantive changes because we believe this type of update reflects routine measure maintenance by measure stewards that do not significantly affect the measure and would not need additional review by the interested parties and CMS. We proposed in new paragraph § 438.510(e)(1)(i)–(iv) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to codify examples of the types of updates that are non-substantive under this proposal. This proposal is consistent with current practice and regulations for the MA and Part D quality rating system at §§ 422.164(d)(1) and 423.184(d)(1). We identified and described the proposed non-substantive updates in detail as listed below and sought comment on the list. Examples of the types of changes we believe would be non-substantive for purposes of proposed § 438.510(e)(1) include, but are not limited to, the following:

- If the change narrows the denominator or population covered by the measure with no other changes, the change would be non-substantive. For example, if an additional exclusion—such as excluding nursing home residents from the denominator—is added, the change will be considered non-substantive and would be incorporated through announcement in the annual technical resource manual.
- If the change does not meaningfully impact the numerator or denominator of the measure, the change would be non-substantive. For example, if additional codes are added that increase the numerator for a measure during or before the measurement period, such a change would not be considered substantive. This type of change has no impact on the current clinical practices of the plan or its providers.
- If revisions are made to the clinical codes used in the measure specifications without change in the target population or the intent of the measure and the target population, the change would be non-substantive. The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. Examples of clinical codes that could be updated this way, include, but are not limited to:
  + ICD–10–CM code sets, which are updated annually,
  + Current Procedural Terminology (CPT) codes, which are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient, and
  + National Drug Code (NDC)), which is updated bi-annually.
- If the measure specification change provides additional clarifications for reporting, without changing the intent of the measure, the change would be non-substantive. Examples include but are not limited to:
  + Adding additional tests that will meet the numerator requirements.
  + Clarifying documentation requirements (for example, medical record documentation).
  + Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.
  + Adding alternative data sources or expanding of modes of data collection to calculate a measure.

Second, we proposed at § 438.510(e)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we could update an existing mandatory measure that has undergone a substantive measure specification update (that is, an update not within the scope of non-substantive

updates) only after following the subregulatory process proposed in § 438.510(b). We believe that most substantive measure specification updates to existing measures could result in new or different measures, thereby necessitating consideration and evaluation against the criteria and standards in proposed paragraph (c) using the process in proposed § 438.510(b). We sought comment on our proposal to incorporate substantive measure specification updates to existing mandatory measures only after consultation with States, other interested parties, and the public, or whether we should consider a separate process for these types of updates.

We did not receive any comments in response to our proposals for updating mandatory measure technical specifications. For the reasons outlined in the proposed rule, we are finalizing proposed §§ 438.510(e) and 457.1240(d) substantively as proposed. We are making one minor revision to the proposed regulation in the last sentence of the introductory language of paragraph (e) to remove the phrase ''but not limited to'' because it is repetitive and unnecessary. The text is clear that the list in paragraphs (e)(1)(i) through (iv) is a non-exhaustive list of examples of non-substantive changes to measure specifications.

Additionally, in section I.B.6.e.2 of the proposed rule we incorrectly stated that we proposed rules at § 438.510(e) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), governing how we would handle updates to the mandatory measures in the MAC QRS that are a result of changes made by a measure steward *other than CMS* to an existing mandatory measure's technical specifications. While we proposed, and are finalizing, that whether CMS is the measure steward should be considered to determine whether CMS may remove a measure from the mandatory measure set under § 438.510(d)(2), the regulation text at § 438.510(e)(1) did not include, and we are not finalizing, that CMS being the measure steward is a consideration for updates to existing measures made under § 438.510(e) for either non-substantive or substantive updates.

(7) Finalization and Display of Mandatory Measures and Updates (§§ 438.510(f) and 457.1240(d))

In new paragraph § 438.510(f) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that CMS would communicate modifications to the mandatory measure set and the timeline States would be given to implement modifications to the mandatory measure set that appear in the annual technical resource manual.

We proposed to use the technical resource manual (described in proposed § 438.530) to communicate the final changes to the mandatory measure set for the MAC QRS. We proposed that States would be given at least 2 calendar years from the start of the measurement year immediately following the technical resource manual in which the mandatory measure addition or substantive update was finalized to display the measurement results and ratings using the new or updated measure(s). We believe giving States at least 2 years would allow for contract and systems updates when new measures are added, or substantive updates are made to the mandatory measure set. For example, if the technical resource manual finalized updates in August 2026, and the next measurement year after August 2026 started in January 2027, States would have, at a minimum, until January 2029 before they would be required to display the ratings for the mandatory measure updates in their MAC QRS. A State could elect to display the ratings for a new mandatory measure sooner. As 2 years from the start of the measurement year will always be in January, we sought comment on whether there is a need for States to have the flexibility to update their quality ratings by the end of the second calendar year, which, based on the example above, would give States the flexibility to update the rating between January and December of 2029.

We proposed the same implementation timeline for substantive updates to existing mandatory measures, since we believe these should be treated in the same manner as new measures. We proposed this timeline based on discussions with States and other interested parties about operational considerations for implementation of new and substantively updated measures and the posting of the associated ratings. We did not propose a specific deadline for States to stop display of a measure that has been removed from the mandatory measure set because States would have the option to continue to display measures removed from the mandatory set as additional measures (see section I.B.6.g.5 of this final rule). We sought comment on this flexibility, considering the criteria under which measures can be removed at proposed § 438.510(d). We sought comment on whether our timeframes are appropriate for updates to the mandatory measure set or whether we should allow for more or less time, and why.

We also noted that under our proposal, we would release the technical resource manual annually regardless of whether we made any modifications to the mandatory measure set, to address any non-substantive changes to measure specifications or any removals that occurred outside of the subregulatory process.

We did not receive any comments in response to our proposals regarding finalization and display of mandatory measures. For the reasons outlined in the proposed rule we are finalizing §§ 438.510(f) and 457.1240(d) regarding the finalization and display of mandatory measure updates as proposed.

f. MAC QRS Methodology (§§ 438.334(d), 438.515 and 457.1240(d))

Fundamental to any QRS is the methodology used to calculate the quality ratings for States' managed care plans. Under current regulations at § 438.334(b)(1), CMS must, after consulting with interested parties and providing public notice and opportunity to comment, develop a methodology that States must use in the MAC QRS adopted by the State to calculate its plans' quality ratings, unless we approve an alternative methodology as part of a State alternative MAC QRS in accordance with proposed § 438.525. During the extensive engagement with States and other interested parties described in section I.B.6.a. of the proposed rule, we identified two main themes to consider in the development of a MAC QRS methodology: (1) States are concerned about the burden associated with data collection and quality rating calculation; and (2) beneficiaries desire transparent, representative quality ratings. In developing the MAC QRS methodology that we proposed, we sought to balance these two often competing preferences, while ensuring that quality ratings remained comparable within and among States. We also considered the Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers [216] final rule (referred to as

[216] ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health

''CMS Interoperability and Patient Access final rule'') published on May 1, 2020. That rule placed several requirements on State Medicaid FFS programs, as well as on Medicaid managed care plans, for the implementation of application programming interfaces to facilitate sharing information between payers, enrollees, and providers. Based on these considerations, at § 438.515(a) we proposed requirements for collecting and using data to calculate managed care quality ratings for mandatory measures and, in § 438.515(a) a MAC QRS methodology that must be applied to calculate quality ratings for MAC QRS mandatory measures, unless we have approved an alternative QRS. The same requirements were proposed for separate CHIP managed care plans through a proposed cross-reference at § 457.1240(d).

Under current regulations at § 438.334(d), each year States are required to collect data from each managed care plan with which they contract and issue an annual quality rating for each managed care plan based on the data collected. We proposed to replace that policy with more specific requirements in proposed new § 438.515(a), pursuant to which States would collect and validate data to be used to calculate and issue quality ratings for each mandatory measure for each plan on an annual basis. We proposed, at § 438.515(a)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that States must collect the data necessary to calculate quality ratings for mandatory measures from their larger contracted managed care plans and, as applicable and available to the extent feasible without undue burden, from the State's Medicaid FFS program providers and Medicare. Specifically, we proposed that data be collected from managed care plans that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year. This enrollment threshold is the same as the enrollment threshold for the enrollee satisfaction survey system that evaluates the level of enrollee satisfaction with QHPs offered through a Marketplace.[217]

We believe that requiring States to calculate quality ratings for plans with fewer than 500 enrollees would be overly burdensome, as such plans may have limited resources for collecting and reporting data and are more likely than plans with higher enrollment to have small denominator sizes that would raise privacy or validity concerns in issuing and displaying quality ratings for some measures. Further, through an analysis of 2019 T–MSIS Analytic Files (which are research-optimized files of T–MSIS data), we determined that neither the number of managed care plans nor the percentage of beneficiaries reported in the MAC QRS would be significantly reduced by excluding plans with enrollment below 500. Thus, we believe the proposed enrollment threshold maximizes inclusion of plans and enrollees, while also minimizing the burden of data collection and reporting on smaller plans. Under the proposed rule, States would have the flexibility to include plans with fewer than 500 enrollees at their discretion, and we would encourage States to do so when appropriate and feasible.

At § 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States would also be required to collect available data from the State's Medicaid FFS program, Medicare (including Medicare Advantage (MA) plans), or both if all necessary data cannot be provided by the managed care plans for the measures and collection of these data does not impose an undue burden on the State. For example, if a State delivers behavioral health services through a managed care program and all other services through its Medicaid FFS program, the State would need to collect both managed care and FFS data to calculate quality ratings for the managed care plans participating in its behavioral health managed care program for many of the proposed behavioral health mandatory measures. This is because many of the behavioral health measures require, in addition to data on the behavioral health service provided by the managed care plan, data on hospital services or pharmaceutical claims provided through the State's FFS program to calculate the measure. Similarly, if a managed care plan provides services to enrollees who are dually eligible for Medicare and Medicaid services, it will be necessary for the State to collect data about services provided by Medicare to such enrollees to calculate quality ratings for some measures included on the proposed mandatory set. While we proposed that States must collect data from these other sources as needed to calculate mandatory measures if the data are available for collection without undue burden, we did not propose that States will calculate or assign quality ratings to Medicaid FFS or Medicare plans.

We considered requiring States to collect data only from their contracted managed care plans and then only when a plan can provide all data necessary to calculate and issue a quality rating for a given performance measure, which is a common practice among measure stewards. However, we were concerned that there would be instances where there is no single plan from which a State could collect all data necessary to calculate one or more of the measures on the mandatory measure list. For example, of the 18 measures on our proposed mandatory measure set, four require data from more than one setting, including three of our proposed behavioral health mandatory measures. These four measures include, Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP), Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET), Follow-Up After Hospitalization for Mental Illness) (FUH), and Asthma Medication Ratio (AMR). To calculate the three behavioral health measures, it is necessary to collect behavioral health or substance use service data, as well as either pharmacy or physical health data. When these services are covered by separate plans or delivery systems, such as where a State has chosen to split Medicaid coverage of these services between separate managed care programs or use a combination of managed care and FFS delivery systems, these mandatory measures would be at risk of going unreported if States were only required to collect data from their contracted managed care plans. Similar issues are raised for obtaining all data needed to generate quality ratings for dually eligible individuals who receive coverage through Medicare and Medicaid. We note that Medicaid is the single largest payer of mental health services in the U.S., and behavioral health and substance use measures would be at particular risk of going unreported as services provided in these settings are commonly provided through a separate managed care plan. We believe that our proposal for States to collect and use data from multiple sources would mitigate the risk of

Plans on the Federally-Facilitated Exchanges, and Health Care Providers'' (CMS–9115–F). Published in the **Federal Register** on May 1, 2020 (85 FR 25510 through 25640). Available online at *https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and.*

[217] See section 1311(c)(4) of the Patient Protection and Affordable Care Act. Also see 45 CFR 156.1125 and *Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2024, section 6.1.*

underreporting of mandatory measures, particularly those measures assessing behavioral health and substance use services.

We stated that our proposal aligned with ongoing efforts to expand access to health plan data at both the State and Federal levels. For example, State data collection required for measures in the Child Core Set [218] and behavioral health measures in the Adult Core Set [219], which will become mandatory effective for CY 2024, requires States to report measures that will require the use of data from both Medicaid managed care and FFS programs, as well as Medicare data for dually eligible beneficiaries.[220] Many of these measures overlap with the mandatory measures proposed for the MAC QRS, which means States already will be obligated to collect Medicaid managed care and FFS data and to obtain Medicare data needed to calculate certain performance measures. Thus, we believe that the benefits of proposed § 438.515(a)(1)(ii) outweigh the costs of any increased burden on States.

Furthermore, there is an ongoing effort at the Federal and State levels to increase data availability and interoperability, including State access to managed care plan data. We noted that at the time of the proposed rule, data available for collection include encounter data received from a State's own Medicaid managed care plans under § 438.242 and data from FFS providers through claims and other reporting. Given existing data availability, we stated our belief that the collection of such data would rarely result in an undue State burden. We also noted that States can request Medicare Parts A, B and D data for dually eligible beneficiaries free of charge through the CMS State Data Resource Center (SDRC), though not all States do so. Although Medicare Part C data are not available publicly through the SDRC, States may use their contracts with MA dual eligible special needs plans (D–SNPs), which are required under § 422.107, to obtain Medicare data about the dually eligible individuals enrolled in those plans. We believe obtaining Medicare Part C data from D–SNPs will not cause additional undue burden for those States that have already opted to obtain some Medicare Part C data from these plans in this way.

We understand that making contractual or systems changes to allow a State to collect such data without causing an undue burden, such as a substantial financial or resource investment, may mean that a State implements these changes over time and that this timeline may extend past the implementation date proposed in § 438.505(a)(2). We proposed the ''without undue burden'' standard in the regulation to facilitate a gradual implementation of contract or system changes to collect the necessary data. We also noted that CMS would be available to provide technical assistance to help States acquire and use available Medicare data to calculate MAC QRS quality ratings. We sought comment on the proposed requirement that States collect available data from multiple sources on the mandatory measures. In addition, we requested comment on the type of technical assistance that would be most helpful in assisting States in obtaining and using data from the sources specified in the proposed regulation.

Once the necessary data are collected to calculate quality ratings for each mandatory measure, proposed § 438.515(a)(2) would require States to ensure that all collected data are validated. This aligns with similar requirements in 45 CFR 156.1120(a)(2), which requires QHP issuers to submit validated data for the QHP quality rating system, and § 422.162(c)(2), which requires MA organizations to provide unbiased, accurate and complete quality data to CMS for the MA and Part D quality rating system. Currently, § 438.320 defines validation for purposes of subpart E of part 438 as the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis. We proposed the same definition for purposes of new subpart G at § 438.500. We noted that States could use the current optional EQR activity at §§ 438.358(c)(6) and 457.1250(a)—for which enhanced match may be available for Medicaid EQR-related activities performed for MCOs per § 438.370(a)—to assist with the calculation and validation of data used to generate quality ratings for the MAC QRS. Use of this optional activity may help reduce burden on States.

We proposed in § 438.515(a)(3) that States use the validated data to calculate performance rates for managed care plans. Under this proposal, States would calculate, for each mandatory measure, a measure performance rate for each managed care plan whose contract includes a service or action being assessed by the measure, as determined by the State. Under this proposal, the mandatory measures would be assigned to plans based on whether the plan's contract covers the service or action being assessed by the measure, as identified by the State. We believe this would be straightforward for measures assessing single services or actions, but, as we noted in this section, some States choose to deliver Medicaid services through different managed care programs. In these States, data necessary to calculate a measure performance rate for a given measure might need to be collected from two managed care plans. However, a State could determine that only one of the services or actions for which data must be collected is being assessed by the measure. In such a case, the State would need to identify, among those plans from which the State collected data, the plan(s) whose contract includes the service or action identified by the State as being assessed by the measure, and calculate and assign quality ratings to that plan accordingly.

We discussed an example in the proposed rule to illustrate this: the Follow-Up After Hospitalization (FUH) measure listed in Table 3 requires data on two services: hospitalization and mental health services. In a State that offers behavioral and physical health services through separate managed care programs, the State would need hospitalization data from plans participating in the physical health program and mental health service data from the plans participating in the behavioral health program to calculate FUH performance rates. Because data are collected from more than one plan, the proposed rule would require States to determine which service or action is being assessed by the measure. If a State determines that the service or action being assessed by the FUH measures is the provision of timely follow-up of mental health services to an enrollee following a hospitalization for mental illness, the State would be required to identify all plans that are contracted to provide the follow-up mental health services that are assessed by the FUH measure and assign each of those plans a quality rating for the FUH measure.

Lastly, our current regulation at § 438.334(d) requires States to issue *an* annual quality rating (that is, a single rating) to each managed care plan using the Medicaid managed care quality rating system. However, based on feedback we received from beneficiaries, we proposed to revise the current policy

[218] *See* 2024 Child Core Set, *https://www.medicaid.gov/media/145571.*

[219] See 2024 Adult Core Set, *https://www.medicaid.gov/media/161841.*

[220] See 437.15(a)(4)(requiring States to report on all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, in their reporting of all Child and Adult Core Set measures, unless otherwise specified by the Secretary).

and to require States to issue to each managed care plan a quality rating for each mandatory measure for which the managed care plan is accountable. As proposed at § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required to issue quality ratings as measure performance rates (that is, the individual percentage rates calculated under proposed § 438.515(a)(3) for each measure). For example, a managed care plan that furnishes behavioral health services would likely be issued a measure performance rate for each of the proposed behavioral health mandatory measures, depending on the availability of data. We also considered requiring States to calculate and display a performance rating that reflects a national baseline for each mandatory measure, which would align with the practice of States that currently publish managed care quality measures using an individual, percentage rating. However, we chose not to propose this requirement. We solicited comments on our proposal to issue individual performance rates and sought additional input on our decision not to require additional percentage ratings to reflect a national baseline for each mandatory measure.

We noted that the proposal to require that States issue quality ratings for individual quality measures is supported by the user testing we conducted during our engagement with interested parties. Beneficiaries stated varying preferences for the level of information that they would like to have, with half preferring more detailed information, 40 percent preferring big picture information, and 10 percent falling in the middle. Many beneficiaries stated interest in quality ratings for specific measures that related to their individual health care needs, especially those that aligned with their understanding of important health indicators identified by trusted health care professionals, such as blood A1c levels for people with diabetes. We concluded that this beneficiary feedback demonstrated the value of requiring individual measure quality ratings.

Our user testing suggested that displaying managed care plan quality ratings both at the individual measure and the domain level would be most desirable to beneficiaries. Examples of potential care domains include behavioral health, chronic conditions, infants and children, and preventive care. This approach would allow beneficiaries who prefer big picture information to concisely compare plans at the domain-level, while beneficiaries who desire more detailed information could drill down into the domains to understand a plan's performance on the individual quality measures from which the domain score is derived. These findings are discussed in additional detail in section I.B.6.g. of the proposed rule. However, we did not significantly test domain level quality ratings and believe that additional engagement with interested parties and beneficiary testing would be necessary before requiring States to calculate and issue domain-level ratings. Therefore, we proposed at § 438.515(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS would engage with States, beneficiaries, and other interested parties before proposing to implement domain-level quality ratings for managed care plans through future rulemaking.

As we believe that including domain-level quality ratings in the MAC QRS, in addition to measure-level quality ratings, would align best with the informational preferences stated by beneficiaries who participated in testing of a MAC QRS prototype, we intend to propose care domains, methodology, and website display requirements for domain-level quality ratings in future rulemaking. We sought feedback on our proposal to include individual percent scores, intended approach to domain-level ratings, and potential MAC QRS care domains.

To ensure that services provided to all Medicaid beneficiaries are reflected in each managed care plan's quality ratings, we proposed at § 438.515(b)(1) that States must ensure that the quality ratings issued under proposed § 438.515(a)(4) include data for all beneficiaries who receive coverage from the managed care plan for a service or action for which data are required to calculate the quality rating. We noted that this includes beneficiaries who are dually eligible for Medicare and Medicaid and receive services through the Medicaid managed care plan, subject to the availability of Medicare data needed to generate the quality rating for a given measure. While we recognized that including dually eligible beneficiaries in quality ratings may require additional effort to obtain and analyze Medicare utilization data, especially where dually eligible beneficiaries are not in programs that integrate Medicare and Medicaid, we believe it is important to ensure that these beneficiaries can assess the quality of care furnished by available Medicaid plans for beneficiaries who also are enrolled in Medicare. Furthermore, including dually eligible individuals in MAC QRS quality ratings would align with the Adult and Child Core Sets, as some Core Set measures also require both Medicaid and Medicare data (see Core Set Final Rule, 88 FR 60278, 60299). We stated that under proposed § 438.515(b)(1), only dually eligible individuals who receive full Medicaid benefits would be included in the MAC QRS, because individuals whose Medicaid eligibility is limited to assistance with Medicare premiums and/or cost sharing receive services exclusively through Medicare. We indicated in the proposed rule our intent to provide additional guidance on which beneficiaries must be included in the quality ratings for each MAC QRS mandatory measure in the technical resource manual proposed at § 438.530. For separate CHIP, § 457.310(b)(2) does not allow for concurrent coverage with other health insurance, so our proposed amendment to § 457.1240(d) excludes dually eligible individuals from the scope of the required CHIP managed care quality rating.

In § 438.515(b)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States would be required to calculate quality ratings at the plan level by managed care program. While some States have one managed care program through which they offer all Medicaid services, most States cover Medicaid services through multiple programs that are defined by the population served by the program and the set of benefits covered by the program. For example, a State may have one program that covers behavioral health services while a second program covers physical health services. Other States may choose to provide similar services through different managed care programs that serve different populations. In these States, different programs cover different services to meet the needs of different subpopulations of Medicaid beneficiaries, such as pregnant individuals, children in foster care, or those with disabilities, chronic conditions, or HIV/AIDS. In States with multiple managed care programs, managed care plans may choose which programs they will participate in by contracting with the State. Generally, beneficiaries will then select from the managed care plans participating in each program for which the beneficiary is determined eligible, subject to requirements on access to multiple managed care plans in § 438.52.

Under our proposals, States that offer multiple managed care programs would calculate plan level ratings for each

managed care plan participating in a managed care program using only the service data described in § 438.515(b)(1) of beneficiaries enrolled in that plan under that managed care program. A managed care plan that participates in multiple managed care programs would therefore receive a distinct rating for each of these programs. These ratings would be produced using data only from those beneficiaries enrolled in the managed care plan under the specific managed care program. That is, ratings would be calculated at the plan level but with the plan dividing up its enrolled population based on the specific managed care program(s) that the State has contracted with the plan for coverage. As eligible beneficiaries select from available managed care plans within a program, we believe that plan level quality ratings for each program in which the plan participates would best align with what beneficiaries may expect to receive from each managed care plan participating in that program. This approach is distinguishable from single plan-level ratings for all the programs in which the plan participates, which would be calculated using all data from the plan regardless of the managed care program. We believe such single plan-level ratings would not provide useful information to potential enrollees because plan-level ratings would reflect the quality of services provided to all beneficiaries covered by the plan, regardless of the program through which the beneficiary receives services from the plan and may not reflect the performance that a beneficiary could expect based on the beneficiary's enrollment choices. The proposed plan-level ratings for each managed care program would produce quality ratings that are most representative of the care beneficiaries can expect to experience because each rating would be calculated only from data for beneficiaries enrolled in the same managed care plan under the same program. If a measure could not be reported for a plan at the program level this way due to low denominator sizes, the plan would be issued an appropriate indicator that data for the measure is not available for that measure as the quality rating. We sought comment on how this proposed policy would interact with our proposed minimum enrollment threshold, such as the extent to which a State's smaller plans may report data unavailable messages.

We considered the level at which ratings are assigned in the MA and Part D quality rating system and the QHP quality ratings systems as part of developing our proposal for the MAC QRS. In the MA and Part D quality rating system, quality ratings for most measures are assigned at the contract level, which consolidates data from all plan benefit packages offered under the contract to calculate a quality rating. If assigned at the contract-level, quality ratings would be calculated based on data from all enrollees served under a given contract between a State and a managed care plan, subject to the technical specifications of the measure.[221] However, we did not believe that contract-level ratings will be as useful to Medicaid beneficiaries and would make it difficult for States to assess the quality of care provided to beneficiaries in separate programs that are often designed to improve the quality of care for a particular subpopulation of beneficiaries with unique care considerations. In the QHP quality rating system, quality ratings are assigned at the product level. Different products may provide access to different provider networks and/or require enrollees follow different processes to obtain services. Examples include Exclusive Provider Organization Plans (EPO), Health Maintenance Organizations (HMO), Point of Service Plans (POS), and Preferred Provider Organizations (PPO)). These products typically provide coverage of a similar set of comprehensive health care services but vary in terms of how enrollees can access these services and at what cost. If a QHP issuer of health care offers multiple products, each separate product will receive its own ratings. In Medicaid, product level ratings could correlate with ratings assigned at the Prepaid Inpatient Health Plan (PIHP), Prepaid Ambulatory Health Plan (PAHP), or MCO level. Like our concern about contract-level ratings, one organization could offer multiple PIHPs, PAHPs, or MCOs across different managed care programs.

Under our proposal at § 438.515(b)(2), managed care plans that participate in multiple managed care programs would receive separate quality ratings under each program. These separate quality ratings would be calculated from data for only those beneficiaries enrolled in the managed care plan under a given program. We believe that this approach best balances the need for representative ratings with the level of effort States must employ to calculate quality ratings for the MAC QRS, while also accommodating the current way that States structure their overall Medicaid and CHIP program and the need for comparable quality ratings both within and among States. While our proposed reporting unit would require the calculation of more quality ratings than those used by the MA, Part D, or QHP quality rating systems, we believe that this additional work would also help States monitor the quality of the managed care programs that they have developed to ensure provision of high-quality, cost-efficient care to their beneficiaries. We noted that States could receive an enhanced match for assistance with quality ratings of MCOs performed by an EQRO, including the calculation and validation of MCO data, under the external quality review optional activity at § 438.358(c)(6), in accordance with § 438.370 and section 1903(a)(3)(C)(ii) of the Act.

We solicited comments on our proposal to use a program-level reporting unit for the MAC QRS, as well as other recommendations for reporting units that would result in quality ratings that are both representative and less burdensome on States.

We summarize and respond to public comments received on the proposed rules for the collection and validation of data necessary to calculate MAC QRS quality ratings, the MAC QRS methodology and calculation and issuance of measure-level ratings (§§ 438.515 and 457.1240(d)) below.

Comment: Several commenters supported the use of Medicaid FFS and Medicare data, in addition to Medicaid managed care data, as necessary to calculate mandatory measures, if it can be used without undue burden. These commenters agreed that the proposal would provide a more comprehensive view of a State's populations, and that it would be unfair to exclude mandatory measures if some portions of an enrollee's care were provided outside of Medicaid managed care. Several other commenters opposed the use of other data (for example, Medicaid FFS and Medicare data), and a few opposed the use of data from more than one Medicaid managed care plan to calculate ratings for a single managed care plan. The commenters raised concerns about the availability of data from sources outside of Medicaid, especially Medicare. Some commenters noted that it could take several years to obtain Medicare encounter and claims data, which would not be feasible with the proposed timelines.

Response: We appreciate commenters' support for our proposal to require States to collect and use data necessary to calculate quality ratings from sources outside of Medicaid and CHIP managed care plans when such data are available for collection by the State without

[221] Some MA quality measures are limited to MA special needs plans.

undue burden. We considered the concerns raised by commenters that were not in favor of this policy as well. We continue to believe that our proposed approach best balances State flexibility to provide Medicaid services through multiple delivery systems and/or multiple managed care programs, the person-centered goal of measuring quality of care for a managed care beneficiary even when their care is provided through multiple delivery systems, and feasibility for providers, plans, health systems, and States.

We recognize the concerns about States' ability to include certain populations of Medicaid managed care enrollees in the MAC QRS ratings, particularly dually eligible enrollees as the Medicaid managed care program is not the primary payer for most health care services for this population. We also recognize that there are challenges with collecting, validating, and integrating the data from both Medicare and Medicaid FFS that are necessary to achieve the inclusion of these individuals. However, we disagree with those recommending that States should not include these individuals in quality ratings for MAC QRS measures. In the 2023 Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting Final Rule, we stated that our intent in implementing mandatory reporting requirements for the Adult and Child Core Sets is for the data collected to be as inclusive of all beneficiaries as possible and noted that dually eligible individuals experience the health care system and incur health outcomes as individuals, regardless of whether Medicare or Medicaid pays for the service.[222] We believe that this statement is true for both dually eligible individuals and Medicaid beneficiaries who receive their care through a Medicaid program that provides services through both FFS and managed care. As such, we intend the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries as possible. Our intention is reflected in the requirements proposed and finalized at § 438.515(a)(1)(ii) and § 438.515(b)(1).

In the proposed rule, we noted that the proposed ''without undue burden'' standard is meant to facilitate a gradual implementation of contract or system changes to collect the data necessary to calculate managed care quality ratings that include the enrollees described in § 438.515(b)(1), which may extend past the implementation date proposed and finalized in § 438.505(a)(2). Because our proposal to require data collection from non-Medicaid managed care sources applied to the extent that the collection of data from such additional sources did not result in an undue burden, we disagree with commenters that it would not be feasible for States to collect data from sources outside of Medicaid managed care within the MAC QRS' proposed timeline. As proposed, States experiencing an undue burden preventing them from collecting one or more of these additional sources of data necessary to calculate fully inclusive MAC QRS ratings, which could not be resolved within the MAC QRS implementation timeline, would have the flexibility to identify and build a pathway to collect that data over a timeline that would not constitute an undue burden, which may extend past the implementation timeline.

However, based on commenter input that the challenges related to utilizing non-Medicaid managed care data to produce quality ratings for the MAC QRS extend beyond data collection—to the State's ability to validate collected data and then use the validated data to calculate and issue a quality rating as well—we are finalizing § 438.515(a)(1)(ii), (a)(2), and (a)(3) with modifications to clarify that, for Medicare and Medicaid FFS data, the requirements of these provisions apply ''to the extent feasible without undue burden.''

As finalized, this standard—''to the extent feasible without undue burden''—would apply at each of the three stages of quality rating production described in § 438.515(a). By including the phrase ''to the extent feasible without undue burden'' in paragraphs (a)(1)(ii), (a)(2) and (a)(3), we are acknowledging that there may be unique challenges related to Medicaid FFS, Medicare Advantage, or other Medicare data at each of these step and we are focusing the flexibility the standard provides on the specific activities to which we intend this flexibility to apply. As finalized, the specific requirements in these paragraphs (collection of data from certain sources outside Medicaid managed care organizations, validation of that data, and calculation of ratings using the data) apply to the State in its administration of its MAC QRS only to the extent that it is feasible for the State to comply without undue burden. By including ''to the extent feasible'' in this regulation text, we are clear that we anticipate that, even where there is an undue burden, it will likely be feasible without undue burden for a State to comply—to some extent—with each of the requirements in paragraph (a). That is, the State will be able to collect some data from these additional sources beyond Medicaid managed care, validate some data from these additional sources, and/or calculate ratings using some of the data from these additional sources, and § 438.515(a) requires the State to collect, validate and use that data to calculate MAC QRS quality ratings. We note that we are not including the ''to the extent feasible without undue burden'' standard in paragraph (a)(4) because we view the issuance of the MAC QRS ratings as fairly nonburdensome once those ratings are calculated based on data that has been collected from relevant sources and validated.

For example, a State that can collect and validate necessary Medicaid FFS, Medicare Advantage or other Medicare data for the initial MAC QRS display year could experience barriers to using that validated data to calculate performance rates if the State does not yet could integrate data from those other sources with Medicaid managed care data to produce plan quality ratings. In such a case, the undue burden standard could permit the State additional flexibility to continue to work towards the ability to integrate such data without undue burden over a timeline that extends past the implementation date finalized in § 438.505(a)(2). However, we expect instances where States are unable to include *any* data from non-Medicaid managed care sources, including Medicare data for *any* dually eligible individuals, in *any* MAC QRS ratings will be the exception, and not the rule.

We emphasize that we do not believe that there will be an undue burden on a State performing the required steps indefinitely. We intend the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries as possible and for the undue burden standard to facilitate the gradual implementation of contract or system changes to collect, validate, and use the Medicaid FFS and Medicare data necessary to accomplish this goal. While there may be cases where the ability to collect, validate, and use Medicaid FFS and Medicare data to calculate a quality rating is all or nothing, we believe that it is more likely that some of this data can be collected, some can be validated, and some can be used to calculate quality ratings for some mandatory measures. Our regulations, as finalized, reflect our belief that some States will be unable to

[222] See Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting Final Rule Core Set Final Rule, 88 FR 60297, available online at *https://www.govinfo.gov/content/pkg/FR-2023-08-31/pdf/2023-18669.pdf.*

fully comply with § 438.515(b)(1) initially; the goal and intent of including ''to the extent feasible'' in the undue burden standards are to give States the ability to continue to work towards full inclusivity over time. Similarly, we stress that whether the work and effort necessary to collect, validate and use the data constitute an undue burden will evolve over time as resource availability, data systems, and data availability continue to progress. We emphasize here that as the duties specified in § 438.515 are to occur each year for the annual issuance of MAC QRS ratings, the evaluation of the feasibility and scope of the State's burden must also occur each year, applying the regulatory standard of ''as feasible without undue burden.''

Finally, we note that the obligation in paragraph (b)(1) to include data for all enrollees who receive coverage through the managed care plan for a service or action assessed by a measure necessarily means the data that has been collected, validated, and used as specified in paragraphs (a)(1) through (a)(3) and the ratings issued as required by paragraph (a)(4). Repeating the standard ''to the extent feasible without undue burden'' in paragraph (b)(1) would be repetitive and suggest that data that can be collected, validated, and used without undue burden could nonetheless be excluded from the final measure ratings. Similar to our thinking related to (a)(4), we are not including this standard (''to the extent feasible without undue burden'') in paragraph (b)(2) because we believe that issuance of a quality rating at the program level will be fairly nonburdensome given that States should have knowledge (or should have the ability to easily acquire knowledge) of which beneficiaries should be attributed to which plans under its established programs at the time quality ratings are calculated using data collected from relevant sources and validated.

In combination, we believe that the MAC QRS's extended timeline and the undue burden standard best balance our intent for the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries with the implementation of this goal within a landscape in which the availability of the data necessary to do so is constantly evolving and expanding. We intend to provide technical assistance to States to help support our goal of inclusivity, and are also finalizing § 438.535 with modifications to include additional information in the MAC QRS annual report that will allow us to identify technical assistance that will best support the ability of States to collect, validate and use Medicaid FFS and Medicare data in their MAC QRS quality ratings and monitor the extent to which the MAC QRS ratings are inclusive of all plan enrollees as required by § 438.515(b)(1).

We are therefore including a new paragraph (a)(8) at § 438.535 that will require States to report the following data if the data necessary to calculate a measure described in § 438.510(a)(1) of this subpart cannot be provided by the managed care plans described in § 438.515(a)(1) of this subpart: (i) a description of any Medicare data, Medicaid FFS data, or both that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure per § 438.515(a) and (b), including an estimate of the proportion of Medicare data or Medicaid FFS data that such missing data represent; (ii) a description of the undue burden(s) that prevents the State from ensuring that such data are collected, validated, or used to calculate the measure, the resources necessary to overcome the burden, and the State's plan to address the burden; and (iii) an assessment of the missing data's impact on the State's ability to fully comply with § 438.515(b)(1).

Finally, in the Core Set final rule, we recognized that States were unlikely to successfully report dually eligible individuals by the implementation date for that final rule, in 2024, which is four years prior to the implementation date for the MAC QRS (December 31, 2028).[223] In addition to the MAC QRS' longer implementation timeline and the flexibility afforded to States by the undue burden standard, we are also finalizing at § 438.515(d) (discussed in more detail in this section) the opportunity to request a one-time, one-year extension to requirement in § 438.515(b). Such an extension could apply to the requirement in (b)(1) that all data for applicable enrollees, including dually eligible individuals, must be included in each plan's quality rating(s), if the State has requested, and CMS has approved, an extension for this requirement. States with an approved extension for § 438.515(b)(1) will have 5 years (until December 31, 2029) to comply with § 438.515(b)(1). Given the relationship described in this response between the ability to comply with paragraph (b)(1) and the State's ability to collect, validate and use enrollee data to produce MAC QRS quality ratings, the barriers to comply with (b)(1) that must be identified by a State per finalized § 438.515(d)(iii) when requesting approval for an extension under § 438.515(d) could include the State's inability to collect, validate, or use data for dually eligible enrollees, even when the State's ability to complete these steps does not rise to the level of an undue burden.

Comment: Some commenters were concerned that using data from more than one plan to calculate and assign quality ratings would not result in valid quality ratings or in fair and accurate comparisons.

Response: We do not agree with commenters that the proposed policy would result in unfair comparisons because our intent is not to hold plans accountable for services provided by other plans. Rather, our intent is for States to use all data obtainable without undue burden to calculate and assign quality ratings to managed care plans for services they are accountable for under a given State managed care program, thereby ensuring that such ratings are as inclusive of all Medicaid managed care beneficiaries as possible. Furthermore, as finalized in § 438.515(b)(2) and discussed in the proposed rule and this final rule in sections I.B.6.f, ratings for MAC QRS measures must be assigned to managed care plans per program. Therefore, measure ratings must be calculated using the data of beneficiaries enrolled in a given managed care plan through the rated program who receive the service or action being assessed by the measure for which the plan is being rated, even if some of the data used to calculate the measure comes from other sources. We also do not believe the validity of the rating would be affected since all measures are required to be validated as required by finalized § 438.515(a)(2) for Medicaid, and § 457.1240(d) for CHIP.

Comment: A few commenters supported our proposal to rate managed care plans only on measures for which they are accountable and agreed that managed care plans should be held accountable for the full range of outcomes their enrollees experience. However, we received many comments expressing concern that our proposed rule would require States to include measures in their MAC QRS that are not applicable to the State's managed care program(s). These commenters sought clarification on whether all mandatory measures would be reported in all States, noting that not all services assessed by each of the proposed MAC QRS mandatory measures are furnished through managed care in a State. A couple of commenters stated concern that managed care plans would be required to report data for services that

[223] The initial round (2024) of Core Sets reporting must be submitted and certified by States by December 31, 2024.

they are not contracted to provide. Others commented that States would be required to collect and validate data for measures that assess services not covered through the State's managed care program(s), and therefore, would ultimately not be used to calculate quality ratings for any managed care plan.

Response: We agree with commenters that, as proposed, the requirement in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), should be finalized with narrower language to avoid implying that States are required to include measures in their MAC QRS that are not applicable to the State managed care programs because they assess services or actions that are not covered through a managed care program established by the State. Because we proposed in § 438.515(a)(1) and (2) that States must collect and validate data for the measures identified in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), the proposal could have been interpreted as requiring States to collect and validate data for measures that were not applicable to the State's managed care program(s). Therefore, we are finalizing our proposal with modifications to address these concerns.

First, we are modifying § 438.510(a) (finalized as § 438.510(a)(1)) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to narrow the scope of measures that must be included in a State's MAC QRS to those measures in the mandatory measure set that are applicable to the State because the measures assess a service or action covered by a managed care program established by the State. As finalized, States will be required to include in their MAC QRS only those mandatory measures that assess the performance of their managed care plans and report that plan level performance by managed care program(s). For example, if a State does not offer dental services through managed care, the Oral Evaluation, Dental Services (OEV) measure would not be applicable to the State because the service or action assessed by the measure is not covered by a managed care program established by the State. Similarly, all States that provide Medicaid services through managed care would include the five measures from the CAHPS survey as they assess customer experience, and therefore are applicable to every State's managed care program. This modification in the scope of the measures and rating system (finalized at § 438.510(a)(1)) narrows the scope of measures that States must include in their MAC QRS and therefore could narrow the scope of data that must be collected and validated under § 438.515(a)(1) and (2) if a State provides some Medicaid services through FFS. For example, if a State provides LTSS services through its FFS program, the State would have no obligation to collect or validate any data on any LTSS measures because such services are not covered by a managed care program established by the State.

Second, we are finalizing the reporting requirement in § 438.535(a)(1) with modifications to require that States provide a list of any mandatory measures identified as not applicable by the State under § 438.510(a)(1) along with a brief explanation for why the measure is not applicable to the State's managed care program(s). (See section I.B.6.j. of this final rule for more detail on § 438.535). The change to the proposed Medicaid provisions at §§ 438.510(a) (finalized at § 438.510(a)(1)) and 438.535(a)(1)(i) are equally applied to separate CHIP by cross-reference through revised 457.1240(d).

Comment: One commenter questioned the appropriateness of including requirements for Medicaid FFS in a Medicaid managed care final rule and whether there is statutory authority for the reporting of Medicaid FFS measures under the managed care regulations. However, the commenter did not specify what specifically they believed that FFS programs would be required to do under our proposal.

Response: Our rule does not require States to calculate and report quality ratings for measures that assess services provided to a State's beneficiaries through FFS and we disagree that our rule establishes requirements for FFS. First, States are responsible for holding managed care plans responsible for the quality and timeliness of services they are contracted to provide, and this may require care coordination between the managed care plan's providers and providers participating in other delivery systems, such as Medicaid FFS. In a State that offers Medicaid services through FFS and managed care, it would be impossible to assess the quality or timeliness of some managed care services provided to Medicaid beneficiaries that require care coordination between the managed care plan and FFS without using the FFS service data owned by the State.

Second, in the mandatory measure set we are finalizing in this rule, the FFS data that may be needed to hold managed care plans responsible for services for which they are accountable is limited to Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP), Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET), Follow-Up After Hospitalization for Mental Illness (FUH), and Asthma Medication Ratio (AMR). As we discussed in section I.B.6.f. of the proposed rule, these MAC QRS measures require data from more than one care setting and calculating quality ratings for one of these measures for a Medicaid managed care plan could require FFS data, but only if a State splits coverage of the services associated with the measure between FFS and managed care. For example, to calculate the three behavioral health measures, it is necessary to collect mental health or substance use service data, as well as either pharmacy or physical health data. In a State that provides physical and behavioral health services through managed care, but offers pharmacy benefits through FFS, FFS data would be required to calculate quality ratings for AAP. If available FFS data is not leveraged, beneficiaries that receive services necessary to calculate quality ratings for these measures through both FFS and managed care would not be represented in the MAC QRS ratings. As stated previously in this final rule, it is our intent for the data collected and quality ratings issued in the MAC QRS to be as inclusive of all managed care beneficiaries as possible. Therefore, our policy to leverage FFS data is an important mechanism for achieving our goal and is consistent with our intention identified in the Adult and Child Core Sets Final Rule in which we stated our intent for the data collected for mandatory Adult and Child Core Set Reporting to be as inclusive of all managed care beneficiaries as possible.

While it is our intent for the data to be as inclusive of all managed care beneficiaries as possible, we reiterate that the requirement to collect, validate, and use data from other delivery systems is subject to the undue burden standard described in § 438.515(a)(1)(ii), (a)(2), and (a)(3) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), and discussed in section I.B.6.f. of the proposed rule and this final rule. Given that FFS data is owned by the States and such data's role in monitoring services provided through a State's FFS program and the quality of those services, we believe that FFS data should almost always be available for collection without undue burden. However, at least one commenter

communicated that they do not currently collect FFS data and, depending on the unique circumstances within a State, we recognize that there could be situations in which it would be an undue burden for States to validate or use FFS data to calculate certain MAC QRS mandatory measures. However, we emphasize again that this does not mean that an undue burden would exist indefinitely in such a State. We noted in the proposed rule and throughout our responses in this final rule that we intend for the undue burden standard to facilitate the gradual implementation of contract or system changes to collect necessary data and we would expect States to identify a pathway that would allow for FFS data to be collected, validated, and used by the State for MAC QRS quality ratings. Furthermore, we have noted throughout our responses in this final rule that finalized § 438.515(a) requires States to collect, validate and use FFS data necessary to calculate MAC QRS ratings that is feasible to collect, validate and use without undue burden. We expect that instances where States cannot collect, validate, or use any Medicaid FFS data to calculate MAC QRS quality ratings will be the exception and not the rule given that the State is responsible for administering and ensuring the quality of services provided by its FFS program.

Comment: One commenter requested flexibility for States to provide explanatory information regarding the inclusion of multiple data sources as part of the MAC QRS reporting or website display.

Response: Although not required for the MAC QRS website display under § 438.520 for Medicaid (which also applies to separate CHIP through a cross-reference at § 457.1240(d)), States have flexibility to include additional explanatory language in their MAC QRS that will assist MAC QRS users, and we encourage States to do so. Such explanations could include the source of data used for the different measures or a description of the specific activities or services furnished by the managed care plan that are reflected in the measure rating.

Comment: Several commenters appreciated the undue burden standard proposed to limit when a State would be required to collect and use data from Medicaid FFS and Medicare sources and recommended CMS consider factors such as Medicaid agency administrative capacity, systems burden, and the general availability of data sources outside of Medicaid managed care when determining if an undue burden exists.

Response: We agree with commenters that Medicaid agency administrative capacity, systems burden, and the general availability of data sources outside of Medicaid managed care should be considered, among other factors, when determining undue burden. We believe that whether an undue burden exists for the collection, validation, or use of Medicare data or Medicaid FFS data to calculate quality ratings for MAC QRS measures may be highly dependent on the circumstances within a specific State. The answer to how to obtain and use Medicaid FFS and Medicare data without undue burden may share similarities and best practices but will often be unique in each State and for each data source. We intend to work with States that have identified challenges—such as through the reporting in § 438.535(a)(8)—and provide technical guidance on how to address these challenges and determine how CMS may best support States in collecting and using such data. We also intend to provide additional guidance on circumstances that may constitute an undue burden and will continue to engage with States, plans, providers and other interested parties in the development of this guidance. We previously noted in this final rule that we proposed the ''without undue burden'' standard to facilitate a gradual implementation of contract or system changes to collect the necessary data that allows States to implement these changes over time, which may extend past the implementation date proposed in § 438.505(a)(2). As such, what constitutes an undue burden will evolve over time as resource availability, data systems, and data availability continue to progress and, likewise, the technical assistance and guidance on what constitutes an undue burden will also evolve over time. We reiterate that the undue burden standard permits States to exclude the specific data for which the undue burden applies. Where it is feasible to collect, validate, and use necessary data without undue burden, the State must ensure that these steps are completed, and the data are used in the calculation of MAC QRS measures.

Comment: A few commenters supported the proposed minimum enrollment threshold. One commenter suggested a modification to our proposal that data be collected from managed care plans that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year. The commenter requested that CMS add a requirement that plans also have 500 or more members as of January 1st of the rating year, which would align with the Medicare and Marketplace enrollment threshold.

Response: We appreciate the commenter's suggestion to modify our proposed minimum enrollment threshold to require 500 or more enrollees on July 1 of the measurement year *and* as of January 1 of the rating year to align with other CMS quality rating programs. We agree with commenters that the MAC QRS should align the dates used to determine whether a plan meets a minimum enrollment threshold with other CMS quality ratings programs. However, neither the QHP nor the Medicare Advantage and Part D quality rating system regulations codify a specific date used for an overall minimum enrollment threshold for collection of all quality data and reporting of all quality ratings. Instead, both the QHP and the Medicare Advantage and Part D quality rating systems establish minimum enrollment requirements in annual technical guidance. For instance, the participation criteria for QHP issuers that must collect and submit validated clinical measure data for the QHP quality rating system include, among other criteria, that the QHP issuer ''had more than 500 enrollees as of July 1, 2024, and more than 500 enrollees as of January 1, 2024.'' [224] Similarly, the MA and Part D quality rating system uses its Medicare 2023 Part C & D Star Ratings Technical Notes to identify minimum enrollment thresholds for Medicare Advantage and Part D plans that are awarded Star Ratings. Instead of establishing a threshold that applies across the program like the QHP quality rating system, the MA and Part D quality rating system identifies minimum enrollment thresholds for some of its quality measures if such thresholds are specified in the measure steward's technical specifications.

To better align with the QHP quality rating system and the MA and Part D quality rating system, we are not finalizing use of the July 1 marker in the regulation text. Like the QHP quality rating system, this information will instead be communicated through the annual MAC QRS technical resource manual. To reflect this, we are finalizing § 438.515(a)(1)(i) with modification to

[224] *See* 2024 Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Operational Instructions'' *https://www.cms.gov/files/document/qrs-qhp-enrollee-survey-operational-instructions-2024.pdf.* The enrollment threshold used for the QHP quality rating system aligns with the one for the QHP enrollee satisfaction survey. See section 1311(c)(4) of the Patient Protection and Affordable Care Act and 45 CFR 156.1125. Also see the *Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2024, section 6.1.*

specify that the enrollment threshold of 500 will be calculated as described by CMS in the technical resource manual. CMS intends to require States to use plan enrollment at both the January and July dates to determine whether a Medicaid managed care plan meets the minimum enrollment threshold of 500 finalized in § 438.515(a)(1)(i). We recognize that changes to the MAC QRS's minimum enrollment threshold could impact the scope of data collection required for the MAC QRS and could be burdensome on States and plans if modified frequently. While the technical resource manual will be issued annually, CMS does not intend to modify the minimum enrollment thresholds discussed here unless CMS determines that changes are necessitated to better align with other Federal rating programs or to ensure that Medicaid beneficiaries are appropriately represented in MAC QRS ratings. We note that the minimum enrollment threshold finalized by CMS at § 438.515(a)(1)(i) and used to identify which *plans* must be included in the MAC QRS is distinct from measure steward specifications that may use dates of plan enrollment to identify the eligible *beneficiary population* for a specific measure and documented in the measure's technical specifications. This information from measure stewards would also be provided in the Technical Resource Manual as part of the MAC QRS technical specifications and any updates to these specifications would be made per finalized § 438.510(e).

Lastly, in section I.B.6.f. of the proposed rule we noted that States would have the option to include plans that do not meet the minimum enrollment threshold in their reported measures, and that we would encourage States to do so when appropriate. For example, a State may decide to include in its MAC QRS managed care plans for pregnant individuals that enroll fewer than 500 individuals because, despite not meeting the minimum enrollment threshold, the State is able to calculate and issue quality ratings that are valid and reliable to the plan for mandatory measures related to the care of pregnant persons because all enrollees are likely to be part of the beneficiary population included in such measures. Should a State decide to include plans with fewer than 500 enrollees in its MAC QRS, this approach would not be considered an alternative methodology for which the State would need approval under § 438.515(c) so long as the State ensures that quality ratings issued to the plan(s) meet the requirements in § 438.515(b). The requirement at § 438.515(a)(1)(i) establishes a floor for the plans that must be included in the MAC QRS, but States are free to include additional managed care plans as appropriate, and could even choose to include data on its FFS program in the MAC QRS. Furthermore, inclusion of additional plans (or even additional ratings or performance information) in a State's MAC QRS does not necessarily impact States' compliance with the CMS methodology established in § 438.515(b)(1) and (2), which establishes requirements related to the enrollees who must be included in quality ratings for the plan and the level at which the rating is assigned to the plan.

Comment: One commenter requested input on how low denominator sizes may impact the requirement to collect data necessary to calculate a measure, citing concerns about rating validity when there are low denominator sizes.

Response: Our minimum enrollment threshold policy at § 438.515(a)(1)(i) for Medicaid, and through a cross-reference at § 457.1240(d) for separate CHIP, requires States to collect data from contracted managed care plans that have 500 or more enrollees. Low denominator sizes do not impact the requirement to collect data from individual plans that meet the enrollment threshold but may impact whether a State reports a measure for a managed care plan if the measure's denominator size does not meet privacy, validity, or reliability standards. We noted in the proposed rule that we will follow data suppression policies for measure stewards in addition to the CMS Cell Size Suppression Policy such that if sample sizes are too small, we will not require States to publicly report data to avoid a potential violation of privacy. At present, CMS cell-size suppression policy for public reporting prohibits the direct reporting of beneficiary values from which users can derive values of 1 to 10, so CMS suppresses in its own release of data any cells with data within that range. We will also follow data suppression policies for measure stewards in addition to our Cell Size Suppression Policy. For instance, some measure stewards permit choosing not to publicly report a quality rating for a specific quality measure due to small numbers if the measure has a denominator that is less than 30. We will publish data suppression guidance in the technical resource manual based on validity or reliability concerns and intend to align this guidance with existing quality reporting practices to determine when a MAC QRS measure should be suppressed due to low denominator sizes to ensure validity of the ratings and privacy of the included beneficiaries. Through their managed care contracts, States must ensure that Medicaid and CHIP managed care plans ensure the privacy of enrollee data pursuant to §§ 438.224 and 457.1233(e) respectively; States are also required to protect beneficiary confidentiality by Subpart F of part 431 of this chapter. In addition, the privacy and security requirements under HIPAA apply to Medicaid and CHIP. *See* 45 CFR part 164.

Comment: Many commenters requested technical assistance on how to obtain and use data from other sources without imposing an undue burden on the State, noting existing challenges in collecting Medicaid managed care data necessary to calculate quality measures from Medicaid data sources and ensuring that all data sources feed into a single point that will calculate ratings. A few commenters specifically requested that CMS provide a standardized data set of Medicare quality data to Medicaid agencies. Other commenters raised concerns about whether States could obtain Medicare data in a timely manner considering the proposed MAC QRS timelines. One commenter noted that some States have confidentiality clauses in managed care contracts that would forbid the exchange of any information pertaining to substance use disorder and HIV, which could affect data collection for the proposed Initiation and Engagement of SUD Treatment and the Follow-up After Hospitalization for Mental Illness measures.

Response: We appreciate the input on assistance that may be helpful to States in the collection and use of Medicaid FFS and Medicare data. We intend to provide both technical assistance and additional guidance on how best to meet this requirement, including the timely collection of Medicare data. We note that in the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (referred to as the CY2025 Medicare Part C/D proposed rule), we have a solicitation for comment on ''Use of MA Encounter Data to Support Required Medicaid Quality Reporting'' to better understand how to balance considerations related to the timeliness of quality reporting with accuracy and

completeness of MA encounter data.[225] [NOTE TO UPDATE IF THIS RELEASES BEFORE THIS FINAL RULE]. We note that in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program final rule (referred to as the CMS Interoperability and Prior Authorization final rule), impacted payers—including States and MA plans—must implement and maintain a Payer-to-Payer API by January 1, 2027 to make available certain data to improve care continuity when a patient changes payers or between concurrent payers for those patients.[226] States may be able to collect claims and encounter data from MA plans under a Payer-to-Payer API for those dually eligible individuals who opt-in to permit the data exchange. We will also consider whether additional resources, such as the requested Medicare data set, should be available through the State Data Resource Center to meet State needs related to the MAC QRS.

In response to the commenter's concern about data exchange of confidential information, we note that the feasibility criterion for including or adding a measure to the mandatory measure set takes into consideration whether States and health plans can access the data needed to calculate the measure. Furthermore, whether an undue burden exists is highly dependent on the circumstances within a specific State. We noted previously in this section that to identify whether an undue burden exists in a particular State may require considering the State's Medicaid agency administrative capacity, systems burden, and the general availability of data sources (among other consideration). As such, the answer to how to obtain and use data from sources other than a State's Medicaid managed care program without undue burden may share similarities and best practices, but will often be unique in each State and for each data source. We will provide technical assistance to States to help them address their own unique barriers to collecting the necessary data and reporting measures, including State laws regarding exchange of health information, and intend to provide best practices where States may face similar challenges to obtain data. If States have data restrictions in place, the State may choose to have health plans calculate the measures.

Comment: Commenters generally supported our proposal to require that data be validated prior to the display of quality ratings to support the integrity of the ratings calculated and displayed as part of a State's MAC QRS. Commenters requested clarification on the role of External Quality Review Organizations (EQROs) in the calculation and validation of plan ratings. One commenter requested clarification about whether data collection and measure calculation must be done by a State, or if States would have flexibility to allow plans to calculate and report their own ratings to the State for certain measures (such as HEDIS measures). The commenter noted that relying on plan-submitted measures would avoid duplication of administrative work when plans have experience calculating measures included in the MAC QRS. Another commenter stated concern over how States would validate Medicare Advantage data, and recommended CMS provide a standard data set and technical assistance to support this process.

Response: We agree with commenters that validation of data is a critical aspect of generating trust in the information displayed on each State's MAC QRS. As noted in the proposed rule, States may use their EQRO to assist with quality ratings for the MAC QRS under the optional EQR activity at § 438.358(c)(6) for Medicaid, which applies to separate CHIP through an existing cross-reference at § 457.1250(a). Such assistance could include both calculation of performance measure rates and/or validation of the data used to calculate the rates. We agree with commenters that plans could collect the data necessary, calculate the performance rates themselves, and submit this information to the State (or EQRO) for data validation, and that allowing plans to submit measures could reduce duplication and burden on States. Therefore, we are modifying § 438.515(a) for Medicaid, and for separate CHIP by cross-reference at § 457.1240(d), in the final rule to use language that does not mandate that the State directly perform the necessary data collection and measure calculation activities. Specifically, we are removing the terms ''Must collect'', ''Must ensure that'', ''Must use'' and ''Must issue'' from § 438.515(a)(1) through (4), respectively.

Under § 438.515(a)(1) and (3), as finalized, collecting necessary data and calculating performance rates may be performed by the State, the plan or an EQRO. This reporting structure aligns with the existing quality reporting regulations at §§ 438.330(c) and 438.358 for Medicaid, which apply to separate CHIP through an existing cross-reference at § 457.1250(a), whereby either the State or the plan can calculate the performance measures before they are validated. We do not believe plans are an appropriate entity to validate data collected pursuant to § 438.515(a)(2) because they are not free from bias. The definition of validation at § 438.500 of the final rule requires that the review be free from bias and § 438.515(a)(2) uses the defined term to ensure that the standards inherent in the definition apply. We are finalizing § 438.515(a)(2) with modification to codify this requirement by adding language to require that the validation of data must not be performed by any entity with a conflict of interest, including managed care plans.

We also note that for States planning to use the optional EQR activity at § 438.358(c) to carry out the validation or calculation of the performance rates, plans are prohibited from performing this external quality review activity. For the activity in § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to issue the quality rating, we believe that it would not be appropriate for plans to issue ratings for themselves, and that this should be solely the State's responsibility. As noted in the proposed rule, States are in the best position to determine which quality ratings should be assigned to the plans within each of their Medicaid managed care programs, based on the services covered under that program. As such, the revisions to § 438.515(a)(4) include that the ratings be issued by the State (not the plan or an EQRO) for each managed care plan.

Finally, as previously discussed, we intend for the data collected and quality ratings issued for the MAC QRS to be as inclusive of all plan enrollees as possible (including dually eligible individuals), but we recognize that there are challenges to the collection, validation, and use of Medicare data necessary to include dually eligible individuals in the MAC QRS. Under finalized § 438.515(a)(2), States must

[225] See 88 FR 78531, *https://www.govinfo.gov/content/pkg/FR-2023-11-15/pdf/2023-24118.pdf.*

[226] See:*https://www.govinfo.gov/content/pkg/FR-2024-02-08/pdf/2024-00895.pdf*

ensure that all Medicare data collected per § 438.515(a)(1)(ii) is validated to the extent feasible without undue burden. (See earlier responses in this section about the standard ''to the extent feasible without undue burden.'') As finalized, States will be afforded the flexibility to continue to work towards complete validation of available Medicare data used for the MAC QRS ratings and their ability to calculate quality ratings that are inclusive of dually eligible individuals enrolled in the State's managed care program. Regarding the commenters' concerns about Medicare Advantage data, including validation of the data, we intend to discuss methods of data collection and validation in the technical resource manual and will be available to provide States with any needed technical assistance. We also believe the provision at § 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), that requires the use of non-Medicaid data to the extent feasible without undue burden, provides flexibility for States that cannot identify a pathway to collect this data without undue burden by the implementation date established in § 438.505(a)(2).

Comment: A few commenters stated concern about leaving the determination of whether a quality rating for a measure should be calculated and assigned to a given managed care plan to the State. Many commenters stated a concern that our proposal would require States to issue quality ratings for all mandatory measures to all managed care plans resulting in some plans being held responsible for measures for which they have no contractual or financial responsibility under a State managed care program.

Response: We disagree with commenters that proposed § 438.515(a)(3) and (a)(4) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), would hold managed care plans responsible for measures for which they have no contractual or financial responsibility under a State managed care program. Under the standard proposed and finalized in § 438.515(a)(3) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), whether a plan receives a quality rating for a given MAC QRS measure is dependent on whether the plan is contractually responsible for the service or action assessed by the measure under the managed care program in which it participates. We continue to believe that States should determine which plans receive a quality rating because they are best situated to determine whether a given managed care program, and the plans within the program, cover a service or action assessed by a measure, and whether the program's participating plans should be assigned a quality rating for the measure. Ultimately, this discretion allows States to determine whether it is fair to hold a plan accountable for a given measure based on the plan's contractual relationship with the State. Further, the modifications finalized to § 438.510(a) at § 438.510(a)(1) about the scope of measures that must be included in each State's MAC QRS also clarifies that measures are to be issued to reflect the services covered and activities performed by each managed care plan.

Comment: Many commenters noted that the proposal to require States to issue percentage quality ratings for each measure (meaning the measure performance rate) was an appropriate starting point for the MAC QRS. We received many comments supporting the future use of domain level ratings within the MAC QRS following additional input and rulemaking. Commenters noted that domain ratings would make it easier for beneficiaries to quickly evaluate differences across key services of relevance to them. Several commenters agreed that CMS should test domain level ratings with beneficiaries prior to proposing domain ratings. A few commenters requested that CMS identify the specific domains to be included, the measures included in each domain, and other technical details such as the methodology for calculating domain ratings. One commenter suggested that CMS attempt to align MAC QRS domain categories with existing Adult and Child Core Set domains. A few commenters, cautioned against the use of a single summary score for quality performance such as Medicare and Part D quality rating system ratings in the future, noting CMS's Medicare and Part D quality rating system has been beset by questions about whether the ratings result in meaningful and equitable performance comparisons.

Response: We appreciate the support from commenters on our proposal to require the use of percentage ratings for the display of the MAC QRS measures. We will take commenters' input into consideration in any future rulemaking regarding the use of domain ratings. We did not propose to require single summary scores in the proposed rule and the final rule similarly does not call for use of single summary scores for the MAC QRS. The informational preferences of users who participated in our prototype testing is consistent with the commenters' perspective that the MAC QRS users' needs are best met by a mix of individual and domain level ratings scores.

Comment: Some commenters requested clarification on whether Medicare-covered services would be rated in the proposed MAC QRS, and whether MAC QRS ratings would be determined based on Medicaid-only services. A few commenters recommended that dually eligible individuals should only be included when they are enrolled to receive Medicare and Medicaid services through the same organization (such as through an integrated D–SNP). A couple of commenters stated concern about duplication between MAC QRS and the Medicare and Part C quality rating system, which could cause confusion. Many commenters requested technical assistance and additional guidance related to the inclusion of data for dually eligible beneficiaries in MAC QRS ratings, including how dually eligible individuals would be included in MAC QRS measures.

Response: We believe it is important for Medicaid managed care plans to support better health outcomes and access to care for the totality of an enrollee's needs, not just those that fall within the covered benefits of a specific contract. While there are some services that are primarily covered by Medicare (such as preventive services) and some that are primarily covered by Medicaid (such as behavioral health and LTSS services), variation on this general rule exists across States. Furthermore, the factors that influence dually eligible enrollees' health and well-being do not always completely align with either the services covered by their Medicaid managed care plan or with those covered by Medicare services. For example, while Medicare would primarily cover services associated with a chronic condition such as diabetes, meals provided to a dually eligible individual diagnosed with diabetes by an LTSS plan may also influence how well that individual's A1c is controlled. Accounting for these complex relationships when rating the quality of an individual plan is an ongoing pursuit, and we continue to believe that our proposed policy balances the need to adequately reflect the quality of care experienced by dually eligible individuals with the challenges associated with care coordination and data sharing among States and both Medicare and Medicaid plans.

Therefore, we stress that when the service or action assessed by the measure is provided to the beneficiary

through *Medicare* and not the Medicaid managed care plan for which the rating is being calculated, we are not *requiring* States to include dually eligible individuals in quality ratings for MAC QRS measures.[227] For example, we do not anticipate that States would include dually eligible individuals (that is, the data about dually eligible individuals) in MAC QRS quality ratings for measures of preventive health services such as Breast Cancer Screening because it is likely that States would determine that the services or actions assessed by this measure are covered by Medicare and not covered by the Medicaid managed care program. This is true even if the Medicaid managed care plan in which the dually eligible individual is enrolled is an integrated D–SNP (for example, a D–SNP offered by an organization that also has a Medicaid managed care contract to cover Medicaid benefits) or part of an integrated Medicare-Medicaid demonstration.

This final rule requires States to include dually eligible enrollees (that is, the data about dually eligible individuals) in quality ratings for a Medicaid managed care plan when the State determines, as described in § 438.515(a)(3), that the service or action assessed by the MAC QRS measure is covered by the Medicaid managed care plan's contract with the State. (See prior responses to public comments in this section about how the undue burden applies to this requirement). In determining whether a service or action assessed by the MAC QRS measure is covered by the Medicaid managed care plan's contract, the State may wish to consider whether the assessed service or action is, in fact, performed by the Medicaid managed care plan (in whole or in part), and whether the design of the State's Medicaid managed care program is such that the plan should be held accountable for the service or action assessed by the measure. For example, we anticipate that most States would include dually eligible enrollees in quality ratings for MAC QRS measures of behavioral health, such as IET, FUH and LTSS. Because these measures are calculated using data for services that are commonly covered for dually eligible individuals through Medicaid as well as data for services covered by Medicare (such as hospital services), data for services provided by Medicare to dually eligible individuals also enrolled in a Medicaid managed care plan would often be necessary to calculate quality ratings for these measures that comply with § 438.515(b)(1). In such cases, the State would be required to collect, validate, and use the data necessary to calculate and issue quality ratings for the plan that include the plan's dually eligible enrollees, including the necessary Medicare data when available for collection without undue burden.

Having provided an overview of when a State would and would not be *required* to include dually eligible individuals in a managed care plan's quality ratings, we highlight that the requirement finalized at § 438.515(a)(3) would *not* prevent a State from determining that a Medicaid managed care plan should be issued a quality rating for a MAC QRS measure, even though the service or action assessed by the measure is not explicitly covered by the plan's contract with the State, if the State determines that the plan should be held accountable for the service or action. Using the example provided earlier, we note that a State would have the flexibility to choose to issue quality ratings for the MAC QRS measure Hemoglobin A1c Control for Patients with Diabetes (HBD) to its LTSS plans.

We disagree with commenters' suggestion that dually eligible enrollees should only be included when they are enrolled to receive Medicare and Medicaid services through the same organization. We believe that including dually eligible individuals who do not receive their care through an integrated product in MAC QRS ratings will be feasible for States for many measures and doing so is beneficial to dually eligible individuals who do not receive their care through an integrated product. Finally, we intend to provide additional guidance to assist States in determining how dually eligible individuals would be included in MAC QRS measures and also intend to provide technical assistance with integrating Medicare and Medicaid data to achieve this.

Comment: A few commenters requested additional guidance on the timeframe for including dually eligible individuals in MAC QRS ratings given the need to collect data from multiple sources.

Response: States must comply with the requirements of § 438.515(b)(1) by the implementation date identified in § 438.505(a)(2), that is, by December 31, 2028. However, as discussed in section I.B.6. of this final rule, we are finalizing the flexibility for States to request a one-time, one-year implementation extension for the MAC QRS methodology requirements described in § 438.515(b), which includes the inclusion of dually eligible individuals who are eligible for full Medicaid benefits that may be required under paragraph (b)(1), at new § 438.515(d). If a State submits an extension request for its compliance with § 438.515(b)(1) to have an additional year to fully comply with the requirement by including dually eligible individuals in their MAC QRS, and CMS approves the request, the State would have until December 31, 2029 to collect and utilize the data necessary to calculate and issue quality ratings that include dually eligible individuals. For instance, a State may have access to the data necessary to include dually eligible individuals in a managed care plan's quality ratings through the State's contracts with its D–SNPs. However, the State may need additional time to integrate this data with Medicaid managed care data to produce quality ratings that include the dually eligible individuals in plan ratings for certain measures. We note, however, that where inclusion of dually eligible individuals in a plan's quality rating is based on use of Medicare data, calculation of the measure using that Medicare data is contingent on the extent to which the Medicare data necessary to calculate the quality rating is available to the State without undue burden.

Comment: Several commenters supported assigning MAC QRS ratings at the plan level by managed care program, noting that this approach would provide beneficiaries with information that is more tailored to their specific needs and would allow managed care plans, States, and CMS to effectively measure and manage all Medicaid programs. One commenter encouraged CMS to define ''managed care programs'' as based on the population they enroll, which would allow for transparent measurement of the performance of MCOs that serve different populations, such as in States that operate more than one D–SNP-based Medicaid managed care program for dually eligible individuals, one for individuals under 65 and another for individuals 65 and over.

Response: We appreciate commenters' support for our proposal and the commenter's request to provide a definition for ''managed care program.'' We decline to provide a more detailed definition for the term managed care

[227] *See* § 438.515(a)(3) requiring States to ''calculate a measure performance rate for each managed care plan whose contract includes a service or action assessed by the measure, *as determined by the State*'' and § 438.515(b)(1) requiring States to ensure that the quality ratings issued to a managed care plan under (a)(3) include data for all enrollees who receive coverage through the managed care plan for a service or action for which data are necessary to calculate the quality rating for the managed care plan, including data for enrollees who are dually eligible for both Medicare and Medicaid, subject to the availability of data under paragraph (1)(1)(ii).

program in this final rule than what is currently defined in § 438.2 for Medicaid. Per that definition, a managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. This definition broadly covers Medicaid managed care delivery systems and Medicaid managed care plans that are available to Medicaid beneficiaries through a managed care program. For separate CHIP, we do not define the term ''managed care program'' in part 457 but we believe that it is clear from the context that the term means a managed care delivery system through which managed care entities have contracts to cover CHIP beneficiaries. We intend to address this as well in the technical resource manual, aligning with how ''managed care program'' is defined in § 438.2 and used in subregulatory guidance for other Medicaid reporting requirements, such as through §§ 438.66(e) and 438.207(d); these other guidance documents generally refer to managed care programs as having a distinct set of benefits and eligibility criteria that is articulated in a contract between the State and managed care plans.[228] [229] In line with these existing reporting requirements, we intend to provide guidance on how States distinguish among their managed care programs in issuing MAC QRS ratings in the technical resource manual or guidance which will align with existing guidance on managed care programs provided for reporting through §§ 438.66(e) and 438.207(d). The provisions at § 438.207(d) also apply to separate CHIP through an existing cross-reference at § 457.1230(b).

Comment: A few commenters stated concern about the ability of States and managed care plans to comply with the MAC QRS methodology requirements proposed at § 438.515(b) by the implementation deadline. Some commenters noted general challenges with the collection of data that is required to comply with the data collection and measure calculation and reporting requirements for each managed care plan in each program while distinguishing between performance in different managed care programs when the same plan has multiple contracts or contracts to participate in multiple managed care programs. Another commenter stated that States may experience data integration issues that could make it challenging for States to comply with these requirements by the implementation date. One commenter stated interest in allowing a voluntary performance year prior to mandating the implementation of the proposed MAC QRS to ensure that States and managed care plans have appropriate time to identify and resolve challenges.

Response: Under § 438.515(b) as proposed and finalized, States must ensure that all enrollees who receive coverage through a managed care plan are included in the MAC QRS ratings issued for that plan and States must issue ratings at the plan level, by managed care program. Based on commenters feedback that States may need additional time beyond the implementation timeline finalized in § 438.505(a)(2) to obtain necessary data or develop a system to house and utilize the data necessary to meet these requirements in this final rule, we are finalizing in § 438.515(d) that States will have the ability to submit a request for a one-time, one-year extension for the methodology requirements in § 438.515(b), as discussed in section I.B.6.d. of this final rule. We believe that this one-year extension is sufficient as we already proposed, and are finalizing, an additional year for implementation beyond the date previously codified at § 438.334. This additional year was proposed in response to State concerns identified prior to rulemaking requesting that CMS consider State current workload and resources when establishing the MAC QRS implementation timeline. Considering the totality of comments we received on the proposals in this final rule, we have considered how we may further stagger implementation deadlines across the board, and believe that the MAC QRS implementation date is one way to reduce State burden and address these continued concerns.

We are finalizing the information that States must submit with their extension request at § 438.515(d)(1), the deadline for submitting an extension request in § 438.515(d)(2), and the conditions under which CMS will grant a requested extension at § 438.515(d)(3). As finalized, States will need to include four things in their extension request. We describe here an example of how a State may meet these requirements when requesting an extension of a requirement under § 438.515(b). First, the State must identify the specific requirement(s) for which it is requesting an extension. When identifying the specific requirement for which a State is requesting an extension, the State should be as specific as possible. For example, we will consider how a State may submit an extension request if it has collected the necessary Medicare data to include dually eligible individuals in quality ratings for its managed care plans that enroll dually eligible individuals, but will need additional time to address technical issues that prevent the State from completing the infrastructure that will allow the collected Medicare data to be integrated with Medicaid managed care data to produce plan quality ratings for MAC QRS measures that require Medicare data to include dually eligible individuals and comply with § 438.515(b)(1). In this example, the State should not request an extension for § 438.515(b)(1) as a whole. Instead, the State should specify the specific requirement under (b)(1) that it will not be able to meet, which in this case would be the inclusion of dually eligible individuals in quality ratings for a subset of the mandatory measures that require data from both Medicaid and Medicare. If the State's extension request was granted, the State would still be required to issue quality ratings for MAC QRS measures by the implementation date finalized in § 438.505(a)(3), but the ratings for any subset of mandatory measures that require Medicare data to incorporate dually eligible individuals would not yet include dually eligible individuals.

Second, the State must include a description of the steps the State has taken to meet the requirement. Continuing with our previous example, the State should describe the steps it has taken to date to establish the infrastructure necessary to integrate Medicare data so that they can be used to calculate MAC QRS quality ratings for managed care plan. States should include sufficient detail to allow CMS to assess whether the State has made a good faith effort to meet the requirement by the implementation date. Third, the State must explain why the State will be unable to comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement by the implementation date identified by CMS. Again, the State should provide sufficient detail to allow CMS to understand why the State will be unable to fully comply with the requirement by the implementation date. The State in this example may describe technical issues it has experienced with its data infrastructure that require the State to solicit a contractor to fix before it can complete

[228] *See* Managed Care Program Annual Report template at *https://www.medicaid.gov/media/124631.*

[229] *See* Network Adequacy and Access Assurances Report template at *https://www.medicaid.gov/media/140906.*

the work necessary to integrate the Medicare data and may provide information showing that the required work will extend past the implementation deadline. Finally, the State must include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, how the State will address the identified implementation barrier. Continuing the example, the State could include an assessment of the work that must be done to allow the State to use the collected data, identify the steps needed to fix the data infrastructure issue and a detailed explanation of how long each step will take and how the State plans to ensure the steps are completed successfully before the end of the one-year extension.

We are finalizing a deadline of September 1 of the fourth calendar year following the effective date of the final rule for requests for a one-year extension to be submitted to CMS. We believe that this is the appropriate date because it provides more than 4 years for States to determine that they need an extension but gives CMS enough time to review and approve the request prior to the implementation deadline of December 31, 2028. Finally, we are also finalizing the standards that CMS will apply in evaluating and determining whether to approve a request for extension of the deadline for collecting data, calculating ratings, and issuing ratings in § 438.515(d)(3). Those standards are discussed and noted in section I.B.6.d of this final rule.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to public comments, we are finalizing § 438.515 generally as proposed but with several modifications. First, we are finalizing § 438.515(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), with modifications to clarify when a State may or may not delegate to a separate party the actions described in § 438.515(a). Second, we are modifying paragraph (a)(4) to require that quality ratings are issued by the State ''for'' each managed care plan instead of ''to'' each managed care plan. We believe this language aligns better with our proposal because the ratings are publicly posted, not just issued to the plan itself. Additionally, we are including the standard for identifying measures that must be included in a State's MAC QRS for each health plan described in paragraph (a)(3) (measures which assesses a service or action covered by the plans' contract with the State, as determined by the State) to (a)(4) instead of including only a reference to the standard. We believe that this change also more clearly reflects our proposed and finalized policy. We are not finalizing the requirement that enrollment as of July 1 of the measurement year be used to determine which managed care plans are subject to the MAC QRS ratings in § 438.515(a)(1)(i) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d) and will instead provide additional detail on how to determine if a plan has 500 or more enrollees through subregulatory guidance. We are finalizing § 438.515(a)(1)(i) to specify that the enrollment threshold of 500 will be calculated as described by CMS in the technical resource manual. We are also modifying § 438.515(a)(1)(ii), (a)(2), (a)(3) to clarify the circumstances in which the undue burden standard may be used to exclude Medicaid FFS or Medicare data from a MAC QRS quality rating, along with minor language updates throughout § 438.515 to implement this change, including removing reference to § 438.515(a)(1) in § 438.515(b)(1), which is no longer necessary due to the modifications made to § 438.515(a)(1)(ii), (a)(2), and (a)(3). We are also modifying § 438.515(a)(2) by adding language to require that the validation of data used to calculate performance rates for MAC QRS measures must not be performed by any entity with a conflict of interest, including managed care plans. We are also adopting a new paragraph (d) to provide an opportunity for States to request one-time one-year extension of the deadline by which the first quality ratings must be issued. Furthermore, we are making minor language updates throughout § 438.515 to better align with how we describe managed care contracts in other sections of Subpart G. Finally, as discussed in section I.B.6.h. of this final rule, we are finalizing the provisions on State alternative methodologies proposed at § 438.525 to § 438.515(c); as part of this final rule, proposed § 438.515(c) regarding potential domain level ratings is finalized as paragraph (e).

g. MAC QRS Website Display (§§ 438.334(e), 438.520(a), 428.520(b), 457.1240(d))

Current regulations at § 438.334(e), which will be redesignated at § 438.520(a) of this final rule, require States to prominently display the quality ratings issued for each MCO, PIHP, or PAHP on the website required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d). Our policies proposed at § 438.520 would establish new requirements for the website display, which were informed by extensive consultation with Medicaid beneficiaries and their caregivers and iterative testing of a MAC QRS website prototype. The consultation and testing revealed that the presentation of quality ratings greatly influences the usability and utility of the MAC QRS as a tool to assist beneficiaries in selecting a plan. Providing information to beneficiaries in a useable way is necessary for compliance with section 1932(a)(5) of the Act regarding provision of information, including comparative information on plan quality, to beneficiaries when a State mandates enrollment in an MCO. The same standards apply under section 2103(f)(3) of the Act to CHIP. To promote the efficient and economical operation of the Medicaid State Plan and CHIP, we proposed to apply the same requirements for all managed care programs through our regulations. Our proposed requirements for Medicaid managed care programs in § 438.520 would also be applicable to separate CHIP through a cross-reference in the CHIP regulations at § 457.1240(d).

(1) Navigational and Orienting Information (§§ 438.334(e), 438.520(a)(1) and (5), 457.1240(d))

In our initial round of testing, participants struggled to understand how to use the MAC QRS prototype, and often dismissed or skipped over the quality ratings, noting that they did not understand the ratings or how they translated to member care. Subsequent revisions of our MAC QRS prototype focused on identifying how best to present quality ratings to prospective users in a way that supported beneficiaries' ability to understand and incorporate quality ratings and use them to inform their selection of a health plan. Based on our testing, it was clear that to truly empower beneficiaries as informed health care consumers, quality ratings are best presented as one part of a comprehensive website that efficiently guides the user through the considerations for identifying a quality health plan. We also learned that to be more useful, the website should address factors commonly considered by individuals in selecting a health plan, which include information not traditionally factored into health plan quality ratings, such as what providers are in the network and drug coverage. Using this feedback, we designed, tested, and refined the MAC QRS display components proposed in this rulemaking to align with the stated preferences of our user-testing participants.

The display components identified as most critical were included in proposed § 438.520; these components fall into three categories: (1) information to help navigate and understand the content of the MAC QRS website; (2) information to allow users to identify available managed care plans and features to tailor display information; and (3) features that allow beneficiaries to compare managed care plans on standardized information, including plan performance, cost and coverage of services and pharmaceuticals, and provider network. Based on the feedback we received during prototype testing, we believe that these components are critically important to ensure quality rating information can be readily understood by beneficiaries and used in decision-making. Therefore, we proposed at § 438.520 that States display a MAC QRS website that includes: (1) clear information that is understandable and usable for navigating a MAC QRS website; (2) interactive features that allows users to tailor specific information, such as formulary, provider directory, and quality ratings based on their entered data; (3) standardized information so that users can compare managed care programs and plans, based on our identified information; (4) information that promotes beneficiary understanding of and trust in the displayed quality ratings, such as data collection timeframes and validation confirmation; and (5) access to Medicaid and CHIP enrollment and eligibility information, either directly on the website or through external resources.

Importantly, we understood from our engagement with States and interested parties that some display requirements we believe align with the goals discussed in section I.B.6.a. of this final rule may require more technology-intensive implementation, such as the interactive features that allow users to tailor displayed information. Therefore, we proposed to implement the proposed website display requirements in two phases. The first phase would be implemented by the end of the fourth year following the release of the final rule, as proposed at § 438.505(a)(2). In this phase, States would develop the MAC QRS website, display quality ratings, and would ensure that users can access information on plan providers, drug coverage, and view quality ratings by sex, race, ethnicity, and dual eligibility status from the MAC QRS website. For instance, in lieu of an interactive search tool, the State could simply hyperlink to each managed care plan's existing provider directory and formulary to meet our proposed requirements. This first phase would accomplish the goal of having a one-stop-shop for beneficiaries to access the information we believe is key to their decision-making but would not require States to develop the interactive tools identified in our research as more beneficial and usable by prospective users. In the second phase, States would be required to modify the website to provide a more interactive user experience with more information readily available to users on the MAC QRS website. This would entail including or moving some of the information required in other parts of part 438 to the MAC QRS website. For example, users could tailor the display of information to their needs and search for plans that cover their providers and medications without leaving the MAC QRS website. We discuss our proposal for phasing-in more interactive features of the website display in more detail later in this section. We sought comment on which requirements should be phased in, as well as how much time will be needed.

Given the visual nature of the website display, we provided with the proposed rule a link to two sample MAC QRS prototypes to illustrate our proposal; a simple website (Prototype A) that represents the information we were considering to require by the proposed implementation date in § 438.505(a)(2) and a more complex MAC QRS prototype (Prototype B) that represents an interactive website that includes both the display features from the first implementation phase and the more technology-intensive features we are considering phasing in. These prototypes can be found at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html* and were meant to show our overall vision for the proposed progression of the website display. In addition to the two prototypes, we indicated our intent to release a MAC QRS design guide following the final rule, which would provide a comprehensive overview of the results of our user testing that States may reference in the design of their MAC QRS website display. These materials would also provide CMS's interpretation of the requirements of the final rule, as well as guidance on potential best practices in complying with the rule. We indicated our intent for the design guide to include several components, including but not limited to desirable features and content that States could implement at their discretion, plain language descriptions of mandatory measures, and display templates that States would have the option to use in the design of their MAC QRS.

We summarize and respond to public comments received on MAC QRS website Display (§§ 438.334(e), 438.520(a), 457.1240(d)) below.

Comment: Almost all commenters supported our decision to include a website display with clearly defined components identified by CMS in the framework for the MAC QRS. Many commenters supported our upfront engagement with States, plans, beneficiaries, and other interested parties in the identification of the MAC QRS website display requirements, as well as our proposal to consult with these parties in the future to continue to evaluate MAC QRS website display requirements for continued alignment with beneficiary preferences and values. Several commenters were especially supportive of requirements meant to assist dually eligible individuals in the selection of a Medicaid managed care plan. Some commenters supported the MAC QRS website display requirements but stated concern about the resources required to develop the website with each of the components identified by CMS, even with our proposal to implement the mandatory MAC QRS website in 2 phases. One commenter noted that enhanced FFP and technical assistance for the website would be vital to successful website development. A couple of commenters requested that we consider providing an exemption from the MAC QRS website display requirements for States with a small number of managed care plans or with a managed care program(s) that offers a single plan. A couple of commenters requested that we clarify whether States will be required to provide an alternative way to access the MAC QRS for enrollees who do not have access to the internet. A few commenters sought clarification on whether it would be acceptable to house the required website display on a State website that requires a login, such as where the State has developed a member portal accessible to those who have already enrolled in Medicaid and are at the stage of choosing their managed care plan(s).

Response: We agree with commenters that the MAC QRS website will require additional State resources to implement. Enhanced Federal match (FFP funding) may be available for the planning, design, implementation, and maintenance of the State's MAC QRS website, and the data infrastructure that supports it, when necessary to comply with the new MAC QRS website requirements we are finalizing in

§ 438.520, as part of FFP available for the State's Medicaid Enterprise System (MES). See State Medicaid Director Letter #22–001 for more information. We encourage States to meet with their MES State Officer for technical assistance on which operational elements of their MAC QRS implementation may be eligible for enhanced FFP.

We understand that technical assistance will be needed to help States successfully implement the MAC QRS website display requirements. To support States, we intend to issue a MAC QRS website design manual with additional guidance, and we intend to provide technical assistance for the design and implementation of the MAC QRS website. The design manual will include CMS developed resources (for example, plain language descriptions of the importance and impact of mandatory measures and metrics), the prototypes for phases 1 and 2 described in the proposed rule, and additional visual resources for how States could choose to display MAC QRS display requirements.

We considered commenters' requests to exclude certain States from the MAC QRS website display requirements, such as smaller States or those in which beneficiaries do not have a choice of managed care plan. After reviewing each of the proposed website display requirements in § 438.520(a), in conjunction with the comments, we believe that each requirement is important to achieve our stated goals for the MAC QRS, discussed in section I.6.B.a of the proposed rule, regardless of State size or number of managed care plans with two exceptions. Specifically, proposed § 438.520(a)(6)(i) and (ii) for Medicaid, applied to separate CHIPs by cross-reference through a proposed amendment at § 457.1240(d), would require States to implement search tools that enable users to identify available managed care plans that provide coverage for a drug identified by the user and plans that include a provider identified by the user in the plan's network of providers. The utility of these search tools is applicable only to programs with two or more plans offering different drug formularies and provider networks. Therefore, we are finalizing § 438.520(a)(6)(i) and (ii) with modifications to require these search tools only for managed care programs with more than one plan. As with all of the MAC QRS regulations in §§ 438.500 through 438.535, the requirements apply to separate CHIP by cross reference adopted in an amendment to § 457.1240(d), subject to specific exclusions for references to dually eligible beneficiaries, a beneficiary support system, and the terms of § 438.525(b)(1) and (c)(2)(ii) of this chapter related to consultation with the Medical Care Advisory Committee.

Regarding the commenter's questions about whether States will be required to provide an additional way to access the MAC QRS for enrollees who do not have access to the internet, we decline to require States to provide the MAC QRS in another format other than the website display in this rule. However, we expect States will make interested parties who counsel beneficiaries on the selection of a managed care plan, such as enrollment brokers, aware of the MAC QRS as a resource, and these interested parties would be available to assist individuals who lack internet access by communicating the information displayed on the website. In addition, independent obligations for States to furnish information (such as in § 438.10) that may be duplicative of information in the MAC QRS website display are not revised here so States may be responsible for making information available in alternative formats or languages under those other rules. We note that the language and format requirements in § 438.10(d) do apply to the MAC QRS website display requirements per § 438.525(a).

Finally, we considered whether it may be acceptable for a State to comply with the website display requirements, or a portion of the website display requirements, using a website that is accessible only to individuals who are enrolled in a managed care program. Though this approach could allow States to better tailor the website display information to the user, we believe our goal of empowering beneficiaries with useful information about the managed care plans available to them is only achievable if the MAC QRS website is available to the public, including caregivers or organizations that counsel or assist individuals with enrollment. States interested in maintaining a log-in only interface could consider allowing beneficiaries to log-in to access a more tailored and detailed version of the MAC QRS website, so long as it is also possible to view the required website display information as a member of the public or as a guest who is not currently enrolled in a managed care program.

While we believe that the requirement to prominently display the requirements on the State's Medicaid website implies that the information must be immediately and easily available to the public, we are modifying § 438.520(a) to further clarify our policy. We are therefore revising § 438.520(a) to include language establishing that the requirements described in § 438.520(a) must be both prominently displayed *and* accessible to the public on the website required under § 438.10(c)(3). Additionally, we are modifying § 438.520(a)(1)(iii) to avoid implying that States may require users to provide log-in credentials prior to using or accessing a State's QRS. Under finalized § 438.520(a)(1)(iii), if users are requested to input user-specific information, including the information described in paragraph (2)(i) of this section, the State must provide an explanation of why the information is requested, how it will be used, and whether it is optional or required to access a QRS feature or type of information. We intend to provide States with technical assistance on how a State could achieve such a site, or modify an existing site, with minimal duplication.

Comment: Many commenters made recommendations for additional website display requirements. These display recommendations included requiring a fair method for the order of health plans displayed on the website, inclusion of State or national benchmarks for displayed measures to provide additional context to beneficiaries when reviewing quality ratings, and an explanation of the benefits and advantages of integrated care products for dually eligible individuals.

Response: We appreciate commenters' enthusiasm to ensure that the MAC QRS website display is helpful to beneficiaries and includes information that supports beneficiaries in identifying a plan that best fits their individual needs. We considered the additional requirements proposed by commenters and are declining to finalize additional website display requirements. To balance the preferences identified during our user testing with the State burden of website development, we included the most desirable information and features shared by testing participants in our requirements at § 438.520(a), which is applicable to separate CHIP under the proposal, through a cross-reference at § 457.1240(d). While the additional information proposed by commenters aligns with many of the beneficiary preferences we identified, a main consideration for our proposal was to establish minimum content and interactive function standards for the MAC QRS to be a usable and meaningful tool to users without overburdening States.

Furthermore, in new § 438.505(a)(1)(ii)—discussed in section I.B.6.d of this final rule—we are clarifying the State's ability to include website features in addition to those

required under § 438.520, including additional measures as described in § 438.520(b). To support States in the development of additional, optional display elements that will further assist MAC QRS users, we will consider providing guidance in our design guide on those elements recommended by commenters that overlap with preferences we identified in user testing to assist those States that wish to include additional display features, such as suggested language to use to describe the benefits and advantages of integrated products for those who are dually eligible. While we are not finalizing additional website display features in this final rule, additional mandatory website display features may be added (or existing required features removed) over time through rulemaking to reflect evolving beneficiary preferences and values identified through our obligation, proposed at § 438.520(c) and finalized at § 438.520(d), to periodically consult with interested parties to evaluate the website display requirements for continued alignment with beneficiary preferences and values.

Lastly, while we agree with commenters that including State or national benchmarks could help users interpret displayed quality ratings, we did not test the use of benchmarks in our user testing or consult with States, plans, or other interested parties on their use, nor did we propose to require display of such benchmarks in the proposed rule. We will consider requiring benchmarking of the quality ratings in future rulemaking after consulting with beneficiaries, States, and other interested parties. While not required, States have the flexibility to include benchmarks as part of their MAC QRS website display as we would consider the display of benchmarks to be an additional website display feature, which are permitted under § 438.520(c).

Comment: As we discussed in sections I.B.6. and I.B.6.d. of this final rule, many commenters provided feedback on the overall implementation timeline for the MAC QRS and the mandatory MAC QRS website display. Several of these commenters stated concern about the ability of States to comply with the MAC QRS website display requirements proposed at § 438.520 by the implementation deadlines, citing the time and resources necessary to implement a website display meeting the proposed requirements. Commenters most frequently stated concern with their ability to display quality ratings stratified as required by proposed § 438.520(a)(2)(v) and (a)(6)(iii), and to implement the more technology-intensive requirements in § 438.520(a)(6).

Response: As discussed in section I.B.6.d. in this final rule, we are finalizing in § 438.520(b) that States will have the ability to submit a request for a one-time, one-year extension for the website display requirements specified at § 438.520(a)(2)(v) and (a)(6), which were the features most commonly characterized as challenging by States and plans both during pre-rulemaking engagement and by commenters in response to our proposed rule. Specifically, States will be able to request a one-year extension to comply with the requirements at § 438.520(a)(2)(v), which requires States to display quality ratings for each managed care plan for mandatory measures stratified by dual eligibility status, race and ethnicity, and sex and § 438.520(a)(6), which requires States to (1) implement interactive search tools that enable users to identify available managed care plans that provide coverage for a drug identified or include a provider identified by the user and (2) to stratify quality ratings by certain additional factors identified by CMS. States will not be able to request an extension for implementing the display requirements, at § 438.520(a)(1), that States include information necessary for beneficiaries to understand and navigate the MAC QRS website; at § 438.520(a)(2)(i) through (iv), that States include information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences; at § 438.520(a)(3), that States provide standardized information identified by CMS that allows users to compare available managed care plans and programs; at § 438.520(a)(4), that information on quality ratings be displayed in a manner that promotes beneficiary understanding of and trust in the ratings; and at § 438.520(a)(5), that the QRS website include information or hyperlinks directing beneficiaries to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. In our view, States currently should have easy access the information required to comply with these provisions.

We also discussed in I.B.6.d. and I.B.6.f. of this rule that we are finalizing authority for States to request and CMS to grant one-time, one-year extensions for calculating and issuing MAC QRS quality ratings that fully comply with the methodology described in § 438.515(b) (§ 438.515(d)) and for implementing certain MAC QRS website display requirements (§ 438.520(b)) using the same requirements for what must be included in the request and what standards CMS will use to decide whether to grant an extension. We are finalizing at § 438.520(b)(1) that an extension request for a requirement under § 438.520 must also include the information described in § 438.515(d)(1) and will be assessed by CMS using the same standards and conditions finalized at § 438.515(d)(3).

Finally, at § 438.520(b)(2), we are finalizing the deadlines by which a State must submit an extension request for a website display requirement, based on whether the requirement must be implemented in phase 1 or phase 2 of the website display implementation. For extensions of the requirements specified in paragraph (a)(2)(v), the extension request must be submitted to CMS no later than September 1 of the fourth calendar year following the effective date of the final rule (that is, September 1, 2028). For extensions of the website requirements specified in paragraph (a)(6) of this section, the extension request must be submitted to CMS no later than four months prior to the implementation date specified by CMS pursuant to paragraph (a)(6) for those requirements. We have chosen this deadline as it maximizes the amount of time that a State has to identify that an extension may be necessary but leaves enough time for CMS to review and provide a determination for the extension request prior to the implementation date.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a) and 457.1240(d) as proposed except we are modifying § 438.520(a) to require that States must prominently display *and make accessible to the public* on the State's Medicaid website required under § 438.10(c)(3) the display requirements in § 438.520(a).

(2) Navigational and Orienting Information (§§ 438.334(e), 438.520(a)(1) and (5), 457.1240(d))

Throughout our pre-rulemaking engagement activities, beneficiaries consistently stated the expectation that State Medicaid websites and the online plan selection processes will be difficult to navigate, and many users shared that they previously had been confused and overwhelmed during the process of selecting a managed care plan. When shown an initial draft MAC QRS prototype, some beneficiaries reported struggling to understand the purpose of the prototype and how and when the information could be useful.

Considering this feedback, we tested a number of features to support users in understanding and navigating potential websites and found that beneficiaries responded positively to live assistance services (such as chat and telephone), and pop-ups and other mechanisms of displaying information to explain content as participants navigated the prototype.

We found that providing upfront clear information about what the MAC QRS is (a State -run, unbiased source of information on managed care plans and their performance) and is not (a sales funnel for a particular managed care plan) and what it can do (help compare available managed care plans and their quality and performance) and what it cannot do (determine eligibility for Medicaid and CHIP or enroll beneficiaries in a health plan) allowed participants to quickly determine the purpose of the MAC QRS and whether the information available will be a useful tool for them when selecting a managed care plan. We also found that some beneficiaries initially needed additional background on relevant programs such as Medicaid, CHIP, and Medicare to understand if they were eligible for, or enrolled in, a plan or program with ratings or information available through the MAC QRS. Once the purpose of the MAC QRS was established, beneficiaries positively responded to features that clearly conveyed how to use the information available in the MAC QRS to select a managed care plan in a simple, easy to understand manner, such as providing the steps to identifying, comparing, and selecting a managed care plan. In our testing prototype, users were wary about entering personal information to help identify and tailor the display of available managed care plans, such as zip code, age, sex, and health conditions–information that can be helpful in navigating a website designed to help individuals select a plan. However, when a clear explanation of how their information will be used, users became more comfortable providing personal information.

Based on these findings from user testing, we proposed certain navigational requirements for the MAC QRS website display requirements in proposed § 438.520(a)(1). Specifically, we proposed in § 438.520(a)(1)(i) that States must provide users with information necessary to understand and navigate the MAC QRS display, including a requirement to provide users with information on the MAC QRS purpose, relevant information on Medicaid, CHIP, and Medicare, and an overview of how the MAC QRS website can be used to select a managed care plan. We proposed in § 438.520(a)(1)(ii) that States must provide information on how to access the beneficiary support system required under existing § 438.71 to answer questions related to the MAC QRS (described in section I.B.6.d. of this final rule). Since beneficiary support systems are not currently required for separate CHIPs, our proposed amendment to § 457.1240(d) excludes references to this requirement. We solicited comments on whether beneficiary supports like those proposed for Medicaid should be required for States for separate CHIP in connection with the MAC QRS information or on a broader basis through future rulemaking. Under proposed § 438.520(a)(1)(iii) for Medicaid, and for separate CHIPs by cross-reference through a proposed amendment at § 457.1240(d), States would be required to explain why user-specific information is requested, inform users of how any information they provide would be used, and whether it is optional or required. Finally, under proposed § 438.520(a)(5), States would be required to provide users with information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. This requirement would ensure that users can easily navigate to the next steps in the plan selection process after reviewing the MAC QRS website.

We noted in the proposed rule that we believe that States could implement these features by relying on information already posted on their websites or expanding current requirements. For instance, States are required to have a beneficiary support system at § 438.71 in place and could train staff who support this system to provide similar support to individuals on navigating the MAC QRS. Through an environmental scan of State Medicaid websites, we found that all States currently have information describing their Medicaid and CHIP programs, as well as programs available to those dually eligible for Medicare and Medicaid. In both phases of the website display implementation, States may use these existing resources to comply with the requirements of proposed § 438.520(a)(1)(i) and (ii) either by hyperlinking to these resources from the MAC QRS website or incorporating existing information into the MAC QRS website display. Finally, we noted that as part of the MAC QRS design guide, we intend to provide plain language descriptions of the information that States would be required to provide under the final rule—for example an overview of how to use the MAC QRS to select a quality managed care plan). We noted that States would be able to use or tailor these CMS-developed descriptions for their MAC QRS websites.

We did not receive any comments on the proposed regulations relating to navigational and orienting information required for the MAC QRS (§§ 438.334(e), 438.520(a)(1) and (5). For the reasons outlined in the proposed rule we are finalizing §§ 438.334(e), 438.520(a)(1) and (5), and 457.1240(d)) as proposed. As discussed in this final rule in Section I.B.6.g, we are finalizing § 438.520(a)(1)(iii) with modification to avoid implying that States may require users to provide log-in credentials prior to using or accessing a State's QRS. This modification aligns with finalized § 438.510(a) establishing that the requirements described in § 438.520(a) must be both prominently displayed *and* accessible to the public on the website required under § 438.10(c)(3).

(3) Tailoring of MAC QRS Display Content (§§ 438.334(e), 438.520(a)(2), 438.520(a)(6) and 457.1240(d))

In conducting user testing to inform development of the proposed rule, we found that testing participants responded positively to features that allowed them to reduce the number of plans displayed to only those that met specific criteria, such as geographic location and eligibility requirements (for example, beneficiary age). However, we also found that testing participants were reluctant to provide information, such as their age, needed for such features unless their privacy concerns were addressed. Providing information on how and why such data would be used generally addressed such privacy concerns. Beneficiaries noted most comfortable providing their age and geographic location to identify health plans and we believe that these data points are likely sufficient to reduce the number of plans available to beneficiaries for comparison while also minimizing burden on States. Furthermore, dually eligible participants responded positively to the ability to easily identify those plans for which they were eligible. Therefore, we proposed at § 438.520(a)(2)(i) for Medicaid, and for separate CHIPs by cross-reference through a proposed amendment at § 457.1240(d), that each State's website must allow users to view available plans for which users may be eligible based on their age, geographic location, and dual eligibility status, as well as other demographic data identified by CMS in display guidance. Under the proposed rule, States would

retain the flexibility to allow users to use additional information or eligibility criteria to further narrow down available managed care plans, such as searching by health condition like pregnancy or diabetes. In both phases of the website display implementation, States could meet this requirement by linking to a PDF that clearly indicates plans available to a beneficiary based on the identified factors (see Prototype A at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*). However, States could instead choose to implement an interactive display that allows the beneficiaries to input information upfront, and then tailors which managed care plans' information is displayed based on this information (see Prototype B at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*).

In our environmental scan of State Medicaid websites, we identified many States that provide such features to help beneficiaries identify plans available to them. We believe this requirement would support the MAC QRS website being a one-stop-shop where beneficiaries could select a plan based on their characteristics or needs. Therefore, we proposed to require the development and use of the MAC QRS website in this manner, which we believe both would support the beneficiary enrollment and disenrollment protections established in section 1932(a)(4)(A) of the Act and would be necessary for the proper and efficient operation of State Medicaid plans, consistent with section 1902(a)(4) of the Act. Based on our testing, we believe that the additional health plan information would be necessary and appropriate for beneficiaries to effectively use the information on plan quality ratings when choosing a managed care plan. Further, providing this flexibility for beneficiaries to choose how certain comparative information is presented is consistent with the requirement in section 1932(a)(5)(C) of the Act. Note that in § 438.505(b), we have extended the requirements in section 1932(a)(5)(C) of the Act to PIHPs and PAHPs, as well as MCOs, under the authority in section 1902(a)(4) of the Act, for States to provide comparative information to beneficiaries about Medicaid managed care plans.

Participants in our user testing also prioritized confirming whether their current provider or prescriptions will be covered under a plan prior to navigating to other details about the plan. Therefore, we proposed at § 438.520(a)(2)(ii) and (iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display drug coverage and provider directory information for each managed care plan in phase one of the website display requirements. This information is already required to be available from managed care plans under existing § 438.10(h)(1) and (2) and438.10(i) which set forth the general requirements for provider directory and formulary information that plans must make available to beneficiaries. In the first phase, States could satisfy the proposed requirements by providing hyperlinks to existing plan formularies and provider directories required under § 438.10(h) and (i) (See Prototype A); this capability would be required under the proposed rule by the general implementation date proposed under § 438.505(a)(2).

As previously mentioned, user-testing participants preferred an integrated search feature that allows them to identify available plans that offered coverage of specific prescription drugs and providers, rather than being directed via hyperlink to each managed care plan's website, which will require them to conduct multiple searches to identify the plans that cover their prescriptions and providers. When consulted during the pre-rulemaking process, States were supportive of the display requirements we ultimately proposed in § 438.520(a)(2) but noted that a searchable formulary or directory would be difficult to design and implement by the implementation date proposed in § 438.505(a)(2). Under § 431.60(a) of the May 2020 CMS Interoperability and Patient Access final rule,[230] States must implement an application programming interface (API) that permits third-party retrieval of certain data specified by CMS, including information about covered outpatient drugs and preferred drug list information (§ 431.60(b)(4)) and provider directory information (§ 431.70(b)). These requirements are applied in Medicaid managed care to MCOs, PIHP, and PAHPs under § 438.242(b)(5) and (6). Therefore, we believe that burden on managed care plans and States to provide the interactive search tools proposed in § 438.520(a)(2) would be minimized given that the data necessary to offer such tools is the same data that plans must make available through an API as specified in § 438.242(b)(5) and (6); States could compile and leverage this existing data to offer the search functionality we proposed. However, we agreed with States that they will need additional time to implement dynamic, interactive website display features. Therefore, we proposed, at § 438.520(a)(6)(i) and (ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that States would be given at least two additional years after a State's initial implementation of their MAC QRS (that is, two additional years after the date proposed at § 438.505(a)(2) for initial implementation) to display provider directory and drug coverage information for each managed care plan through an integrated, interactive search feature that would allow users to identify plans that cover certain providers and prescriptions (see Prototype B). We solicited comment on this phased-in approach and a reasonable timeline for the second phase. In addition, we sought comment on the display requirements and technical assistance needs.

Proposed § 438.520(a)(6)(iii) and (iv) also included the display of stratified quality ratings. In this second phase, States would be required implement an interactive display that allows beneficiaries to view and filter quality ratings for specific mandatory measures (to be identified by CMS). The factors by which the quality ratings would be filtered include the stratification factors already required in phase one under proposed § 438.520(a)(2)(v) (that is, dual eligibility status, race and ethnicity, and sex) plus additional factors identified by CMS for the second implementation phase under § 438.520(a)(6)(iii) including, but not limited to, age, rural/urban status, disability, and language spoken by the enrollees who have received services (see Prototype B). This proposal addressed feedback we received in testing the MAC QRS prototype websites with beneficiaries. We tested dynamic filters that allowed participants to view quality ratings representing services provided only to plan beneficiaries that aligned with participant-selected factors such as race, sex, and age. This feature increased participant positivity and trust in the quality ratings displayed, especially among those who raised concerns about

[230] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. CMS–9115–F. (85 FR 25510).), which appeared in the **Federal Register** on May 1, 2020. (available online at *https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf*).

the uniformity of experience among beneficiaries.

Like our proposal to phase-in interactive plan provider directory and formulary tools, we proposed to phase in the interactive display of quality ratings stratified by various demographic factors. In § 438.520(a)(2)(v) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed a first phase of implementation for this information that will require States to display quality ratings for mandatory measures stratified by factors including dual eligibility status, race and ethnicity, and sex. To reduce burden on States, we proposed to permit States to report the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Access proposed rule.[231] Measuring health plan performance and making quality ratings available on a stratified basis will assist in identifying health disparities. Driving improvements in quality is a cornerstone of the CMS approach to advancing health equity and aligns with the CMS Strategic Priorities. In the first phase of implementation that we proposed for the MAC QRS website display, a State's website would need to provide access to quality ratings that reflect the quality of care furnished to all of a plan's enrollees, as well as quality ratings that reflect the quality of care furnished to these subpopulations of a plan's enrollees (see Prototype A). We noted that this requirement would be consistent with current efforts among measure stewards and other Federal reporting programs, such as the Child and Adult Core Sets, to stratify data by various demographic factors to ensure that disparities in health outcomes are identified and addressed (See Core Set proposed rule, 87 FR 51313). We proposed selecting the same factors required for the Core Sets as our initial stratification factors, as we believe this information would be most likely to be collected as compared to our other potential stratification factors. Furthermore, many testing participants shared their concern that health outcomes and customer experience may vary when stratified by race, ethnicity, or sex. We also believe that those who are dually eligible to receive Medicare and full Medicaid benefits would find it particularly useful to see quality ratings that focus specifically on the experience of such dually eligible beneficiaries. We believe that such ratings would allow beneficiaries who are dually eligible for Medicare and Medicaid to best identify a high-quality health plan, given the unique access considerations among this population. Under the proposed rule, States would be required to display this information by the general MAC QRS implementation date proposed under § 438.505(a)(2). We sought comment on the feasibility of the proposed factors for stratifying quality ratings by the initial implementation date for the first phase of the website display requirements, and whether certain mandatory measures may be more feasible to stratify by these factors than others. We proposed that the interactive tools required under the proposed rule would need to be available no earlier than 2 years after the general MAC QRS implementation date. We requested comment on this proposal, including the timeline for implementation, technical assistance that may be necessary for States to implement the proposed feature, and the proposed factors by which quality ratings should be stratified.

We summarize and respond to public comments received on tailoring the MAC QRS website display content (§§ 438.334(e), 438.520(a)(2) and (a)(6), and 457.1240(d)) below.

Comment: Several commenters supported our proposal to require that display of quality ratings for mandatory measures be stratified by factors identified by CMS. Many commenters shared current challenges related to capturing and reporting high-quality, reliable data that can be used to stratify quality measures and requested that CMS continue to work with States and other interested parties to improve collection of this data, with many requesting that CMS enhance current guidance to standardize data collection for race, ethnicity and language, sexual orientation and gender identity (SOGI), and Social Determinants of Health information so that these data can be stratified. Many commenters requested that we require age, language and rural/urban status be implemented as stratification factors in phase 1 instead of phase 2, because they thought that this information is easily accessible to plans and the State. Several commenters requested that we clarify that we would require States to display quality ratings for mandatory measures stratified by all the factors listed in § 438.520(a)(6)(iii) in the second phase of MAC QRS website implementation. Many commenters requested that we add to or modify our proposed stratification factors to include SOGI and that we stratify not by disability as proposed, but by disability type. One commenter requested that we include pregnancy as a stratification factor.

Response: We recognize that stratification of measures is an evolving area and CMS will continue to provide guidance and technical assistance to support States and plans in the collection of data necessary to implement CMS required stratification factors. We are declining to finalize changes to the stratification factors implemented in phase 1, as we continue to believe that data on dual eligibility status, race and ethnicity, and sex are most accessible to States and likely to be collected as compared to the other stratification factors that are identified in proposed § 438.520 for Medicaid and through a cross-reference at revised § 457.1240(d) for separate CHIP. We are also declining to identify a definitive list of stratification factors for phase two, though we encourage States to include additional stratification factors in either phase if they have the data to do so. We agree that the stratification factors proposed by commenters are important in highlighting areas of inequity and we intend to consider SOGI, pregnancy, and disability type as stratification factors for phase two of website implementation. When issuing guidance on stratification of mandatory measures, we will consider whether stratification is currently required by the measure steward or other CMS programs and by which factors, in accordance with our finalized provisions at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d).

Comment: Most commenters supported the additional website components proposed in § 438.520(a)(6) for phase two, including the searchable formulary and provider directories and an interactive tool that allows user to view plan ratings stratified by factors identified by CMS. A couple of commenters questioned the utility of the phase 2 requirements and whether they would provide beneficiaries with tools and information that are important to beneficiaries.

Response: We appreciate the support commenters gave to the additional website components and disagree with commenters that questioned the utility and desirability of the tools and information required in phase 2 of the MAC QRS website display. These features were identified as desirable to MAC QRS users through the extensive user testing described in section I.B.6.g

[231] See Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting, 87 FR 51303 page 51328 (finalized at 42 CFR 437.10(b)(7) in 88 FR 60278) and Medicaid Program; Ensuring Access to Medicaid Services, 88 FR 27960 page 28084.

of the proposed rule. The formulary and provider search tools were developed directly from beneficiary input that they often have several prescribed medications, several providers, or both and searching each available plan's formulary or provider directory to determine coverage of a drug and their current provider(s) is time-consuming and unrealistic. Once we presented a website prototype that included these tools, they were consistently identified among the most desirable features. As noted previously, the provider directory and preferred drug list data available through the MAC QRS tools is the same data that plans must make available through an API as specified in § 438.242(b)(5) and (6) and States could compile and leverage this existing data to offer the required search functionality. Additionally, our proposal to display stratified quality ratings was based on initial conversations with beneficiaries during which participants frequently shared their own experience with health inequities and, once stratified ratings were included in the prototype, we consistently received positive feedback from users who found it meaningful to understand the quality of care provided to ''people like them'' who are enrolled in a health plan.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a)(2) and 457.1240(d), including the redesignation of the requirements about the availability of MAC QRS information from § 438.334(e) as proposed. We are also finalizing § 438.520(a)(6) with modification to narrow the scope of the requirements proposed in § 438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan's network. In this final rule we are applying these requirements only to managed care plans that participate in managed care programs with two or more participating plans.

(4) Plan Comparison Information (§§ 438.334(e), 438.520(a)(3) and 457.1240(d))

Our prototype testing showed that participants were often frustrated and confused by the need to navigate multiple websites to obtain health plan information (such as out of pocket expenses, plan coverage of benefits, providers, and prescription drug coverage) and health plan metrics (such as average time spent waiting for care, weekend and evening hours, and appointment wait times). When all this information was compiled into a standardized display along with quality ratings in our website prototype, participants responded positively. They found the ability to compare plans on out-of-pocket expenses and covered benefits to be particularly useful. After identifying available plans that aligned with their needs and preferences on these two variables, some participants reflected that they would use quality ratings as an additional way to narrow down and filter their options. When presented alongside quality ratings, this information allowed beneficiaries to better compare plans. Based on this testing, we proposed in § 438.520(a)(3) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display, for each managed care plan, standardized information identified by CMS that would allow users to compare available managed care plans and programs, including the name, website, and customer service telephone hot line for the plan; premium and cost sharing information; a summary of covered benefits; certain metrics of managed care plan access and performance; and whether the managed care plan offers an integrated Medicare-Medicaid plan. Under proposed § 438.520(a)(3)(iii) and (iv), States would be required to identify comparative information about plans, specifically differences in premiums, cost-sharing, and a summary of benefits including differences among managed care plans, to help users quickly identify where managed care plans do and do not differ. We believe that this information should be readily available to States and that providing comparative information of this type is consistent with the information disclosure requirements in section 1932(a)(5) of the Act. These requirements were illustrated in Prototypes A and B.

Under proposed § 438.520(a)(3)(v), States would also be required to provide on their MAC QRS website certain metrics of managed care plan performance that States must make available to the public under part 438, subparts B and D of the Medicaid regulations, including certain data most recently reported to CMS on each managed care program under § 438.66(e) (Medicaid only) and the results of a secret shopper survey proposed at § 438.68(f). Proposed paragraph (a)(3)(v) would authorize CMS to specify the metrics that would be required to be displayed. States already report information related to grievances, appeals, availability, and accessibility of covered services under § 438.66(e) and we believe that providing some of this information on the MAC QRS website would be responsive to input we received from our testing participants and improve transparency for beneficiaries without imposing significant burden on States since the information is already reported to us. Under the proposed rule, States could integrate these metrics into the display of MAC QRS measures on the MAC QRS website or, as illustrated in Prototypes A and B, they could provide a hyperlink to an existing page with the identified information in the MAC QRS web page. We noted that these proposed requirements also would support our goal for the MAC QRS to be a one-stop-shop where beneficiaries can access a wide variety of information on plan quality and performance in a user-friendly format to help inform their plan selection. We sought comment on the inclusion of metrics to be specified by CMS, and whether we should consider phasing in certain metrics first before others.

Lastly, at § 438.530(a)(3)(vi), we proposed to require States to indicate when a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D–SNP, and to provide a link to the integrated plan's rating under the MA and Part D quality rating system. (The definitions of fully integrated dual eligible special needs plan and highly integrated dual eligible special needs plan are at 42 CFR 422.2.) We believe this is the simplest and most efficient way to help dually eligible users understand how to use the two quality ratings together. Both Prototype A and B illustrate this requirement through a hyperlink to the integrated plan's MA and Part D quality rating. We sought comment on these requirements and requested feedback on the feasibility of providing this information on plan integration and MA and Part D ratings by the date initial implementation date.

We summarize and respond to public comments received on the proposed requirements for the MAC QRS website to include plan comparison information (§§ 438.334(e), 438.520(a)(3), and 457.1240(d)) below.

Comment: A couple of commenters recommended including additional plan comparison information about the accessibility of covered benefits, such as an indication of the services and drugs that require prior authorization by the plan and appointment wait times.

Response: We agree that including information on the extent to which a covered service is accessible to beneficiaries (such as whether prior authorization is required and appointment wait times) is desirable and helpful to beneficiaries. Our proposed regulations give CMS discretion to include information about prior authorization requirements related to drug coverage as ''other similar information'' under § 438.520(a)(2)(ii), which requires States to provide a description of the drug coverage of each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS. To respond to requests to provide prior authorization information for both drugs and services, and to align with § 438.520(a)(2)(ii), we are modifying § 438.520(a)(3)(iv) to add discretion for CMS to specify, in addition to requiring that the MAC QRS website display a summary of benefits including differences in benefits among available managed care plans within a single program, other similar information on benefits to be included on the website such as whether access to the benefit requires prior authorization from the plan. This modification also aligns with § 438.520(a)(3)(v), which provides CMS with the discretion to require States to display in their MAC QRS metrics of existing managed care performance that States already report to CMS under subparts B and D of this part. We intend to include access metrics from these sources, including the Access Standards Report required in § 438.207(d) through (f), which include new requirements to establish and report on standards for appointment wait times finalized in this final rule at § 438.207(f).

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a)(3) and 457.1240(d) as proposed and with a modification at § 438.520(a)(3)(iv) to add discretion for CMS to require States to include on the MAC QRS website, in addition to displaying a summary of benefits including differences in benefits among available managed care plans within a single program, other similar information on benefits such as whether access to the benefit requires prior authorization from the plan. We are also finalizing the proposed changes to § 438.334.

(5) Information on Quality Ratings (§§ 438.334(e), 438.520(a)(4), 438.520(c) and 457.1240(d))

Our user testing found that participants were initially skeptical of data provided in the MAC QRS, stating confusion regarding the source of the data used and mistrust in the ratings generated because they were uncertain how they were derived. Additionally, some participants stated that they did not trust information from the health plans. In an effort to improve user trust through data transparency, we tested providing clear and comprehensive information on displayed quality ratings and identified three types of information that together resulted in increased participant trust of the quality ratings. These include descriptions of the quality ratings in plain language, how recent the data displayed are, and how the data were confirmed to be accurate. Based on this user feedback, in § 438.520(a)(4)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States will provide plain language descriptions of the importance and impact of each quality measure. We found that a simple explanation of what a quality measure is assessing, as well as how the measure relates to a beneficiary's health and well-being, were most helpful to users in understanding displayed quality ratings. A simple explanation will satisfy the proposed requirement. Both Prototype A and B include example explanations for our proposed mandatory measures, and we intend to include a sample explanation of the quality ratings for each final mandatory measure in the design guide discussed in section I.B.6.g. of the proposed rule, which States may choose to use.

Users responded positively to information that showed when data were collected and whether data were validated. They appreciated knowing that an external, neutral organization calculated the measures, noting that they will not trust the measures if they were calculated solely by the managed care plan. In § 438.520(a)(4)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States be required to indicate the measurement period during which data were produced to calculate the displayed quality ratings. In § 438.520(a)(4)(iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States must provide on the MAC QRS website when, how, and by whom quality ratings have been validated. Under our proposal, this information would be provided in plain language and convey the role of parties (other than the rated plans) in validating data used to calculate the quality ratings, which will promote transparency and trustworthiness in the data. We note that States may use the External Quality Review optional activity described at § 438.358(c)(6) for EQRO assistance with quality ratings and link to the validated data included in the EQR technical reports. We solicited comments on the display requirement proposed in § 438.520(a)(4) and request feedback on the feasibility of implementing these requirements by the initial implementation date proposed at § 438.505(a)(2).

Finally, we believe that user preferences for how information should be displayed may change over time as the available data and the technology that enables website display of available data evolves. To ensure that the MAC QRS website continues to be a useful tool, we intend to periodically engage in additional consultations with MAC QRS users as part of a continuous improvement approach. We proposed in § 438.520(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS periodically consult with interested parties, including MAC QRS users such as Medicaid and CHIP beneficiaries and their caregivers, to maintain and update the website display requirements for the information required in proposed § 438.520(a). These consultations may result in proposed changes through rulemaking that add to or refine existing requirements or remove existing requirements that beneficiaries no longer find useful.

We did not receive any comments in response to our proposals for the MAC QRS website to include certain information about the published quality ratings and, for the reasons outlined in the proposed rule, we are finalizing §§ 438.520(a)(4) and (c), and 457.1240(d) as proposed along with the proposed changes to § 438.334.

(6) Display of Additional Measures Not on The Mandatory Measure Set (§§ 438.334(e), 438.520(c) and 457.1240(d))

Section § 438.510(a), as proposed and finalized at § 438.510(a)(2), provides that States will have the option to display additional measures that are not included in the mandatory measure set if the two requirements set forth in proposed § 438.520(b)(1) and (2) (finalized at § 438.520(c)(2)(i) and (ii))

are met. The same standards will apply to separate CHIP as proposed in § 457.1240(d) by cross-referencing part 438, subpart G.

The first requirement, proposed in § 438.520(b)(1), would require a State that chooses to display quality ratings for additional measures not included in the mandatory measures set described in § 438.510(a), to obtain input from prospective MAC QRS users, including beneficiaries, their caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy. In both the proposed rule and this final rule, we have extensively noted the importance of the prospective user testing we engaged in and the extent to which this feedback directed our design of the MAC QRS framework and selection of the preliminary mandatory measure set. Just as beneficiary participation was, and will continue to be, critical in our design of the MAC QRS, we believe beneficiary participation is critical in the identification of any additional measures included in a State's MAC QRS. States could meet this requirement by ensuring that beneficiary members of the MCAC are present when obtaining input from the State's MCAC, or may engage in direct beneficiary interviews, focus groups, or prototype testing.

The second requirement, proposed at § 438.520(b)(2), would require that States must document the input received from prospective MAC QRS users on such additional measures, the modifications made to the proposed additional measures in response to the input, and rationale for not accepting input. We also proposed this documentation to be reported as part of the MAC QRS annual report proposed under § 438.535(a)(3). For States that currently publish a QRS-like website, measures that are not in the mandatory measure set will be considered additional measures and will be subject to this process prior to display. If a State obtained user input for the additional measure prior to displaying the measure on its current website, the State may use this input to meet this requirement.

We did not receive any comments in response to our proposals authorizing display of additional measures not on the mandatory measure list, subject to requirements for States to obtain and document input on the additional measures. For the reasons outlined in the proposed rule, we are finalizing the provisions proposed at §§ 438.520(b) and 457.1240(d) largely as proposed and the proposed changes to § 438.334(e), except that we are finalizing these provisions at § 438.520(c)(2) to address the addition of new paragraph § 438.520(b) finalizing an implementation extension for certain website requirements. Furthermore, we are modifying paragraph (c) to clearly establish that States may implement additional website features not described in § 438.520(a) in their MAC QRS (to align with modifications to § 438.505(a)(1)(ii) establishing the same), including the display of additional measures not included in the mandatory measure set.

h. Alternative Quality Rating System (§§ 438.334(c), 438.525 and 457.1240(d))

Current regulations at § 438.334(c) allow States, with CMS approval, to implement an alternative managed care quality system (alternative QRS) that uses different quality measures or applies a different methodology if the conditions set forth in § 438.334(c)(1)(i) through (iii) are met, including that the measure or methodology must be substantially comparable to the measures and methodology established by CMS under the MAC QRS framework. Based on feedback we received during our engagement with States and other interested parties, we proposed to redesignate § 438.334(c) at § 438.525 for Medicaid and to modify the current policy by narrowing the changes that would require our approval. We proposed to apply the same requirements for both Medicaid and separate CHIP managed care programs by revising § 457.1240(d) to require States to comply with § 438.525.

First, we proposed to remove the requirement in current § 438.334(c)(1) that CMS must approve use of ''different performance measures'' as part of CMS's approval of an alternative QRS prior to a State's use of the different measures. Current regulations at § 438.334(c)(1) require States to submit for our review and approval an alternative QRS request to include measures different than those included in the mandatory measure set identified by CMS. We believe requiring States to obtain our approval to include measures not included in the mandatory measure set creates unnecessary administrative burden for both States and CMS. Under the proposed regulation, instead of requiring approval of different measures, we proposed that States would be required to include all measures in the mandatory measure set identified by CMS in their MAC QRS, but that they would have the flexibility to add additional measures without prior approval from CMS.

We highlighted that the measure specifications established by measure stewards for measures in the mandatory measure set established by CMS under proposed § 438.510(a) are not considered part of the methodology described in proposed § 438.515, and therefore, States would not have an option to request changes to mandatory measure technical specifications under our proposal at § 438.525. We stated that modifications to measure specifications that are approved by the measure steward would not require a State to request approval of an alternative QRS in order to use the steward-approved modifications. These steward-approved modifications could include allowable adjustments to a measure's specifications published by the measure steward or measure specification adjustments requested from and approved by the measure's steward. However, we noted in the proposed rule that we would consider quality ratings calculated for a mandatory measure to be ratings for a different measure if the modifications have not been approved by the measure steward. We believe that this policy provides flexibility to States while ensuring that ratings for mandatory measures remain comparable among States because measure specification modifications approved by a measure steward have been reviewed and subjected to the measure steward's own process to ensure that modified specifications allow for comparisons across health plans.

Second, we proposed to further define the criteria and process for determining if an alternative methodology is substantially comparable to the MAC QRS methodology described in proposed § 438.515. The current regulations at § 438.334(c)(4) provide that we would issue guidance on the criteria and process for determining if an alternative QRS meets the substantial comparability standard in § 438.334(c)(1)(ii). We proposed to eliminate § 438.334(c)(4) and redesignate the requirements for an alternative QRS methodology as proposed § 438.525(c)(2)(i) through (iii). We also proposed at § 438.525(c)(2)(iv) that States would be responsible for submitting documents and evidence that demonstrates compliance with the substantial comparability standard. We believe eliminating § 438.334(c)(4) was appropriate as this rulemaking provides an opportunity for States and other interested parties to submit comments on how CMS should evaluate alternative quality rating systems for substantial comparability.

We indicated in the proposed rule that we intend to issue future instructions on the procedures and the dates by which States must submit an alternative QRS request to meet the

implementation date specified in proposed § 438.505(a)(2). For requests for a new or modifications of an existing alternative QRS made after the proposed implementation date, we indicated we would consider accepting rolling requests instead of specifying certain dates or times of year when we would accept such requests. We believe this would be necessary given that States may have different contract cycles with managed care plans. We solicited comment on these different approaches.

Current § 438.334(c)(2) describes the information that States would submit to CMS as part of their request to implement an alternative QRS. We proposed to redesignate and revise § 438.334(c)(2) at § 438.525(c)(2)(iv) to allow States to provide additional supporting documents and evidence that they believe demonstrates that a proposed alternative QRS will yield information regarding managed care plan performance that is substantially comparable to that yielded by the MAC QRS methodology developed by CMS and described in proposed § 438.515(b). Examples of such additional supporting documents could include a summary of the results of a quantitative or qualitative analysis of why the proposed alternative methodology yields ratings that are substantially comparable to the ratings produced using the methodology required under § 438.515(b).

We solicited comments on these proposals, in particular, the described process and documentation for assessing whether a proposed alternative QRS framework is substantially comparable, by when States will need alternative QRS guidance, and by when States will need to receive approval of an alternative QRS request to implement the alternative by the implementation date specified in proposed § 438.505(a)(2).

We summarize and respond to public comments received on the alternative quality rating system section (§§ 438.334(c), proposed 438.525, and 457.1240(d)) below.

Comment: We received comments both in support of the flexibility provided for use by a State of an alternative QRS, as well as some concerns about how it would reduce standardization. Those commenters in support appreciated the flexibility that an alternative QRS would provide and requested timely approvals of alternative QRS requests by CMS (that is, within 1 year of the final rule) and technical assistance on the substantial comparability standard. Many commenters emphasized the importance of both a standardized set of measures and a standardized methodology for calculating those measures. These commenters raised concerns that the alternative QRS may reduce alignment with other quality rating systems and that substituting mandatory measures or calculating quality ratings for mandatory measures without the CMS methodology or the measure steward's technical specifications would create unnecessary complexity for plans and undermine the ability to make inter-State comparisons among MAC QRS plans.

Response: We agree with commenters about the importance of alignment and standardization for the MAC QRS for the methodology for calculating quality ratings for mandatory measures and the mandatory measure set and believe that our proposal has sufficient guardrails to address these concerns. Regarding concerns related to the standardization of mandatory measures, we do not agree with commenters that the flexibility to use an approved alternative rating methodology will impact the standardization of the mandatory measures set as this flexibility does not permit a State to substitute a mandatory measure with another measure that is ''substantially comparable.'' Regardless of whether a State applies the CMS methodology or an approved alternative methodology, per finalized § 438.510(a), all States must include the mandatory measures that are applicable to the State's managed care program in their QRS.

In response to the concerns stated by commenters related to the standardization of quality ratings produced using the CMS methodology versus an approved alternative rating methodology, we believe that standardization of the MAC QRS quality ratings will be maintained due to the limitations on the scope of the alternative methodology flexibility and the substantial comparability standard proposed at § 438.525(a)(2) and finalized at § 438.515(c)(1)(i). As we discussed in section I.B.6 of the final rule, the policy we proposed and are finalizing permits a State to request approval to use an alternative rating methodology to the methodology finalized at § 438.515(b) for Medicaid, and in separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Subject to the undue burden standard finalized at § 438.515(a)(1)(ii), (2), and (3), all States must ensure that MAC QRS quality ratings comply with the requirements related to data collection, data validation, performance rate calculation, and issuance of quality ratings finalized in § 438.515(a). Additionally, prior to approval, a State must demonstrate that any alternative methodology generates ratings that yield information on plan performance that is ''substantially comparable'' to information yielded by the CMS methodology (that is, the methodology required by § 438.515(b)).

In response to concerns related to the calculation of MAC QRS quality ratings that do not align with the measure steward's technical specification, as we discussed in section I.B.6.h. of the proposed rule and in section I.B.6.f. of this final rule, the measure steward specifications for a mandatory measure are not part of the methodology identified in § 438.515(b) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d). Those specifications are inherently part of the mandatory minimum measure set that all States must use when the State's managed care program covers the service or action assessed by the measure. Per finalized § 438.510(a)(1), States must display applicable mandatory measures as described by CMS in the technical resource manual, which will include the measure steward specifications for measures in the mandatory set as well as guidance on calculating and issuing quality ratings. As discussed in section I.B.6.f. of the proposed rule, such technical specifications could include allowable adjustments identified by the measure steward as well as adjustments approved by the measure steward for an individual State. As such, regardless of whether a State applies the CMS methodology or an alternative methodology, a State must calculate quality ratings for applicable mandatory measures using technical specifications approved by the measure steward. Furthermore, as required under § 438.535(a)(6) and discussed in section I.B.6.j. of the proposed rule, CMS will require States to report the use of any technical specification adjustments to mandatory measures that are outside the measure steward's allowable adjustments, which the measure steward has approved for use by the State or a plan within the State. This will allow CMS to better understand if the flexibility to use such adjustments impact plan-to-plan comparability or comparability within and among States.

In combination, we believe that quality ratings for mandatory measure produced in line with these policies, whether calculated using the CMS methodology or an approved alternative rating methodology, will be sufficiently standardized and allow ratings that are comparable among States. To ensure that these guardrails remain sufficient, CMS will monitor the use of alternative rating methodologies among States to

determine if additional guardrails are necessary to maintain alignment and standardization of the MAC QRS mandatory measure set and methodology. In response to commenters' concerns about maintaining the ability to make inter-State comparisons of MAC QRS measures, we believe that the guardrails that maintain alignment and standardization also ensure the ability to make these inter-State comparisons.

Comment: One commenter recommended we update the reference to the MCAC in § 438.525(b)(1) to align with proposed changes to § 431.12, renaming the MCAC as the Medicaid Advisory Group, and creating a new Beneficiary Advisory Group.

Response: As described in section I.B.6.a. of this rule, we received many comments noting a general concern about the administrative complexity and the time and resources needed to implement the MAC QRS in light of other Medicaid requirements established in the proposed rule. In that section we also outline several changes that we are finalizing in this rule after considering how to reduce the overall implementation burden of the MAC QRS. One of these changes is the removal of the requirement that States obtain input from their Medical Care Advisory Committee and provide an opportunity for public comment on the State's proposed alternative rating system or modification to an approved alternative rating system. We believe that eliminating these consultation and public notice and comment requirements will reduce burden on States to implement an alternative QRS methodology with minimal impact on the availability of desirable information. While the MCAC plays an important role in providing feedback within State Medicaid programs, we believe that it could be overly burdensome for States to present methodology changes, many of which may be highly technical and nuanced, in a way that will elicit actionable feedback through the MCAC and a public comment process. In response to the suggestion that we rename the MCAC, as noted, we are removing reference to the MCAC in the final rule.

Comment: Several commenters believed that the alternative methodology would provide a pathway for States to substitute mandatory measures with alternative measures or substitute website display requirement for alternative website display features or to exempt them from some website display features altogether.

Response: As proposed and finalized, the ability of a State to use an alternative methodology does not include authority to modify either the mandatory measure set or the minimum website display requirements in § 438.520. We are finalizing this proposal in this final rule largely as proposed, but we are modifying how the alternative QRS requirements are described and organized in this final rule to address the confusion stated by commenters.

To address the confusion from commenters on the scope of the of the alternative methodology, we are finalizing modifications to the proposed regulation. First, as described in section I.B.6.g.4 of the proposed rule, we proposed to modify current regulations at § 438.334(c)(1) to no longer require States to obtain CMS approval if they wished to include measures different than those included in the mandatory measure set identified by CMS because we believe that requiring approval of additional, different measures not required in the mandatory measure set creates unnecessary burden for States and CMS. To implement this change, we also proposed at § 438.520(b) (finalized at § 438.520(c)) that States would have the flexibility to add measures that are not mandatory measures without prior approval from CMS. Under our proposal, States could add additional measures beyond those identified by CMS without CMS approval, but neither the current regulations at § 438.334(c), nor our proposal, would have allowed States to substitute mandatory measures with different measures. This final rule also does not permit States to substitute mandatory measures with different measures. Ratings for the mandatory measures must always be published when the mandatory measures are applicable to the State's managed care program (see section I.B.6.f. for additional detail). How those ratings are calculated under the State's MAC QRS may be changed using an alternative methodology, subject to CMS approval.

As the proposed alternative QRS provision in § 438.525 provides States with the flexibility to request to apply an alternative methodology only, we are removing references to ''alternative MAC QRS'' throughout this subpart and using instead the term ''alternative QRS methodology'' in the regulation text. Throughout this final rule, we use the terms ''alternative QRS methodology,'' ''alternative methodology,'' or ''alternative rating methodology'' to focus on the limits of what type of alternative is available to States. We proposed at § 438.525 and are finalizing at § 438.515(c) the requirements to receive approval to apply an alternative QRS methodology in part 438. (As discussed in a prior response to a public comment, we are not retaining the requirement that the State consult with the MCAC or engage in a public notice and comment process before seeking approval from CMS of the State's alternative QRS methodology). As § 438.515(b) codifies the requirements for the MAC QRS methodology, we believe that codifying the authority and parameters for State use of an alternative QRS methodology in the same section addresses the confusion around the scope of the authority for States to have an alternative rating methodology. We also believe that including the alternative methodology provisions in § 438.515, where the CMS methodology is codified, is more consistent with the MAC QRS framework definition in § 438.500, which, as finalized, describes the MAC QRS methodology as either the CMS methodology or an alternative methodology approved by CMS. We are also finalizing a conforming modification at § 438.505(a)(1)(i) to reflect the new location of the alternative QRS methodology provisions.

Second, we are finalizing a new provision, at § 438.515(c)(3), to further establish the scope of the flexibility to implement an alternative methodology. As finalized, (c)(3) establishes that CMS will not review or approve requests to implement a MAC QRS that does not comply with the requirements to include mandatory measures established in § 438.510(a)(1), the general requirements for calculating quality ratings established in § 438.515(a)(1) through (4), or the requirement to include the website features identified in § 438.520(a)(1) through (6). We are also finalizing that CMS will not review or approve requests to implement additional measures or website features as these are permitted, without CMS review or approval, as established in § 438.520(c). Lastly, we are finalizing that CMS will not review or approve requests to include plans that do not meet the threshold established in 483.515(a)(1)(i), which State may choose to do as appropriate as discussed in section I.B.6.f. We believe that new paragraph (c)(3) gives States clarity in the requests to use an alternative methodology that may be submitted to CMS under § 438.515(c) while also reducing burden on States to ensure that they do not design a MAC QRS that does not comply with the general rule in § 438.505(a).

Thirdly, we are not finalizing § 438.525(a)(1), which proposed that an alternative QRS includes the mandatory

measures identified by CMS under § 438.510(a). This provision is duplicative of finalized § 438.510(a)(1), which requires States to include applicable mandatory measures in their MAC QRS, regardless of whether the State uses the CMS or an alternative methodology.

Finally, we are addressing technical errors in the proposed rule. We are modifying proposed § 438.525(a) (moved to § 438.515(c)(1) in the final rule), which permits States to implement a MAC QRS that applies an alternative methodology from that described in § 438.510(a)(3). Proposed § 438.525(a) should have cited § 438.515(b), which describes the MAC QRS methodology established by CMS instead of § 438.510(a)(3) (there is no paragraph (a)(3) proposed in § 438.510). The purpose of the cross reference was to make clear that requests to implement an alternative methodology may be requested and approved for the methodology requirements in § 438.515(b). At § 438.515(a)(3) we proposed to require States to ''use the methodology described in paragraph (b)'' of § 438.515. Additionally, we proposed that the methodology requirements in § 438.515(b) were subject to the flexibility to implement an alternative methodology in § 438.525 and finalized at § 438.515(c)(1). These two proposals show our intention to establish § 438.515(b) as the CMS methodology and to require States to implement those requirements unless the State received CMS approval to apply an alternative methodology under flexibility proposed in § 438.525 and finalized at § 438.515(c). We are also making conforming technical changes to the provision proposed at § 438.525(a)(2), which is moved to § 438.515(c)(i) in the final rule, by citing specifically to § 438.515(b) describing the CMS methodology instead of more broadly to § 438.515. These technical changes apply equally to separate CHIP by cross-reference through an amendment at § 457.1240(d).

i. Annual Technical Resource Manual (§§ 438.334, 438.530 and 457.1240(d))

We proposed at §§ 438.530(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS would develop and update annually a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, and update it annually thereafter. Providing clear and detailed information for reporting on MAC QRS measures not only supports States in implementing their MAC QRS but is also essential for consistent reporting and comparable quality ratings across States and managed care plans. This manual will include information needed by States and managed care plans to calculate and issue quality ratings for all mandatory measures that States will be required to report under this final rule. This includes the mandatory measure set, the measure steward technical specifications for those measures, and information on applying our proposed methodology requirements to the calculation of quality ratings for mandatory measures. We proposed we would publish an initial technical resource manual following the final rule and would update the manual annually thereafter to maintain its relevance. We considered releasing the technical resource manual less frequently than annually, but we did not believe this manual could be properly maintained unless it is updated annually due to the inclusion of updates to the technical specifications for the mandatory measures.

Proposed § 438.530(a) identifies the components of the technical resource manual that would be issued by CMS. As described in § 438.530(a)(1), we proposed to use the technical resource manual to identify the mandatory measures, as well as any measures newly added or removed from the previous year's mandatory measure set. We intend for the first technical resource manual to include details on the initial MAC QRS mandatory measure set.

These content requirements for the technical resource manual proposed at new § 438.530(a)(1) through (3) include the following:

- The mandatory measure set so States know what they are required to report.
- The specific MAC QRS measures newly added to or removed from the prior year's mandatory set, as well as a summary of the engagement and public comments received during the engagement process in § 438.510(b) used for the most recent modifications to the mandatory measure set. To provide a complete picture of any changes being made to the MAC QRS measures, we proposed this summary to include a discussion of the feedback and recommendations received, the final modifications and timeline for implementation, and the rationale for recommendations or feedback not accepted.
- The subset of mandatory measures that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by CMS in the annual technical resource manual as required under § 438.520(a)(2)(v) and (6)(iii). We discuss the rationale for inclusion of stratification in section I.B.6.g.2. of this final rule.
- How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans. We sought comment on which topics States and health plans would like technical assistance or additional guidance to ensure successful implementation of the rating system.
- Technical specifications for mandatory measures produced by measure stewards. We believe this information will assist States and health plans in the calculation of quality ratings for mandatory measures and aligns with the practices of the Adult and Child Core Set, the MA and Part D quality rating system, and the QHP quality rating system.

Lastly, at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed a general rule that CMS consider stratification guidance issued by the measure steward and other CMS reporting programs when identifying which measures, and by which factors, States must stratify mandatory measures. We stated that we plan to implement a phased-in approach that would increase over time the total number of mandatory measures for which data must be stratified. We also proposed to phase-in the factors by which data would be stratified. We stated our intent to align with the stratification schedule proposed in § 437.10(d) of the Mandatory Medicaid and CHIP Core Set Reporting Proposed Rule (see 87 FR 51327). We believe this alignment with the Core Set stratification will minimize State and health plan burden to report stratified measures. For any MAC QRS measures that are not Core Set measures, we will consider, and align where appropriate, with the stratification policies for the associated measure steward or other CMS reporting programs. We described additional information regarding MAC QRS stratification requirements in section I.B.6.g.2. of the proposed rule.

Based on feedback we received through listening sessions with interested parties, we considered releasing an updated technical resource manual at least 5 months prior to the measurement period for which the technical resource manual will apply. This aligned with the proposed date for the first technical resource manual of August 1, 2025, for a 2026 measurement year, and ensured that States have enough time to implement any necessary changes before the

measurement period and, if necessary, submit and receive approval for an alternative QRS request. In our listening sessions, interested parties noted that this timeline will align with those used by other measure stewards (for example, NCQA for HEDIS measures) and will ensure that States and managed care plans are able to identify and make necessary contractual, systems, and data collection changes to facilitate additional data collection required for the upcoming measurement period. We sought comment on whether this timing is appropriate for States to implement any changes included in the reporting and technical guidance for the initial measurement year, as well as subsequent measurement years.

We summarize and respond to public comments received on our proposals related to the annual technical resource manual (§§ 438.334, 438.530, and 457.1240(d)) below.

Comment: We received comments related to our proposed date for releasing the initial technical resource manual, and comments pertaining to future release dates. In general, these comments requested that we release the technical resource manual information earlier than 5 months prior to the measurement year, including requests for releasing the manual at least 9 months or 12 months before the start of the measurement year. Additionally, some commenters urged us to better align the timing of the release of the annual technical resource manual with the timeline used by measure stewards to update their measure specifications.

Response: Based on commenter's feedback, we are modifying how the technical resource manual information identified in § 438.530(a) will be released. We considered whether we could release a technical resource manual 9 to 12 months prior to the measurement year as a couple of commenters requested and still include all the information identified in § 438.530(a). We found that this timeline is not feasible because we cannot guarantee that the information identified in § 438.530(a) will exist 9 to 12 months prior to the measurement year to which the technical resource manual applies. For example, under § 438.530(a)(1)(ii) and (a)(4), CMS must include the list of measures newly added or removed from the prior year's mandatory measure set and the summary of interested party engagement and public comments. At 9 to 12 months prior to the measurement year, CMS will likely still be engaged in the subregulatory process proposed in § 438.510(b) and unable to publish a manual with the final decision from that process.

Though it is not feasible to release the technical resource manual 9 to 12 months prior to the measurement year, we believe that we can get the information identified in § 438.530(a) to States as early as reasonably possible by releasing the information in installments as the content of the manual is available throughout the year (as opposed to releasing all such information at the same time and in one document, as proposed). Therefore, we are finalizing at § 438.530(a) that CMS may publish the technical resource manual information identified in § 438.530(a) in installments throughout the year to give CMS the flexibility to publish the individual pieces of information identified in § 438.530(a) as they are available. For instance, as finalized CMS can release an updated list of mandatory measures, as required under § 438.530(a)(1)(ii), and the summary of the subregulatory process used to identify the updated mandatory measure set, as required under § 438.530(a)(4), prior to releasing the technical specifications, as required under § 438.530(a)(3).

We have also determined a need to modify the release date of the first complete technical resource manual from August 1, 2025 to CY 2027. We arrived at this determination after considering a commenter's input that our proposed release date could align more closely with when the measure stewards update their specifications. We reviewed schedules for measure stewards' annual updates and found that the technical specifications for measurement year 2026 will not be available by the proposed technical resource manual release date in CY 2025. For example, NCQA, which is the measure steward for 12 of the measures in the initial mandatory set, currently finalizes their technical specifications in the second quarter of the measurement year in which the technical specifications apply. To ensure that the technical specifications for the initial measurement year in 2026 align with the measure steward technical specifications for the same year, CMS can release those technical specifications no earlier than CY 2027. States will then be able to use this information as they calculate quality ratings for MY 2026 in CY 2027. As States and health plans are accustomed to receiving technical specifications in the measurement year to which they apply, after data collection has begun, we believe that receiving the specification soon after the measurement ends will not impact State's ability to collect the data necessary to calculate quality ratings for mandatory measures.

Furthermore, because the guidance on the application of the methodology used to calculate and issue quality ratings required under § 438.530(a)(2) is related to the technical specifications, the release date for this information would need to be pushed back as well. Additionally, the summary of information of the subregulatory process that must be included in the technical resource manual under § 438.530(a)(4) will not be available by August 1, 2025 as proposed. In section I.B.6.e.3 of the proposed rule, we discussed options for when we could begin implementing the subregulatory process to update the mandatory measure set finalized at § 438.510(b). Due to commenters support for our proposal to update the mandatory measure set no less than every 2 years, we intend to implement the subregulatory process by which these updates will be made no less than two years after the final rule, so beginning in CY 2026. (See section I.B.6.e.3 for a discussion of the final policy to engage in the public consultation process to evaluate the mandatory measure set every 2 years.)

Therefore, we are finalizing that CMS will begin annual publication of the complete technical resource manual in CY 2027. In combination with our modification to allow the technical resource information to be released in increments throughout the year to account for instances when certain components described in § 438.530(a) can be released sooner than others, we believe this approach is responsive to both commenters who requested we release information as soon as possible and those who requested that we more closely align with the release of measure steward technical specifications. To implement these changes, we are finalizing, with modifications, the policy at § 438.530(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to use the new date and authorize the incremental release of the technical resource manual. We did not propose and, therefore, are not finalizing the schedule for the annual technical resource manual beyond 2027. We will continue to balance recommendations from commenters in setting future release dates for the technical resource manual and to align closely with the publication of the Annual Core Set technical specifications.

Finally, based on our pre-rulemaking consultations with States, we understand that States will need the MAC QRS measure information

identified in § 438.530(a)(1) prior to the initial measurement year of CY 2026. Unlike the information in § 438.530(a)(2) through (4), the measure information will be available for CMS to release prior to CY 2027. Therefore, we are modifying § 438.530 to add a paragraph (c), which retains the requirement for CMS to publish the information specified in paragraph § 438.530(a)(1) no later than August 1, 2025. As finalized, this will require CMS to provide, no later than August 1, 2025, the initial list of mandatory measures finalized in this rule, any measures removed from the initial mandatory measure set before August 2025 by CMS following the final rule as permitted under § 438.510(d)(2)–(4), and the subset of initial mandatory measures that must be stratified and by which stratification factors. We note that, regarding the identification of measures newly added or removed from the prior year's mandatory measure set as required under § 438.530(a)(1)(ii), CMS cannot add additional measures to the mandatory measure set for the initial measurement year published with this final rule. However, it is possible that CMS may remove measures from the set published in this rule if changes made to the measure that meet the removal criteria finalized in § 438.515(d)(2) through (4) occur after CMS finalizes this rule. This includes instances where the measure steward retires or stops maintaining a measure or CMS determines either that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes or that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e). Per § 438.510(a), the MAC QRS implemented by the State must include the measures in this list released under § 438.530(c).

Comment: We received some comments on the contents of the annual technical resource manual, including requests that the manual include resources on data collection and validation, free source coding materials, and a clear process with timelines that States should follow. A few commenters noted it would be challenging if CMS deviated from the measure specifications of the measure steward.

Response: We thank commenters for the recommendation to include information on data collection and validation. We intend to provide additional detail on the requirements finalized in § 438.515 for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), related to data collection, validation, and calculation of quality ratings for mandatory measures through two resources: the annual technical resource manual and the external quality review protocols associated with the optional activity for the MAC QRS at § 438.358(c)(6), which would allow States to use an EQRO if desired to assist with the quality ratings. We appreciate the recommendation to include free source coding materials in the technical resource manual and intend to align with the current approach used in the Core Set technical specifications whereby we include links to available free source code sets in the manual. We agree that including a clear process and timeline to follow for each measurement year and display year, relative to the release of the measure list and measure technical specifications, will be helpful to detail for States in the technical resource manual. In response to the concern about deviations from measure specifications, we agree with commenters that any deviations in measure specifications could result in complications and discrepancies across programs and quality reporting systems, and CMS works closely with measure stewards in developing reporting guidance to make as few adaptations to the technical specifications as possible.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.530, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), with modifications. We are finalizing § 438.530(a) with modifications to change the date for the first annual technical resource manual to no later than CY 2027. We are adding § 438.530(c) to indicate that the measure list in § 438.530(a)(1)(i) and subset of measures that must be stratified, and by which factors, in and § 438.530(a)(1)(iii) will be released no later than August 1, 2025. We are also making a technical change to § 438.530(a)(4) to indicate that a summary of public comments would be included in the technical resource manual only in the years when the engagement with interested parties occurs.

j. Reporting (§§ 438.334, 438.535 and 457.1240(d))

We proposed requirements at § 438.535 for States to submit to CMS, upon request, information on their MAC QRS to support our oversight of Medicaid and CHIP and compliance with MAC QRS requirements, to ensure beneficiaries can meaningfully compare ratings between plans, and to help us monitor trends in additional measures and use of permissible modifications to measure specifications used among States, which could inform future additions to the mandatory measures and modifications of our methodology. We proposed any request for reporting by States would be no more frequently than annually. We proposed the report would include the following components:

- A list of all measures included in the State's MAC QRS, including a list of the mandatory measures reported and any additional measures a State has chosen to display in their MAC QRS, which CMS could use to inform updates to the measures list;
- An attestation that displayed quality ratings for all mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate any additional measures when it deviates from the methodology proposed in § 438.515;
- If a State chooses to display additional quality measures, a description of and the required documentation for the process required under proposed § 438.520(b);
- The date on which the State publishes or updates their quality ratings for the State's managed care plans;
- The link to the State's MAC QRS website, which will enable CMS to ensure the MAC QRS ratings are current; and
- The use of any technical specification adjustments to MAC QRS mandatory measures that are outside the measure steward's allowable adjustment for the mandatory measure, but that the measure steward has approved for use by the State. As discussed in section I.B.6.f. of the proposed rule, we do not consider measure steward technical specifications to be part of the MAC QRS rating methodology, but they are part of the measures. Therefore, we do not require States to submit such adjustments to us for approval as an alternative QRS and believe State reporting is more appropriate to better understand if such adjustments impact plan-to-plan comparability or comparability within and among States.
- A summary of each alternative QRS (meaning alternative methodology) approved by CMS, including the effective dates (the period during which the alternative QRS was, has been, or will be applied by the State) for each approved alternative QRS.

We proposed these reporting requirements at new § 438.535(a)(1) through (7) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at

§ 457.1240(d). We proposed in § 438.535(a) the report would be ''in a form and manner determined by CMS'' because we intend to establish an online portal that States could access to easily submit this information to us. At § 438.535(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed that States would be given a minimum of 90 days' notice to provide such a report. We sought comment on whether States prefer one annual reporting date or a date that is relative to their MAC QRS updates. We summarize and respond to public comments received on the proposed reporting requirements (§§ 438.535 and 457.1240(d)) below.

Comment: Two commenters supported the use of one annual reporting date versus a State-specific date that is relative to MAC QRS updates.

Response: We will take the comments regarding timing into account when finalizing our guidance related to annual reporting. However, we are finalizing that reports will be required no more frequently than annually, and that CMS will provide no less than 90 days of notice that a report is due.

After reviewing public comments and for the reasons outlined in this rulemaking, we are finalizing these provisions largely as proposed but with modifications. We are finalizing § 438.535(a)(1) with modifications, which will also apply to separate CHIP, to add content to the required report: (1) identification of mandatory measures that are not included in their MAC QRS because they are not appliable to the State's Medicaid managed care program; (2) for any measures identified as inapplicable to the State's managed care program, a brief explanation of why the State determined that the measure is inapplicable; and (3) for any measure identified as applicable to the State's managed care program, the managed care programs to which the measure is applicable. This modification aligns with revisions we are also finalizing in § 438.510(a), which are discussed in section I.B.6.e. of the final rule. We are also adding new paragraph (a)(8) to include additional reporting requirements related to Medicare and Medicaid data that is not included in MAC QRS quality ratings, as discussed in section I.B.6.f of this final rule. In addition, we are finalizing minor changes in references to other regulations to take into account changes made in this final rule compared to the proposal (for example, codifying the rules for a State to use an alternative QRS methodology at § 438.515(c)).

k. Technical Changes (§§ 438.334, 438 Subpart G, 438.358 and 457.1240(d))

We proposed several technical changes to conform our regulations with other parts of our proposed rule, which included:

- Redesignating the regulations under current § 438.334(a) to part 438, subpart G, § 438.505 with changes in policy and modifications to take into account new subpart G provisions, as discussed throughout section I.B.6 of this final rule; and
- In current § 438.358(c)(6), changing the reference for this EQR optional activity from § 438.334 to part 438, subpart G to align with the proposed redesignation of § 438.334 § 438.

Unless otherwise noted, these technical changes are equally proposed for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d).

II. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the preamble, ''collection of information'' is defined under 5 CFR 1320.3 of the PRA's implementing regulations. To fairly evaluate whether a collection of information should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our May 3, 2023 (88 FR 28092) proposed rule (CMS–2439–P; RIN 0938–AU99) we solicited public comment on each of the aforementioned issues for the following sections of the rule that contained information collection requirements. One comment is noted below that addresses the overall burden of the entire rule. Additionally, ICR #4 (Rate Certification Submission) and #16 (Program Integrity Requirements Under the Contract) also received public comment and a summary of the comment and response can be found below under the applicable ICR section.

Comment: A few commenters opined on the overall level of burden imposed by this rule. (Individual comments on burden are addressed in the respective topic areas of this final rule.) Commenters stated that the numerous, interrelated, and overlapping obligations that Medicaid agencies will have to undertake if all of the elements of this rule are adopted as proposed will cost exponentially more than CMS has estimated, require extensive new Medicaid agency staffing and large-scale vendor contracts, intersect with numerous systems obligations that are already in the pipeline, as well as those that are anticipated under various pieces of Federal legislation, and require staging and more time than is anticipated by CMS's proposed implementation deadlines.

Response: We acknowledged commenters' concerns and have reviewed our burden estimates and made revisions when appropriate. We recognize that many factors impact the burden associated with each provision and we attempt to address them appropriately. We also gave careful consideration to the level of burden associated with each provision and selected applicability dates for each one that provided time for activities necessary to implement. The burden estimates in this rule are incorporated into and comply with the Paperwork Reduction Act and will be reviewed and revised as required.

Comment: One commenter stated support for CMS's proposals to make all Medicaid proposals generally applicable to CHIP plans except where provisions are not relevant, which helps to ensure equal protections for CHIP recipients, promotes consistency between Federal programs, and reduces burden on States and providers.

Response: We appreciate the support for the alignment of most CHIP provisions in this final rule with those finalized for Medicaid. We agree that alignment promotes consistency between Medicaid and separate CHIP managed care programs. When appropriate, we made exceptions for situations in which separate CHIP differs from Medicaid and considered implications for managed care plans that serve smaller separate CHIP populations. We also agree with the commenter that alignment between programs provides equity for beneficiaries, promotes operational and administrative efficiencies, and reduces financial burden on States, plans, and providers.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2022/may/oes_nat.htm*). Table 4 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 4: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
All Occupations	00-0000	29.76	n/a	n/a
Accountant	13-2011	41.70	41.70	83.40
Actuary	15-2011	61.34	61.34	122.68
Business Operations Specialist, All Other	13-1199	39.75	39.75	79.50
Database Administrator	15-1242	49.29	49.29	98.58
General and Operations Manager	11-1021	59.07	59.07	118.14
Medical Records Specialist	29-2072	24.56	24.56	49.12
Office Clerk, General	43-9061	19.78	19.78	39.56
Registered Nurse	29-1141	42.80	42.80	85.60
Software and web developers, programmers, and testers	15-1250	60.07	60.07	120.14
Statistician	15-2041	50.73	50.73	101.46
Web Developer	15-1254	42.11	42.11	84.22

States and the Private Sector: As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believed that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

After reviewing the public comments, we are updating the specific occupation title and code for 15–1251. In error, the proposed rule listed the occupation code 15–1251 for ''computer programmer.'' However, the occupation code 15–1250 ''Software and web developers, programmers, and testers'' encompasses a larger pool of work types for information technology related tasks.

Beneficiaries: To derive average costs for beneficiaries we believed that the burden will be addressed under All Occupations (BLS occupation code 00–0000) at $29.76/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

To estimate the burden for the requirements in part 438, we utilized State submitted data by States for enrollment in managed care plans for CY 2021.[232] The enrollment data reflected 67,655,060 enrollees in MCOs, 36,285,592 enrollees in PIHPs or PAHPs, and 5,326,968 enrollees in PCCMs, and a total of 77,211,654 Medicaid managed care enrollees. This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. These data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. The estimates below reflect deduplicated State counts as data permitted.

To estimate the burden for these requirements in part 457, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion CHIP and 2,593,827 separate CHIP managed care enrollees.[233] These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 MCOs, PIHPs, and PAHPs, as well as 17 PCCMs.

1. ICRs Regarding Standard Contract Requirements (§§ 438.3 and 457.1203)

The following changes to § 438.3 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1203 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.3(i) and 457.1203(f) will require that MCOs, PIHPs, and PAHPs report provider incentive payments based on standard metrics for provider performance. Amendments to § 438.8(e)(2) will define the provider incentive payments that could be included in the MLR calculation; however, the administrative burden for these changes is attributable to the managed care contracting process, so we are attributing these costs to the contracting requirements in § 438.3(i). Approximately half (or 315 Medicaid contracts and 100 CHIP contracts) of all MCO, PIHP, and PAHP contracts will require modification to reflect these changes. For the contract modifications, we estimate it will take 2 hours at $79.50/hr for a business operations

[232] *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html.*

[233] Data source: Statistical Enrollment Data System (SEDS) Form 21E, Children Enrolled in Separate CHIP, and Form 64.21E, Children enrolled in Medicaid expansion CHIP.

specialist and 1 hour at $118.14/hr for a general operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time State burden of 945 hours (315 contracts × 3 hr) at a cost of $87,299 [315 contracts × ((2 hr × $79.50/hr) + (1 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 315 hours (945 hr/3 yr) and $29,100 ($87,299/3 yr). The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time State burden of 300 hours (100 contracts × 3 hr) at a cost of $27,714 [100 contracts × ((2 hr × $79.50/hr) + (1 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 100 hours (300 hr/3 yr) and $9,238 ($27,714/3 yr). The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To report provider incentive payment based on standard metrics, MCOs, PIHP, and PAHPs will need to select standard metrics, develop appropriate payment arrangements, and then modify the affected providers' contracts. We estimate it will take 120 hours consisting of 80 hours × $79.50/hr for a business operations specialist and 40 hours × $118.14/hr for a general and operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time private sector burden of 37,800 hours (315 contracts × 120 hr) at a cost of $3,491,964 [315 contracts × ((80 hr × $79.50/hr) + (40 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 12,600 hours and $1,163,988. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time private sector burden of 12,000 hours (100 contracts × 120 hr) at a cost of $1,108,560 [100 contracts × ((80 hr × $79.50/hr) + (40 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 4,000 hours (12,000hr/3 yr) and $369,520 ($1,108,560/3 yr). The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856).

Amendments to § 438.6(c)(2) will require all SDP expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) (that is, the SDPs that require prior written approval under this final rule) must be submitted and have written approval by CMS prior to implementation.

We estimate that 38 States will submit 50 new SDP proposals for minimum/maximum fee schedules, value-based payment, or uniform fee increases. To complete a new preprint, we estimate that it will take 2 hours at $122.68/hr for an actuary, 6 hours at $79.50/hr for a business operations specialist, and 2 hours at $118.14/hr for a general and operations manager for development and submission. We estimate an annual State burden of 500 hours (50 proposals × 10 hr) at a cost of $47,932 [50 proposals x ((2 hr × $122.68/hr) + (6 hr × $79.50/hr) + (2 hr × $118.14/hr))].

We estimate that 38 States will submit 150 renewals of existing SDPs or amendments to existing SDPs per year. To make revisions to an existing preprint, we estimate it will take 1 hour at $79.50/hr for a business operations specialist, 1 hour at $122.68/hr for an actuary, and 1 hour at $118.14/hr for a general and operations manager for any proposal updates or renewals. In aggregate, we estimate an annual State burden of 450 hours (150 proposals × 3 hr) and $48,048 [150 renewal/amendment proposals × ((1 hr × $79.50/hr) + (1 hr × $118.14/hr) + (1 hr × 122.68/hr))].

The amendments to § 438.6(c)(2)(iii) will require that all SDPs subject to prior approval under paragraphs (c)(1)(i) through (iii) for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center, include a written analysis, showing that the total payment for such services does not exceed the average commercial rate. We estimate that 38 States will develop and submit 60 of these SDPs that include a written analysis to CMS. We also estimate it will take 6 hours at $122.68/hr for an actuary, 3 hours at $118.14/hr for a general and operations manager, and 6 hours at $120.14/hr for a software and web developers, programmers and testers for each analysis. In aggregate we estimate a one-time State burden of 900 hours (60 SDPs × 15 hr) and at a cost of $108,680 [60 certifications × ((6 hr × $122.68/hr) + (3 hr × $118.14/hr) + (6 hr × $120.14/hr))]. As this will be a requirement to update once every 3 years, we annualize our time and cost estimates to 300 hours and $36,227. The annualization divides our estimates by 3 years to reflect OMB's likely approval period.

Section 438.6(c)(2)(iv) will require that States that use SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) must prepare and submit a written evaluation plan to CMS. The evaluation plan must include specific components under this proposal and is intended to measure the effectiveness of those State directed payments in advancing at least one of the goals and objectives in the quality strategy on an annual basis and whether specific performance targets are met. We estimate that 38 States will submit 50 written evaluation plans for new proposals. We also estimate it will take 5 hours at $120.14/hour for a software and web developers, programmers and testers, 2.5 hours at $118.14/hr for a general and operations manager, and 2.5 hours at $79.50/hr for a business operations specialist for each new evaluation plan. In aggregate, we estimate an annual State burden of 500 hours (50 evaluation plans × 10 hr) and at a cost of $54,741 [50 evaluation plans × ((5 hr × 120.14/hr) + (2.5 hr × $118.14) + (2.5 hr × $79.50/hr))].

We estimate that 38 States will prepare and submit 150 written evaluation plans for amendment and renewal of existing proposals. We also estimate it will take 2 hours at $120.14/hr for a software and web developers, programmers and testers, 2 hours at $118.14/hr for a general and operations manager and 2 hours at $79.50/hr for a business operations specialist for each evaluation plan amendment and renewal. In aggregate we estimate an annual State burden of 900 hours (150 evaluation plans × 6 hr) at a cost of $95,334 [150 evaluation plans × ((2 hr × 120.14/hr) + (2 hr × $118.14) + (2 hr × $79.50/hr))].

Section 438.6(c)(2)(v) will require for all SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) that have an actual Medicaid managed care spending percentage greater than 1.5 must complete and submit an evaluation report using the approved

evaluation plan to demonstrate whether the SDP results in achievement of the State goals and objectives in alignment with the State's evaluation plan. Section 438.6(c)(2)(ii)(F) also requires that States provide evaluation reports to CMS, upon request, that demonstrate whether the SDP results in achievement of the State goals and objectives in alignment with the State's evaluation plan.

We estimate 38 States will submit 57 evaluation reports. We also estimate it will take 3 hours at $120.14/hr for a software and web developers, programmers, and testers, 1 hour at $118.14/hour for a general and operations manager, and 2 hours at $79.50/hr for a business operations specialist for each report. In aggregate we estimate an annual State burden of 342 hours (57 reports × 6 hr) at a cost of $36,341 [57reports × ((3 hr × $120.14/hr) + (1 hr × $118.14/hr) + (2 hr × $79.50hr)].

The provision at § 438.6(c)(7) will require States to submit a final SDP cost percentage as a separate actuarial report concurrently with the rate certification only if a State wishes to demonstrate that the final SDP cost percentage is below 1.5 percent. We anticipate that 10 States will need: 5 hours at $122.68/hr for an actuary, 5 hours at $120.14/hr for a software and web developers, programmers and testers, and 7 hours at $79.50/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 170 hours (17 hr × 10 States) at a cost of $17,706 (10 States × [(5 hr × $122.68/hr) + (5 hr × $120.14/hr) + (7 hr × $79.50/hr)]).We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

3. ICRs Regarding Special Contract Provisions Related to Payment—Attestations (§ 438.6(c)(2)(ii)(H))

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10856). Upon approval, it will be folded into 0938–1453 (CMS–10856).

Amendments to § 438.6(c)(2)(ii)(H) will require all States with managed care delivery systems to collect attestations from providers who would receive an SDP attesting that they do not participate in any hold harmless arrangements. The paperwork burdens associated with this requirement include the following for States: developing instructions and communication for providers/plans; recordkeeping; and reporting to CMS when requested. For providers, the burden associated with this requirement relates to reviewing and signing the attestations. Although States will have the flexibility to delegate work of collecting attestations to managed care plans, we cannot predict how many States will elect this option. As such, we are not accounting for that burden separately in these estimates.

States: We estimate that 44 States with MCOs, PIHPs and PAHPs will need to develop an attestation process and prepare attestations and communicate with providers. For each State, we estimate on a one-time basis it will take 200 hours at $79.50/hr for a business operations specialist to plan the data collection process and develop the attestations and communications providers, and 200 hours at $120.14/hr for a software and web developers, programmers, and testers to program an ingest and recordkeeping process for the attestations. In total, we estimate a one-time burden of $1,756,832 and 17,600 hours (44 States × [(200 × $79.50/hr) + (200 × $120.14/hr)]), or $39,928 per State. Taking into account the 50 percent Federal administrative match, we estimate one time cost per State of $19,964 ([$15,900 + $24,028] × 0.5).

On an ongoing basis, we estimate that annually, it will take 200 hours at $79.50/hr for a business operations specialist to manage the data collection process and 232 hours at $39.56/hr for an office clerk to input the attestations. On an annual, national basis, we estimate States will submit 55 SDPs across 44 States with MCOs, PIHPs, and PAHPs for which they would need to provide attestations at CMS's request. We estimate at each instance it will take a general and operations manager 2 hours at $118.14/hr for to prepare the submission and any necessary explanations, or 110 hours annually across all States. In total, we estimate an annual burden of $1,116,424 and 19,118 hours [(44 States × [(200 × $79.50) + (232 × $39.56)]) + (55 SDPs × (2 × $118.14)], or $25,373 per State. Taking into account the 50 percent Federal administrative match, we estimate ongoing costs per State of $12,687 ($25,373 × 0.5).

Providers: For the purposes of these estimates, we are using a provider estimate of 1,088,050 providers enrolled with MCOs, PIHPs, and PAHPs, based on T–MSIS Analytic Files (also known as TAF) data, that will need to submit an attestation to the State. We are further assuming for the purposes of these estimates that these collections will occur on an annual basis, one per provider, but want to note States may elect different timing or number of attestations per provider that would increase or decrease these estimates. We estimate it will take a healthcare administrator at a provider 6 minutes to review and sign the attestation at $93.04/hr. In total, we estimate an annual burden of $10,123,217 and 108,805 hours (1,088,050 providers × ($93.04/hr × 0.1)).

4. ICRs Regarding Rate Certification Submission (§ 438.7)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). One public comment was received. It is summarized and responded to under this ICR section.

Amendments to § 438.7 set out revisions to the submission and documentation requirements for all managed care actuarial rate certifications. The certification will be reviewed and approved by CMS concurrently with the corresponding contract(s). Currently, § 438.7(b) details certain requirements for documentation in the rate certifications. We believed these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

We estimate that 44 States would develop 253 certifications at 250 hours for each certification. Of the 250 hours, we estimate that it will take 110 hours at $122.68/hr for an actuary, 15 hours at $118.14/hr for a general and operations manager, 53 hours at $120.14/hr for a software and web developers, programmers and testers, 52 hours at $79.50/hr for a business operations specialist, and 20 hours at $39.56/hr for an office and administrative support worker. In aggregate we estimate an annual State burden of 63,250 hours (250 hr × 253 certifications) at a cost of $6,719,559 [253 certifications × ((110 hr × $122.68/hr) + (15 hr × $118.14/hr) + (53 hr × $120.14/hr) + (52 hr × $79.50/hr) + (20 hr × $39.56/hr))]. We solicited public comment on these issues. We summarize and respond to public comments below:

Comment: One commenter stated that the provisions at § 438.7(c)(4) and (5) could increase State administrative burden if a revised rate certification would be required when there is a programmatic change for ILOSs and SDPs.

Response: We agree with the commenter that the provisions at § 438.7(c)(4) could increase State administrative burden. The commenter did not provide an estimate on the potential administrative burden. We believe it would be reasonable to increase the ICR by approximately 2 percent (that is, 5 rate certifications) to account for any revised rate certifications necessary for ILOS

changes and to increase the ICR by approximately 10 percent (23 certifications) to account for any revised rate certifications for SDP changes. This increases the total number of rate certifications for the ICR from 225 certifications to 253 rate certifications.

After reviewing the public comments, we are finalizing the ICRs with revision to account for a total of 253 rate certifications rather than 225 certifications while all ICR estimates on the total number of hours remains unchanged. In aggregate, we estimate an annual State burden of 63,250 hours at a cost of $6,719,559 as reflected in the estimate above.

5. ICRs Regarding Medical Loss Ratio Standards (§§ , 438.8, 438.74, and 457.1203)

The following changes to §§ 438.8 and 438.74 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1203 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.8 and 457.1203 will require that MCOs, PIHPs, and PAHPs report to the State annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to States amount to 629 Medicaid contracts and 199 CHIP contracts. All MCOs, PIHPs, and PAHPs need to report the information specified under §§ 438.8 and 457.1203 regardless of their credibility status.

Amendments to §§ 438.8(k)(1)(vii) and 457.1203(f) will require that MCOs, PIHPs, and PAHPs develop their annual MLR reports compliant with the expense allocation methodology.[234] To meet this requirement we anticipate it will take: 1 hr at $83.40/hr for an accountant, 1 hr at $79.50/hr for a business operations specialist, and 1 hr at $118.14/hr for a general operations manager. In aggregate for Medicaid for § 438.8(k)(1)(vii), we estimate an annual private sector burden of 1,887 hours (629 contracts × 3 hr) at a cost of $176,775 [629 contracts × ((1 hr × $83.40/hr) + (1 hr × $79.50/hr) + (1 hr × $118.14/hr))]. In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 597 hours (199 contracts × 3 hr) at a cost of $55,927 [199 contracts × ((1 hr × $83.40/hr) + (1 hr × $79.50/hr) + (1 hr × $118.14/hr))].

To do the annual reconciliations needed to make the incentive payments and include the expenditures in their annual report required by § 438.8(k), we estimate MCOs, PIHPs, and PAHPs will take 1 hour at $79.50/hr for a business operations specialist. In aggregate for Medicaid we estimate an annual private sector burden of 315 hours (315 contracts × 1 hr) at a cost of $25,043 (315 contracts × 1 hr × $79.50/hr). In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 100 hours (100 contracts x 1 hr) and $7,950 (100 contracts × 1 hr × $79.50/hr).

Amendments to §§ 438.74 and 457.1203(e) will require States to comply with data aggregation requirements for their annual reports to CMS. We estimate that only 5 States will need to resubmit MLR reports to comply with the data aggregation changes. We anticipate that it will take 5 hours x $79.50/hr for a business operations specialist.

In aggregate, for Medicaid for § 438.74, we estimate a one-time State burden of 25 hours (5 States × 5 hr) at a cost of $1,988 (5 States × 5 hr × $79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 8 hours (25 hr/3 yr) and $663 ($1,988/3 yr).

In aggregate for CHIP for § 457.1203(e) we estimate a one-time State burden of 25 hours (5 States × 5 hr) at a cost of $1,988 (5 States × 5 hr × $79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates for CHIP to 8 hours (25 hr/3 yr) and $663 ($1,988/3 yr).

The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

6. ICRs Regarding Information Requirements (§§ 438.10 and 457.1207)

The following changes to § 438.10 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1207 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.10(c)(3) and 457.1207 will require States to operate a website that provides the information required in § 438.10(f). We are estimating 45 States will need to operate the website. We are finalizing that States must include required information on one page, use clear labeling, and verify correct functioning and accurate content at least quarterly. We anticipate it will take 20 hours at $120.14/hr once for a software and web developers, programmers, and testers to place all required information on one page and ensure the use of clear and easy to understand labels on documents and links.

In aggregate for Medicaid for § 438.10(c)(3), we estimate a one-time State burden of 900 hours (45 States × 20 hr) at a cost of $108,126 (900 hr × $120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 300 hours and $36,042.

In aggregate for CHIP for § 457.1207, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of $76,890 (640 hr × $120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 213 hours and $25,630.

The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

We also anticipate that it will take 40 hours at $120.14/hr for a software and web developers, programmers, and testers to periodically add content and verify the function of the site at least quarterly (10 hours/quarter).

In aggregate for Medicaid, we estimate an annual State burden of 1,800 hours (45 States x 40 hr) at a cost of $216,252 (1,800 hr x $120.14/hr).

Due to the additional finalized requirement to post summary enrollee experience survey results by separate CHIP managed care plan on the State's website, we estimate an additional 1 hour at $120.14/hr for a software and web developers, programmers, and testers to post these comparative data annually for a total of 41 hours. For CHIP, we estimate an annual State burden of 1,312 hours (32 States x 41 hr) at a cost of $157,624 (1,312 hr x $120.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

7. ICRs Regarding ILOS Contract and Supporting Documentation Requirements (§§ 438.16 and 457.1201)

The following changes to § 438.16 will be submitted to OMB for approval

[234] Methodology(ies) for allocation of expenditures as described at 45 CFR 158.170(b).

under control number 0938–1453 (CMS–10856). The following changes to § 457.1201 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

The provisions at §§ 438.16 and 457.1201 will require States that provide ILOSs, with the exception of short term IMD stays, to comply with additional information collection requirements. 44 States utilize MCOs, PIHPs and PAHPs in Medicaid managed care programs. We do not have current data readily available on the number of States that utilize ILOSs and the types of ILOSs in Medicaid managed care. We believed it is a reasonable estimate to consider that half of the States with MCOs, PIHPs and PAHPs (22 States) may choose to provide non-IMD ILOSs. Similarly, for CHIP, we estimated that half of the States with MCOs, PIHPs, and PAHPS (16 States) provide ILOSs and would be subject to the additional information collection requirements.

The provision at § 438.16(c)(4)(i) will require States to submit a projected ILOS cost percentage to CMS as part of the rate certification. The burden for this provision is accounted for in ICR #2 (above) for § 438.7 Rate Certifications.

The provision at § 438.16(c)(5)(ii) will require States to submit a final ILOS cost percentage and summary of actual MCO, PIHP and PAHP ILOS costs as a separate actuarial report concurrently with the rate certification. We anticipated that 22 States will need: 5 hours at $122.68/hr for an actuary, 5 hours at $120.14/hr for a software and web developers, programmers and testers, and 7 hours at $79.50/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 374 hours (17 hr × 22 States) at a cost of $38,953 (22 States × [(5 hr × $122.68/hr) + (5 hr × $120.14/hr) + (7 hr × $79.50/hr)]).

Provisions at §§ 438.16(d)(1) and 457.1201(e) will require States that elect to use ILOS to include additional documentation requirements in their managed care plan contracts. We anticipate that 22 States for Medicaid and 16 States for CHIP will need 1 hour at $79.50/hr for a business operations specialist to amend 327 Medicaid MCO, PIHP, and PAHP contracts and 100 CHIP contracts annually. In aggregate for Medicaid for § 438.16(d)(1), we estimated an annual State burden of 327 hours (327 contracts × 1 hr) at a cost of $25,997 (327 hr × $79.50/hr). In aggregate for CHIP for § 457.1201(e) we estimated an annual State burden of 100 hours (100 contracts × 1 hr) at a cost of $7,950 (100 hr × $79.50/hr).

Provisions at §§ 438.16(d)(2) and 457.1201(e) will require some States to provide to CMS additional documentation to describe the process and supporting data the State used to determine each ILOS to be a medically appropriate and cost effective substitute. This additional documentation will be required for States with a projected ILOS cost percentage greater than 1.5 percent. We anticipated that approximately 5 States may be required to submit this additional documentation. We estimated it will take 2 hours at $79.50/hr for a business operations specialist to provide this documentation. In aggregate for Medicaid for § 438.16(d)(2), we estimated an annual State burden of 10 hours (5 States × 2 hr) at a cost of $795 (10 hr × $79.50/hr). In aggregate for CHIP for § 457.1201(e) we estimate the same annual State burden of 10 hours (5 States × 2 hr) at a cost of $795 (10 hr × $79.50/hr).

Provisions at §§ 438.16(e)(1) and 457.1201(e) will require States with a final ILOS cost percentage greater than 1.5 percent to submit an evaluation for ILOSs to CMS. We anticipated that approximately 5 States may be required to develop and submit an evaluation. We estimated it will take 25 hours at $79.50/hr for a business operations specialist. In aggregate for Medicaid for § 438.16(e)(1), we estimated an annual State burden of 125 hours (5 States × 25 hr) at a cost of $9,938 (125 hr × $79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimated the same annual State burden of 125 hours (5 States × 25 hr) at a cost of $9,938 (125 hr × $79.50/hr).

An ILOS may be terminated by either a State, a managed care plan, or by CMS. Provisions as §§ 438.16(e)(2)(iii) and 457.1201(e) will require States to develop an ILOS transition of care policy. We believed all States with non-IMD ILOSs should proactively prepare a transition of care policy in case an ILOS is terminated. We estimated both a one-time burden and an annual burden for these provisions. We believed there is a higher one-time burden as all States that currently provide non-IMD ILOSs will need to comply with this requirement by the applicability date, and an annual burden is estimated for States on an on-going basis. We estimated for a one-time burden, it will take: 2 hours at $120.14/hr for a software and web developers, programmers and testers and 2 hours at $79.50/hr for a business and operations specialist for initial development of a transition of care policy. In aggregate for Medicaid for § 438.16(e)(2)(iii), we estimate a one-time State burden 88 hours (22 States × 4 hr) at a cost of $8,784 (22 States × [(2 hr × $120.14/hr) + (2 hr × $79.50/hr)]). As this will be a one-time requirement, we annualized our time and cost estimates to 30 hours and $2,928. In aggregate for CHIP for § 457.1201(e), we estimated a one-time State burden 64 hours (16 States × 4 hr) at a cost of $6,389 (16 States × [(2 hr x $120.14/hr) + (2 hr × $79.50/hr)]). As this will be a one-time requirement, we annualized our time and cost estimates to 21 hours and $2,130. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For updates to reflect specific ILOSs, we also estimated that this ILOS transition of care policy will have an annual burden of 1 hour at $79.50/hr for a business operations specialist per State. In aggregate for Medicaid for § 438.16(e)(2)(iii), we estimate an annual State burden of 22 hours (22 States × 1 hr) at a cost of $1,749 (22 hr × $79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual State burden of 16 hours (16 States × 1 hr) at a cost of $1,272 (16 hr × $79.50/hr).

For MCOs, PIHPs, or PAHPs that will need to implement a transition policy when an ILOS is terminated, we estimate that on an annual basis, 20 percent of managed care plans (65 plans for Medicaid and 40 plans for CHIP) may need to implement this policy. We estimated an annual managed care plan burden of 2 hours at $79.50/hr for a business operations specialist to implement the policy. In aggregate for Medicaid for § 438.16(e)(2)(iii)(B), we estimated an annual burden of 130 hours (65 plans × 2 hr) at a cost of $10,335 (130 hr × $79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual burden of 80 hours (40 plans × 2 hr) at a cost of $6,360 (80 hr × $79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

8. ICRs Regarding State Monitoring Requirements (§ 438.66)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856).

Amendments to § 438.66(c) will require States to conduct, or contract for, an enrollee experience survey annually. We believed most, if not all, States will use a contractor for this task and base our burden estimates on that assumption. In the first year, for procurement, contract implementation

and management, and analysis of results, we estimate 85 hours at $79.50/hr for a business operations specialist and 25 hours at $118.14/hr for general operations manager. In aggregate for § 438.66(c), we estimate a one-time State burden of 5,390 hours (49 States × 110 hr) at a cost of $475,840 (49 States × [(85 hr × $79.50/hr) + (25 hr × $118.14)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,796 hours and $158,614. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of experience survey results, we estimated 50 hours at $79.50/hr for a business operations specialist and 15 hours at $118.14/hr for general operations manager. In aggregate, we estimated an annual State burden of 3,185 hr (49 States × 65 hr) at a cost of $281,608 (49 States × [(50 hr × $79.50/hr) + (15 hr × $118.14/hr)]).

Amendments to § 438.66(e)(1) and (2) will require that States submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for § 438.66(b) and the utilization of the data in § 438.66(c), including reporting in § 438.16, will be used to complete the report. We anticipate it will take 80 hours at $79.50/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual State burden of 3,920 hours (49 States × 80 hr) at a cost of $311,640 (3,920 hr × $79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

9. ICRs Regarding Network Adequacy Standards (§§ 438.68 and 457.1218)

The following changes to § 438.68 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1218 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Sections 438.68(e) and 457.1218 will require States with MCOs, PIHPs, or PAHPs to develop appointment wait time standards for four provider types. We anticipate it will take: 20 hours at $79.50/hr for a business operations specialist for development and 10 hours at $79.50/hr a business operations specialist for ongoing enforcement of all network adequacy standards. In aggregate for Medicaid for § 438.68(e), we estimate a one-time State burden of 880 hours (44 States × 20 hr) at a cost of $69,960 (880 hr × $79.50/hr). As this will be a one-time requirement, we annualize our one-time burden estimates to 293 hours and $23,320. The annualization divides our one-time by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Additionally, § 438.68(e) has an annual State burden. We anticipate it will take: 10 hours at $79.50/hr for a business operations specialist for development. In aggregate for Medicaid for § 438.68(e), we anticipate an annual State burden of 440 hours (44 States × 10 hr) at a cost of $34,980 (440 hr × $79.50/hr).

In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of $50,880 (640 hr × $79.50/hr) for States to develop appointment wait time standards for four provider types and an annual State burden of 320 hours (32 States × 10 hr) at a cost of $25,440 (320 hr × $79.50/hr) for enforcement of all network adequacy standards. As the development of appointment wait time standards will be a one-time requirement, we annualize our one-time burden estimates to 213 hours (640hr/3yr) and $16,960 (50,880/3yr). The annualization divides our one-time estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to §§ 438.68(f) and 457.1218 will require States with MCO, PIHPs, or PAHPs to contract with an independent vendor to perform secret shopper surveys of plan compliance with appointment wait times and accuracy of provider directories and send directory inaccuracies to the State within three days of discovery. In the first year, for procurement, contract implementation, and management, we anticipate it will take: 85 hours at $79.50/hr for a business operations specialist and 25 hours at $118.14/hr for general operations manager. In aggregate for Medicaid for § 438.68(f), we estimate a one-time State burden of 4,840 hours (44 States × 110 hr) at a cost of $427,284 (44 States × [(85 hr × $79.50/hr) + (25 hr × $118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,614 hours and $142,428. In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 3,520 hours (32 States × 110 hr) at a cost of $310,752 (32 States × [(85 hr × $79.50/hr) + (25 hr × $118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,173 hours and $103,584. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of results, we anticipate it will take 50 hours at $79.50/hr for a business operations specialist and 15 hours at $118.14/hr for general operations manager. In aggregate for Medicaid for § 438.68(f), we estimate an annual State burden of 2,860 hours (44 States × 65 hr) at a cost of $252,872 (44 States × [(50 hr × $79.50/hr) + (15 hr × $118.14)]).

In aggregate for CHIP for § 457.1218 we estimate an annual State burden of 2,080 hours (32 States × 65 hr) at a cost of $183,907 (32 States × [(50 hr × $79.50/hr) + (15 hr × $118.14/hr)]).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

10. ICRs Regarding Assurance of Adequate Capacity and Services (§§ 438.207 and 457.1230)

The following changes to § 438.207 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1230 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.207(b) and 457.1230(b) will require MCOs, PIHPs, and PAHPs to submit documentation to the State of their compliance with § 438.207(a). As we finalized in this rule to add a reimbursement analysis at § 438.207(b)(3) (and at § 457.1230(b) for separate CHIP), we estimate a one-time plan burden of: 50 hours at $79.50/hr for a business operations specialist, 20 hours at $118.14/hr for a general operations manager, and 80 hours at $120.14/hr for software and web developers, programmers and testers. In aggregate for Medicaid for § 438.207(b), we estimate a one-time private sector burden of 94,350 hours (629 MCO, PIHPs, and PAHPs × 150 hr) at a cost of $10,031,921 (629 MCOs, PIHPs, and PAHPs × [(50 hr × $79.50/hr) + (20 hr × $118.14/hr) + (80 hr × $120.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 31,449 hours and $3,343,974. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are

annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1230(b), we estimate a one-time private sector burden of 29,850 hours (199 MCO, PIHPs, and PAHPs × 150 hr) at a cost of $3,173,851 (199 MCOs, PIHPs, and PAHPs × [(50 hr × $79.50/hr) + (20 hr × $118.14/hr) + (80 hr × $120.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 9,950 hours and $1,057,950. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For ongoing analyses and submission of information that will be required by amendments to § 438.207(b), we estimate it will take: 20 hours at $79.50/hr for a business operations specialist, 5 hours at $118.14/hr for a general operations manager, and 20 hours at $120.14/hr for software and web developers, programmers and testers. In aggregate for Medicaid, we estimate a one-time private sector burden of 28,305 hours (629 MCO, PIHPs, and PAHPs × 45 hr) at a cost of $2,883,021 (629 MCO, PIHPs, and PAHPs × [(20 hr × $79.50/hr) + (5 hr × $118.14/hr) + (20 hr × $120.14/hr)]).

In aggregate for CHIP, we estimate a one-time private sector burden of 8,955 hours (199 MCO, PIHPs, and PAHPs × 45 hr) at a cost of $912,117 (199 MCO, PIHPs, and PAHPs × [(20 hr × $79.50/hr) + (5 hr × $118.14/hr) + (20 hr × $120.14/hr)]).

Amendments to §§ 438.207(d) and 457.1230(b) will require States to submit an assurance of compliance to CMS that their MCOs, PIHPs, and PAHPs meet the State's requirements for availability of services. The submission to CMS must include documentation of an analysis by the State that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP and the accessibility of covered services. By including the requirements in this rule at §§ 438.68(f) and 438.208(b)(3), we anticipate it will take 40 hours at $79.50/hr for a business operations specialist. Although States may need to submit a revision to this report at other times during a year (specified at § 438.207(c)), we believed these submissions will be infrequent and require minimal updating to the template; therefore, the burden estimated here in inclusive of occasional revisions. In aggregate for Medicaid, we estimate an annual State burden of 1,760 hours (44 States × 40 hr) at a cost of $139,920 (1,760 hr × $79.50/hr).

Due to the additional finalized requirement to include enrollee experience survey results in the State's separate CHIP analysis of network adequacy, we anticipate an additional 4 hours at $79.50/hr for a business operations specialist to analyze these data for a total of 44 hours annually. In aggregate for CHIP, we estimate an annual State burden of 1,408 hours (32 States × 44 hr) at a cost of $111,936 (1,408 hr × $79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

11. ICRs Regarding External Quality Review Results (§§ 438.364 and 457.1250)

The following changes to § 438.364 and § 438.360 will be submitted to OMB for approval under control number 0938–0786 (CMS–R–305), and the changes to § 457.1250 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to § 438.360(a)(1) will remove the requirement that plan accreditation must be from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158. Eliminating this requirement will simplify the plan accreditation process. We assume that States will apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we anticipate that this provision will offset the burden associated with § 438.358(b)(1)(i) through (iii) for 65 MCOs, PIHPs, and PAHPs (since these activities will no longer be necessary for these 65 plans). To develop the burden reduction estimate, we applied the currently approved estimates in CMS–R–305, which quantifies the burden for § 438.358(b)(1)(i) through (iii). The existing burden estimate assumes for the first mandatory EQR-related activity that each MCO, PIHP, or PAHP will conduct 2 PIPs at 65 hours per PIP for a total of 130 hours (65 hr × 2 PIP validations). For the next two mandatory activities, we estimate that each MCO, PIHP, PAHP, or PCCM entity will calculate 3 performance measures each year at 53 hours per performance measure. A compliance review will also occur every three years and burden is annualized. This totals 279.33 hours ([53 hours × 3 performance measures] + [361 hours/3 years compliance review]). In total, for one entity we estimate 409.33 hours (130 + 279.33) to conduct the mandatory EQR activities. All activities are conducted by a business operations specialist at $79.50/hr for a total cost per entity of $32,541.74 (409.33 × $79.50/hr). Therefore, for § 438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual State burden of minus 26,606 hours [(−65 MCOs, PIHPs × 409.33 hr)] and minus $2,115,213 (−26,606.45 hr × $79.50/hr).

The proposed amendments to § 438.364(a)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, will (1) require that the EQR technical reports include ''any outcomes data and results from quantitative assessments'' for the applicable EQR activities in addition to whether or not the data has been validated, and (2) add the mandatory network adequacy validation activity to the types of EQR activities to which the requirement to include data in the EQR technical report applies. For Medicaid § 438.364(a)(2)(iii), we assume 44 States and 654 MCOs, PIHPs and PAHPs will be subject to the EQR provisions. For CHIP, we assume 32 States and 199 MCOs, PIHPs and PAHPs will be subject to the proposed EQR provisions.

We estimate it will take 1 hour at $79.50/hr for a business operations specialist to describe the data and results from quantitative assessments and 30 minutes at $39.56/hr for an office clerk to collect and organize data. In aggregate for Medicaid, we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $64,929 (654 reports × [(1 hr × $79.50/hr) + (0.5 hr × $39.56/hr)]). In aggregate for CHIP for § 457.1250(a), we estimate an annual State burden of 299 hours (199 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $19,757 (199 reports × [(1 hr × $79.50/hr) + (0.5 hr × $39.56/hr)]).

Amendments to § 438.364(c)(2)(i) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, will require States to notify CMS within 14 calendar days of posting their EQR technical reports on their quality website and provide CMS with a link to the report. Previously States were not required to notify CMS when reports were posted. We estimate it will take 30 minutes at $79.50/hr for a business operations specialist to notify CMS of the posted reports. In aggregate for Medicaid, we estimate an annual State burden of 22 hours (44 States × 0.5 hr) at a cost of $1,749 (22 hr × $79.50/hr). In aggregate for CHIP, we estimate an annual State burden of 16 hours (32

States × 0.5 hr) at a cost of $1,272 (16 hr × $79.50/hr).

Amendments to § 438.364(c)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, will require States to maintain an archive of at least the previous 5 years of EQR technical reports on their websites. Currently, almost half of States maintain an archive of at least 2 years' worth of EQR reports. Initially, we assume 75 percent of reports completed within the previous 5 years need to be archived on State websites. We estimate it will take 5 minutes (0.0833 hr) at $79.50/hr for a business operations specialist to collect and post a single EQR technical report to a State website. In aggregate for Medicaid for § 438.364(c)(2)(iii), we estimate a one-time burden of 204 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 0.75 × 5 years × 0.0833 hr) at a cost of $16,218 (204 hr × $79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 68 hours and $5,406. In aggregate for CHIP for § 457.1250(a), we estimate a one-time burden of 62 hours [(199 MCOs, PIHPs, and PAHPs yearly reports × 0.75 × 5 years × 0.0833/hr) at a cost of $4,929 (62 hr × $79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 21 hours and $1,643. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Based on the public comments received on our proposed change to 438.364(c)(1) to the annual due date of the EQR technical reports, we decided not to finalize this change, and therefore, have removed the associated burden. The associated burden was based on an estimate of 1 hour at $79.50/hr for a business operations specialist and 30 minutes at $118.14/hr a general operations manager to amend vendor contracts to reflect the new reporting date. In aggregate for Medicaid, we estimated an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $90,625 (654 contracts [(1 hr × $79.50/hr) + (0.5 hr × $118.14/hr)]). This change is discussed in more detail in section I.B.5.c. of this final rule.

12. ICRs Regarding Requirements for PCCMs and New Optional EQR Activity (§§ 438.310(c)(2), 438.350, 438.358, and 457.1250)

The following changes to § 438.310(c)(2) and § 438.350 will be submitted to OMB for approval under control number 0938–0786 (CMS–R–305). The following changes to § 457.1250 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.310(c)(2), 438.350, and 457.1250(a) will remove PCCMs from the managed care entities subject to EQR. We estimate the burden on States of completing EQR mandatory and optional activities which include:

Mandatory EQR activities include the validation of performance measures and a compliance review. We assume States validate 3 performance measures each year and conduct a compliance review once every 3 years. We expect it will take 53 hours at $79.50/hr for a business operations specialist to complete each performance measure validation and 361 hours at $79.50/hr for a business operations specialist to conduct a compliance review. Alleviating this burden will result in an annual State Medicaid savings of minus 2,793 hours (10 PCCM entities × [(53 hr/validation × 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $222,044 (− 2,793 hr × $79.50/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 2,196 hours (7 PCCM entities × [(53 hr/validation × 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $174,582 (− 2,196 hr × $79.50/hr).

Optional EQR activities include: (1) validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; (5) conduct of focused studies; and (6) assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with §§ 438.334 and 457.1240(d). Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of PCCM entities (approximately 1 PCCM) will be subject to each of the optional EQR-related activities. To conduct the optional activities we estimate it will take: 250 hours at $120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 549 hours at $79.50/hr for a business operations specialist to collect data and administer surveys; and 200 hours at $118.14/hr for general and operations manager to oversee and manage the process. Alleviating this burden will result in an annual state Medicaid savings of minus 999 hours (250 hr + 549 hr + 200hr) and minus $97,309 ([250 hr × $120.14/hr] + [549 hr × $79.50/hr] + [200 hr × $118.14). Adjusting for 7 PCCMs for CHIP for § 457.1250(a), we estimate annual State savings of minus 650 hours (− 228 hr − 49 hr − 16 hr − 103 hr − 127 hr − 127 hr) and minus $63,302 [(− 650 hr × 0.20 × $118.14/hr) + (− 650 hr × 0.25 × $120.14/hr) + (− 650 hr × 0.55 × $79.50/hr)].

Per § 438.364(c)(2)(ii), each State agency will provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees, and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. This change will eliminate the burden on States to provide PCCM EQR reports. We estimate an annual State burden of 5 minutes (on average) or 0.0833 hours at $39.56/hr for an office clerk to disclose the reports (per request), and that a State will receive five requests per PCCM entity. Alleviating this burden, for § 438.310(c)(2) and § 438.350, will result in an annual Medicaid State savings of minus 4 hours (10 PCCM entities × 5 requests × 0.0833/hr) and minus $158 (− 4 hr × $39.56/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 3 hours (7 PCCM entities × 5 requests × 0.0833/hr) and minus $119(− 3 hr × $39.56/hr).

For the mandatory and optional EQR activities, in aggregate for Medicaid, for § 438.310(c)(2) and § 438.350, we estimate an annual State savings of minus 3,796 hours (− 2,793 hr + − 999 hr + − 4 hr) and minus $319,4951($222,044 + $97,309 + $158). Similarly, in aggregate for CHIP for § 457.1250(a), we estimate an annual State savings of minus 2,849 (− 2,196 hr − 650 hr–3 hr) and minus $238,003 (− $174,582 − $63,302 − $119).

Additionally, the burden associated with § 438.358(b)(2) also includes the time for a PCCM entity (described in § 438.310(c)(2)) to prepare the information necessary for the State to conduct the mandatory EQR-related activities. The currently approved burden estimate in CMS–305 assumes 200 hr for a MCO, PIHP, or PAHP to prepare the information for all mandatory EQR activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)), we estimate it will take half the time (or 100 hr) to prepare the documentation for these 2 activities, half (50 hr) at $79.50/hr by a business operations specialist and half (50 hr) at $39.56/hr by an office clerk. In aggregate for Medicaid, we estimate an annual private sector savings of minus 1,000 hours (10 PCCM entities × 100 hr) and minus $59,530 [(− 500 hr × $79.50/hr) +

(−500 hr × $39.56/hr)]. In aggregate for CHIP for § 457.1250(a), we estimate an annual private sector savings of minus 200 hours (2 PCCM entities × 100 hr) and minus $11,906 [(−100 hr × $79.50/hr) + (−100 hr × $39.56/hr)].

Amendments to §§ 438.358(c)(7) and 457.1250(a) add a new optional EQR activity to assist in evaluations for ILOSs, quality strategies and SDPs that pertain to outcomes, quality, or access to health care services. Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of MCOs, PIHPs and PAHPs will be subject to each of the optional EQR-related activities, though we note that the exact States and number vary from year to year. We also estimate that it will take 80 hours for a mix of professionals will work on each optional EQR-related activity: 16 hours for a general and operations manager at $118.14/hr; 20 hours for software and web developers, programmers and testers at $120.14/hr; and 44 hours for a business operations specialist at $79.50/hr. In aggregate for Medicaid, the annual State burden to assist in evaluations is 4,640 hours (58 MCOs, PIHPs and PAHPs × 80 hr) at a cost of $451,880 [(58 MCOs, PIHPs and PAHPs × 16 hr × $118.14/hr) + (58 MCOs, PIHPs and PAHPs × 20 hr × $120.14/hr) + (58 MCOs, PIHPs and PAHPs × 44 hr × $79.50/hr)]. In aggregate for CHIP for § 457.1250(a), the annual State burden to assist in evaluations is 1,600 hours (20 MCOs, PIHPs and PAHPs × 80 hr) at a cost of $155,821 [(1,600 hr × 0.20 × $118.14/hr) + (1,600 hr × 0.25 × $120.14/hr) + (1,600 hr × 0.55 × $79.50/hr)].

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

13. ICRs Regarding Quality Rating System Measure Collection (§§ 438.515 and 457.1240)

The following changes to § 438.515 will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.515(a)(1) and 457.1240(d) will revise the existing QRS requirements by mandating that the State collect specified data from each managed care plan with which it contracts that has 500 or more enrollees on July 1 of the measurement year. Based on the data collected, the State will calculate and issue an annual quality rating to each managed care plan. The State will also collect data from Medicare and the State's FFS providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans. Annual quality ratings will serve as a tool for States, plans and beneficiaries. The annual quality ratings will hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries, provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs, and empower beneficiaries with useful information about the plans available to them. States will be required to collect data using the framework of a mandatory QRS Measure Set. We used the mandatory measure set, found in Table 2 of this final rule, as the basis for the measure collection burden estimate. The mandatory measure set consists of 16 measures, including CAHPS survey measures, and reflects a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries. For Medicaid managed care, we assume 629 MCOs, PIHPs and PAHPs and 44 States to be subject to the mandatory QRS measure set collection and reporting provision. For CHIP managed care, we assume 199 MCOs, PIHPs and PAHPs and 32 States to be subject to the mandatory QRS measure set collection and reporting provision. We assume that plans with CHIP populations will report the subset of QRS measures which apply to beneficiaries under 19 years of age and to pregnant and postpartum adults, where applicable.

For Medicaid, we expect reporting the QRS non-survey measures will take: 680 hours at $120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 212 hours at $79.50/hr for a business operations specialist to manage the data collection process; 232 hours at $39.56/hr for an office clerk to input the data; 300 hours at $85.60/hr for a registered nurse to review medical records for data collection; and 300 hours at $49.12/hr for medical records and health information analyst to compile and process medical records. For Medicaid, for § 438.515(a)(1) for one managed care entity we estimate an annual private sector burden of 1,724 hours (680 hr + 212 hr + 232 hr + 300 hr + 300 hr) at cost of $148,143([680 hr × $120.14/hr] + [212 hr × $79.50/hr] + [232 hr × $39.56/hr] + [300 hr × $85.60/hr] + [300 hr × $49.12/hr]).

For Medicaid, we also estimate that conducting the QRS survey measures comprised of the CAHPS survey will take: 20 hours at $79.50/hr for a business operations specialist to manage the data collection process; 40 hours at $39.56/hr for an office clerk to input the data; and 32 hours at $101.46/hr for a statistician to conduct data sampling. For 438.515(a)(1), for one Medicaid managed care entity we estimate an annual private sector burden of 92 hours (20 hr + 40 hr + 32 hr) at cost of $6,419 ([20 hr × $79.50/hr] + [40 hr × $39.56/hr] + [32 hr × $101.46]).

For one Medicaid managed care entity, for mandatory QRS non-survey and survey measures we estimate an annual private sector burden of 1,816 hours (1,724 hr + 92 hr) at a cost of $154,562 ($148,143 + $6,419). In aggregate, for Medicaid, for 438.515(a)(1), we estimate an annual private sector burden of 1,142,264 hours (629 Medicaid MCOs, PIHPs and PAHPs × 1,816 hours) and $97,219,498 (629 Medicaid MCOs, PIHPs and PAHPs × $154,562).

For CHIP for § 457.1240(d), we expect reporting non-survey QRS measures will take: 400 hours at $120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 148 hours at $79.50/hr for a business operations specialist to manage the data collection process; 152 hours at $39.56/hr for an office clerk to input the data; 60 hours at $85.60/hr for a registered nurse to review medical records for data collection; and 60 hours at $49.12/hr for medical records specialist to compile and process medical records. For one CHIP managed care entity we estimate an annual private sector burden of 820 hours (400 hr + 148 hr + 152 hr + 60 hr + 60 hr) at cost of $68,782 ([400 hr × $120.14/hr] + [148 hr × $79.50/hr] + [152 hr × $39.56/hr] + [60 hr × $85.60/hr] + [60 hr × $49.12/hr])

For CHIP for § 457.1240(d), we also estimate that conducting the survey measures (comprised of the CAHPS survey and secret shopper) will take: 20 hours at $79.50/hr for a business operations specialist to manage the data collection process; 56 hours at $39.56/hr for an office clerk to input the data; and 32 hours at $101.46/hr for a statistician to conduct data sampling. For one CHIP managed care entity we estimate an annual private sector burden of 108 hours (20 hr + 56 hr + 32 hr) at cost of $7,052 ([20 hr × $79.50/hr] + [56 hr × $39.56/hr] + [32 hr × $101.46]).

For one CHIP managed care entity, for mandatory QRS non-survey and survey measures, we estimate an annual private sector burden of 928 hours (820 hr +108 hr) at a cost of $80, 970 ($73,918 + $7,052). In aggregate, for CHIP for § 457.1240(d), we estimate an annual

private sector burden of 184,672 hours (199 CHIP MCOs, PIHPs and PAHPs × 928hr) and $16,113,110 (199 CHIP MCOs, PIHPs and PAHPs × $80,970).

The CAHPS survey measures also include a new burden on Medicaid beneficiaries. Beneficiaries complete the survey via telephone or mail. Response rates vary slightly by survey population. The adult CAHPS survey aims for 411 respondents out of a 1,350-person sampling and the Child CAHPS survey aims for 411 respondents out of a 1,650-person sampling. For Medicaid, the survey will be conducted twice, once for children and once for adults. We estimate it will take 20 minutes (0.33 hr) at $29.76/hr for a Medicaid beneficiary to complete the CAHPS Health Plan Survey. For Medicaid, in aggregate, we estimate a new beneficiary burden of 170,623 hours (629 MCOs, PIHPs and PAHPs × 0.33 hr per survey response × 822 beneficiary responses) at a cost of $5,077,727 (170,623 hr × $29.76/hr). Since it is not a new requirement for States to complete CAHPS surveys for CHIP beneficiaries, no new burden estimates are provided CHIP.

Additionally, amendments to § 438.515(a)(1)(i) that require reporting of QRS measures will require States to update existing managed care contracts. We estimate it will take 1 hour at $79.50/hr for a business operations specialist and 30 minutes at $118.14/hr a general operations manager to amend vendor contracts to reflect the new reporting requirements. In aggregate for Medicaid, we estimate a one-time State burden of 944 hours (629 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $87,161 (629 contracts × [(1 hr × $79.50/hr) + (0.5 hr × $118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 315 hours and $29,054. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 299 hours (199 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $27,575 (199 contracts × [(1 hr × $79.50/hr) + (0.5 hr × $118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 99 hours and $9,192. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to § 438.515(a)(1)(ii) require States to collect data from Medicare and the State's FFS providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans and the data are available for collection by the State without undue burden. We expect a that subset of States will need to collect Medicare data or State Medicaid FFS data to report the mandatory quality measures. We assume that plans have access to Medicare data for their enrollees and have included this burden in the cost of data collection described above. However, we assume Medicaid FFS data will need to be provided and that this requirement will impact 5 States. For a State to collect the FFS data needed for QRS reporting, we expect it will take: 120 hours at $120.14/hr for a software and web developers, programmers and testers to program and synthesize the data and 20 hours at $79.50/hr for a business operations specialist to manage the data collection process. In aggregate for Medicaid, we estimate an annual State burden of 700 hours (5 States × [120 hr + 20 hr]) at a cost of $80,034 (5 States × [(120 hr × $120.14/hr) + (20 hr × $79.50/hr)]).

Amendments to §§ 438.515(a)(2) and 457.1240(d) require the QRS measure data to be validated. We estimate it will take 16 hours at $79.50/hr for a business operations specialist to review, analyze and validate measure data. In aggregate for Medicaid, we estimate an annual private sector burden of 10,064 hours (629 MCOs, PIHPs, PAHPs and PCCMs × 16 hr) at a cost of $800,088 (10,064 hr × $79.50/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $253,128 (3,184 hr × $79.50/hr).

Amendments to §§ 438.515(d)(2) and 457.1240(d) allow the State to request a one-year extension on the implementation of certain methodology requirements outlined in § 438.515. The extension request must: identify the specific requirement(s) for which the extension is requested; describe the barriers to the requirement's implementation; demonstrate that, despite making good-faith efforts to identify and begin executing an implementation strategy, the State has good reason to believe that it will be unable to meet the specified requirement(s) by the implementation date identified by CMS in this subpart. The request must also include a detailed plan to implement the requirement(s) by the end of the extension including, but not limited to, the operational steps the State will take to address any identified implementation barrier(s). We assume that a small subset of States (7 States) will be unable to meet the QRS methodology requirements, and therefore, will submit an extension request. We estimate it will take 24 hours at $118.14/hr for a general operations manager to draft and submit the extension request. In aggregate for Medicaid, we estimate an annual private sector burden of 168 hours (7 States × 24 hr) at a cost of $19,848 (168 hr × $118.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed except modifications to reflect the inclusion of the option to submit a MAC QRS extension request in the final rule, discussed in more detail in section I.B.6.d. of this final rule and finalized at §§ 438.515(d) and 438.520(b). We have updated our burden calculations to reflect the inclusion of the option to submit a MAC QRS extension request.

14. ICRs Regarding Requirements for QRS Website Display (§§ 438.520(a) and 457.1240)

The following changes to § 438.520(a) will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

The amendments to §§ 438.520(a) and 457.1240(d) will require the State to prominently post an up-to-date display on its website that provides information on available MCOs, PIHPs and PAHPs. The display must: allow users to view tailored information, compare managed care plans, provide information on quality ratings and directs users to resources on how to enroll in a Medicaid or CHIP plan. Additionally, the display must offer consumer live assistance services. After the display is established, the State will need to maintain the display by populating the display with data collected from the mandatory QRS measure set established in this final rule. The final rule outlines a phase-in approach to the QRS website display requirements; however, the burden estimate reflects the full implementation of the website. We recognize this may result in an overestimate during the initial phase of the website display but believed the estimate is representative of the longer-term burden associated with the QRS website display requirements.

To develop the initial display, we estimate it will take: 600 hours at

$120.14/hr for a software and web developers, programmers and testers to create and test code; 600 hours at $84.22/hr for a web developer to create the user interface; 80 hours at $79.50/hr for a business operations specialist to manage the display technical development process; and 450 hours at $98.58/hr for a database administrator to establish the data structure and organization. We estimate that 44 States for Medicaid and 32 States for CHIP will develop QRS website displays. For one State, we estimate a burden of 1,730 hours (600 hr + 600 hr + 80 hr + 450 hr) at a cost of $173,337 ([600 hr × $120.14/hr] + [600 hr × $84.22/hr] + [80 hr × $79.50/hr] + [450 hr × $98.58/hr]). In aggregate for Medicaid, we estimate a one-time State burden of 76,120 hours (44 States × 1,730 hr) at a cost of $7,626,828 (44 States × $173,337). As this will be a one-time requirement, we annualize our Medicaid burden estimates to 25,373 hours and $2,542,276. In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 55,360 hours (32 States × 1,730 hr) and $5,546,784 (32 States × $173,337). As this will be a one-time requirement, we annualize our time and cost estimates for CHIP to 18,453 hours and $1,848,928. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To maintain the QRS display annually, we estimate it will take: 384 hours at $120.14/hr for a software and web developers, programmers and testers to modify and test code; 256 hours at $84.22/hr for a web developer to update and maintain the user interface; 120 hours at $79.50/hr for a business operations specialist to manage the daily operations of the display; and 384 hours at $98.58/hr for a database administrator to organize data. We estimate that 44 States for Medicaid and 32 States for CHIP will maintain QRS displays annually. For one State, we estimate a burden of 1,144 hours (384 hr + 256 hr + 120 hr + 384 hr) at a cost of $115,089 ([384 hr × $120.14/hr] + [256 hr × $84.22/hr] + [120 hr × $79.50/hr] + [384 hr × $98.58/hr]). In aggregate for Medicaid, we estimate an annual State burden of 50,336 hours (1,144 hours × 44 States) at a cost of $5,063,916 ($115,089 × 44 States). In aggregate for CHIP for § 457.1240(d), we estimate an annual State burden of 36,608 hours (1,144 hr × 32 States) at a cost of $3,682,842($115,089 × 32 States).

Amendments to §§ 438.520(a)(2)(iv) and 457.1240(d) will require the display to include quality ratings for mandatory measures which may be stratified by factors determined by CMS. We estimate it will take 24 hours at $120.14/hr for a software and web developers, programmers, and testers to develop code to stratify plan data. In aggregate for Medicaid (§ 438.520(a)(2)(iv)), we estimate an annual private sector burden of 15,096 hours (629 MCOs, PIHPs and PAHPs × 24 hr) at a cost of $1,813,633, (15,096 hr × $120.14/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 4,776 hours (199 MCOs, PIHPs and PAHPs × 24 hr) at a cost of $573,789 (4,776 hr × $120.14/hr).

Amendments to § 438.520(a)(3)(v) will require the QRS website display to include certain managed care plan performance metrics, as specified by CMS including the results of the secret shopper survey specified in § 438.68(f). The secret shopper survey is currently accounted for by OMB under control number 0938–TBD (CMS–10856). Plans will complete the secret shopper independent of the QRS requirements. To meet QRS requirements, States will enter data collected from the secret shopper survey and display the results of the survey on the QRS. Since the burden for the secret shopper survey is accounted for under a separate control number, for the purposes of MAC QRS, we account for the incremental burden associated with meeting the QRS requirements. We estimate it will take 16 hours at $39.56/hr for an office clerk to enter the results from the secret shopper survey into the QRS. In aggregate for Medicaid § 438.520(a)(3)(v), we estimate an annual private sector burden of 10,064 hours (629 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $398,132 (10,064 hr × $39.56/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs × 16 hr) at a cost of $125,959 (3,184 hr × $39.56/hr).

Amendments to §§ 438.520(b)(1) and 457.1240(d) allow the State to request a one-year extension on the implementation of certain website display requirements outlined in §§ 438.520(a). The extension request must: identify the specific requirement(s) for which the extension is requested; describe the barriers to the requirement's implementation; demonstrate that, despite making good-faith efforts to identify and begin executing an implementation strategy, the State has good reason to believe that it will be unable to meet the specified requirement(s) by the implementation date identified by CMS in this subpart. The request must also include a detailed plan to implement the requirement(s) by the end of the extension including, but not limited to, the operational steps the State will take to address any identified implementation barrier(s). We assume that a small subset of States (11 States) will be unable to meet the QRS website requirements, and therefore, will submit an extension request. We estimate it will take 24 hours at $118.14/hr for a general operations manager to draft and submit the extension request. In aggregate for Medicaid, we estimate an annual private sector burden of 264 hours (11 States × 24 hr) at a cost of $31,189 (264 hr × $118.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

15. ICRs Regarding QRS Annual Reporting Requirements (Part 438 Subpart G and §§ 438.520(a) and 457.1240)

The following changes will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.535(a) and 457.1240(b) will mandate that on an annual basis, the State submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. We estimate that 44 States for Medicaid and 32 States for CHIP will submit annual MAC QRS reports. We estimate it will take 24 hours at $79.50/hr for a business operations specialist to compile the required documentation to complete this report and attestation that the State is in compliance with QRS standards. In aggregate for Medicaid for § 438.535(a), we estimate an annual State burden of 1,056 hours (44 States × 24 hr) at a cost of $83,952 (1,056 hr × $79.50/hr). In aggregate for CHIP for § 457.1240(b), we estimate an annual State burden of 768 hours (32 States × 24 hr) at a cost of $61,056 (768 hr × $79.50/hr).

The addition of part 438, subpart G for Medicaid, and through an amendment at § 457.1240(d) for separate CHIP, will revise the quality rating system requirements and associated burden previously issued under § 438.334. Given the QRS requirements have substantively changed, our currently approved burden estimates for making changes to an approved alternative Medicaid managed care QRS are no longer applicable.

To implement an alternative Medicaid managed care QRS, we estimate it will take: 5 hours at $39.56/hr for an office and administrative support worker, 25 hours at $79.50/hr for a business operations specialist to complete the public comment process, and 5 additional hours at $79.50/hr for a business operations specialist to seek and receive approval from CMS for the change. We assume that a subset of States will opt for an alternative QRS and that the subset will revise their QRS once every 3 years.

Therefore, alleviating this burden will result in an annual Medicaid State reduction of minus 116.7 hours [(10 States × 35 hr)/3 years] and minus $8,609 (10 States × [(5 hr × $39.56/hr) + (30 × $79.50/hr)]/3 years). Similarly, we estimate an annual CHIP State savings of minus 117 hours [(10 States × 35 hr)/3 years] and minus $8,609 [(10 States × ((5 hr × $39.56/hr) + (30 × $79.50/hr))/3 years)]. We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

16. ICRs Regarding Program Integrity Requirements Under the Contract (§§ 438.608 and 457.1285)

The following changes to § 438.608 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1285 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.608 and 457.1285 will require States to update all MCO, PIHP, and PAHP contracts to require managed care plans to report overpayments to the State within 30 calendar days of identifying or recovering an overpayment. We estimate that the changes to the timing of overpayment reporting (from timeframes that varied by State to 30 calendar days for all States) will apply to all MCO, PIHP, and PAHP contracts, excluding contracts for NEMT, that is, a total of 629 contracts for Medicaid, and 199 contracts for CHIP. We estimate it will take: 2 hours at $79.50/hr for a business operations specialist and 1 hour at $118.14/hr for a general and operations manager to modify State contracts with plans. In aggregate for Medicaid for § 438.608, we estimate a one-time State burden of 1,887 hours (629 contracts × 3 hr) at a cost of $174,321 [629 contracts × ((2 hr × $79.50/hr) + (1 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 629 hours and $58,107.

In aggregate for CHIP for § 457.1285, we estimate a one-time State burden of 597 hours (199 contracts × 3 hr) at a cost of $55,151 [199 contracts × ((2 hr × $79.50/hr) + (1 hr × $118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 199 hours and $18,384. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate that it will take MCOs, PIHPs, and PAHPs 1 hour at $120.14/hr for software and web developers, programmers, and testers to update systems and processes already used to meet the previous requirement for ''prompt'' reporting. In aggregate for Medicaid for § 438.608, we estimate a one-time private sector burden of 629 hours (629 contracts × 1 hr) at a cost of $75,568 (629 hr × $120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 210 hours and $25,189. In aggregate for CHIP for § 457.1285, we estimate a one-time private sector burden of 199 hours (199 contracts × 1 hr) at a cost of $23,908 (199 contracts × $120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 66 hours and $7,969. The annualization divides our estimates by 3 years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

One public comment was received with regard to program integrity requirements under the contract (§§ 438.608 and 457.1285). A summary of the comment and our response follows:

Comment: One commenter noted that CMS should clarify if the proposed changes applied to NEMT PAHPs.

Response: We note that the proposed changes to overpayment reporting (from 10 calendar days to 30 calendar days) do not apply to NEMT PAHPs. We have updated the applicable number of contracts in these estimates to exclude NEMT contracts.

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TABLE 5: Summary of Medicaid Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.3(i) contract modifications	0938–1453 (CMS–10856)	315 Medicaid contracts	315	3	945	Varies	87,299	Once	315	29,100
438.3(i) provider incentive payment reporting	0938–1453 (CMS–10856)	315 Medicaid contracts	315	120	37,800	Varies	3,491,964	Once	12,600	1,163,988
438.3(i) annual reconciliation	0938–1453 (CMS–10856)	315 Medicaid contracts	315	3	945	Varies	87,299	Once	4,200	29,100
438.6(c)(2)(ii) New SDP submissions	0938–1453 (CMS–10856)	38 States	50	10	500	Varies	47,932	Annual	n/a	n/a
438.6(c)(2)(ii) Renewal/Amend. SDP submissions	0938–1453 (CMS–10856)	38 States	150	3	450	Varies	48,048	Annual	n/a	n/a
438.6(c)(2)(ii)(H) SDP Attestations	0938-TBD (CMS-10856)	44 States	44	400	17,600	Varies	1,756,832	Once	133	585,611
438.6(c)(2)(ii)(H) SDP Attestations	0938-TBD (CMS-10856)	44 States	44	434	19,118	Varies	1,116,424	Annual	n/a	n/a
438.6(c)(2)(ii)(H) SDP Attestations	0938-TBD (CMS-10856)	1,088,050 Providers	1,088,050	0.1	108,805	Varies	10,123,217	Annual	n/a	n/a
438.6(c)(2)(iii) specific SDPs and ACR rate	0938–1453 (CMS–10856)	38 States	60	15	900	Varies	108,680	Once	300	36,227
438.6(c)(2)(iv) SDP written eval plan	0938–1453 (CMS–10856)	38 States	50	10	500	Varies	54,741	Annual	n/a	n/a
438.6(c)(2)(iv) eval plan for amendment and renewal	0938–1453 (CMS–10856)	38 States	150	6	900	Varies	95,334	Annual	n/a	n/a
438.6(c)(2)(v) eval report spending greater than 1.5 percent and 438.6(c)(2)(ii)(f) – evaluation reports	0938–1453 (CMS–10856)	38 States	57	6	282	Varies	36,341	Annual	n/a	n/a
438.6(c)(7) final SDP cost percentage actuarial report with rate certification	0938-1453 (CMS-10856)	10 States	10	17	170	Varies	17,706	Annual	n/a	n/a
438.7(b) actuarial	0938–1453	44 States	253	250	63,250	Varies	6,719,558	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
rate submission	(CMS–10856)									
438.8(k) annual MLR reports	0938-0920 (CMS-10856)	629 Medicaid contracts	629	3	1887	Varies	176,775	Annual	n/a	n/a
438.10(c)(3) website	0938–1453 (CMS–10856)	45 States	45	20	900	120.14	108,126	Once	300	36,042
438.10(c)(3) periodic update to website	0938–1453 (CMS–10856)	45 States	45	40	1,800	120.14	216,252	Annual	n/a	n/a
438.16(c)(5)(ii) ILOS reporting	0938–1453 (CMS–10856)	22 States	22	17	374	Varies	38,953	Annual	n/a	n/a
438.16(d)(1) documentation for ILOS in contract	0938–1453 (CMS–10856)	22 States	327	1	327	79.50	25,997	Annual	n/a	n/a
438.16(d)(2) ILOS additional documentation	0938–1453 (CMS–10856)	5 States	5	2	10	79.50	795	Annual	n/a	n/a
438.16(e)(1) ILOS evaluation	0938–1453 (CMS–10856)	5 States	5	25	125	79.50	9,938	Annual	n/a	n/a
438.16(e)(2)(iii) ILOS transition of care policy	0938–1453 (CMS–10856)	22 States	22	4	88	varies	8,784	Once	30	2928
438.16(e)(2)(iii) updates to ILOS policy	0938–1453 (CMS–10856)	22 States	22	1	22	79.50	1,749	Annual	n/a	n/a
438.16(e)(2)(iii) ILOS termination transition policy	0938–1453 (CMS–10856)	65 MCOS, PIHPs and PAHPs	65	2	130	79.50	10,335	Annual	n/a	n/a
438.66(c) enrollee experience survey – first year	0938–1453 (CMS–10856)	49 States	49	110	5390	Varies	475,840	Once	1,796	158,614
438.66(c) conduct experience surveys	0938–1453 (CMS–10856)	49 States	49	65	3185	Varies	281,608	Annual	n/a	n/a
438.66(e) annual program assessment report	0938–1453 (CMS–10856)	49 States	49	80	3,920	79.50	311,640	Annual	n/a	n/a
438.68(e) network adequacy standards	0938–1453 (CMS–10856)	44 States	44	20	880	79.50	69,960	Once	293	23,320
438.68(e) – network adequacy standards	0938–1453 (CMS–10856)	44 States	44	10	440	79.50	34,980	Annual	n/a	n/a
438.68(f) secret shopper survey vendor	0938–1453 (CMS–10856)	44 States	44	110	4840	Varies	427,284	Once	1,614	142,428

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.68(f) contract management and analysis of results	0938–1453 (CMS–10856)	44 States	44	65	2,860	Varies	252,872	Annual	n/a	n/a
438.74 Data aggregation for MLR reporting	0938–1453 (CMS–10856)	5 States	5	5	25	79.50	1,988	Once	8	663
438.207(b)(3) payment analysis	0938–1453 (CMS–10856)	629 MCOS, PIHPs and PAHPs	629	150	94,350	Varies	10,031,921	Once	31,449	3,343,974
438.207(b)(3) payment analysis	0938–1453 (CMS–10856)	629 MCOS, PHIPs and PAHPs	629	45	28,305	Varies	2,883,021	Annual	n/a	n/a
438.207(d) assurance of compliance	0938–1453 (CMS–10856)	44 States	44	40	1,760	79.50	139,920	Annual	n/a	n/a
438.310(c)(2), 438.350 removing PCCM EQR requirements	0938-0786 (CMS-R-305)	10 States	10	379.6	-3,796	varies	-319,510	Annual	n/a	n/a
438.334(c)(1)(a) Alternative QRS	0938-0786 (CMS-R-305)	10 States	-10	-35	-117	varies	-8,609	Annual	n/a	n/a
438.358(b)(2) PCCM EQR data preparation	0938-0786 (CMS-R-305)	10 PCCMs	-10	-100	-1,000	varies	-59,530	Annual	n/a	n/a
438.358(c)(7) New optional EQR activity	0938-0786 (CMS-R-305)	58 MCOS, PHIPs and PAHPs	58	80	4,640	Varies	451,880	Annual	n/a	n/a
438.360(a)(1) EQR plan accreditation requirements	0938-0786 (CMS-R-305)	65 MCOS, PHIPs and PAHPs	-65	-409.33	-26,606	79.50	-2,115,177	Annual	n/a	n/a
438.364(a)(2)(iii) adding outcome data to EQR reports	0938-0786 (CMS-R-305)	654 MCOS, PHIPs and PAHPs	654	1.5	981	varies	64,929	Annual	n/a	n/a
438.364(c)(2)(i) Notification of EQR report publishing	0938-0786 (CMS-R-305)	44 States	44	0.5	22	79.50	1,749	Annual	n/a	n/a
438.364(c)(2)(iii) Archiving EQR reports for 5 years	0938-0786 (CMS-R-305)	44 States	2452.5	0.0833	204	79.50	16,218	Once	68	5,406
438.515(a)(1) QRS measure collection	0938-1282 (CMS-10553)	629 MCOS, PHIPs and PAHPs	629	1816	1,142,264	Varies	97,219498	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.515(a)(1)(i) QRS vendor contract updates	0938-1282 (CMS-10553)	44 States	629	1.5	944	Varies	87,161	Once	315	29,054
438.515(a)(1)(ii) QRS FFS data collection	0938-1282 (CMS-10553)	5 States	5	140	700	varies	80,034	Annual	n/a	n/a
438.515(a)(2) QRS measure validation	0938-1282 (CMS-10553)	629 MCOS, PHIPs and PAHPs	629	16	10,064	79.50	800,088	Annual	n/a	n/a
438.515(d)(2) QRS optional methodology implementation extension	0938-1282 (CMS-10553)	7 States	7	24	168	118.14	19,848	Annual	n/a	n/a
438.520(a) QRS website display creation	0938-1282 (CMS-10553)	44 States	44	1730	76,120	varies	7,626,828	Once	25,373	2,542,276
438.520(a) QRS website display yearly maintenance	0938-1282 (CMS-10553)	44 States	44	1,144	50,336	varies	5,063,916	Annual	n/a	n/a
438.520(a)(2)(iv) QRS measure stratification	0938-1282 (CMS-10553)	629 MCOS, PHIPs and PAHPs	629	24	15,096	120.14	1,813,633	Annual	n/a	n/a
438.520(a)(3)(v) QRS secret shopper survey data entry	0938-1282 (CMS-10553)	629 MCOS, PHIPs and PAHPs	629	16	10,064	39.56	398,132	Annual	n/a	n/a
438.520(b)(1) QRS optional website implementation extension	0938-1282 (CMS-10553)	11 States	11	24	264	118.14	31,189	Annual	n/a	n/a
438.535(a) QRS annual reporting	0938-1282 (CMS-10553)	44 States	44	24	1056	79.50	83,952	Annual	n/a	n/a
438.608(a)(2) – contract modifications	0938–1453 (CMS–10856)	629 Medicaid contracts	629	3	1887	Varies	174,321	Once	629	58,107
438.608(a)(2) system updates	0938–1453 (CMS–10856)	629 MCOs, PIHPs, and PAHPs	629	1	629	120.14	75,568	Once	210	25,189
Total		Varies	18,956	Varies	1,529,955	Varies	136,346,234	Varies	75,213	7,130,225

TABLE 6: Summary of CHIP Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1201(e) additional documentation for ILOs in contract	0938-1282 (CMS-10554)	16 States	100	1	100	79.50	7,950	Annual	n/a	n/a
457.1201(e) ILOS additional documentation	0938-1282 (CMS-10554)	5 States	5	2	10	79.50	795	Annual	n/a	n/a
457.1201(e) ILOS evaluation	0938-1282 (CMS-10554)	5 States	5	25	125	79.50	9,938	Annual	n/a	n/a
457.1201(e) ILOS transition of care policy	0938-1282 (CMS-10554)	16 States	16	4	64	Varies	6,389	Once	21	2,130
457.1201(e) updates to ILOS policy	0938-1282 (CMS-10554)	16 States	16	1	16	79.50	1,272	Annual	n/a	n/a
457.1201(e) ILOS termination transition policy	0938-1282 (CMS-10554)	40 CHIP contracts	40	2	80	79.50	6,360	Annual	n/a	n/a
457.1203(f) contract modifications	0938-1282 (CMS-10554)	100 CHIP contracts	100	3	300	Varies	27,714	Once	100	9,238
457.1203(f) provider incentive payment reporting	0938-1282 (CMS-10554)	100 CHIP contracts	100	120	12,000	Varies	1,108,560	Once	4,000	369,520
457.1203(f) annual reconciliation	0938-1282 (CMS-10554)	100 CHIP contracts	100	1	100	79.50	7,950	Annual	n/a	n/a
457.1203(f) annual MLR reports	0938-1282 (CMS-10554)	199 CHIP contracts	199	3	597	Varies	55,927	Annual	n/a	n/a
457.1203(e) Data aggregation for MLR reporting	0938-1282 (CMS-10554)	5 CHIP contracts	5	5	25	79.50	1,988	Once	8	663
457.1207 website	0938-1282 (CMS-10554)	32 States	32	20	640	120.14	76,890	Once	213	25,630

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1207 periodic updates to website	0938-1282 (CMS-10554)	32 States	32	41	1,312	120.14	157,624	Annual	n/a	n/a
457.1218 network adequacy standards	0938-1282 (CMS-10554)	32 States	32	20	640	79.50	50,880	Once	213	16,960
457.1218 network adequacy standards	0938-1282 (CMS-10554)	32 States	32	10	320	79.50	25,440	Annual	n/a	n/a
457.1218 vendor for secret shopper	0938-1282 (CMS-10554)	32 States	32	110	3,520	Varies	310,752	Once	1173	103,584
457.1218 contract management and analysis of results	0938-1282 (CMS-10554)	32 States	32	65	2,080	Varies	183,907	Annual	n/a	n/a
457.1230(b) reimbursement analysis	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	150	29,850	Varies	3,173,851	Once	9,950	1,057,950
457.1230(b) analysis for amendments	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	45	8,955	Varies	912,117	Once	2,985	304,039
457.1230(b) assurance of compliance and posting survey summaries	0938-1282 (CMS-10554)	32 States	32	44	1,408	79.50	111,936	Annual	n/a	n/a
457.1240(d) QRS measure collection	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	928	184,672	Varies	16,113,110	Annual	n/a	n/a
457.1240(d) QRS vendor contract updates	0938-1282 (CMS-10554)	32 States	199	1.5	299	Varies	27,575	Once	99	9,192
457.1240(d) QRS measure validation	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	16	3,184	79.50	253,128	Annual	n/a	n/a
457.1240(d) QRS website	0938-1282 (CMS-10554)	32 States	32	1,730	55,360	Varies	5,546,784	Once	18,453	1,848,928

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
display creation										
457.1240(d) QRS website display yearly maintenance	0938-1282 (CMS-10554)	32 States	32	1,144	36,608	Varies	3,682,842	Annual	n/a	n/a
457.1240(d) QRS measure stratification	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	24	4,776	120.14	573,789	Annual	n/a	n/a
457.1240(d) QRS secret shopper survey data entry	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	16	3,184	39.56	125,959	Annual	n/a	n/a
457.1240(d) QRS annual reporting	0938-1282 (CMS-10554)	32 States	32	24	768	79.50	61,056	Annual	n/a	n/a
457.1240(d) Alternative QRS	0938-1282 (CMS-10554)	(10 States)	(10)	(35)	(117)	Varies	(8,609)	Annual	n/a	n/a
457.1250(a) adding outcome data to EQR reports	0938-1282 (CMS-10554)	199 MCOs, PIHPs and PAHPs	199	1.5	299	Varies	19,757	Annual	n/a	n/a
457.1250(a) Notification of EQR report publishing	0938-1282 (CMS-10554)	32 States	32	.5	16	79.50	1,272	Annual	n/a	n/a
457.1250(a) Archiving EQR reports for 5 years	0938-1282 (CMS-10554)	32 States	746	.0833	62	79.50	4,929	Once	21	1,643
457.1250(a) removing PCCM EQR requirements	0938-1282 (CMS-10554)	(7 States)	(7)	(407)	(2,849)	Varies	(238,003)	Annual	n/a	n/a
457.1250(a) PCCM EQR data preparation	0938-1282 (CMS-10554)	(2 PCCMs)	(2)	(100)	(200)	Varies	(11,906)	Annual	n/a	n/a
457.1250(a) New optional EQR activity	0938-1282 (CMS-10554)	20 MCOs, PIHPs and PAHPs	20	80	1600	Varies	155,821	Annual	n/a	n/a
457.1285 contract	0938-1282 (CMS-10554)	199 CHIP contracts	199	3	597	Varies	55,151	Once	199	18,384

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
modifications										
Total		Varies	3,576	Varies	350,401	Varies	32,600,895	Varies	37,435	3,767,861

TABLE 7: Summary of Medicaid and CHIP Requirements and Burden

	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
Medicaid	0938–1453(CMS–10856) 0786 (CMS-R-305) 1282 (CMS-10553)	Varies	18,956	Varies	1,529,955	Varies	136,346,234	Varies	75,213	7,130,225
CHIP	0938-1282 (CMS-10554)	Varies	3,576	Varies	350,401	Varies	32,600,895	Varies	37,435	3,767,861
Total		Varies	22,532	Varies	1,880,356	Varies	168,947,129	Varies	112,648	10,898,086

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III. Regulatory Impact Analysis

A. Statement of Need

This final rule will advance CMS's efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees. The final rule will specifically address standards for timely access to care and States' monitoring and enforcement efforts, reduce burden for State directed payments and certain quality reporting requirements, add new standards that will apply when States use ILOSs to promote effective utilization and identify the scope and nature of ILOS, specify MLR requirements, and establish a QRS for Medicaid and CHIP managed care plans.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review will meaningfully further the President's priorities or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant under Section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

We have examined the proposed provisions in this rule and determined that most of the proposed revisions to part 438 and part 457 outlined in this final rule are expected to minimally or moderately increase administrative burden and associated costs as we note in the COI (see section II. of this final rule). Aside from our analysis on burden in the COI, we believed that certain provisions in this final rule should specifically be analyzed in this regulatory impact analysis as potentially having a significant economic impact. Those proposed provisions include State directed payments, MLR reporting standards, and ILOS due to the impact these proposed provisions could have on the associated and corresponding managed care payments.

1. State Directed Payments (SDPs) (§§ 438.6 and 438.7)

Neither the May 6, 2016 final rule (81 FR 27830) nor the November 13, 2020 final rule (85 FR 72754) included a regulatory impact analysis that discussed the financial and economic effects of SDPs. At the time the 2016 final rule was published and adopted regulations explicitly governing State directed payments, we believed that States would use the SDPs in three broad ways to: (1) transition previous pass-through payments into formal arrangements as SDPs; (2) add or expand provider payment requirements to promote access to care; and (3) implement quality or value payment models that include Medicaid managed care plans. However, since § 438.6(c) was issued in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDPs being submitted by States for approval has also grown steadily. In CY 2017, CMS received 36 preprints for our review and approval from 15 States; in CY 2021, CMS received 223 preprints from 39 States. For CY 2022, CMS received 309 preprints from States. As of March 2023, CMS has reviewed more than 1,100 SDP proposals and approved more than 1,000 proposals since the 2016 final rule was issued. To accommodate these requests from States, CMS applied discretion in interpreting and applying § 438.6(c) in reviewing and approving SDPs. The 2016 final rule required criteria to determine if provider payment rates are ''reasonable, appropriate, and attainable'' and that SDPs must relate to utilization, quality, or other goals described in § 438.6(c). CMS has interpreted these sections of the regulation broadly, and therefore, the amount of SDP payments has grown significantly over time.

SDPs also represent a substantial amount of State and Federal spending. The MACPAC reported that CMS approved SDPs in 37 States, with spending exceeding more than $25 billion.[235] The U.S. Government Accountability Office also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 proposals.[236]

We have tracked SDP spending trends as well. Using the total spending captured for each SDP through the end of 2023, we calculate that SDP payments in 2022 were $52.2 billion and that such payments were $78.1 billion in 2023. We note that there may be some SDPs for which CMS does not have projected or actual spending data. In addition, our data reporting and collection is not standardized, and in some cases may be incomplete, so spending data for some SDP approvals may be less accurate. CMS began collecting total dollar estimates for SDPs incorporated through adjustments to base rates, as well as those incorporated through separate payment terms with the revised preprint form published in January 2021; States were required to use the revised preprint form for rating periods beginning on or after July 1, 2021.

[235] Medicaid and CHIP Payment and Access Commission, ''Report to Congress on Medicaid and CHIP,'' *June 2022, available at https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*

[236] U.S. Government Accountability Office, ''Medicaid: State Directed Payments in Managed Care,'' *June 28, 2022, available at https://www.gao.gov/assets/gao-22-105731.pdf.*

We estimate that SDP spending comprises approximately 15.6 percent of total managed care payments in 2023 ($499.8 billion) and 9.0 percent of total Medicaid benefit expenditures ($869.7 billion). SDP spending varies widely across States. Thirty-nine (39) States reported the use of one or more SDPs in 2022 and/or 2023. In 2022, the percentage of Medicaid managed care spending paid through SDPs ranged from 1 percent to 58 percent across these States, with a median of 8 percent; as a share of total Medicaid spending, SDPs ranged from 0 percent to 33 percent, with a median of 3 percent. (Data for 2023 is not yet available.)

From 2016 through 2023, SDPs were a significant factor in Medicaid expenditure growth. Total benefit spending increased at an average annual rate of 6.8 percent per year from 2016 through 2023; excluding SDPs, benefit spending grew at an average rate of 5.4 percent. Managed care payments grew 9.6 percent on average over 2016 to 2023, but excluding SDPs, the average growth rate was 6.9 percent. While some SDP spending may have been included in managed care payments prior to 2016 (either as a pass-through payment or some other form of payment), by 2023 we expect that much of this is new spending.

In 2023, we estimate that about 70 percent of SDP spending went to hospitals for inpatient and outpatient services, and another 4 percent went to academic medical centers. 10 percent of SDP spending was reported for multiple provider types, which mostly were hospitals and academic medical centers. The remaining 16 percent of SDP spending went to nursing facilities, primary care physicians, specialty physicians, HCBS and personal care service providers, behavioral health service providers, and dentists.

The data available do not allow us to determine how much of this baseline SDP spending was incorporated into managed care expenditures prior to the 2016 final rule, or reflected historical transfers from prior payment arrangements. For example, States transitioned pass-through payments to SDPs or transferred spending from FFS payments (for example, supplemental payments) to SDPs. Some States indicate that the SDP has had no net impact on rate development while other States have reported all estimated spending for the services and provider class affected by the SDP. Based on our experience working with States, we believed much of the earlier SDP spending was largely existing Medicaid spending that was transitioned to managed care SDPs. However, in more recent years, we believed that most SDP spending reflects new expenditures. For context, States reported $6.7 billion in pass-through payments after the 2016 final rule.[237] States also have reported only a small decrease in FFS supplemental payments since 2016 (from $28.7 billion in 2016 to $27.5 billion in 2022).[238] SDP spending in 2023 significantly exceeds the originally reported pass-through payments and the changes in FFS supplemental payments.

The proposals in this rule are intended to ensure the following policy goals: (1) Medicaid managed care enrollees receive access to high-quality care under SDPs; (2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDPs; and (3) CMS has the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and feasibility of SDPs.

The proposal expected to have the most significant economic impact is setting a payment ceiling at 100 percent of the ACR for SDPs for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. As discussed in section I.B.2.f. of this final rule, we have used the ACR as a benchmark for total payment levels for all SDP reviews since 2018 and have not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR. Based on the available data, we estimate that $15 billion to $20 billion of SDPs in 2023 reflect payments at or near the ACR. It is difficult to determine the amounts of these payments due to data quality and inconsistent reporting of these details. For example, if payment data are aggregated across multiple providers or provider types, it can be difficult to determine if providers are being paid at different levels. Additionally, many SDPs report payment rates relative to Medicare instead of ACR; for some SDPs, the payment rates relative to Medicare suggest effective payment rates will be near the ACR. These will include SDPs with effective payment rates of 150 percent or more of the Medicare rate (with several over 200 percent).

Under current policy, we project that SDP spending will increase from $78 billion in 2023 (or 15.6 percent of managed care spending) to about $99 billion by 2029 (or 16.5 percent of managed care spending).

TABLE 8: Projected Medicaid Managed Care and State Directed Spending Under Current Policy, FY 2022-2029 ($ Billions)

	2022	2023	2024	2025	2026	2027	2028	2029
Managed care spending	$442	$488	$457	$467	$498	$530	$565	$602
SDP spending	$52	$78	$74	$76	$82	$88	$93	$99
SDP as share of managed care	11.8%	16.0%	16.2 %	16.4 %	16.4 %	16.5 %	16.5 %	16.5 %

Estimating the impact of the proposed SDP provisions is challenging for several reasons. First, as noted previously, the projected and actual spending data that we collect from States is not standardized, and in some cases aggregated across providers. It is also often difficult to determine how payment rates compare, especially when States use different benchmarks for payment (for example, comparing SDPs using Medicare payment rates to those

[237] Our data reflects documentation provided from 15 States with pass-through payments in rating periods beginning from July 1, 2017 through June 30, 2018.

[238] CMS–64. *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html.*

using ACR payment rates). In addition, there is frequently limited information on ACR payment rates. It is difficult to determine how the ACR may be calculated and how the calculation may vary across different States and providers. Furthermore, it may be difficult to determine how many more providers are not paid under SDPs and how much they could be paid if SDPs were expanded to them.

Second, it is difficult to determine how much providers are paid in managed care programs without SDPs. These data appear to be less frequently reported, and we have virtually no information about provider payments when the State does not use an SDP. This information is important when estimating the impact of changes in SDPs, because the initial payment rate matters as much as the final rate. In some cases, the initial payment rates for existing SDPs are significantly low (for example, there are several SDPs where the reported initial payment rates are 10 to 20 percent of ACR or commercial rates, 25 to 30 percent of Medicare rates, or 10 to 35 percent of Medicaid State plan rates). In other cases, the initial payment rates are relatively higher. Thus, it may be difficult to determine how large new SDPs will be.

Third, there is significant variation in the use of SDPs across States. States have significant discretion in developing SDPs (including which providers receive SDPs and the amounts of the payments), and it is challenging to predict how States will respond to changes in policy. Some States may add more SDPs or expand spending in existing SDPs. Moreover, as many SDPs are funded through sources other than State general revenues (such as intergovernmental transfers or provider taxes), decisions about SDPs may be dependent on the availability of these funding sources.

Fourth, how states finance these arrangements may also have some effect on the increase in spending through SDPs. The final rule requires states to obtain provider attestations of compliance with Federal restrictions on hold harmless arrangements no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028. We acknowledge that States may be motivated to submit SDP preprints at a higher than usual rate prior to the effective date of these provisions.

For these reasons, we believe it is prudent to provide a range of estimated impacts for this section of the final rule. The following estimates reflect a reasonable expectation of the impacts of this final rule on Medicaid expenditures, but do not necessarily include all possible outcomes.

The estimate of the upper end of the range is based on the expectation that the provisions of the final rule will prompt States to increase SDP spending. We believed that by setting the payment limit at the ACR rates for certain services, States may increase the size and scope of future SDPs to approach this limit. In particular, there are many SDPs that currently have effective reimbursement rates at or around 100 percent of Medicare reimbursement rates, and others with rates below 100 percent of ACR, and that States may potentially increase payments associated with these SDPs. The high end of the range also reflects possible short-term increases of SDPs prior to the effective date of the hold harmless requirements.

For the high scenario, we assumed that Medicaid SDP spending will increase at a faster rate than projected under current law. Under current law, Medicaid SDP spending is projected to reach 16.5 percent of managed care spending by 2027. We assumed in the high scenario that SDP spending will reach about 22.8 percent of managed care spending in 2027, and then decrease to 21.5 percent in 2028 as the financing requirements go into effect. Under this scenario, SDP spending will increase by approximately 49 percent by 2027 (or about $43 billion). From 2025 through 2027, SDP spending will increase somewhat faster than assumed under current law to reach those levels. This increase will include additional spending from current SDPs increasing payment rates to the ACR and may also include new or expanded SDPs. We also expected that this will occur mostly among SDPs for hospitals and academic medical centers, as those are currently the providers that receive the majority of SDPs. We have not estimated a breakdown of impacts by provider type or by State in this analysis. We project that SDPs would increase by $129.6 billion over 2024 through 2028 in the high case.

In the proposed rule, we estimated that the low end of the range of impacts for the changes to SDPs would be 0. However, we have updated our estimates in the final rule for the low end of the range to reflect an increase in expenditures. In particular, some States have already indicated that they would increase SDPs with the clarification that CMS would allow effective payment rates up to ACR. As a result, we believe that it is more accurate to estimate for the low case that there are some increases in spending. We estimate that the low end of the range of impacts for these provisions in the final rule would be half of the impact of the high end of the range. We project that SDPs would increase by $27.0 billion over 2024 through 2028 in the low case.

The median estimates of these two cases are the middle scenario. The estimated impacts are provided in Table 9.

TABLE 9: Projected Medicaid State Directed Payment Spending Under Final Rule, High, Middle, and Low Scenarios, FY 2024-2028 ($ Billions)

	2024	**2025**	**2026**	**2027**	**2028**	**2024-2028**
Current law	$74.2	$76.4	$81.8	$87.5	$93.2	$413.1
High scenario	$75.4	$90.6	$117.2	$130.5	$129.0	$542.7
High scenario impact	$1.2	$14.2	$35.4	$43.0	$35.8	$129.6
Middle scenario	$74.9	$86.0	$102.6	$112.8	$115.1	$491.4
Middle scenario impact	$0.7	$9.6	$20.8	$25.3	$21.9	$78.3
Low scenario	$74.4	$81.4	$88.0	$95.1	$101.2	$440.1
Low scenario impact	$0.2	$5.0	$6.2	$7.6	$8.0	$27.0

Note: The impact represents the difference between the projected SDP spending under each scenario and the current law projections.

In Table 10, we provide estimates of the impacts on the Federal government and on States.

TABLE 10: Projected Medicaid State Directed Payment Spending Under Final Rule by Payer, High, Middle, and Low Scenarios, FY 2024-2028 ($ Billions)

	2024	2025	**2026**	**2027**	2028	2024-2028
High *Scenario*						
Total Impact	$1.2	$14.2	$35.4	$43.0	$35.8	$129.6
Federal Impact	$0.8	$9.2	$23.0	$27.9	$23.0	$83.9
State Impact	$0.4	$5.0	$12.4	$15.1	$12.8	$45.7
Middle Scenario						
Total Impact	$0.7	$9.6	$20.8	$25.3	$21.9	$78.3
Federal Impact	$0.5	$6.2	$13.5	$16.4	$14.1	$50.7
State Impact	$0.2	$3.4	$7.3	$8.9	$7.8	$27.6
Low Scenario						
Total Impact	$0.2	$5.0	$6.2	$7.6	$8.0	$27.0
Federal Impact	$0.1	$3.3	$4.1	$4.9	$5.2	$17.6
State Impact	$0.1	$1.7	$2.1	$2.7	$2.8	$9.4

Under the high scenario, we project that Federal spending would increase $83.9 billion over 2024 through 2028, and States spending would increase by $45.7 billion. For the middle scenario, projected Federal spending would be $50.7 billion higher from 2024 through 2028, and projected State spending would be $27.6 billion higher over these 5 years. In the low scenario, we project the Federal impact would be $17.6 billion over the next 5 years, and the impact on the States would be $9.4 billion over that time period. We note that the States will have discretion of whether or not to increase SDP spending (through existing or new SDPs), and that the source of the non-Federal share may vary. Many States already use sources other than State general revenues (such as IGTs and provider taxes, as noted previously) and certain financing provisions are not effective in this final rule until 2028, and therefore, the direct impact to State expenditures may be less than projected.

As noted previously, there is a wide range of possible outcomes of this final rule on SDP expenditures. The actual changes in spending may be difficult to determine, as there is uncertainty in the future amount of spending through SDPs in the baseline. The specific impacts could also vary over time, by State, and by provider type. We believed actual impacts can reasonably be expected to fall within the range shown here.

There are additional proposals in this rule that may also slightly increase SDP spending. This includes allowing States to:

(1) Direct expenditures for non-network providers;

(2) Set the amount and frequency for VBP SDPs;

(3) Recoup unspent funds for VBP SDPs; and

(4) Exempting minimum fee schedules at the Medicare rate from prior approval.

We did not have quantitative data to analyze the impact of these provisions. However, based on a qualitative analysis of our work with States, we believed these regulatory changes will have much more moderate effects on the economic impact in comparison to the

ceiling on payment levels described above. Allowing States to direct expenditures for non-network providers will likely increase the number of State contract provisions; however, we anticipated that most States will want to require minimum fee schedules tied to State plan rates, which will likely result in very small changes from existing rate development practices. Regarding the proposal to remove the existing regulatory requirements for setting the amount and frequency for VBP SDPs and recouping unspent funds for VBP SDPs, we anticipated this will change the types of SDPs States seek, encouraging them to pursue VBP models, that will replace existing VBPs, though a few States may pursue new models. The proposed regulatory requirement to exempt minimum fee schedules tied to Medicare rates will likely cause some increase in spending as more States may take up this option, but again, we did not anticipate this to have as significant impact on rate development.

There are a few proposals in this rule that are likely to exert some minor downward pressure on the rate of growth in SDP spending, such as the enhanced evaluation requirements, requirements related to financing of the non-Federal share, the elimination of the use of separate payment terms, and eliminating States' ability to use reconciliation processes. We expect that these provisions will not have any significant effect on Medicaid expenditures.

Aside from spending, we believe many of the proposals in section I.B.2. of this final rule will have significant qualitative impacts on access, quality, and transparency. One example is our proposal to permit the use of SDPs for non-network providers (section I.B.2.d. of this final rule). One of the most frequently used non-network provider types is family planning. Permitting States to use SDPs for family planning providers could greatly improve access and ease access for enrollees consistent with the statutory intent of section 1902(a)(23)(B) of the Act. Our proposal to permit States to set the frequency and amount of SDP payments (section I.B.2.h. of this final rule) should remove unnecessary barriers for States implementing VBP initiative. This should have direct impacts on quality of care as States will be more inclined to use VBP SDPs. It will allow the payments to be more closely linked to the services provided in a timely fashion, and it will allow States to establish strong parameters and operational details that define when and how providers will receive payment to support robust provider participation. Lastly, our proposal (section I.B.2.b. of this final rule) to require specific information in managed care plan contracts will improve accountability to ensure that the additional funding included in the rate certification is linked to a specific service or benefit provided to a specific enrollee covered under the contract.

Taken together, we believed our SDP related proposals in this rule will enable us to ensure that SDPs will be used to meet State and Federal policy goals to improve access and quality, used for the provision of services to enrollees under the contract, and improve fiscal safeguards and transparency. The proposals in this rule will provide a more robust set of regulations for SDPs and are informed by 6 years of experience reviewing and approving SDP preprints. We believe the resulting regulations will enable more efficient and effective use of Medicaid managed care funds.

We summarize and respond to public comments received on detailed economic analysis below.

Comment: Several commenters were critical of the analysis in the proposed rule. Some commenters were critical of the analysis because they claimed that the provisions in the rule would reduce payments and access to care and harm beneficiaries. Some requested analyses on the impact by individual hospital, by population, and by State.

Response: We disagree with the commenters' assertions that these provisions would reduce spending and access to care. As we note, we expect that these provisions will increase spending, not decrease spending. To date, CMS is not aware of any SDP that results in effective payment rates in excess of ACR. We also believe it would be impossible to project how changes in the rule would lead to changes by provider given the large amount of discretion States continue to have regarding SDP.

After reviewing the public comments, we are finalizing this section of the regulatory impact analysis with changes described above.

2. Medical Loss Ratio (MLR) and Program Integrity Standards (§§ 438.3, 438.8, 438.74, 457.1201, 457.1203, 457.1285)

We proposed to amend §§ 438.3(i), 438.8(e)(2), 457.1201, and 457.1203 to specify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. If managed care plans currently include (in reported incurred claims) payments to providers that significantly reduce or eliminate remittances while providing no value to consumers, the proposed clarification will result in transfers from such managed care plans to States in the form of higher remittances or lower capitation rates. Although we did not know how many managed care plans currently engage in such reporting practices or the amounts improperly included in MLR calculations, using information from a prior CCIIO RIA analysis,[239] we estimated the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the Medicaid MLR data for 2018, the proposed clarification will increase remittances paid by managed care plans to States by approximately $12 million per year (total computable).

We proposed to amend §§ 438.8(e)(3) and 457.1203(c) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. This proposed change will result in transfers from managed care plans that currently include indirect expenses in QIA to States in the form of higher remittances or lower capitation rates. Although we did not know how many managed care plans include indirect expenses in QIA, using information from a previous CCIIO RIA analysis,[240] we estimated the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent to 50 percent range observed during CCIIO MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in CCIIO MLR examinations). Based on these assumptions and the Medicaid MLR data for 2018, the proposed

[239] 87 FR 703.

[240] 87 FR 703.

clarification will increase remittances paid by managed care plans to States by approximately $49.8 million per year.

We proposed to amend §§ 438.608(a)(2) and (d)(3), and 457.1285 to require States' contracts with managed care plans to include a provision requiring managed care plans to report any overpayment (whether identified or recovered) to the State. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. Given that States do not provide this level of payment reporting to CMS, we were unable to quantify the benefits and costs of this proposed change; however, this proposed change may result in transfers from managed care plans to States in the form of higher remittances or lower capitation rates.

At the low end of the range, we projected that there will be no impact on Medicaid expenditures. In these cases, we will assume (1) most States currently base provider incentive payments on performance metrics; and (2) most States currently monitor QIA for unallowable administrative expenditures. At the high end of the range, we projected that there will be some increase in Medicaid remittances, that is, savings to States and the Federal government. In total these changes would increase remittances by $61.8 million in 2024. We project that remittances would increase by $373 million between 2024 and 2028. The estimates are provided in Table 10.

TABLE 11: Projected Changes in Medicaid MLR remittances Under Final Rule by Payer, FY 2024-2028 ($ Billions)

	2024	2025	2026	2027	2028	2024-2028
Total impact	($0.06)	($0.07)	($0.07)	($0.08)	($0.09)	($0.37)
Federal government	($0.04)	($0.04)	($0.05)	($0.05)	($0.06)	($0.23)
States	($0.02)	($0.02)	($0.03)	($0.03)	($0.03)	($0.14)

We proposed to amend § 438.8(e) and (f) to require managed care plans to report SDPs to States in their MLR reports. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and the remittance calculation arrangements are based on § 438.8, the remittance amounts may be affected. Given that CMS does not have data on actual revenue and expenditure amounts for SDPs that will allow for modeling the effect of the line-item reporting on remittances, we were unable to quantify the benefits and costs of this proposed change. We expected that this proposed change may result in transfers from States and the Federal government to managed care plans in the form of lower remittances or higher capitation rates.

We did not receive any comments in response to our regulatory impact analysis on our proposed Medical Loss Ratio (MLR) and program integrity standards (§§ 438.3, 438.8, 438.74, 457.1201, 457.1203, 457.1285). Therefore, we are finalizing these provisions as described in section I.B.3. of this final rule.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

In the May 6, 2016 final rule (81 FR 27830), the regulatory impact analysis addressed the financial and economic effects of allowing FFP for capitation payments made for enrollees that received inpatient psychiatric services during short-term stays in an institution for mental disease (IMD) as an ILOS; however, it did not address other potential ILOS (see 81 FR 27840 and 27841 for further details). When we analyzed the May 6, 2016 final rule for the regulatory impact analysis, we concluded that the financial and economic effects of all other ILOSs will be offset by a decrease in expenditures for the State plan-covered services and settings for which ILOSs are a medically appropriate and cost effective substitute. The use of ILOSs is a longstanding policy in managed care given the flexibility that managed care plans have historically had in furnishing care in alternate settings and services in a risk-based delivery system, if cost effective, on an optional basis and to the extent that the managed care plan and the enrollee agree that such setting or service will provide medically appropriate care. States and managed care plans historically have utilized ILOSs that are immediate substitutes for covered services and settings under the State plan, such as a Sobering Center as a substitute for an emergency department visit. More recently, a few States and managed care plans have begun utilizing ILOSs as longer term substitutes for covered services and settings under the State plan. On January 7, 2021, CMS published a State Health Official (SHO) letter (SHO# 21–001) [241] that described opportunities under Medicaid and CHIP to better address SDOH. Additionally, on January 4, 2023, CMS published a State Medicaid Director (SMD) letter (SMD# 23–001) [242] that outlined additional guidance for ILOSs in Medicaid managed care. Since CMS published this guidance, States have been working to implement changes in their Medicaid managed care programs to meet the HRSNs of Medicaid beneficiaries more effectively, including partnering with community-based organizations that routinely address HRSNs.

We believe that expanding the definition of what is allowable as ILOSs in Medicaid managed care will likely lead to an increase in Medicaid expenditures. Many of these services intended to address HRSNs may not have been previously eligible for coverage under Medicaid as an ILOS. While guidance requires these to be cost effective, the proposed rule does not require cost effectiveness to be ''budget neutral.'' Moreover, for ILOSs that are intended to be in lieu of some future service, the cost effectiveness may need to be measured over years.

Data on ILOS is extremely limited, and CMS does not currently collect any data (outside of ILOS spending for IMDs as part of the managed care rate contract). Moreover, there is limited

[241] Opportunities in Medicaid and CHIP to Address Social Determinants of Health, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

[242] Additional Guide on Use of In Lieu of Services and Settings in Medicaid Managed Care, *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.*

information on the additional ILOSs that States may use. Therefore, we provided a range of potential impacts for this section as well.

At the low end of the range, we projected that there will be no impact on Medicaid expenditures. In these cases, we will assume (1) the use of new ILOSs are relatively lower; and (2) additional ILOS spending is offset by savings from other Medicaid services.

At the high end of the range, we projected that there will be some increase in Medicaid spending. We made the following assumptions for the high scenario: (1) half of States will use new ILOSs; (2) States will increase use of ILOSs to 2 percent of total Medicaid managed care spending; and (3) additional ILOSs will offset 50 percent of new spending. Table 12 shows the impacts in the high scenario.

TABLE 12: Projected Medicaid ILOS spending under final rule by payer, high scenario, FY 2024-2028 ($ Billions)

	2024	2025	2026	2027	2028	2024-2028
Total impact	$0.0	$0.8	$1.8	$2.8	$3.0	$8.4
Federal government	$0.0	$0.5	$1.1	$1.8	$1.9	$5.3
States	$0.0	$0.3	$0.6	$1.0	$1.1	$3.0

We also believed it is important for CMS to begin to capture data on ILOS expenditures as a portion of total capitation payments that are eligible for FFP to ensure appropriate fiscal oversight, as well as detail on the managed care plans' ILOS costs. Therefore, we proposed reporting related to the final ILOS cost percentage and actual MCO, PIHP and PAHP ILOS costs in §§ 438.16(c) and 457.1201(c). This will also aid us in future regulatory impact analyses.

We did not receive any public comments on in Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120) in response to our proposals. Therefore, we are finalizing these provisions as proposed.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the 2016 final rule will be the number of reviewers of this final rule. We received 415 unique comments on the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the 2016 proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of commenters was a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $100.80 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimated that it will take approximately 20 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $4,032. Therefore, we estimated that the total cost of reviewing this regulation is $2 million.

We did not receive any comments in response to our proposals on regulatory review cost estimation. Therefore, we are finalizing this estimate as proposed.

D. Alternatives Considered

1. State Directed Payments (SDPs)

As discussed in section I.B.2.f. of this final rule on provider payment limits, we considered alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. The alternatives we considered include the Medicare rate, some level between Medicare and the ACR, or a Medicare equivalent of the ACR. We also considered an alternative that will establish a total payment rate limit for any SDPs described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDPs described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. We also considered and sought public comment on establishing a total payment rate limit for all services for all SDP arrangements described in § 438.6(c)(1)(i) and (ii), and (c)(1)(iii)(C) through (E) at the Medicare rate. For each of these alternatives, we acknowledged that some States currently have SDPs that have total payment rates up to the ACR. Therefore, these alternative proposals could be more restrictive, and States could need to reduce funding from current levels, which could have a negative impact on access to care and health equity initiatives.

Public comments received on the alternatives described above are responded to in detail in section I.B.2.f. of this final rule. We are finalizing these provisions as described in section I.B.2.f. of this final rule.

2. Medical Loss Ratio (MLR) Standards

For all MLR-related proposed changes, except those relating to SDP reporting, the only alternative considered was no change. We considered alternatives to requiring actual SDP amounts as part of MLR reports, including creating a new separate reporting process for SDPs or modifying existing reporting processes to include SDPs. We determined that creating a new separate reporting process specific to SDPs will impose significant burden on States as it will require State staff to learn a new process and complete an additional set of documents for SDP reporting. We considered modifying other State managed care reporting processes, for

example, MCPAR, to include SDPs but, unlike MLR reporting, those processes were not specific to reporting financial data. We proposed integrating SDP reporting in the MLR as the current MLR process requires reporting of financial data from managed care plans, and in turn, States provide a summary of these reports to CMS in the form of the annual MLR summary report. The integration of managed care plan and State SDP reporting using current MLR processes will encourage States to add the monitoring and oversight of SDPs as a part of a State's established MLR reporting process.

Public comments received on the alternatives to MLR-related changes, except those relating to SDP reporting, are responded to in detail in section I.B.3. of this final rule. We are finalizing those provisions as described in section I.B.3. of this final rule. Public comments received on the alternatives to MLR-related changes for SDP reporting are responded to in section I.B.2.o. of this final rule. We are finalizing those provisions as described in section I.B.2.o. of this final rule.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

One alternative we considered was leaving the 2016 final rule as it is today; however, since the rule was finalized in 2016, we continue to hear of increased State and plan utilization and innovation in the use of ILOSs, and we did not believe the current regulation ensures appropriate enrollee and fiscal protections. As a result, we proposed many additional safeguards in this rule. The ILOS proposals seek to ensure appropriate safeguards while also specifying that States and managed care plans can consider both short term and longer term substitutes for State plan-covered services and settings. Additionally, we considered including enrollee protections and ILOS transparency without the 5 percent limit on the ILOS cost percentage and the ILOS evaluation, when applicable. However, we have concerns regarding the potential unrestrained growth of ILOS expenditures.

We did not receive any public comments in response in lieu of services and settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120) below. Therefore, we are finalizing these provisions as proposed.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 13 showing the classification of the impact associated with the provisions of this final rule. In the case *of* SDPs, we categorize these *as transfers* from the Federal government *and* States to health care providers. For ILOSs, we categorize these as transfers from the Federal government and States to beneficiaries in the form of additional services. Finally, for MLR requirements, we categorize these as transfers from managed care plans to the Federal government and States.

This provides our best estimates of the transfer payments outlined in the ''Section C. Detailed Economic Analysis'' above. We detail our estimates of the low and high end of the ranges in this section, and the primary estimate is the average of the low and high scenario impacts. This reflects a wide range of possible outcomes but given the uncertainty *in* the ways and degrees to which States may use the SDPs and ILOSs, we believed that *this* is a reasonable estimate of the potential impacts under this final rule. For the MLR provisions, we have not provided a range given the relatively small size of the estimated impact.

These impacts are discounted at seven percent and three percent, respectively, as reflected in Table 13.

TABLE 13: Accounting Statement [$ Millions of 2024 dollars]

Benefits						
Non-Quantified	This final rule will support many benefits to the Medicaid program, including to align State and Federal efforts to improve timely access to care for Medicaid managed care enrollees, enhance and improve quality-based provider payments to better support care delivery, and support better quality improvement throughout the Medicaid managed care program.					
Transfers						
Annual Monetized **Transfers**	Primary Estimate	Low Estimate	High Estimate	Units		
				Year Dollars	Discount Rate	Period Covered (Fiscal years)
From Federal Government to Providers	$9,626	$3,358	$15,912	2024	7%	2024-2028
	$9,917	$3,450	$16,404	2024	3%	2024-2028
From States to Providers	$5,230	$1,792	$8,649	2024	7%	2024-2028
	$5,391	$1,842	$8,922	2024	3%	2024-2028
From Federal Government to Beneficiaries	$495	$0	$991	2024	7%	2024-2028
	$515	$0	$1,030	2024	3%	2024-2028
From States to Beneficiaries	$280	$0	$561	2024	7%	2024-2028
	$291	$0	$583	2024	3%	2024-2028
From Managed Care Plans to Federal Government	$24	$0	$47	2024	7%	2024-2028
	$24	$0	$48	2024	3%	2024-2028
From Managed Care Plans to States	$13	$0	$26	2024	7%	2024-2028
	$13	$0	$26	2024	3%	2024-2028

F. Regulatory Flexibility Act (RFA)

Effects on MCOs, PIHPs or PAHPs (referred to as ''managed care plans'') will not have a significant economic impact. As outlined in section II.B. of this final rule, we utilized data submitted by States for enrollment in Medicaid managed care plans for CY 2020. The enrollment data reflected 58,521,930 enrollees in MCOs, 37,692,501 enrollees in PIHPs or PAHPs, and 6,089,423 enrollees in PCCMs, for a total of 67,836,622 Medicaid managed care enrollees.[243] This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. For CHIP, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion and 2,593,827 separate CHIP managed care enrollees.[244] These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 managed care entities.[245]

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that some managed care plans

[243] Medicaid Managed Care Enrollment and Program Characteristics (2020).

[244] Centers for Medicare and Medicaid Services, Statistical Enrollment Data System (2017), Quarterly Enrollment Data Form 21E: Number of Children Served in Separate CHIP Program/ Quarterly Enrollment Data Form 64.21E: Number of Children Served in CHIP Medicaid Expansion Program/Quarterly Enrollment Data Form 21PW: Number of Pregnant Women Served, accessed December 5, 2022.

[245] Results of managed care survey of States completed by Centers for Medicare & Medicaid Services, Center for Medicaid and CHIP Services, Children and Adults Health Programs Group, Division of State Coverage Programs, 2017.

may be small entities as that term is used in the RFA. We believed that only a few managed care plans may qualify as small entities. Specifically, we believed that approximately 14–25 managed care plans may be small entities. We believed that the remaining managed care plans have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of $41.5 million; therefore, we did not believe that this final rule will have a significant economic impact on a substantial number of small businesses.

For purposes of the RFA, approximately 0.04 percent of Medicaid managed care plans may be considered small businesses according to the Small Business Administration's size standards with total revenues of $8 million to $41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. The cost impact on Medicaid managed care plans on a per entity basis is approximately $54,500. This final rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities.

The final rule will specifically address standards for (1) timely access to care and States' monitoring and enforcement efforts; (2) reduce burden for State directed payments (SDPs) and certain quality reporting requirements; (3) add new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and identify the scope and nature of ILOS; (4) specify medical loss ratio (MLR) requirements; and (5) establish a quality rating system (QRS) for Medicaid and CHIP managed care plans. As outlined, these efforts do not impact small entities.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We did not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. Provisions include some proposed new standards for State governments and managed care plans but no direct requirements on providers, including hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with Medicaid managed care plans, but any additional burden on small rural hospitals should be negligible. We invited comment on our proposed analysis of the impact on small rural hospitals regarding the provisions of this final rule. We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that is approximately $183 million. This final rule does not contain any Federal mandate costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs. We have determined that this final rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $183 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We believed this proposed regulation gives States appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also better aligning Medicaid and CHIP managed care standards with those for QHPs in the Marketplaces and MA to better streamline the beneficiary experience and to reduce administrative and operational burdens on States and health plans across publicly-funded programs and the commercial market. We have determined that this final rule will not significantly affect States' rights, roles, and responsibilities.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

I. Waiver Fiscal Responsibility Act Requirements

The Director of OMB has waived the requirements of section 263 of the Fiscal Responsibility Act of 2023 (Pub. L. 118–5) pursuant to section 265(a)(2) of that Act.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on February 28, 2024.

List of Subjects

42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

■ 1. The authority citation for part 430 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 430.3, by adding paragraph (e) to read as follows:

§ 430.3 Appeals under Medicaid.

* * * * *

(e) Disputes that pertain to disapproval of written approval by CMS of State directed payments under 42 CFR 438.6(c)(2)(i) are also heard by the Board in accordance with procedures set forth in 45 CFR part 16. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Amend § 438.2 by—

■ a. Adding the definition of ''In lieu of service or setting (ILOS)'' in alphabetical order;

■ b. Revising paragraph (9) in the definition of ''Primary care case management entity (PCCM entity)''; and

■ c. Adding the definition of ''State directed payment (SDP)'' in alphabetical order.

The additions and revision read as follows:

§ 438.2 Definitions.

* * * * *

In lieu of service or setting (ILOS) is a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan.

* * * * *

Primary care case management entity (PCCM entity) * * *

(9) Coordination with mental and substance use disorder health systems and providers.

* * * * *

State directed payment (SDP) means a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under § 438.6(c).

* * * * *

■ 5. Amend § 438.3 by:

■ a. Revising paragraphs (c)(1)(ii) and (e)(2);

■ b. Adding paragraphs (i)(3) and (4); and

■ c. Revising paragraph (v).

The additions and revisions read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(c) * * *

(1) * * *

(ii) The final capitation rates must be based only upon services covered under the State plan, ILOS, and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

* * * * *

(e) * * *

(2) An MCO, PIHP, or PAHP may cover, for enrollees, an ILOS as follows:

(i) The State determines that the ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the ILOS, and the MCO, PIHP, or PAHP must comply with the following requirements:

(A) An enrollee who is offered or utilizes an ILOS offered as a substitute for a covered service or setting under the State plan retains all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option; and

(B) An ILOS may not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and an MCO, PIHP, or PAHP may not deny access to a service or setting covered under the State plan, on the basis that the enrollee has been offered an ILOS as an optional substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past;

(iii) The approved ILOS is authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP;

(iv) The utilization and actual cost of the ILOS is taken into account in developing the component of the capitation rates that represents the covered State plan services and settings, unless a statute or regulation explicitly requires otherwise; and

(v) With the exception of a short term stay as specified in § 438.6(e) in an Institution for Mental Diseases (IMD), as defined in § 435.1010 of this chapter, for inpatient mental health or substance use disorder treatment, an ILOS must also comply with the requirements in § 438.16.

* * * * *

(i) * * *

(3) The State, through its contracts with an MCO, PIHP, and PAHP must require that incentive payment contracts between the MCO, PIHP, and PAHP and network providers:

(i) Have a defined performance period that can be tied to the applicable MLR reporting periods.

(ii) Be signed and dated by all appropriate parties before the commencement of the applicable performance period.

(iii) Include clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that the provider must meet to receive the incentive payment.

(iv) Specify a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment.

(4) The State through its contracts with an MCO, PIHP, and PAHP must:

(i) Define the documentation that must be maintained by the MCO, PIHP, and PAHP to support the provider incentive payments.

(ii) Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation.

(iii) Require the MCO, PIHP, and PAHP to make incentive payment contracts, and any documentation in paragraph (e)(4)(i) of this section, available to the State upon request and at any routine frequency established in the State's contract with the MCO, PIHP, and PAHP.

* * * * *

(v) *Applicability date.* Paragraphs (e)(2)(v) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following July 9, 2024, and paragraphs (i)(3) and (4) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 1 year following July 9, 2024.

■ 6. Amend § 438.6—

■ a. In paragraph (a) by:

■ i. Revising the introductory text;

■ ii. Adding definitions for ''Academic medical center,'' ''Average commercial rate,'' ''Condition-based payment,'' ''Final State directed payment cost percentage,'' ''Inpatient hospital

services,'' ''Maximum fee schedule,'' ''Minimum fee schedule,'' ''Nursing facility services,'' ''Outpatient hospital services,'' ''Performance measure,'' ''Population-based payment,'' ''Qualified practitioner services at an academic medical center,'' ''Total payment rate,'' ''Total published Medicare payment rate,'' and ''Uniform increase'' in alphabetical order; and

■ b. By revising paragraphs (c) and (e).

The revisions and additions read as follows:

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Academic medical center means a facility that includes a health professional school with an affiliated teaching hospital.

Average commercial rate means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume.

* * * * *

Condition-based payment means a prospective payment for a defined set of Medicaid covered service(s) that are tied to a specific condition and delivered to Medicaid managed care enrollees under the contract.

Final State directed payment cost percentage means the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section and for each managed care program.

* * * * *

Inpatient hospital services means the same as specified at § 440.10.

Maximum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no more than a certain amount for a covered service(s).

Minimum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s).

Nursing facility services means the same as specified in § 440.40(a).

Outpatient hospital services means the same as specified in § 440.20(a).

* * * * *

Performance measure means, for State directed payments, a quantitative measure with a numerator and denominator that is used to monitor performance at a point in time or track performance over time, of service delivery, quality of care, or outcomes as defined in § 438.320 for enrollees.

Population-based payment means a prospective payment for a defined set of Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group.

Qualified practitioner services at an academic medical center means professional services provided by both physicians and non-physician practitioners affiliated with or employed by an academic medical center.

* * * * *

Total payment rate means the aggregate for each managed care program of:

(i) The average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the State directed payment;

(ii) The effect of the State directed payment on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(iii) The effect of any and all other State directed payments on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section; and

(iv) The effect of any and all allowable pass-through payments, as defined in paragraph (a) of this section, to be paid to any and all providers included in the provider class specified in the State directed payment for which the State is seeking prior approval under paragraph (c)(2)(i) of this section on the average payment rate to providers in the specified provider class.

Total published Medicare payment rate means amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B.

Uniform increase means any State directed payment that directs the MCO, PIHP, or PAHP to pay the same amount (the same dollar amount or the same percentage increase) per Medicaid covered service(s) in addition to the rates the MCO, PIHP or PAHP negotiated with the providers included in the specified provider class for the service(s) identified in the State directed payment.

* * * * *

(c) *State directed payments under MCO, PIHP, or PAHP contracts*—(1) *General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the State may not in any way direct the MCO's, PIHP's or PAHP's expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for providers that provide a particular service under the contract using State plan approved rates.

(B) Adopt a minimum fee schedule for providers that provide a particular service under the contract using a total published Medicare payment rate that was in effect no more than 3 years prior to the start of the rating period and the minimum fee schedule to be used by the MCO, PIHP, or PAHP is equivalent to 100 percent of the specified total published Medicare payment rate.

(C) Adopt a minimum fee schedule for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in paragraph (c)(1)(iii)(B) of this section.

(D) Provide a uniform dollar or percentage increase for providers that provide a particular service under the contract.

(E) Adopt a maximum fee schedule for providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Standards for State directed payments.* (i) State directed payments specified in paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) of this section must have written prior approval that the standards and requirements in this section are met.

(ii) Each State directed payment must meet the following standards. Specifically, each State directed payment must:

(A) Be based on the utilization and delivery of services;

(B) Direct expenditures equally, and using the same terms of performance,

for a class of providers providing the service under the contract;

(C) Expect to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Have an evaluation plan that measures the degree to which the State directed payment advances at least one of the goals and objectives in the quality strategy in § 438.340 and includes all of the elements outlined in paragraph (c)(2)(iv) of this section;

(E) Not condition provider participation in State directed payments on the provider entering into or adhering to intergovernmental transfer agreements;

(F) Result in achievement of the stated goals and objectives in alignment with the State's evaluation plan and, upon request from CMS, the State must provide an evaluation report documenting achievement of these stated goals and objectives;

(G) Comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR 433, subpart B;

(H)(*1*) Ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement for any health care-related tax as specified in § 433.68(f)(3) of this subchapter in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount, and

(*2*) Ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations;

(I) Ensure that the total payment rate for each service and provider class included in the State directed payment must be reasonable, appropriate, and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class; and

(J) Be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, and 438.8.

(iii) The total payment rate for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center must not exceed the average commercial rate. To demonstrate compliance with this paragraph, States must submit:

(A) The average commercial rate demonstration, for which States must use payment data that:

(*1*) Is specific to the State;

(*2*) Is no older than from the three most recent and complete years prior to the rating period of the initial request following the applicability date of this section;

(*3*) Is specific to the service(s) addressed by the State directed payment;

(*4*) Includes the total reimbursement by the third-party payer and any patient liability, such as cost sharing and deductibles;

(*5*) Excludes payments to FQHCs, RHCs, and from any non-commercial payers, such as Medicare; and

(*6*) Excludes any payment data for services or codes that the applicable Medicaid MCOs, PIHPs, or PAHPs do not cover.

(B) A total payment rate comparison, for which States must provide a comparison of the total payment rate for these services included in the State directed payment to the average commercial rate that:

(*1*) Is specific to each managed care program that the State directed payment applies to;

(*2*) Is specific to each provider class to which the State directed payment applies;

(*3*) Is projected for the rating period for which the State is seeking prior approval of the State directed payment under paragraph (c)(2)(i) of this section;

(*4*) Uses payment data that are specific to each service included in the State directed payment; and

(*5*) Describes each of the components of the total payment rate as a percentage of the average commercial rate (demonstrated by the State as provided in paragraph (c)(2)(iii)(A) of this section) for each of these services included in the State directed payment.

(C) The ACR demonstration described in paragraph (c)(2)(iii)(A) of this section must be included with the initial documentation submitted for written prior approval of the State directed payment under paragraph (c)(2)(i) of this section, and then subsequently updated at least once every 3 years thereafter as long as the State continues to include the State directed payment that requires prior approval under paragraph (c)(2)(i) of this section in any MCO, PIHP, or PAHP contract. The total payment rate comparison described in paragraph (c)(2)(iii)(B) of this section must be included with the documentation submitted for written prior approval under paragraph (c)(2)(i) of this section and updated with each amendment and subsequent renewal.

(iv) For State directed payments for which written prior approval under paragraph (c)(2)(i) of this section is required, the State must include a written evaluation plan with its submission for written prior approval under paragraph (c)(2)(i) of this section and an updated written evaluation plan with each amendment and subsequent renewal. The evaluation plan must include the following elements:

(A) Identification of at least two metrics that will be used to measure the effectiveness of the State directed payment in advancing at least one of the goals and objectives in the quality strategy on an annual basis, which must:

(*1*) Be specific to the State directed payment and, when practicable and relevant, attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the State directed payment applies; and

(*2*) Include at least one performance measure as defined in § 438.6(a) as part of the metrics used to measure the effectiveness of the State directed payment;

(B) Include baseline statistics on all metrics that will be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section;

(C) Include performance targets for all metrics to be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section that demonstrate either maintenance or improvement over the baseline statistics and not a decline relative to baseline. The target for at least one performance measure, as defined in § 438.6(a), must demonstrate improvement over baseline; and

(D) Include a commitment by the State to submit an evaluation report in accordance with § 438.6(c)(2)(v) if the final State directed payment cost percentage exceeds 1.5 percent.

(v) For any State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section that has a final State directed payment cost percentage greater than 1.5 percent, the State must complete and submit an evaluation report using the evaluation plan outlined during the prior approval process under paragraph (c)(2)(iv) of this section.

(A) This evaluation report must:

(*1*) Include all of the elements in paragraph (c)(2)(iv) of this section as specified in the approved evaluation plan;

(*2*) Include three most recent and complete years of annual results for each metric as required in paragraph (c)(2)(iv)(A) of this section; and

(*3*) Be published on the public facing website as required under § 438.10(c)(3).

(B) States must submit the initial evaluation report as described in paragraph (c)(2)(v)(A) of this section to CMS no later than 2 years after the conclusion of the 3-year evaluation period. Subsequent evaluation reports must be submitted to CMS every 3 years.

(vi) Any State directed payments described in paragraph (c)(1)(i) or (ii) of this section must:

(A) Make participation in the value-based purchasing, delivery system reform, or performance improvement initiative available using the same terms of performance to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) If the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section conditions payment upon performance, the payment to providers under the State directed payment:

(*1*) Cannot be conditioned upon administrative activities, such as the reporting of data nor upon the participation in learning collaboratives or similar administrative activities;

(*2*) Must use a common set of performance measures across all of the payers and providers specified in the State directed payment;

(*3*) Must define and use a performance measurement period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered;

(*4*) Must identify baseline statistics on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP; and

(*5*) Must use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the State directed payment applies, that demonstrate maintenance or improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP.

(C) If the State directed payment is a population-based or condition-based payment, the State directed payment must:

(*1*) Be based upon the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider for treatment during the rating period;

(*2*) If basing payment on the attribution of enrollees to a provider, have an attribution methodology that uses data that are no older than the three most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers;

(*3*) Replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the population or condition-based payment; no other payment may be made by an MCO, PIHP, or PAHP to the same provider on behalf of the same enrollee for the same services included in the population or condition-based payment; and

(*4*) Include at least one metric in the evaluation plan required under paragraph (c)(2)(iv) of this section that measures performance at the provider class level; the target for this performance measure, as defined in § 438.6(a), must be set to demonstrate improvement over baseline.

(vii) Any State directed payment described in paragraph (c)(1)(iii) of this section must:

(A) Condition payment from the MCO, PIHP, or PAHP to the provider on the utilization and delivery of services under the contract for the rating period for which the State is seeking written prior approval only; and

(B) Not condition payment from the MCO, PIHP, or PAHP to the provider on utilization and delivery of services outside of the rating period for which the State is seeking written prior approval and then require that payments be reconciled to utilization during the rating period.

(viii) A State must complete and submit all required documentation for each State directed payment for which written prior approval is required under (c)(2)(i) and for each amendment to an approved State directed payment, respectively, before the start date of the State directed payment or the start date of the amendment.

(3) *Approval and renewal timeframes.* (i) Approval of a State directed payment described in paragraphs (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval of up to three rating periods is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the State directed payment in the contract as a multi-year State directed payment, including a description of the State directed payment by year and if the State directed payment varies by year.

(B) The State has developed and described its plan for implementing a multi-year State directed payment, including the State's plan for multi-year evaluation, and the impact of a multi-year State directed payment on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the State directed payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year State directed payment without CMS written prior approval. If the State determines that changes to the State directed payment methodology, or magnitude of the payment, are necessary, the State must obtain written prior approval of such changes under paragraph (c)(2) of this section.

(ii) Written prior approval of a State directed payment described in paragraph (c)(1)(iii)(C) through (E) of this section is for one rating period.

(iii) State directed payments are not automatically renewed.

(4) *Reporting requirements.* The State must submit to CMS, no later than 1 year after each rating period, data to the Transformed Medicaid Statistical Information System, or in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for State directed payments, including amounts paid to individual providers. The initial report will be due after the first rating period that begins after the release of reporting instructions by CMS. Minimum data fields to be collected include the following, as applicable:

(i) Provider identifiers.

(ii) Enrollee identifiers.

(iii) MCO, PIHP or PAHP identifiers.

(iv) Procedure and diagnosis codes.

(v) Allowed, billed, and paid amounts. Paid amounts include the amount that represents the MCO's, PIHP's or PAHP's negotiated payment amount, the amount of the State directed payment, and any other amounts included in the total amount paid to the provider.

(5) *Requirements for Medicaid Managed Care contract terms for State directed payments.* State directed payments must be specifically described and documented in the MCO's, PIHP's,

or PAHP's contracts. The MCO's, PIHP's or PAHP's contract must include, at a minimum, the following information for each State directed payment:

(i) The State directed payment start date and, if applicable, the end date within the applicable rating period;

(ii) A description of the provider class eligible for the State directed payment and all eligibility requirements;

(iii) A description of the State directed payment, which must include at a minimum:

(A) For State directed payments described in paragraphs (c)(1)(iii)(A), (B), and (C) of this section:

(*1*) The required fee schedule;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies;

(*4*) For State directed payments that specify State plan approved rates, the contract must also reference the State plan page, when it was approved, and a link to the currently approved State plan page when possible; and

(*5*) For State directed payments that specify a Medicare-referenced fee schedule, the contract must also include information about the Medicare fee schedule(s) that is necessary to implement the State directed payment, including identifying the specific Medicare fee schedule, the time period for which the Medicare fee schedule is in effect, and any material adjustments due to geography or provider type that need to be applied.

(B) For State directed payments described in paragraphs (c)(1)(iii)(D) of this section:

(*1*) Whether the uniform increase will be a specific dollar amount or a percentage increase of negotiated rates;

(*2*) The procedure and diagnosis codes to which the uniform dollar or percentage increase applies;

(*3*) The specific dollar amount or percentage increase that the MCO, PIHP or PAHP must apply or the methodology to establish the specific dollar amount or percentage increase;

(*4*) The applicable dates of service within the rating period for which the uniform increase applies; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, and other significant relevant information.

(C) For State directed payments described in paragraph (c)(1)(iii)(E) of this section:

(*1*) The fee schedule the MCO, PIHP, or PAHP must ensure that payments are below;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies; and

(*4*) Details of the State's exemption process for MCOs, PIHPs, or PAHPs and providers to follow if they are under contractual obligations that result in the need to pay more than the maximum fee schedule.

(D) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section that condition payment based upon performance:

(*1*) The approved performance measures upon which payment will be conditioned;

(*2*) The approved measurement period for those measures;

(*3*) The approved baseline statistics for all measures against which performance will be measured;

(*4*) The performance targets that must be achieved on each measure for the provider to obtain the performance-based payment;

(*5*) The methodology to determine if the provider qualifies for the performance-based payment, as well as the amount of the payment; and

(*6*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, what to do with any unearned payments, and other significant relevant information.

(E) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section using a population-based or condition-based payment as defined in paragraph (a) of this section:

(*1*) The Medicaid covered service(s) that the population or condition-based payment is for;

(*2*) The time period that the population or condition-based payment covers;

(*3*) When the population or condition-based payment is to be made and how frequently;

(*4*) A description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how the attribution methodology will be communicated to providers; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP in operationalizing the attribution methodology if an attribution methodology is used.

(iv) Any encounter reporting and separate reporting requirements necessary for auditing the State directed payment in addition to the reporting requirements in paragraph (c)(4) of this section; and

(v) All State directed payments must be specifically described and documented in the MCO's, PIHP's, and PAHP's contracts that must be submitted to CMS no later than 120 days after the start date of the State directed payment.

(6) *Payment to MCOs, PIHPs, and PAHPs for State Directed Payments.* The final capitation rate for each MCO, PIHP, or PAHP as described in § 438.3(c) must account for all State directed payments. Each State directed payment must be accounted for in the base data, as an adjustment to trend, or as an adjustment as specified in § 438.5 and § 438.7(b). The State cannot withhold a portion of the capitation rate to pay the MCO, PIHP, or PAHP separately for a State directed payment nor require an MCO, PIHP, or PAHP to retain a portion of the capitation rate separately to comply with a State directed payment.

(7) *Final State directed payment cost percentage.* For each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section, unless the State voluntarily submits the evaluation report per paragraph (c)(2)(v) of this section, the State must calculate the final State directed payment cost percentage and if the final State directed payment cost percentage is below 1.5 percent the State must provide a final State directed payment cost percentage report to CMS as follows:

(i) *State directed payment cost percentage calculation.* The final State directed payment cost percentage must be calculated on an annual basis and recalculated annually.

(ii) *State directed payment cost percentage certification.* The final State directed payment cost percentage must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(iii) *Calculation of the final State directed payment cost percentage.* The final State directed payment cost percentage is the result of dividing the amount determined in paragraph (c)(7)(iii)(A) of this section by the amount determined in paragraph (c)(7)(iii)(B) of this section.

(A) The portion of the actual total capitation payments that is attributable to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section, for each managed care program.

(B) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d).

(iv) *Annual CMS review of the final State directed payment cost percentage.* The State must submit the final State directed payment cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes a State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(8) *Applicability dates.* States must comply with:

(i) Paragraphs (a), (c)(1), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) and (J), (c)(2)(vi)(A), (c)(3) of this section beginning on July 9, 2024.

(ii) Paragraphs (c)(2)(iii), (c)(2)(vi)(B), and (c)(2)(vi)(C)(*1*) and (*2*) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after July 9, 2024.

(iii) Paragraphs (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(viii) and (c)(5)(i) through (iv) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

(iv) Paragraphs (c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v), (c)(2)(vii), (c)(6) and (c)(7) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after July 9, 2024.

(v) Paragraph (c)(5)(v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

(vi) Paragraph (c)(4) of this section no later than the date specified in the T–MSIS reporting instructions released by CMS.

(vii) Paragraph (c)(2)(ii)(H) of this section no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028.

* * * * *

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is a hospital providing mental health or substance use disorder inpatient care or a sub-acute facility providing mental health or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient mental health or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii). For purposes of rate setting, the State may use the utilization of services provided to an enrollee under this section when developing the inpatient mental health or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through providers included under the State plan.

■ 7. Amend § 438.7 by—

■ a. Revising paragraph (b)(6); and

■ b. Adding paragraphs (c)(4) through (6) and (f).

The revisions and additions read as follows:

§ 438.7 Rate certification submission.

* * * * *

(b) * * *

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 and ILOS in § 438.3(e)(2) that are applied in the contract.

(c) * * *

(4) The State must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under paragraph (a) of this section for any special contract provisions related to payment described in § 438.6 and ILOS in § 438.3(e)(2) not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

(5) Retroactive adjustments to the capitation rates, as outlined in paragraph (c)(2) of this section, resulting from a State directed payment described in § 438.6(c) must be a result of adding or amending any State directed payment consistent with the requirements in § 438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that modifications are necessary to correct the error.

(6) The rate certification or retroactive adjustment to capitation rates resulting from any State directed payments must be submitted no later than 120 days after the start date of the State directed payment.

* * * * *

(f) *Applicability dates.* (1) Paragraph (b)(6) of this section applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following July 9, 2024. Until that applicability date, States are required to continue to comply with paragraph (b)(6) of this section contained in 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

(2) Paragraph (c)(6) of this section apply no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

■ 8. Amend § 438.8 by—

■ a. Revising paragraph (e)(2)(iii)(A);

■ b. Adding paragraph (e)(2)(iii)(C);

■ c. Revising paragraph (e)(3)(i);

■ d. Adding paragraph (f)(2)(vii); and

■ e. Revising paragraphs (h)(4) introductory text and (k)(1)(vii).

The revisions and additions read as follows:

§ 438.8 Medical loss ratio (MLR) standards.

* * * * *

(e) * * *

(2) * * *

(iii) * * *

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

(C) The amount of payments made to providers under State directed payments described in § 438.6(c).

* * * * *

(3) * * *

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(a) and (b) and is not excluded under 45 CFR 158.150(c).

* * * * *

(f) * * *

(2) * * *

(vii) Payments to the MCO, PIHP, or PAHP for expenditures under State directed payments described in § 438.6(c).

* * * * *

(h) * * *

(4) CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

* * * * *

(k) * * *

(1) * * *

(vii) Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45 CFR 158.170(b).

* * * * *

■ 9. Amend § 438.10 by—
■ a. Revising paragraphs (c)(3), (d)(2), (g)(2)(ix), and (h)(1) introductory text;
■ b. Adding paragraph (h)(1)(ix);
■ c. Revising paragraph (h)(2)(iv);
■ d. Adding paragraph (h)(3)(iii); and
■ e. Revising paragraph (j).

The revisions and additions read as follows:

§ 438.10 Information requirements.

* * * * *

(c) * * *

(3) The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity web pages, specified at § 438.602(g) and elsewhere in this part. States must:

(i) Include clear and easy to understand labels on documents and links;

(ii) Include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, on one web page;

(iii) Verify no less than quarterly, the accurate function of the website and the timeliness of the information presented; and

(iv) Explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages, written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

* * * * *

(d) * * *

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees and experience surveys for enrollees must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

* * * * *

(g) * * *

(2) * * *

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100 and, if applicable, § 438.3(e)(2)(ii).

* * * * *

(h) * * *

(1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and searchable electronic form, the following information about its network providers:

* * * * *

(ix) Whether the provider offers covered services via telehealth.

(2) * * *

(iv) Mental health and substance use disorder providers; and

* * * * *

(3) * * *

(iii) MCOs, PIHPs, or PAHPs must use the information received from the State pursuant to § 438.68(f)(1)(iii) to update provider directories no later than the timeframes specified in paragraphs (h)(3)(i) and (ii) of this section.

* * * * *

(j) *Applicability.* States will not be held out of compliance with the requirements of paragraph (c)(3) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(c)(3) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (d)(2) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after the July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(d)(2) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (h)(1) of this section prior to July 1, 2025, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(h)(1) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (h)(1)(ix) of this section prior to July 1, 2025. Paragraph (h)(3)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

* * * * *

■ 10. Section 438.16 is added to read as follows:

§ 438.16 In lieu of services and settings (ILOS) requirements.

(a) *Definitions.* As used in this part, the following terms have the indicated meanings:

Final ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(3) of this section, specific to each managed care program that includes ILOS.

Projected ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(2) of this section, specific to each managed care program that includes ILOS.

Summary report of actual MCO, PIHP, and PAHP ILOS costs is the report calculated, in accordance with paragraph (c)(4) of this section, specific to each managed care program that includes ILOS.

(b) *General rule.* An ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act.

(c) *ILOS Cost Percentage and summary report of actual MCO, PIHP, and PAHP ILOS costs.*

(1) *General rule.* (i) The projected ILOS cost percentage calculated as required in paragraph (c)(2) of this section may not exceed 5 percent and the final ILOS cost percentage calculated as required in paragraph (c)(3) of this section may not exceed 5 percent.

(ii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be calculated on an annual basis and recalculated annually.

(iii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(2) *Calculation of the projected ILOS cost percentage.* The projected ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(2)(i) of this section by the amount determined in paragraph (c)(2)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The projected total capitation payments for each managed care program, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(3) *Calculation of the final ILOS cost percentage.* The final ILOS cost percentage is the result of dividing the amount determined in paragraph

(c)(3)(i) of this section by the amount determined in paragraph (c)(3)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The actual total capitation payments, defined at § 438.2, for each managed care program, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(4) *Summary report of actual MCO, PIHP, and PAHP ILOS costs.* The State must submit to CMS a summary report of the actual MCO, PIHP, and PAHP costs for delivering ILOSs based on the claims and encounter data provided by the MCO(s), PIHP(s), and PAHP(s).

(5) *CMS review of the projected ILOS cost percentage, the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs.*

(i) The State must annually submit the projected ILOS cost percentage to CMS for review as part of the rate certification required in § 438.7(a).

(ii) The State must submit the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes an ILOS.

(d) *Documentation requirements*—(1) *State requirements.* All States that include an ILOS in an MCO, PIHP, or PAHP contract are required to include, at minimum, the following:

(i) The name and definition of each ILOS;

(ii) The covered service or setting under the State plan for which each ILOS is a medically appropriate and cost effective substitute;

(iii) The clinically defined target populations for which each ILOS is determined to be medically appropriate and cost effective substitute by the State;

(iv) The process by which a licensed network or MCO, PIHP, or PAHP staff provider, determines and documents in the enrollee's records that each identified ILOS is medically appropriate for the specific enrollee;

(v) The enrollee rights and protections, as defined in § 438.3(e)(2)(ii); and

(vi) A requirement that the MCO, PIHP, or PAHP will utilize specific codes established by the State that identify each ILOS in encounter data, as required under § 438.242.

(2) *Additional documentation requirements.* A State with a projected ILOS cost percentage that exceeds 1.5 percent is also required to provide the following documentation concurrent with the contract submission for review and approval by CMS under § 438.3(a).

(i) A description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(ii) A description of the process and supporting data the State used to determine that each ILOS is a cost effective substitute for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(3) *Provision of additional information.* At the request of CMS, the State must provide additional information, whether part of the MCO, PIHP, or PAHP contract, rate certification or supplemental materials, if CMS determines that the requested information is pertinent to the review and approval of a contract that includes ILOS.

(e) *Monitoring, evaluation, and oversight.* (1) *Retrospective evaluation.* A State is required to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) following the applicability date in paragraph (f) of this section, or as required in paragraph (v) of this section. The retrospective evaluation must:

(i) Be completed separately for each managed care program that includes an ILOS and include all ILOSs in that managed care program.

(ii) Be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii). The State must utilize these data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.

(iii) Evaluate at least:

(A) The impact each ILOS had on utilization of State plan approved services or settings, including any associated cost savings;

(B) Trends in MCO, PIHP, or PAHP and enrollee use of each ILOS;

(C) Whether encounter data supports the State's determination that each ILOS is a medically appropriate and cost effective substitute for the identified covered service and setting under the State plan or a cost effective measure to reduce or prevent the future need to utilize the covered service and setting under the State plan;

(D) The impact of each ILOS on quality of care;

(E) The final ILOS cost percentage for each year consistent with the report in paragraph (c)(5)(ii) of this section with a declaration of compliance with the allowable threshold in paragraph (c)(1)(i) of this section;

(F) Appeals, grievances, and State fair hearings data, reported separately, related to each ILOS, including volume, reason, resolution status, and trends; and

(G) The impact each ILOS had on health equity efforts undertaken by the State to mitigate health disparities.

(iv) The State must submit the retrospective evaluation to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent.

(v) CMS reserves the right to require the State to submit additional retrospective evaluations to CMS.

(2) *Oversight.* Oversight for each ILOS must include the following:

(i) *State notification requirement.* The State must notify CMS within 30 calendar days if:

(A) The State determines that an ILOS is no longer a medically appropriate or cost effective substitute for the covered service or setting under the State plan identified in the contract as required in paragraph (d)(1)(ii) of this section; or

(B) The State identifies noncompliance with requirements in this part.

(ii) *CMS oversight process.* If CMS determines that a State is out of compliance with any requirement in this part or receives a State notification in paragraph (e)(2)(i) of this section, CMS may require the State to terminate the use of an ILOS.

(iii) *Process for termination of ILOS.* Within 30 calendar days of receipt of a notice described in paragraph (e)(2)(iii)(A), (B), or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval.

(A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS;

(B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees.

(C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS.

(iv) *Requirements for an ILOS Transition Plan.* The transition plan must include at least the following:

(A) A process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as the enrollee's health condition requires.

(B) A transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to care to any enrollee who is currently receiving the ILOS that will be terminated. The State must make the transition of care policy publicly available.

(C) An assurance the State will submit the modification of the MCO, PIHP, or PAHP contract to remove the ILOS and submission of the modified contracts to CMS as required in § 438.3(a), and a reasonable timeline for submitting the contract amendment.

(D) An assurance the State and its actuary will submit an adjustment to the actuarially sound capitation rate, as needed, to remove utilization and cost of the ILOS from capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2), and a reasonable timeline for submitting the revised rate certification.

(f) *Applicability date.* Section 438.16 applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following July 9, 2024.

■ 11. Amend § 438.66 by revising paragraphs (b)(4), (c)(5), (e)(2)(vi) and (vii), (e)(3)(i), and (f) to read as follows:

§ 438.66 State monitoring requirements.

* * * * *

(b) * * *

(4) Enrollee materials, enrollee experience, and customer services, including the activities of the beneficiary support system.

* * * * *

(c) * * *

(5) Results from an annual enrollee experience survey conducted by the State (or as otherwise conducted when all enrollees are also in affiliated Medicare Advantage dual eligible special needs plans subject to the condition in § 422.107(e)(1)(i)) and any provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

* * * * *

(e) * * *

(2) * * *

(vi) Availability and accessibility of covered services, including any ILOS, within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures and results of an enrollee experience survey, including as applicable, consumer report card, provider surveys, or other reasonable measures of performance.

* * * * *

(3) * * *

(i) Posted on the website required under § 438.10(c)(3) within 30 calendar days of submitting it to CMS.

* * * * *

(f) *Applicability.* States will not be held out of compliance with the requirements of paragraphs (b)(4), (c)(5), and (e)(2)(vii) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) 42 CFR 438.66 (effective as of October 1, 2023).

■ 12. Amend § 438.68 by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(iii), (d)(1) and (2), and (e); and

■ b. Adding paragraphs (f) through (h).

The revisions and additions read as follows:

§ 438.68 Network adequacy standards.

* * * * *

(b) * * *

(1) *Provider types.* At a minimum, a State must develop a quantitative network adequacy standard, other than appointment wait times, for the following provider types, if covered under the contract:

* * * * *

(iii) Mental health and substance use disorder, adult and pediatric.

* * * * *

(d) * * *

(1) To the extent the State permits an exception to any of the network standards developed under this section, the standard by which the exception will be evaluated and approved must:

(i) Be specified in the MCO, PIHP, or PAHP contract.

(ii) Be based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.

(iii) Include consideration of the payment rates offered by the MCO, PIHP, or PAHP to the provider type or for the service type for which an exception is being requested.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to an MCO, PIHP, or PAHP must monitor enrollee access to that provider type or service on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66(e).

(e) *Appointment wait time standards.* States must establish and enforce appointment wait time standards.

(1) *Routine appointments.* Standards must be established for routine appointments for the following services and within the specified limits:

(i) If covered in the MCO's, PIHP's, or PAHP's contract, outpatient mental health and substance use disorder, adult and pediatric, within State-established timeframes but no longer than 10 business days from the date of request.

(ii) If covered in the MCO's, PIHP's, or PAHP's contract, primary care, adult and pediatric, within State-established timeframes but no longer than 15 business days from the date of request.

(iii) If covered in the MCO's, PIHP's, or PAHP's contract, obstetrics and gynecological within State-established timeframes but no longer than 15 business days from the date of request.

(iv) State-selected, other than those listed in paragraphs (e)(1)(i) through (iii) of this section and covered in the MCO's, PIHP's, or PAHP's contract, chosen in an evidence-based manner within State-established timeframes.

(2) *Minimum compliance.* MCOs, PIHPs, and PAHPs will be deemed compliant with the standards established in paragraph (e)(1) of this section when secret shopper results, consistent with paragraph (f)(2) of this section, reflect a rate of appointment availability that meets the standards established at paragraph (e)(1)(i) through (iv) of this section of at least 90 percent.

(3) *Selection of additional types of services.* After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of services to be added to paragraph (e)(1) of this section.

(f) *Secret shopper surveys.* States must contract with an entity, independent of the State Medicaid agency and any of its contracted MCOs, PIHPs and PAHPs subject to the survey, to conduct annual secret shopper surveys of each MCO's, PIHP's, and PAHP's compliance with the provider directory requirements in § 438.10(h) as specified in paragraph (f)(1) of this section and appointment wait time requirements as specified in paragraph (f)(2) of this section.

(1) *Provider directories.* (i) A secret shopper survey must be conducted to determine the accuracy of the information specified in paragraph

(f)(1)(ii) of this section in each MCO's, PIHP's, and PAHP's most current electronic provider directories, as required at § 438.10(h), for the following provider types:

(A) Primary care providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(B) Obstetric and gynecological providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(C) Outpatient mental health and substance use disorder providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory; and

(D) The provider type that provides the service type chosen by the State in paragraph (e)(1)(iv) of this section.

(ii) A secret shopper survey must assess the accuracy of the information in each MCO's, PIHP's, and PAHP's most current electronic provider directories for at least:

(A) The active network status with the MCO, PIHP, or PAHP;

(B) The street address(es) as required at § 438.10(h)(1)(ii);

(C) The telephone number(s) as required at § 438.10(h)(1)(iii); and

(D) Whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi).

(iii) States must receive information, sufficient to facilitate correction by the MCO, PIHP, or PAHP, on errors in directory data identified in secret shopper surveys from the entity conducting the secret shopper survey no later than 3 business days from the day the error is identified by the entity conducting the secret shopper survey.

(iv) States must send information required in paragraph (f)(1)(iii) of this section to the applicable MCO, PIHP, or PAHP no later than 3 business days from receipt.

(2) *Timely appointment access.* A secret shopper survey must be used to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards in paragraph (e)(1) of this section.

(i) After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of appointments to be added to a secret shopper survey.

(ii) Appointments offered via telehealth can only be counted toward compliance with the appointment wait time standards in paragraph (e)(1) of this section if the provider being surveyed also offers in-person appointments to the MCO's, PIHP's, or PAHP's enrollees and must be identified separately from in-person appointments in survey results.

(3) *Independence.* An entity will be considered independent of the State as specified in paragraph (f)(3)(i) of this section and independent of the MCOs, PIHPs, or PAHPs subject to the surveys as specified in paragraph (f)(3)(ii) of this section.

(i) An entity will be considered independent of the State if it is not part of the State Medicaid agency.

(ii) An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.

(4) *Methodological standards.* Secret shopper surveys required in this paragraph must:

(i) Use a random sample;

(ii) Include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract; and

(iii) For secret shopper surveys required in paragraph (f)(2) of this section for appointment wait time standards, be completed for a statistically valid sample of providers.

(5) *Results reporting.* Results of the secret shopper surveys conducted pursuant to paragraphs (f)(1) and (2) of this section must be analyzed, summarized, and:

(i) Reported to CMS using the content, form, and submission times as specified at § 438.207(d); and

(ii) Posted on the State's website required at § 438.10(c)(3) within 30 calendar days of submission to CMS.

(g) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2), and (e) of this section on the website required by § 438.10(c)(3). Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

(h) *Applicability.* States will not be held out of compliance with the requirements of paragraph (b)(1) and of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (b) (effective as of October 1, 2023). Paragraph (d)(1)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (d)(2) and of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (d)(2) (effective as of October 1, 2023). Paragraph (e) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (g) of this section prior to the first rating period that begins on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in paragraph 42 CFR 438.68 (g) (effective as of October 1, 2023).

■ 13. Amend § 438.74 by revising paragraph (a) to read as follows:

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of each report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must be provided for each MCO, PIHP, or PAHP under contract with the State and must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

* * * * *

■ 14. Amend § 438.206 by revising paragraphs (c)(1)(i) and (d) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(1) * * *

(i) Meet and require its network providers to meet State standards for timely access to care and services taking into account the urgency of the need for services, as well as appointment wait times specified in § 438.68(e).

* * * * *

(d) *Applicability date.* States will not be held out of compliance with the requirements of paragraphs (c)(1)(i) of this section prior to the first rating

period that begins on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.206(c)(1)(i) (effective as of October 1, 2023).

■ 15. Amend § 438.207—

■ a. In paragraph (b)(1), by removing the ''.'' at the end of the paragraph and adding in its place ''; ''.

■ b. In paragraph (b)(2), by removing the ''.'' at the end of the paragraph and adding in its place ''; and'';

■ c. By adding paragraph (b)(3);

■ d. By revising paragraphs (d) through (f); and

■ e. By adding paragraph (g).

The revisions and additions read as follows:

§ 438.207 Assurances of adequate capacity and services.

* * * * *

(b) * * *

(3) Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO's, PIHP's, or PAHP's contract, provides an annual payment analysis using paid claims data from the immediate prior rating period that demonstrates each MCO's, PIHP's, or PAHP's level of payment as specified in paragraphs (b)(3)(i) and (ii) of this section.

(i) The payment analysis must provide the total amount paid for evaluation and management current procedural terminology codes in the paid claims data from the immediate prior rating period for primary care, obstetrical and gynecological, mental health, and substance use disorder services, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services.

(A) A separate total and percentage must be reported for primary care, obstetrics and gynecology, mental health, and substance use disorder services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(ii) For homemaker services, home health aide services, personal care services, and habilitation services, the payment analysis must provide the total amount paid and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same services.

(A) A separate total and percentage must be reported for homemaker services, home health aide services, personal care services, and habilitation services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(iii) Payments by MCOs, PIHPS, and PAHPs for the services specified in § 438.207(b)(3)(i) and (ii) for which the MCO, PIHP, or PAHP is not the primary payer are excluded from the analysis required in this paragraph.

(iv) Services furnished by a Federally-qualified health center as defined in section 1905(l)(2) and services furnished by a rural health clinic as defined in section 1905(l)(1) are excluded from the analysis required in this paragraph.

* * * * *

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP as specified in paragraph (b) of this section and the secret shopper evaluation results as required at § 438.68(f), the State must submit an assurance of compliance to CMS, in the format prescribed by CMS, that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in §§ 438.68 and 438.206.

(1) The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(2) The analysis in paragraph (d)(1) of this section must include the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, and contain:

(i) The data provided by each MCO, PIHP, and PAHP in paragraph (b)(3) of this section; and

(ii) A State level payment percentage for each service type specified in paragraphs (b)(3)(i) and (ii) of this section produced by using the number of member months for the applicable rating period to weight each MCO's, PIHP's, or PAHP's reported percentages, as required in paragraph (b)(3) of this section.

(3) States must submit the assurance of compliance required in paragraph (d) of this section as specified in paragraphs (i) through (iii) of this section and post the report on the State's website required in § 438.10(c)(3) within 30 calendar days of submission to CMS.

(i) Sufficiently in advance to enable CMS to make a determination that the contract entered into as specified at § 438.207(c)(1) is approved under § 438.3(a).

(ii) On an annual basis and no later than 180 calendar days after each rating period.

(iii) At any time there has been a significant change as specified in paragraph (c)(3) of this section and with the submission of the associated contract, as required at § 438.3(a).

(e) *CMS's right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP, as well as documentation from all secret shopper surveys required at § 438.68(f).

(f) *Remedy plans to improve access.* (1) When the State, MCO, PIHP, PAHP, or CMS identifies an area in which an MCO's, PIHP's, or PAHP's access to care under the access standards in this part could be improved, including the standards at §§ 438.68 and 438.206, the State must:

(i) Submit to CMS for approval a remedy plan as specified in paragraph (f)(ii) of this section no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue;

(ii) Develop a remedy plan that addresses the identified access issue within 12 months and that identifies specific steps with timelines for implementation and completion, and responsible parties. State's and MCO's, PIHP's, or PAHP's actions may include a variety of approaches, including but not limited to: increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization;

(iii) Ensure that improvements in access are measurable and sustainable; and

(iv) Submit quarterly progress updates to CMS on implementation of the remedy plan.

(2) If the remedy plan required in paragraph (f)(1) of this section does not result in addressing the MCO's, PIHP's, or PAHP's access issue by improving access within 12 months, CMS may require the State to continue the remedy plan for another 12 months and may require revision to the remedy plan required in paragraph (f)(1) of this section.

(g) *Applicability date.* Paragraphs (b)(3) and (d)(2) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024. Paragraph (d)(3) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (e) of this section prior to the

rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 year after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.207 (e) (effective as of October 1, 2023) Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after July 9, 2024.

■ 16. Amend § 438.214 by revising paragraph (b)(1) and adding paragraph (d)(2) to read as follows:

§ 438.214 Provider selection.

* * * * *

(b) * * *

(1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, mental health, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.

* * * * *

(d) * * *

(2) States must ensure through its contracts that MCOs, PIHPs, and PAHPs terminate any providers of services or persons terminated (as described in section 1902(kk)(8) of the Social Security Act) from participation under this title, title XVIII, or title XXI from participating as a provider in any network.

* * * * *

■ 17. Amend § 438.310 by revising paragraphs (b)(5) introductory text, (c)(2), and (d) to read as follows:

§ 438.310 Basis, scope, and applicability.

* * * * *

(b) * * *

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP including—

* * * * *

(c) * * *

(2) The provisions of § 438.330(b)(2) and (3), (c), and (e), and § 438.340 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

* * * * *

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of July 9, 2024:

(1) States must comply with updates to § 438.340(c) no later than 1 year from July 9, 2024.

(2) States must comply with updates to §§ 438.358(a)(3), 438.358(b)(1) and 438.364(c)(2)(iii) no later than December 31, 2025.

(3) States must comply with § 438.364(a)(2)(iii) no later 1 year from the issuance of the associated protocol.

■ 18. Amend § 438.330 by revising paragraph (d)(4) to read as follows:

§ 438.330 Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA organization chronic care improvement program conducted under § 422.152(c) of this chapter for one or more of the performance improvement projects otherwise required under this section.

* * * * *

§ 438.334 [Removed and reserved]

■ 19. Section 438.334 is removed and reserved.

■ 20. Amend § 438.340 by revising paragraphs (b)(4), (c)(1) introductory text, (c)(2)(ii), and (c)(3) to read as follows:

§ 438.340 Managed care State quality strategy.

* * * * *

(b) * * *

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.

* * * * *

(c) * * *

(1) Make the strategy available for public comment before submitting the strategy to CMS for review in accordance with paragraph (c)(3) of this section, including:

* * * * *

(2) * * *

(ii) The State must make the results of the review, including the evaluation conducted pursuant to paragraph (c)(2)(i) of this section, available on the website required under § 438.10(c)(3).

* * * * *

(3) Prior to adopting as final, submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback.

(ii) A copy of the strategy—

(A) Every 3 years following the review in paragraph (c)(2) of this section;

(B) Whenever significant changes, as defined in the State's quality strategy per paragraph (b)(10) of this section, are made to the document;

(C) Whenever significant changes occur within the State's Medicaid program.

* * * * *

■ 21. Amend § 438.350 by revising the introductory text and paragraph (a) to read as follows:

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, or PAHP.

* * * * *

■ 22. Amend § 438.354 by revising paragraph (c)(2)(iii) to read as follows:

§ 438.354 Qualifications of external quality review organizations.

* * * * *

(c) * * *

(2) * * *

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) services that it will review as an EQRO, except for the related activities specified in § 438.358;

* * * * *

■ 23. Amend § 438.358 by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraph (a)(3);

■ c. Revising and republishing paragraph (b)(1);

■ d. Revising paragraphs (b)(2); and

■ e. Revising and republishing paragraph (c).

The revisions and addition read as follows:

§ 438.358 Activities related to external quality review.

(a) * * *

(1) The State, its agent that is not an MCO, PIHP, or PAHP or an EQRO may perform the mandatory and optional EQR-related activities in this section.

* * * * *

(3) For the EQR-related activities described in paragraph (b)(1) of this section (except paragraph (b)(1)(iii) of this section), the review period begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity and is 12 months in duration.

(b) * * *

(1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed in the 12 months preceding the finalization of the annual report:

(i) Validation of performance improvement projects required in

accordance with § 438.330(b)(1) that were underway during the EQR review period per paragraph (a)(3) of this section.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the EQR review period described in paragraph (a)(3) of this section.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the EQR review period per paragraph (a)(3) of this section to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).

(2) For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section may be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO, PIHP, or PAHP and validated by an EQRO in accordance with paragraph (b)(1)(ii) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP or PAHP and/or validated by an EQRO in accordance with paragraph (b)(1)(i) of this section.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with 42 CFR part 438, subpart G.

(7) Assist with evaluations required under §§ 438.16(e)(1), 438.340(c)(2)(i), and 438.6(c)(2)(iv) and (v) pertaining to outcomes, quality, or access to health care services.

* * * * *

■ 24. Amend § 438.360 by revising paragraph (a)(1) to read as follows:

§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) * * *

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS;

* * * * *

■ 25. Amend § 438.362 by revising and republishing paragraph (b)(2) to read as follows:

§ 438.362 Exemption from external quality review.

* * * * *

(b) * * *

(2) *Medicare information from a private accrediting organization.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used to fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

* * * * *

■ 26. Amend § 438.364 by—

■ a. Revising paragraphs (a)(1), (a)(2)(iii), (a)(3) through (6), and (c)(2)(i) and (ii); and

■ b. Adding paragraph (c)(2)(iii).

The revisions and addition read as follows:

§ 438.364 External quality review results.

(a) * * *

(1) A description of the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, or PAHP.

(2) * * *

(iii) The data and a description of data obtained, including validated performance measurement, any outcomes data and results from quantitative assessments, for each activity conducted in accordance with § 438.358(b)(1)(i), (ii) and (iv) of this subpart; and

* * * * *

(3) An assessment of each MCO's, PIHP's, or PAHP's-strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, including how the State can target goals and objectives in the quality strategy, under § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, or PAHPs, consistent with guidance included in the EQR protocols issued in accordance with § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

* * * * *

(c) * * *

(2) * * *

(i) Post the most recent copy of the annual EQR technical report on the website required-under § 438.10(c)(3) by April 30th of each year and notify CMS, in a form and manner determined by CMS, within 14 calendar days of the Web posting.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public.

(iii) Maintain at least the previous 5 years of EQR technical reports on the on the website required under § 438.10(c)(3).

* * * * *

■ 27. Add subpart G to part 438 to read as follows:

Subpart G—Medicaid Managed Care Quality Rating System

Sec.

§ 438.500 Definitions.

(a) Definitions. As used in this subpart, the following terms have the indicated meanings:

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measurement year means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

Medicaid managed care quality rating system framework (QRS framework) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system) means the rating system described in subpart D of parts 422 and 423 of this chapter.

Qualified health plan quality rating system (QHP quality rating system) means the health plan quality rating system developed in accordance with 45 CFR 156.1120.

Quality rating means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

Technical resource manual means the guidance described in § 438.530.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.505 General rule and applicability.

(a) *General rule.* As part of its quality assessment and improvement strategy for its managed care program, each State contracting with an applicable managed care plan, as described in paragraph (b) of this section, to furnish services to Medicaid beneficiaries—

(1)(i) Must adopt the QRS framework developed by CMS, which must implement either the MAC QRS methodology developed by CMS or an alternative MAC QRS rating methodology approved by CMS in accordance with § 438.515(c) of this subpart.

(ii) May, in addition to the MAC QRS framework adopted under paragraph (a)(1)(i) of this section, implement website features in addition to those identified in § 438.520(a), as described in § 438.520(c).

(2) Must implement such managed care quality rating system by the end of the fourth calendar year following July 9, 2024, unless otherwise specified in this subpart.

(3) Must use the State's beneficiary support system implemented under § 438.71 to provide the services identified at § 438.71(b)(1)(i) and (ii) to beneficiaries, enrollees, or both seeking assistance using the managed care quality rating system implemented by the State under this subpart.

(b) *Applicability.* The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The provisions of this subpart do not apply to Medicare Advantage Dual Eligible Special Needs Plans that contract with States for only Medicaid coverage of Medicare cost sharing.

(c) *Continued alignment.* To maintain the QRS framework, CMS aligns the mandatory measure set and methodology described in §§ 438.510 and 438.515 of this subpart, to the extent appropriate, with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the MA and Part D quality rating system, and other similar CMS quality measurement and rating initiatives.

§ 438.510 Mandatory QRS measure set for Medicaid managed care quality rating system.

(a) *Measures required.* The quality rating system implemented by the State—

(1) Must include the measures that are:

(i) In the mandatory QRS measure set identified and described by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and

(ii) Applicable to the State because the measures assess a service or action covered by a managed care program established by the State.

(2) May include other measures identified by the State as provided in § 438.520(c)(1).

(b) *Subregulatory process to update mandatory measure set.* Subject to paragraph (d) of this section, CMS will—

(1) At least every other year, engage with States and other interested parties (such as State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations) to evaluate the current mandatory measure set and make recommendations to CMS to add, remove or update existing measures based on the criteria and standards in paragraph (c) of this section; and

(2) Provide public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) on any planned modifications to the mandatory measure set following the engagement described in paragraph (b)(1) of this section.

(c) *Standards for adding mandatory measures.* Based on available relevant information, including the input received during the process described in paragraph (b) of this section, CMS will add a measure in the mandatory measure set when each of the standards described in (c)(1) through (3) of this section are met.

(1) The measure meets at least 5 of the following criteria:

(i) Is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan;

(ii) Aligns, to the extent appropriate, with other CMS programs described in § 438.505(c);

(iii) Measures health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity;

(iv) Presents an opportunity for managed care plans to influence their performance on the measure;

(v) Is based on data that are available without undue burden on States, managed care plans, and providers such that it is feasible to report by many States, managed care plans, and providers;

(vi) Demonstrates scientific acceptability, meaning that the measure, as specified, produces consistent and credible results;

(2) The proposed measure contributes to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set, and

(3) The burdens associated with including the measure does not outweigh the benefits to the overall quality rating system framework of including the new measure based on the criteria listed in paragraph (c)(1) of this section.

(4) When making the determinations required under paragraphs (c)(2) and (3) of this section, to add, remove, or update a measure, CMS may consider the measure set as a whole, each

specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas.

(d) *Removing mandatory measures.* CMS may remove existing mandatory measures from the mandatory measure set if—

(1) After following the process described in paragraph (b) of this section, CMS determines that the measure no longer meets the standards described in paragraph (c) of this section;

(2) The measure steward (other than CMS) retires or stops maintaining a measure;

(3) CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes; or

(4) CMS determines that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e) of this chapter.

(e) *Updating existing mandatory measures.* CMS will modify the existing mandatory measures that undergo measure technical specifications updates as follows—

(1) *Non-substantive updates.* CMS will update changes to the technical specifications for a measure made by the measure steward; such changes will be in the technical resource manual issued under paragraph (f) of this section and § 438.530. Examples of non-substantive updates include those that:

(i) Narrow the denominator or population covered by the measure.

(ii) Do not meaningfully impact the numerator or denominator of the measure.

(iii) Update the clinical codes with no change in the target population or the intent of the measure.

(iv) Provide additional clarifications such as:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(D) Adding alternative data sources or expanding of modes of data collection to calculate a measure.

(2) *Substantive updates.* CMS may adopt substantive updates to a mandatory measure not subject to paragraphs (e)(1)(i) through (iv) of this section only after following the process specified in paragraph (b) of this section.

(f) *Finalization and display of mandatory measures and updates.* CMS will finalize modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual. For new or substantively updated measures, CMS will provide each State with at least 2 calendar years from the start of the measurement year immediately following the release of the annual technical resource manual in which the modification to the mandatory measure set is finalized to display measurement results and ratings using the new or updated measure(s).

§ 438.515 Medicaid managed care quality rating system methodology.

(a) *Quality ratings.* For each measurement year, the State must ensure that—

(1) The data necessary to calculate quality ratings for each quality measure described in § 438.510(a)(1) of this subpart are collected from:

(i) The State's contracted managed care plans that have 500 or more enrollees from the State's Medicaid program, to be calculated as described by CMS in the technical resource manual; and

(ii) Sources of Medicare data (including Medicare Advantage plans, Medicare providers, and CMS), the State's Medicaid fee-for-service providers, or both if all data necessary to calculate a measure cannot be provided by the managed care plans described in paragraph (a)(1) of this section and such data are available for collection by the State to the extent feasible without undue burden.

(2) Validation of data collected under paragraph (a)(1) of this section is performed, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section. Validation of data must not be performed by any entity with a conflict of interest, including managed care plans.

(3) A measure performance rate for each managed care plan whose contract covers a service or action assessed by the measure, as determined by the State, is calculated, for each quality measure identified under § 438.510(a)(1) of this subpart, using the methodology described in paragraph (b) of this section and the validated data described in paragraph (a)(2) of this section, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section.

(4) Quality ratings are issued by the State for each managed care plan for each measure that assesses a service or action covered by the plan's contract with the State, as determined by the State under paragraph (a)(3) of this section.

(b) *Methodology.* The State must ensure that the quality ratings issued under paragraph (a)(4) of this section:

(1) Include data for all enrollees who receive coverage through the managed care plan for a service or action for which data are necessary to calculate the quality rating for the managed care plan including Medicaid FFS and Medicare data for enrollees who receive Medicaid benefits for the State through FFS and managed care, are dually eligible for both Medicare and Medicaid and receive full benefits from Medicaid, or both).

(2) Are issued to each managed care plan at the plan level and by managed care program, so that a plan participating in multiple managed care programs is issued distinct ratings for each program in which it participates, resulting in quality ratings that are representative of services provided only to those beneficiaries enrolled in the plan through the rated program.

(c) *Alternative QRS methodology.* (1) A State may apply an alternative QRS methodology (that is, other than that described in paragraph (b) of this section) to the mandatory measures described in § 438.510(a)(1) of this subpart provided that—

(i) The ratings generated by the alternative QRS methodology yield information regarding managed care plan performance which, to the extent feasible, is substantially comparable to that yielded by the methodology described in § 438.515(b) of this subpart, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(ii) The State receives CMS approval prior to implementing an alternative QRS methodology or modifications to an approved alternative QRS methodology.

(2) To receive CMS approval for an alternative QRS methodology, a State must:

(i) Submit a request for, or modification of, an alternative QRS methodology to CMS in a form and manner and by a date determined by CMS; and

(ii) Include the following in the State's request for, or modification of, an alternative QRS methodology:

(A) The alternative QRS methodology to be used in generating plan ratings;

(B) Other information or documentation specified by CMS to

demonstrate compliance with paragraph (c)(1) of this section; and

(C) Other supporting documents and evidence that the State believes demonstrates compliance with the requirements of (c)(1)(i) of this section.

(3) Subject to requirements established in paragraphs (c)(1)(i) and (ii) and (c)(2) of this section, the flexibility described in paragraph (c)(1) of this section permits the State to request and receive CMS approval to apply an alternative methodology from that described in paragraph (b)(1) and (2) of this section when calculating quality ratings issued to health plans as required under paragraph (a)(4) of this section. CMS will not review or approve an alternative methodology request submitted by the State that requests to implement a MAC QRS that—

(i) Does not comply with—

(A) The requirement to include mandatory measures established in § 438.510(a)(1).

(B) The general requirements for calculating quality ratings established in paragraphs (a)(1) through (4) of this section.

(C) The requirement to include the website features identified in § 438.520(a)(1) through (6) established in § 438.520(a).

(ii) Requests to include plans that do not meet the threshold established in paragraph (a)(1)(i) of this section, which is permitted without CMS review or approval.

(iii) Requests to implement additional measures or website features, which are permitted, without CMS review or approval, as described § 438.520(c).

(d) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a one-year extension to the implementation date specified in this subpart for one or more MAC QRS requirements established in paragraph (b) of this section.

(1) A request for extension of the implementation deadline for the methodology requirements in this section must meet the following requirements:

(i) Identify the specific requirement(s) for which an extension is requested and;

(ii) Include a timeline of the steps the State has taken to meet the requirement as well as an anticipated timeline of the steps that remain;

(iii) Explain why the State will be unable to fully comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement; and

(iv) Include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, the operational steps the State will take to address identified implementation barriers.

(2) The State must submit an extension request by September 1 of the fourth calendar year following July 9, 2024.

(3) CMS will approve an extension for 1 year if it determines that the request:

(i) Includes the information described in paragraph (d)(1) of this section;

(ii) Demonstrates that the State has made a good-faith effort to identify and begin executing an implementation strategy but is unable to comply with the specified requirement by the implementation date identified in this subpart; and

(iii) Demonstrates that the State has an actionable plan to implement the requirements by the end of the 1-year extension.

(e) *Domain ratings.* After engaging with States, beneficiaries, and other interested parties, CMS implements domain-level quality ratings, including care domains for which States are required to calculate and assign domain-level quality ratings for managed care plans, a methodology to calculate such ratings, and website display requirements for displaying such ratings on the MAC QRS website display described in § 438.520.

§ 438.520 website display.

(a) *website display requirements.* In a manner that complies with the accessibility standards outlined in § 438.10(d) of this part and in a form and manner specified by CMS, the State must prominently display and make accessible to the public on the website required under § 438.10(c)(3):

(1) Information necessary for users to understand and navigate the contents of the QRS website display, including:

(i) A statement of the purpose of the Medicaid managed care quality rating system, relevant information on Medicaid, CHIP and Medicare and an overview of how to use the information available in the display to select a quality managed care plan;

(ii) Information on how to access the beneficiary support system described in § 438.71 to answer questions about using the State's managed care quality rating system to select a managed care plan; and

(iii) If users are requested to input user-specific information, including the information described in paragraph (a)(2)(i) of this section, an explanation of why the information is requested, how it will be used, and whether it is optional or required to access a QRS feature or type of information.

(2) Information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences including:

(i) All available managed care programs and plans for which a user may be eligible based on the user's age, geographic location, and dually eligible status, if applicable, as well as other demographic data identified by CMS;

(ii) A description of the drug coverage for each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS;

(iii) Provider directory information for each managed care plan including all information required by § 438.10(h)(1) and (2) and such other provider information as specified by CMS;

(iv) Quality ratings described at § 438.515(a)(4) that are calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS in the technical resource manual, and

(v) The quality ratings described in § 438.520(a)(2)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, stratified by dual eligibility status, race and ethnicity, and sex.

(3) Standardized information identified by CMS that allows users to compare available managed care plans and programs, including:

(i) The name of each managed care plan;

(ii) An internet hyperlink to each managed care plan's website and each available managed care plan's toll-free customer service telephone number;

(iii) Premium and cost-sharing information including differences in premium and cost-sharing among available managed care plans within a single program;

(iv) A summary of benefits including differences in benefits among available managed care plans within a single program and other similar information specified by CMS, such as whether access to the benefit requires prior authorization from the plan;

(v) Certain metrics, as specified by CMS, of managed care plan performance that States must make available to the public under subparts B and D of this part, including data most recently reported to CMS on each managed care program pursuant to § 438.66(e) of this part and the results of the secret shopper survey specified in § 438.68(f) of this part;

(vi) If a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D–SNP (as those terms are defined in § 422.2 of this chapter), an indication that an integrated plan is available and a link to the integrated plan's most recent rating under the Medicare Advantage and Part D 5-Star Rating System.

(4) Information on quality ratings displayed in accordance with paragraph (a)(2)(iv) of this section in a manner that promotes beneficiary understanding of and trust in the ratings, including:

(i) A plain language description of the importance and impact of each quality measure assigned a quality rating;

(ii) The measurement period during which the data used to calculate the quality rating was produced; and

(iii) Information on quality ratings data validation, including a plain language description of when, how and by whom the data were validated.

(5) Information or hyperlinks directing users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan.

(6) By a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in § 438.505:

(i) The quality ratings described in paragraph (a)(2)(iv) of this section calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, including the display of such measures stratified by dual eligibility status, race and ethnicity, sex, age, rural/urban status, disability, language of the enrollee, or other factors specified by CMS in the annual technical resource manual.

(ii) An interactive tool that enables users to view the quality ratings described at paragraph (a)(2)(iv) of this section, stratified by the factors described in paragraph (a)(6)(i) of this section.

(iii) For managed care programs with two or more participating plans—

(A) A search tool that enables users to identify available managed care plans within the managed care program that provide coverage for a drug identified by the user; and

(B) A search tool that enables users to identify available managed care plans within the managed care program that include a provider identified by the user in the plan's network of providers.

(b) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a 1-year extension to the implementation date specified in this subpart for one or more of the requirements established under paragraphs (a)(2)(v) and (6) of this section.

(1) A request for extension of the implementation deadline for the website display requirements in this section must meet the requirements described in § 438.515(d)(1);

(2) For extensions of the website requirements specified in paragraph (a)(6) of this section, the extension request must be submitted no later than 4 months prior to the implementation date specified pursuant to paragraph (a)(6) of this section for those requirements; for extensions of the requirements specified in paragraphs (a)(2)(v) of this section, the extension request must be submitted no later than September 1, 2027.

(3) CMS will approve the State's request for a 1-year extension if CMS determines that the request meets the conditions described in § 438.515(d)(3).

(c) *Additional website features.* The State may choose to display additional website features not described in § 438.520(a) in their MAC QRS, or may choose to implement the features described in § 438.520(a)(6)(i) through (iv) before the date specified by CMS as described in paragraph (a)(6) of this section.

(1) Additional website features may include additional measures not included in the mandatory measure set described in § 438.510(a)(1), supplementary data on displayed quality measures, and extra interactive functions, and may be implemented without CMS review.

(2) If the State chooses to display quality ratings for additional measures as described in paragraph (c)(1) of this section, the State must:

(i) Obtain input on the additional measures, prior to their use, from prospective users, including beneficiaries, caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy; and

(ii) Document the input received from prospective users required under paragraph (c)(2)(i) of this section, including modifications made to the additional measure(s) in response to the input and rationale for input not accepted.

(d) *Continued consultation.* CMS will periodically consult with States and interested parties including Medicaid managed care quality rating system users to evaluate the website display requirements described in this section for continued alignment with beneficiary preferences and values.

§ 438.525 [Reserved]

§ 438.530 Annual technical resource manual.

(a) Beginning in calendar year 2027, CMS will publish a Medicaid managed care quality rating system technical resource manual annually, which may be released in increments throughout the year. Subject to the limitation described in paragraph (a)(4) of this section, the technical resource manual must include all the following:

(1) Identification of all Medicaid managed care quality rating system measures, including:

(i) A list of the mandatory measures

(ii) Any measures newly added or removed from the prior year's mandatory measure set.

(iii) The subset of mandatory measures that must be displayed and stratified by factors such as race and ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the CMS in accordance with § 438.520(a)(2)(v) and (a)(6)(i).

(2) Guidance on the application of the methodology used to calculate and issue quality ratings as described in § 438.515(b).

(3) Measure steward technical specifications for mandatory measures.

(4) If the public notice and comment process described in § 438.510(b) of this subpart occurs in the calendar year in which the manual is published, a summary of interested party engagement and public comments received during the notice and comment process using the process identified in § 438.510(c) for the most recent modifications to the mandatory measure set including:

(i) Discussion of the feedback and recommendations received on potential modifications to mandatory measures;

(ii) The final modifications and the timeline by which such modifications must be implemented; and

(iii) The rationale for not accepting or implementing specific recommendations or feedback submitted during the consultation process.

(b) In developing and issuing the manual content described in paragraphs (a)(1) and (2) of this section, CMS will take into account whether stratification is currently required by the measure steward or other CMS programs and by which factors when issuing guidance that identifies which measures, and by which factors, States must stratify mandatory measures.

(c) No later than August 1, 2025, CMS will publish the information described at paragraph (a)(1) of this section for the initial mandatory measure set.

§ 438.535 Annual reporting.

(a) Upon CMS' request, but no more frequently than annually, the State must submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. Such report must include:

(1) The following measure information:

(i) A list of all mandatory measures identified in the most recent technical resource manual that indicates for each measure:

(A) Whether the State has identified the measure as applicable or not applicable to the State's managed care program under § 438.510(a)(1) of this subpart;

(B) For any measures identified as inapplicable to the State's managed care program, a brief explanation of why the State determined that the measure is inapplicable; and,

(C) For any measure identified as applicable to the State's managed care program, the managed care programs to which the measure is applicable.

(ii) A list of any additional measures the State chooses to include in the Medicaid managed care quality rating system as permitted under § 438.510(a)(2).

(2) An attestation that all displayed quality ratings for mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate ratings for any additional measures if such methodology deviates from the methodology in § 438.515.

(3) The documentation required under § 438.520(c), if including additional measures in the State's Medicaid managed care quality rating system.

(4) The date on which the State publishes or updates the quality ratings for the State's managed care plans.

(5) A link to the State's website for their Medicaid managed care quality rating system.

(6) The application of any technical specification adjustments used to calculate and issue quality ratings described in § 438.515(a)(3) and (4), at the plan- or State-level, that are outside a measure steward's allowable adjustments for a mandatory measure but that the measure steward has approved for use by the State.

(7) A summary of each alternative QRS methodology approved by CMS, including the effective dates for each approved alternative QRS.

(8) If all data necessary to calculate a measure described in § 438.510(a)(1) of this subpart cannot be provided by the managed care plans described in § 438.515(a)(1) of this subpart:

(i) A description of any Medicare data, Medicaid FFS data, or both that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure per § 438.515(a) and (b), including an estimate of the proportion of Medicare data or Medicaid FFS data that such missing data represent.

(ii) A description of the undue burden(s) that prevents the State from ensuring that such data are collected, validated, or used to calculate the measure, the resources necessary to overcome the burden, and the State's plan to address the burden.

(iii) An assessment of the impact of the missing data on the State's ability to fully comply with § 438.515(b)(1).

(b) States will be given no less than 90 days to submit such a report to CMS on their Medicaid managed care quality rating system.

■ 28. Amend § 438.602 by adding paragraphs (g)(5) through (13) and (j) to read as follows:

§ 438.602 State responsibilities.

* * * * *

(g) * * *

(5) Enrollee handbooks, provider directories, and formularies required at § 438.10(g) through (i).

(6) The information on rate ranges required at § 438.4(c)(2)(iv), if applicable.

(7) The reports required at §§ 438.66(e) and 438.207(d).

(8) The network adequacy standards required at § 438.68(b)(1) through (2) and (e).

(9) The results of secret shopper surveys required at § 438.68(f).

(10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C).

(11) Information on all required Application Programming Interfaces including as specified in § 431.60(d) and (f).

(12) Quality related information as required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i).

(13) Documentation of compliance with requirements in subpart K—Parity in Mental Health and Substance Use Disorder Benefits.

* * * * *

(j) *Applicability.* Paragraphs (g)(5) through (13) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

■ 29. Amend § 438.608 by revising paragraphs (a)(2) and (d)(3) and adding paragraph (e) and (f) to read as follows:

§ 438.608 Program integrity requirements under the contract.

(a) * * *

(2) Provision for reporting within 30 calendar days all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

* * * * *

(d) * * *

(3) Each MCO, PIHP, or PAHP must report annually to the State on all overpayments identified or recovered.

* * * * *

(e) *Standards for provider incentive or bonus arrangements.* The State, through its contract with the MCO, PIHP or PAHP, must require that incentive payment contracts between managed care plans and network providers meet the requirements as specified in §§ 438.3(i)(3) and (4).

(f) *Applicability date.* Paragraphs (a)(2), (d)(3) and (e) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year from July 9, 2024.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 30. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 31. Amend § 457.10 by adding the definition of ''In lieu of service or setting (ILOS)'' in alphabetical order to read as follows:

§ 457.10 Definitions and use of terms.

* * * * *

In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter.

* * * * *

■ 32. Amend § 457.1200 by adding paragraph (d) to read as follows:

§ 457.1200 Basis, scope, and applicability.

* * * * *

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates established at §§ 438.3(v), 438.10(j), 438.16(f), 438.68(h), 438.206(d), 438.207(g), 438.310(d), 438.505(a)(2), 438.602(j), and 438.608(f) of this chapter, so long as they comply with the corresponding standard(s) of this subpart, edition revised as of July 9, 2024. States will not be held out of compliance with the requirement at § 457.1207 to post comparative summary results of enrollee experience surveys by managed care plan annually on State websites, nor the requirement for States to evaluate annual enrollee experience survey results as part of the State's annual analysis of network adequacy as described at § 457.1230(b), so long as

they comply with the corresponding standard(s) of this subpart, 2 years after July 9, 2024.

■ 33. Amend § 457.1201 by revising paragraphs (c), (e), and (n)(2) to read as follows:

§ 457.1201 Standard contract requirements.

* * * * *

(c) *Payment.* The final capitation rates for all MCO, PIHP or PAHP contracts must be identified and developed, and payment must be made in accordance with §§ 438.3(c) and 438.16(c)(1) through (3) of this chapter, except that the requirement for preapproval of contracts, certifications by an actuary, annual cost reports, contract arrangements described in § 438.6(c), and references to pass through payments do not apply, and contract rates must be submitted to CMS upon request of the Secretary.

* * * * *

(e*) Services that may be covered by an MCO, PIHP, or PAHP.* An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with §§ 438.3(e) and 438.16(b), (d), and (e) of this chapter, except that references to § 438.7, IMDs, and rate certifications do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part.

* * * * *

(n) * * *

(2) Contracts with PCCMs must comply with the requirements of paragraph (o) of this section; § 457.1207; § 457.1240(b) (cross-referencing § 438.330(b)(2), (b)(3), (c), and (e) of this chapter); § 457.1240(e) (cross-referencing § 438.340 of this chapter).

* * * * *

■ 34. Amend § 457.1203 by revising paragraphs (e) and (f) to read as follows:

§ 457.1203 Rate development standards and medical loss ratio.

* * * * *

(e) The State must comply with the requirements related to medical loss ratios in accordance with the terms of § 438.74 of this chapter, except contract arrangements described in § 438.6(c) do not apply and the description of the reports received from the MCOs, PIHPs and PAHPs under § 438.8(k) of this chapter will be submitted independently, and not with the rate certification described in § 438.7 of this chapter.

(f) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements in § 438.8 of this chapter, except that contract arrangements described in § 438.6(c) do not apply.

■ 35. Revise § 457.1207 to read as follows:

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM, and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E), and (g)(2)(xii) of this chapter do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part. The State must annually post comparative summary results of enrollee experience surveys by managed care plan on the State's website as described at § 438.10(c)(3) of this chapter.

■ 36. Revise § 457.1230(b) to read as follows:

§ 457.1230 Access standards.

* * * * *

(b) *Assurances of adequate capacity and services.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment in accordance with the terms of § 438.207 of this chapter, except that the reporting requirements in § 438.207(d)(3)(i) of this chapter do not apply. The State must evaluate the most recent annual enrollee experience survey results as required at section 2108(e)(4) of the Act as part of the State's analysis of network adequacy as described at § 438.207(d) of this chapter.

* * * * *

■ 37. Amend § 457.1240 by revising paragraphs (d) and (f) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(d) *Managed care quality rating system.* The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth in subpart G of part 438 of this chapter, except that references to dually eligible beneficiaries, a beneficiary support system, and the terms related to consultation with the Medical Care Advisory Committee do not apply.

* * * * *

(f) *Applicability to PCCM entities.* For purposes of paragraphs (b) and (e) of this section, a PCCM entity described in this paragraph is a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

■ 38. Revise § 457.1250(a) to read as follows:

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350 (except for references to § 438.362), 438.352, 438.354, 438.356, 438.358 (except for references to § 438.6), 438.360 (only for nonduplication of EQR activities with private accreditation) and 438.364 of this chapter.

* * * * *

■ 39. Revise § 457.1285 to read as follows:

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2), 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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