DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 153, 155, 156, and 158

[CMS–9888–F]

RIN 0938–AV41

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation (HHS–RADV) programs, as well as 2026 benefit year user fee rates for issuers that participate in the HHS-operated risk adjustment program and the 2026 benefit year user fee rates for issuers offering qualified health plans (QHPs) through Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal platform (SBE–FPs). This final rule also includes requirements related to modifications to the calculation of the Basic Health Program (BHP) payment; and changes to the Initial Validation Audit (IVA) sampling approach and Second Validation Audit (SVA) pairwise means test for HHS–RADV. It also addresses HHS' authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies for violations of HHS' Exchange standards and requirements; HHS' system suspension authority to address noncompliance by agents and brokers; an optional fixed-dollar premium payment threshold; permissible plan-level adjustment to the index rate to account for cost-sharing reductions (CSRs); reconsideration standards for certification denials; changes to the approach for conducting Essential Community Provider (ECP) certification reviews; a policy to publicly share aggregated, summary-level Quality Improvement Strategy (QIS) information on an annual basis; and revisions to the medical loss ratio (MLR) reporting and rebate requirements for qualifying issuers that meet certain standards.

DATES: These regulations are effective on January 15, 2025.

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SUPPLEMENTARY INFORMATION:

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I. Executive Summary

We are finalizing changes to the provisions and parameters implemented through prior rulemaking to implement the ACA.[1] These requirements are published under the authority granted to the Secretary by the ACA and the Public Health Service (PHS) Act.[2] In this final rule, we are finalizing changes related to some of the ACA provisions and parameters we previously

[1] The Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1049), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this rulemaking, the two statutes are referred to collectively as the ''Patient Protection and Affordable Care Act,'' ''Affordable Care Act,'' or ''ACA.''

[2] See sections 1301, 1302, 1311, 1312, 1313, 1321, 1331, and 1343 of the ACA and sections 2718 and 2792 of the PHS Act.

implemented and are finalizing new provisions. Our goal with these requirements is to provide quality, affordable coverage to consumers while minimizing administrative burden and ensuring program integrity. The changes in this final rule are intended to help advance health equity, mitigate health disparities, and alleviate discrimination.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets. These provisions of the PHS Act were later augmented by other laws, including the ACA. Subtitles A and C of title I of the ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.

Below, we summarize sections of the PHS Act and ACA that are relevant to this final rule.

Section 2718 of the PHS Act, as added by the ACA, generally requires health insurance issuers offering group or individual health insurance coverage to submit an annual medical loss ratio (MLR) report to HHS and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 1301(a)(1)(B) of the ACA directs all issuers of qualified health plans (QHPs) to cover the essential health benefits (EHB) package described in section 1302(a) of the ACA, including coverage of the services described in section 1302(b) of the ACA, adherence to the cost-sharing limits described in section 1302(c) of the ACA, and meeting the Actuarial Value (AV) levels established in section 1302(d) of the ACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in section 1302(c)(1) of the ACA.

Section 1302 of the ACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary of HHS), cost-sharing limits, and AV requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Sections 1302(b)(4)(A) through (D) of the ACA establish that the Secretary must define EHB in a manner that: (1) reflects appropriate balance among the 10 categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHBs based on age, life expectancy, disability, degree of medical dependency, or quality of life.

Section 1302(d) of the ACA describes the various levels of coverage based on AV. Consistent with section 1302(d)(2)(A) of the ACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the ACA directs the Secretary of HHS to develop guidelines that allow for de minimis variation in AV calculations.

Section 1311(c) of the ACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(c)(1)(B) of the ACA requires, among the criteria for certification that the Secretary must establish by regulation, that QHPs ensure a sufficient choice of providers. Section 1311(d)(4)(A) of the ACA requires the Exchange to implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by the Secretary under section 1311(c) of the ACA. Section 1311(e)(1) of the ACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State. Section 1311(c)(6)(C) of the ACA directs the Secretary of HHS to require an Exchange to provide for special enrollment periods and section 1311(c)(6)(D) of the ACA directs the Secretary of HHS to require an Exchange to provide for a monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1311(d)(3)(B) of the ACA permits a State, at its option, to require QHPs to cover benefits in addition to EHB. This section also requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits.

Section 1312(c) of the ACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the ACA.

Section 1312(e) of the ACA provides the Secretary with the authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through Exchanges and (2) assist individuals in applying for advance payments of the premium tax credit (APTC) and CSRs for QHPs sold through an Exchange.

Section 1312(f)(1)(B) of the ACA provides that an individual shall not be treated as a qualified individual for enrollment in a QHP if, at the time of enrollment, the individual is incarcerated, other than incarceration pending the disposition of charges.

Sections 1313 and 1321 of the ACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1313(a)(5)(A) of the ACA provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges. Section 1321 of the ACA provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the ACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA,

including such other requirements as the Secretary determines appropriate. When operating an FFE under section 1321(c)(1) of the ACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the ACA to collect and spend user fees. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the public.

Section 1321(d) of the ACA provides that nothing in title I of the ACA must be construed to preempt any State law that does not prevent the application of title I of the ACA. Section 1311(k) of the ACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1331 of the ACA provides States with an option to establish a Basic Health Program (BHP). In the States that elect to operate a BHP, the BHP makes affordable health benefits coverage available for individuals under age 65 with household incomes between 133 percent and 200 percent of the Federal poverty level (FPL) who are not otherwise eligible for Medicaid, the Children's Health Insurance Program (CHIP), or affordable employer-sponsored coverage, or for individuals whose income is equal to or below 200 percent of FPL but are lawfully present non-citizens ineligible for Medicaid. For those States that have expanded Medicaid coverage under section 1902(a)(10)(A)(i)(VIII) of the Social Security Act (the Act), the lower income threshold for BHP eligibility is effectively 138 percent of the FPL due to the application of a required 5 percent income disregard in determining the upper limits of Medicaid income eligibility (section 1902(e)(14)(I) of the Act).

Section 1343 of the ACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by charges collected from those issuers that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. Section 1343(b) of the ACA provides that the Secretary, in consultation with States, shall establish criteria and methods to be used in carrying out the risk adjustment activities under this section. Consistent with section 1321(c) of the ACA, the Secretary is responsible for operating the HHS risk adjustment program in any State that fails to do so.[3]

Section 1401(a) of the ACA added section 36B to the Internal Revenue Code (the Code), which, among other things, requires that a taxpayer reconcile APTC for a year of coverage with the amount of the premium tax credit (PTC) the taxpayer is allowed for the year.

Section 1402 of the ACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level QHPs offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 1411(f) of the ACA requires the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Homeland Security, and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations. Section 1411(f)(1)(B) of the ACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the ACA allows the use of applicant information only for the limited purpose of, and to the extent necessary for, ensuring the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs, and limits the disclosure of such information.

Section 1413 of the ACA directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs.

Section 5000A of the Code, as added by section 1501(b) of the ACA, requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018. Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals aged 30 and above qualify to enroll in catastrophic coverage under §§ 155.305(h) and 156.155(a)(5).

Section 1902(r)(2)(A) of the Act permits States to apply less restrictive methodologies than cash assistance program methodologies in determining eligibility for certain eligibility groups.

1. Premium Stabilization Programs

The premium stabilization programs refer to the risk adjustment, risk corridors, and reinsurance programs established by the ACA.[4] For past rulemaking, we refer readers to the following rules:

- In the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), we implemented the premium stabilization programs.
- In the March 11, 2013 **Federal Register** (78 FR 15409) (2014 Payment Notice), we finalized the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs.
- In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the modification to the HHS risk adjustment methodology related to community rating States.
- In the November 6, 2013 **Federal Register** (78 FR 66653), we issued a correcting amendment to the 2014 Payment Notice to address how an enrollee's age for the risk score calculation would be determined under the HHS risk adjustment methodology.
- In the March 11, 2014 **Federal Register** (79 FR 13743) (2015 Payment Notice), we finalized the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish payment parameters in those programs.
- In the May 27, 2014 **Federal Register** (79 FR 30240), we announced the fiscal year 2015 sequestration rate for the HHS-operated risk adjustment program.
- In the February 27, 2015 **Federal Register** (80 FR 10749) (2016 Payment Notice), we finalized the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish the payment parameters in those programs.
- In the March 8, 2016 **Federal Register** (81 FR 12203) (2017 Payment

[3] In the 2014 through 2016 benefit years, HHS operated the risk adjustment program in every State and the District of Columbia, except Massachusetts. Beginning with the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

[4] See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

Notice), we finalized the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, set forth certain oversight provisions, and establish the payment parameters in those programs.

- In the December 22, 2016 **Federal Register** (81 FR 94058) (2018 Payment Notice), we finalized the benefit and payment parameters for the 2018 benefit year, added the high-cost risk pool parameters to the HHS risk adjustment methodology, incorporated prescription drug factors in the adult models, established enrollment duration factors for the adult models, and finalized policies related to the collection and use of enrollee-level External Data Gathering Environment (EDGE) data.
- In the April 17, 2018 **Federal Register** (83 FR 16930) (2019 Payment Notice), we finalized the benefit and payment parameters for the 2019 benefit year, created the State flexibility framework permitting States to request a reduction in risk adjustment State transfers calculated by HHS, and adopted a new error rate methodology for HHS–RADV adjustments to transfers.
- In the May 11, 2018 **Federal Register** (83 FR 21925), we issued a correction to the 2019 HHS risk adjustment coefficients in the 2019 Payment Notice.
- On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final HHS risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE data set.[5]
- In the July 30, 2018 **Federal Register** (83 FR 36456), we adopted the 2017 benefit year HHS risk adjustment methodology as established in the final rules issued in the March 23, 2012 (77 FR 17220 through 17252) and March 8, 2016 (81 FR 12204 through 12352) editions of the **Federal Register**. The final rule set forth an additional explanation of the rationale supporting the use of Statewide average premium in the State payment transfer formula for the 2017 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner. The final rule also permitted HHS to resume 2017 benefit year HHS risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of the publication of the final rule.
- In the December 10, 2018 **Federal Register** (83 FR 63419), we adopted the 2018 benefit year HHS risk adjustment methodology as established in the final rules issued in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. In the rule, we set forth an additional explanation of the rationale supporting the use of Statewide average premium in the State payment transfer formula for the 2018 benefit year, including the reasons why the program is operated by HHS in a budget-neutral manner.
- In the April 25, 2019 **Federal Register** (84 FR 17454) (2020 Payment Notice), we finalized the benefit and payment parameters for the 2020 benefit year, as well as the policies related to making the enrollee-level EDGE data available as a limited data set for research purposes and expanding the HHS uses of the enrollee-level EDGE data, approval of the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the small group market for the 2020 benefit year, and updates to HHS–RADV program requirements.
- On May 12, 2020, consistent with § 153.320(b)(1)(i), we issued the 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website.[6]
- In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized the benefit and payment parameters for the 2021 benefit year, as well as adopted updates to the HHS risk adjustment models' hierarchical condition categories (HCCs) to transition to the 10th revision of the International Classification of Diseases (ICD–10) codes, approved the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the small group market for the 2021 benefit year, and modified the outlier identification process under the HHS–RADV program.
- In the December 1, 2020 **Federal Register** (85 FR 76979) (Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program (2020 HHS–RADV Amendments Rule)), we adopted the creation and application of Super HCCs in the sorting step that assigns HCCs to failure rate groups, finalized a sliding scale adjustment in HHS–RADV error rate calculation, and added a constraint for negative error rate outliers with a negative error rate. We also established a transition from the prospective application of HHS–RADV adjustments to apply HHS–RADV results to risk scores from the same benefit year as that being audited.
- In the September 2, 2020 **Federal Register** (85 FR 54820), we issued an interim final rule containing certain policy and regulatory revisions in response to the COVID–19 public health emergency (PHE), wherein we set forth HHS risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year.
- In the May 5, 2021 **Federal Register** (86 FR 24140) (part 2 of the 2022 Payment Notice), we finalized a subset of proposals from the December 4, 2020 **Federal Register** (85 FR 78572) (the 2022 Payment Notice proposed rule), including policy and regulatory revisions related to the HHS-operated risk adjustment program, finalization of the benefit and payment parameters for the 2022 benefit year, and approval of the request from Alabama to reduce HHS risk adjustment transfers by 50 percent in the individual and small group markets for the 2022 benefit year. In addition, this final rule established a revised schedule of collections for HHS–RADV and updated the provisions regulating second validation audit (SVA) and initial validation audit (IVA) entities.
- On July 19, 2021, consistent with § 153.320(b)(1)(i), we released Updated 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients on the CCIIO website, announcing some minor revisions to the 2022 benefit year final HHS risk adjustment adult model coefficients.[7]
- In the May 6, 2022 **Federal Register** (87 FR 27208) (2023 Payment Notice), we finalized revisions related to the HHS-operated risk adjustment program, including the benefit and payment parameters for the 2023 benefit year, HHS risk adjustment model recalibration, and policies related to the collection and extraction of enrollee-level EDGE data. We also finalized the adoption of the interacted HCC count specification for the adult and child models, along with modified enrollment duration factors for the adult models, beginning with the 2023 benefit year.[8]

[5] CMS. (2018). *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[6] CMS. (2020). Final 2021 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2021-Benefit-Year-Final-HHS-Risk-Adjustment-Model-Coefficients.pdf.*

[7] CMS. (2021). 2022 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://www.cms.gov/files/document/updated-2022-benefit-year-final-hhs-risk-adjustment-model-coefficients-clean-version-508.pdf.*

[8] CMS (2022). 2023 Benefit Year Final HHS Risk Adjustment Model Coefficients. *https://*

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We also repealed the ability for States, other than prior participants, to request a reduction in HHS risk adjustment State transfers starting with the 2024 benefit year. In addition, we approved a 25 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's individual market and a 10 percent reduction to 2023 benefit year HHS risk adjustment transfers in Alabama's small group market. We also finalized further refinements to the HHS–RADV error rate calculation methodology beginning with the 2021 benefit year.

• In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized the benefit and payment parameters for the 2024 benefit year, amended the EDGE discrepancy materiality threshold and data collection requirements, and reduced the risk adjustment user fee. For the 2024 benefit year, we approved 50 percent reductions to HHS risk adjustment transfers for Alabama's individual and small group markets and repealed prior participant States' ability to request reductions of their risk adjustment transfers for the 2025 benefit year and beyond. We finalized several refinements to HHS–RADV program requirements, such as shortening the window to confirm SVA findings or file a discrepancy report, changing the HHS–RADV materiality threshold for random and targeted sampling, and no longer exempting exiting issuers from adjustments to risk scores and HHS risk adjustment transfers when they are negative error rate outliers. We also announced the discontinuance of the Lifelong Permanent Condition List (LLPC) and Non-EDGE Claims (NEC) in HHS–RADV beginning with the 2022 benefit year.

• In the April 15, 2024 **Federal Register** (89 FR 26218) (2025 Payment Notice), we finalized the benefit and payment parameters for the 2025 benefit year, including the 2025 risk adjustment models and updated the adjustment factors for the receipt of CSRs for the American Indian and Alaska Native (AI/AN) subpopulation who are enrolled in zero and limited cost-sharing plans to improve prediction in the HHS risk adjustment models. In addition, we finalized that in certain cases, we may require a corrective action plan (CAP) to address an observation identified in an HHS risk adjustment program audit.

2. Program Integrity

We have finalized program integrity standards related to the Exchanges and premium stabilization programs in two rules: the ''first Program Integrity Rule'' issued in the August 30, 2013 **Federal Register** (78 FR 54069), and the ''second Program Integrity Rule'' issued in the October 30, 2013 **Federal Register** (78 FR 65045). We also refer readers to the 2019 Patient Protection and Affordable Care Act; Exchange Program Integrity final rule (2019 Program Integrity Rule) issued in the December 27, 2019 **Federal Register** (84 FR 71674).

In the April 27, 2023 **Federal Register** (88 FR 25740) (2024 Payment Notice), we finalized a policy to implement improper payment pre-testing and assessment (IPPTA) requirements for State Exchanges to ensure adherence to the Payment Integrity Information Act of 2019. In addition, we finalized allowing additional time for HHS to review evidence submitted by agents and brokers to rebut allegations pertaining to Exchange Agreement suspensions or terminations. We also introduced consent and eligibility application documentation requirements for agents, brokers, and web-brokers that assist Exchange consumers in FFE and SBE–FP States.

3. Market Rules

In the February 27, 2013 **Federal Register** (78 FR 13406), we issued the health insurance market rules, including provisions related to the single risk pool. We amended requirements related to index rates under the single risk pool provision in a final rule issued in the July 2, 2013 **Federal Register** (78 FR 39870). In the October 30, 2013 **Federal Register** (78 FR 65046), we clarified when issuers may establish and update premium rates. In the March 8, 2016 **Federal Register** (81 FR 12203), we clarified single risk pool provisions related to student health insurance coverage. We finalized minor adjustments to the single risk pool regulations in the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

4. Exchanges

We requested comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. In the March 27, 2012 **Federal Register** (77 FR 18310) (Exchange Establishment Rule), we implemented the Affordable Insurance Exchanges (Exchanges), consistent with title I of the ACA, to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options based on price, quality, and other factors. This included implementation of components of the Exchanges and standards for eligibility for Exchanges, as well as network adequacy and ECP certification standards.

In the August 17, 2011 **Federal Register** (76 FR 51201), we issued a proposed rule regarding eligibility determinations, including the regulatory requirement to verify incarceration status. In the March 27, 2012 **Federal Register** (77 FR 18310), we finalized the regulatory requirement to verify incarceration attestation using an approved electronic data source that is current and accurate, and to resolve the inconsistency when attestations are not reasonably compatible with information in an approved data source. We also established requirements regarding accessible communications for individuals with disabilities and those with LEP.

In the 2014 Payment Notice and the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, issued in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, issued in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In the 2016 Payment Notice, we also set forth the ECP certification standard at § 156.235, with revisions in the 2017 Payment Notice in the March 8, 2016 **Federal Register** (81 FR 12203) and the 2018 Payment Notice in the December 22, 2016 **Federal Register** (81 FR 94058).

In the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058), we set forth the standards for the request for reconsideration of denial of certification specific to the FFEs at § 155.1090.

In an interim final rule, issued in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice, issued in the December 22, 2016 **Federal Register** (81 FR 94058).

In the Market Stabilization final rule, issued in the April 18, 2017 **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice, issued in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the 2020 Payment Notice

www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf.

established a new special enrollment period.

In the May 14, 2020 **Federal Register** (85 FR 29164) (2021 Payment Notice), we finalized revisions to the parameters of special enrollment periods and the quality rating information display standards for State Exchanges and amended the periodic data matching requirements.

In the January 19, 2021 **Federal Register** (86 FR 6138) (part 1 of the 2022 Payment Notice), we finalized only a subset of the proposals in the 2022 Payment Notice proposed rule. In the May 5, 2021 **Federal Register** (86 FR 24140), we issued part 2 of the 2022 Payment Notice. In part 3 of the 2022 Payment Notice, issued in the September 27, 2021 **Federal Register** (86 FR 53412), in conjunction with the Department of the Treasury, we finalized amendments to certain policies in part 1 of the 2022 Payment Notice.

In the May 6, 2022 **Federal Register** (87 FR 27208), we finalized changes to maintain the user fee rate for issuers offering plans through the FFEs and maintain the user fee rate for issuers offering plans through the SBE–FPs for the 2023 benefit year. We also finalized various policies to address certain agent, broker, and web-broker practices and conduct. We also finalized updates to the requirement that all Exchanges conduct special enrollment period verifications.

In the 2024 Payment Notice, issued in the April 27, 2023 **Federal Register** (88 FR 25740), we revised Exchange Blueprint approval timelines, lowered the user fee rate for QHPs in the FFEs and SBE–FPs, and amended re-enrollment hierarchies for enrollees. We also finalized policies to update FFE and SBE–FP standardized plan options; reduce the risk of plan choice overload on the FFEs and SBE–FPs by limiting the number of non-standardized plan options that issuers may offer through Exchanges on the Federal platform to four for Plan Year (PY) 2024 and to two for PY 2025 and subsequent years; and ensure correct QHP information. In addition, we amended coverage effective date rules, lengthened the special enrollment period from 60 to 90 days for those who lose Medicaid coverage, and prohibited QHPs on FFEs and SBE–FPs from terminating coverage mid-year for dependent children who reach the applicable maximum age. We also finalized policies on verifying consumer income and permitting door-to-door assisters to solicit consumers. To ensure provider network adequacy, we finalized provider network and ECP policies for QHPs. We revised the failure to file and reconcile process to ensure enrollees would not lose APTC eligibility until they or their tax filer failed to file their Federal income taxes and reconcile APTC for 2 consecutive tax years.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we required a State seeking to operate a State Exchange to first operate an SBE–FP for at least one PY, revised Exchange Blueprint requirements for States transitioning to a State Exchange, established additional minimum standards for Exchange call center operations, required an Exchange to operate a centralized eligibility and enrollment platform on its website, and finalized various policies for web-brokers and direct enrollment entities. In addition, we required State Exchanges and State Medicaid agencies to remit payment to HHS for their use of certain income data, amended re-enrollment hierarchies for enrollees enrolled in catastrophic coverage, revised the parameters around a State Exchange adopting an alternative open enrollment period, and extended the availability of a special enrollment period for APTC-eligible qualified individuals with a projected annual household income no greater than 150 percent of the Federal Poverty Level (FPL). To ensure provider network adequacy in State Exchanges and SBE–FPs, we finalized provider network adequacy policies applicable to such Exchanges for PY 2026 and subsequent plan years. We also further lowered the user fee rate for QHPs in the FFEs and SBE–FPs. In addition, we finalized the policy to maintain FFE and SBE–FP standardized plan option metal levels from the 2024 Payment Notice and finalized an exceptions process to the limitation on non-standardized plan options in FFEs and SBE–FPs. We also finalized the requirement for Exchanges to provide notification to enrollees or their tax filers who have failed to file their Federal income taxes and reconcile APTC for 1 tax year.

5. Essential Health Benefits

We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was issued in the February 25, 2013 **Federal Register** (78 FR 12834) (EHB Rule). We established at § 156.135(a) that AV is generally to be calculated using the AV Calculator developed and made available by HHS for a given benefit year. In the 2015 Payment Notice (79 FR 13743), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years. In the 2017 Payment Notice (81 FR 12349), we amended the provisions at § 156.135(g) to allow for additional flexibility in our approach and options for updating of the AV Calculator.

In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we revised § 155.170(a) to codify that benefits covered in a State's EHB-benchmark plan are not considered in addition to EHB, even if they had been required by State action taking place after December 31, 2011, other than for purposes of compliance with Federal requirements. We finalized three revisions to the standards for State selection of EHB-benchmark plans for benefit years beginning on or after January 1, 2026: we revised the typicality standard at § 156.111 for States to demonstrate that their new EHB-benchmark plan provides a scope of benefits that is equal to that of a typical employer plan in the State and removed the generosity standard; removed the requirement for States to submit a formulary drug list as part of their application unless they are changing their prescription drug EHBs; and consolidated the options for States to change their EHB-benchmark plans. We also removed the regulatory prohibition at § 156.115(d) on issuers from including routine non-pediatric dental services as an EHB beginning with PY 2027.

In addition, we revised § 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB. We also stated that the 2025 Payment Notice does not address the application of this policy to large group market health plans and self-insured group health plans, and that HHS and the Departments of Labor and the Treasury intend to propose rulemaking that would align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans, so that all group health plans and health insurance coverage subject to sections 2711 and 2707(b) of the PHS Act, as applicable, would be required to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing, which would further strengthen the consumer protections in the ACA.

6. Medical Loss Ratio (MLR)

We requested comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297)

and issued an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74864). A final rule with a 30-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was issued in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was issued in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules issued in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), the May 14, 2020 **Federal Register** (85 FR 29164), the May 5, 2021 **Federal Register** (86 FR 24140), the May 6, 2022 **Federal Register** (87 FR 27208), and an interim final rule that was issued in the September 2, 2020 **Federal Register** (85 FR 54820).

7. Quality Improvement Strategy

We issued regulations in § 155.200(d) to direct Exchanges to evaluate quality improvement strategies, and § 156.200(b) to direct QHP issuers to implement and report on a quality improvement strategy or strategies consistent with section 1311(g) standards as QHP certification criteria for participation in an Exchange. In the 2016 Payment Notice, issued in the February 27, 2015 **Federal Register** (80 FR 10749), we finalized regulations at § 156.1130 to establish standards and the associated timeframe for QHP issuers to submit the necessary information to implement quality improvement strategy standards for QHPs offered through an Exchange.

8. Basic Health Program

In the March 12, 2014, **Federal Register** (79 FR 14111), we issued a final rule entitled the ''Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity'' (hereinafter referred to as the BHP final rule) implementing section 1331 of the ACA, which governs the establishment of BHPs. The BHP final rule established the standards for State and Federal administration of BHPs, including provisions regarding eligibility and enrollment, benefits, cost-sharing requirements and oversight activities. In the BHP final rule, we specified that the BHP Payment Notice process would include the annual publication of both a proposed and final BHP payment methodology.

On October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury (the Departments) with a legal opinion [9] indicating that the permanent appropriation at 31 U.S.C. 1324, from which the Departments had historically drawn funds to make CSR payments, cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides for an appropriation. As a result of this opinion, CMS discontinued CSR payments to issuers in the States operating a BHP (that is, New York and Minnesota). The States then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York.[10] On May 2, 2018, the parties filed a stipulation requesting a stay of the litigation so that HHS could issue an administrative order revising the 2018 BHP payment methodology. After consideration of the States' comments on the administrative order revising the payment methodology, we issued a Final Administrative Order on August 24, 2018 (Final Administrative Order) setting forth the payment methodology that would apply to the 2018 BHP program year.

In the November 5, 2019 **Federal Register** (84 FR 59529) (hereinafter referred to as the November 2019 final BHP Payment Notice), we finalized the payment methodologies for BHP program years 2019 and 2020.[11] The 2019 payment methodology is the same payment methodology described in the Final Administrative Order. The 2020 payment methodology is the same methodology as the 2019 payment methodology with one additional adjustment to account for the impact of individuals selecting different metal tier level plans in the Exchange, referred to as the Metal Tier Selection Factor (MTSF).[12] In the August 13, 2020 **Federal Register** (85 FR 49264) (hereinafter referred to as the August 2020 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2021. The 2021 payment methodology is the same methodology as the 2020 payment methodology, with one adjustment to the income reconciliation factor (IRF). In the July 7, 2021 **Federal Register** (86 FR 35615) (hereinafter referred to as the July 2021 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2022. The 2022 payment methodology is the same as the 2021 payment methodology, with the exception of the removal of the Metal Tier Selection Factor.

In the December 20, 2022 **Federal Register** (87 FR 77722) (hereafter referred to as the 2023 final BHP Payment Notice), we finalized the payment methodology for BHP program year 2023. The 2023 payment methodology is the same as the 2022 payment methodology, except for the addition of a factor to account for a State operating a BHP and implementing an approved State Innovation Waiver under section 1332 of the ACA; this is the section 1332 waiver factor (WF). In the 2023 final BHP Payment Notice (87 FR 77722), we also revised the schedule for issuance of payment notices and allowed payment notices to be effective for 1 or multiple program years, as determined by and subject to the direction of the Secretary, beginning with the 2023 payment methodology. In the 2025 Payment Notice, issued in the April 15, 2024 **Federal Register** (89 FR 26218), we finalized that States may start BHP applicants' effective date of eligibility on the first day of the month following the date of application. In addition, we finalized that, subject to HHS approval, a State may establish its own effective date of eligibility for enrollment policy.

B. Summary of Major Provisions

The regulations outlined in the final rule are codified in 42 CFR part 600 and 45 CFR parts 153, 155, 156, and 158.

1. 42 CFR Part 600

We are finalizing changes to the methodology regarding the premium adjustment factor (PAF), which is used to calculate the adjusted reference

[9] Sessions, J. (2017, Oct. 11). *Legal Opinion Re: Payments to Issuers for Cost Sharing Reductions (CSRs).* Office of the Attorney General. *https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.*

[10] See Complaint, *New York* v. *U.S. Dep't of Health & Human Servs.,* No. 1:18–cv–00683 (RJS) (S.D.N.Y. filed Jan. 26, 2018).

[11] BHP program year means a calendar year for which a standard health plan provides coverage for BHP enrollees. *See* 42 CFR 600.5.

[12] ''Metal tiers'' refer to the different actuarial value plan levels offered on the Exchanges. Bronze-level plans generally must provide 60 percent actuarial value; silver-level 70 percent actuarial value; gold-level 80 percent actuarial value; and platinum-level 90 percent actuarial value. See 45 CFR 156.140.

premium (ARP) for BHP payment. We are finalizing maintaining the PAF value at 1.188 for States that have fully implemented BHP and are using Second Lowest Cost Silver Plan (SLCSP) premiums from a year in which BHP was fully implemented. As previously clarified, for States in their first year of implementing BHP and choosing to use prior year SLCSP premiums to determine BHP payment, the PAF value will be set to 1.00. We are finalizing that if a State is using SLCSP premiums from a year in which BHP was not fully implemented, the PAF is calculated by determining the CSR adjustment that QHP issuers included in the SLCSP premiums, reporting the CSR adjustments for the SLCSP for each region in the State to CMS, and then CMS calculating the PAF as 1.20 divided by 1 plus the adjustment. Additionally, we are finalizing a technical clarification for BHP payment rates in cases of multiple SLCSP premiums in an area.

2. 45 CFR Part 153

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.[13] Therefore, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2025 resources (that is, funds collected during the 2025 fiscal year) at a rate of 5.7 percent.

We are unable to complete the calculations for the final coefficients for the 2026 benefit year in time to publish them in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we are finalizing the datasets to be used to calculate the final coefficients in this rule and will publish the final coefficients for the 2026 benefit year in guidance after the publication of this final rule. Starting with the 2026 benefit year, we are finalizing the proposal to begin phasing out the market pricing adjustment to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models (see, for example, 84 FR 17463 through 17466). We are also finalizing the incorporation of pre-exposure prophylaxis (PrEP) as a separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. We are finalizing a risk adjustment user fee for the 2026 benefit year of $0.20 per member per month (PMPM).

Beginning with the 2025 benefit year of HHS–RADV, we are finalizing the proposals to exclude enrollees without HCCs, which includes adult enrollees with only prescription drug categories (RXCs), from the IVA sample, remove the Finite Population Correction (FPC) from the IVA sampling methodology, and replace the source of the Neyman allocation data used for HHS–RADV sampling with the most recent 3 consecutive years of HHS–RADV data. In addition, beginning with the 2024 benefit year of HHS–RADV, we are finalizing the proposals to modify the SVA pairwise means test, which tests for statistically significant differences between the IVA and SVA results, to use a bootstrapped 90 percent confidence interval methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees.

3. 45 CFR Part 155

We address our authority to investigate and undertake compliance reviews and enforcement actions in response to misconduct or noncompliance with applicable agent, broker, and web-broker Exchange requirements or standards occurring at the insurance agency level and how we intend to hold lead agents of insurance agencies accountable for such misconduct or noncompliance.

We are finalizing revisions at § 155.220(k)(3) to reflect our authority to suspend an agent's or broker's ability to transact information with the Exchange in instances where HHS discovers circumstances that pose unacceptable risk to accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

We are finalizing updates to the model consent form that agents, brokers, and web-brokers can use to obtain and document consumer consent.[14] The updates expand the resource to include a standardized form that agents, brokers, and web-brokers can use to document the consumer's review and confirmation of the accuracy of information in their Exchange eligibility application, which is a new standard of conduct that was also implemented as part of the 2024 Payment Notice (88 FR 25809 through 25814). The updates also add scripts that agents, brokers, and web-brokers may utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice via an audio recording.

We are finalizing, in connection with the failure to file and reconcile process at § 155.305(f)(4), that Exchanges are required to send notices to tax filers or their enrollees for the second year in which they have been determined to have failed to reconcile APTC explaining that they risk being determined ineligible for APTC. A notice to the tax filer may specifically explain that if they fail to file and reconcile for a second consecutive year, they risk being determined ineligible for APTC. Alternatively, an Exchange may send a more general notice to the enrollee or their tax filer explaining that they are at risk of losing APTC, without the additional detail that the tax filer has failed to file and reconcile APTC.

We are finalizing the addition of § 155.400(d)(1) to codify HHS' guidance that requires that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange that includes a description of an inaccuracy that meets the requirements at § 156.1210(a) through (c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, State Exchanges must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.[15]

We are finalizing a provision at § 155.400(g) to allow issuers to adopt a fixed-dollar payment threshold of $10 or less, to be adjusted for inflation by annual agency guidance, under which issuers would not be required to trigger a grace period or terminate enrollment for enrollees who fail to pay the full amount of their portion of premium owed, provided they do not owe more than the threshold amount. We are also finalizing a provision allowing issuers to adopt a gross percentage-based premium threshold of 98 percent or higher, which similarly would not require issuers to trigger a grace period

[13] OMB. (2024). OMB Report to *the* Congress on *the* BBEDCA *251A* Sequestration for *Fiscal Year* 2025. *https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.*

[14] CMS. (2022, December 14). *CMS Model Consent Form for Marketplace Agents and Brokers.* PRA package (CMS–10840, OMB Control Number 0938–1438). *https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.*

[15] OMB Control No: 0938–1312 and 0938–1341.

or terminate enrollment for enrollees who fail to pay the full amount of their portion of premium owed, provided they do not owe more than the threshold amount. In addition, we are finalizing a provision that permits issuers to set the premium payment threshold based on net premium owed by the enrollee at 95 percent or higher of the net premium, rather than providing for a ''reasonable'' standard as is currently set forth in regulation. We are finalizing a policy limiting application of the fixed-dollar payment threshold and gross premium percentage-based threshold to premium payments after coverage is effectuated. Issuers will be allowed to apply the fixed-dollar payment threshold and/or one of two percentage-based thresholds (but not both percentage-based thresholds). Issuers will be required to apply all chosen premium payment thresholds uniformly to all enrollees and without regard to their health status.

We are finalizing a provision at § 155.505(b) to codify an option for application filers as defined under § 155.20 to file appeals on behalf of applicants and enrollees on the application filer's Exchange application.

We are finalizing amendments at § 155.1000 to state explicitly that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). We also finalize amending § 155.1090 with refinements to the standards for a request for the reconsideration of a denial of certification specific to the FFEs.

We are finalizing that in addition to collecting the information and data currently provided by State Exchanges under § 155.1200 to monitor performance and compliance, we would use the information and data that State Exchanges submit to increase transparency into Exchange operations and to promote program improvements. We anticipate publicly releasing the State Exchange spending on outreach (including Navigators), Open Enrollment call center metrics (call center volume, average wait time, average call abandonment rate), and website visits and visitors. We are stating in this final rule that we no longer intend to publicly release the State Exchanges' annual State-based Marketplace Annual Reporting Tools (SMARTs). In addition, we intend to only post those metrics for which we also have reasonably comparable data from Exchanges on the Federal platform.

4. 45 CFR Part 156

We are finalizing 2026 benefit year FFE and SBE–FP user fee rates of 2.5 percent and 2.0 percent of total monthly premiums, respectively. We are also finalizing alternative 2026 benefit year FFE and SBE–FP user fee rates of 2.2 percent and 1.8 percent of total monthly premiums, respectively, if enhanced PTC subsidies,[16] at the level currently enacted or at a higher level, are extended through the 2026 benefit year by July 31, 2025.

We are finalizing amendments to § 156.80(d)(2)(i) to affirm that CSR loading practices that are permitted by State regulators are permissible under Federal law to the extent that they are actuarially justified and provided the issuer does not otherwise receive reimbursement for such CSR amounts.

We are finalizing changes to the method for updating the AV Calculator, starting with the 2026 AV Calculator. Under this approach, for a plan year, we will only release a single, final version of the AV Calculator.

We are finalizing minor updates to the standardized plan option designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis range* for each metal level and to maintain a high degree of continuity with the approaches to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. In response to comments requesting the expanded bronze metal level designs revert to the 50 percent coinsurance rate used in previous years, we have revised this plan design to maintain this consistency, instead of raising it to 60 percent for PY 2026, as proposed. We made several additional modifications to both sets of plan designs at the expanded bronze metal.

In addition, we are finalizing amendments at § 156.201 to require issuers that offer multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, included prescription drugs, or a combination of some or all these factors.

We are finalizing amendments at § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since these requirements were introduced to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

We are finalizing conducting ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions, beginning in PY 2026.

We are finalizing the proposal to share aggregated, summary-level QIS information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period.

We are finalizing an amendment to § 156.1220(a) to introduce a new materiality threshold for HHS–RADV appeals, such that we will rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal when the impact of that appeal to the filer's HHS–RADV adjustments to State transfers is greater than or equal to $10,000.

5. 45 CFR Part 158

We are finalizing amendments to § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027), with certain modifications. Specifically, we are finalizing that at the option of qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium, such that these net receipts would impact the MLR denominator rather than MLR numerator. We are also finalizing an amendment to § 158.103 to add a definition of ''qualifying issuer,'' with certain clarifications.

We also are finalizing amendments to § 158.240(c) to add an illustrative example of how qualifying issuers that opt to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii) will calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers will incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) will apply to issuers that are not qualifying issuers and to qualifying issuers that do not opt to apply risk

[16] ARP, Public Law 117–2, 135 Stat. 4 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169, 136 Stat. 1818 (2022) and are scheduled to expire after the 2025 calendar year.

adjustment transfer amounts as described in § 158.140(b)(4)(ii).

III. Summary of the Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. 42 CFR Part 600—BHP Methodology Regarding the Value of the Premium Adjustment Factor (PAF)

1. Overview of the Payment Methodology and Calculation of the Payment Amount

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82317), we proposed to make a change to the calculation of the PAF starting in program year 2026. Section 1331(d)(3) of the ACA directs the Secretary to consider several factors when determining the Federal BHP payment amount, which, as specified in the statute, must equal 95 percent of the value of the PTC under section 36B of the Code and CSRs under section 1402 of the ACA that would have been paid on behalf of BHP enrollees had they enrolled in a QHP through an Exchange. Thus, the BHP payment methodology is designed to calculate the PTC and CSRs as consistently as possible and in general alignment with the methodology used by Exchanges to calculate advance payments of the PTC (APTC) and CSRs, and the methodology used to reconcile APTC with the amount of the PTC allowed for the tax year under section 36B of the Code. In accordance with section 1331(d)(3)(A)(iii) of the ACA, the final payment methodology must be certified by the Chief Actuary of CMS, in consultation with the Office of Tax Analysis (OTA) of the Department of the Treasury, as having met the requirements of section 1331(d)(3)(A)(ii) of the ACA.

Section 1331(d)(3)(A)(ii) of the ACA specifies that the payment determination shall take into account all relevant factors necessary to determine the value of the PTC and CSRs that would have been paid on behalf of eligible individuals, including but not limited to, the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic differences in average spending for health care across rating areas, the health status of the enrollee for purposes of determining risk adjustment payments and reinsurance payments that would have been made if the enrollee had enrolled in a QHP through an Exchange, and whether any reconciliation of APTC and CSR would have occurred if the enrollee had been enrolled. Under all previous payment methodologies, the total Federal BHP payment amount has been calculated using multiple rate cells in each BHP State. Each rate cell represents a unique combination of age range (if applicable), geographic area, coverage category (for example, self-only or two-adult coverage through the BHP), household size, and income range as a percentage of FPL, and there is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. The BHP payment rates developed are also consistent with the State's rules on age rating. Thus, in the case of a State that does not use age as a rating factor on an Exchange, the BHP payment rates would not vary by age.

Under the methodology finalized in the July 2021 final BHP Payment Notice, the rate for each rate cell is calculated in two parts. The first part is equal to 95 percent of the estimated PTC that would have been allowed if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. The second part is equal to 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. These two parts are added together and the total rate for that rate cell would be equal to the sum of the PTC and CSR rates. As noted in the July 2021 final BHP Payment Notice, we currently assign a value of zero to the CSR portion of the BHP payment rate calculation, because there is presently no available appropriation from which we can make the CSR portion of any BHP payment.

The 2023 final BHP Payment Notice provides a detailed description of the structure of the BHP payments, including the equations, factors, and the values of the factors used to calculate the BHP payments. We proposed one change to the methodology regarding the premium adjustment factor (PAF).

The PAF is used to calculate the adjusted reference premium (ARP) that is used to calculate the BHP payment. The ARP is used to calculate the BHP payment. The ARP is used to calculate the estimated PTC that would be allowed if BHP-eligible individuals enrolled in QHPs through an Exchange and is based on the premiums for the applicable second lowest cost silver plan during the applicable plan year. The PAF considers the premium increases in other States that took effect after we discontinued payments to issuers for CSRs provided to enrollees in QHPs offered through Exchanges. Despite the discontinuance of Federal payments for CSRs, QHP issuers are required to provide CSRs to eligible enrollees. As a result, many QHP issuers increased the silver-level plan premiums to account for those additional costs; these premium adjustments and how they were applied (for example, to only silver-level plans or to all metal tier plans) varied across States. For the States operating BHPs in 2018, the increases in premiums were relatively minor, because the majority of enrollees eligible for CSRs (and all who were eligible for the largest CSRs) were enrolled in the BHP and not in QHPs on the Exchanges, and therefore, issuers in BHP States did not significantly raise premiums to cover costs related to HHS not making CSR payments.

In the Final Administrative Order and the 2019 through 2023 final BHP Payment Notices, we incorporated the PAF into the BHP payment methodologies to capture the impact of how other States responded to HHS ceasing to make CSR payments.[17] We also reserved the right that in the case an appropriation for CSR payments is made for a future year, to determine whether and how to modify the PAF in the payment methodology.

Under the Final Administrative Order, we calculated the PAF by using information sought from QHP issuers in each State and the District of Columbia and determined the premium adjustment that the responding QHP issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers. Based on the data collected, we estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP States). To the extent that QHP issuers made no adjustment (or the adjustment was zero), this was counted as zero in determining the median adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or we determined that it should be excluded for methodological reasons (for example, the adjustment was negative, an outlier, or unreasonable)—then we did not count the adjustment towards determining the median adjustment.[18] The median adjustment for silver level QHPs is referred to as the nationwide median adjustment.

For each of the two BHP States, we determined the median premium adjustment for all silver level QHPs in that State, which we refer to as the State

[17] *https://www.medicaid.gov/sites/default/files/2019-11/final-admin-order-2018-revised-payment-methodology.pdf.*

[18] Some examples of outliers or unreasonable adjustments include (but are not limited to) values over 100 percent (implying the premiums doubled or more because of the adjustment), values more than double the otherwise highest adjustment, or non-numerical entries.

median adjustment. The PAF for each BHP State equaled one plus the nationwide median adjustment divided by one plus the State median adjustment for the BHP State. In other words,

PAF = (1 + Nationwide Median Adjustment) ÷ (1 + State Median Adjustment).

To determine the PAF described above, we sought to collect QHP information from QHP issuers in each State and the District of Columbia to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, we sought information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to our 2018 records, there were 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to our request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of HHS making CSR payments. These 318 QHPs operated in 26 different States, with 10 of those States running State Exchanges (while we requested information only from QHP issuers in States serviced by an FFE, many of those issuers also had QHPs in State Exchanges and submitted information for those States as well). Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the State median adjustment was 1.0 percent. We believed that this was an appropriate adjustment for QHPs in Minnesota, as well, based on the observed changes in New York's QHP premiums in response to the discontinuance of CSR payments (and the operation of the BHP in that State) and our analysis of expected QHP premium adjustments for States with BHPs. We calculated the proposed PAF as (1 + 20 percent) ÷ (1 + 1 percent) (or 1.20/1.01), which results in a value of 1.188.

We set the value of the PAF to 1.188 for all program years for 2018 through 2024, with limited exceptions.[19] We believe that this value for the PAF continues to reasonably account for the increase in silver-level premiums experienced in non-BHP States that took effect after the discontinuance of the CSR payments.

Starting in 2023, we made one limited exception in setting the value of the PAF as part of the 2023 final BHP Payment Notice.[20] In the case of a State in the first year of implementing a BHP, if the State chooses to use prior year second lowest cost silver plan (SLCSP) premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. In this case, we believe that adjustment to the QHP premiums to account for the discontinuation of CSR payments would be included fully in the prior year premiums, and no further adjustment would be necessary.

We proposed to make a change to the calculation of the PAF starting in program year 2026. There are cases in which a State may not have fully implemented BHP for a full program year. For example, a State may operate BHP for only a portion of the year (in other words, less than 12 months); there may be other such cases in which a State would be deemed to have partially implemented BHP for a program year.

For a State that initially only partially implemented BHP, it is likely that, in the year (or years) when the BHP is only partially implemented, the percentage adjustment to the premiums for the program year to account for the discontinuation of CSR payments may be significantly higher than the 1 percent adjustment we determined for BHP States in 2018. In these cases, it is probable that QHP issuers would include a larger premium adjustment (that is, greater than 1 percent) because more individuals would be eligible for CSRs (and individuals eligible for relatively larger CSRs) would be enrolled in a QHP on the Exchange, for part or all of the initial implementation year. If premiums with a larger CSR adjustment are used as a basis for calculating the BHP payments and the current value of the PAF (1.188) is used, it is likely that this would ''double count'' a portion of the adjustment and lead to an effective CSR adjustment over 20 percent.

For example, assume a State implements BHP for only 6 months in a program year. As a result, QHP issuers may include a 10 percent adjustment to the premiums to account for the discontinuation of the CSR for the portion of the year when CSR eligible individuals would have QHP coverage. The issuers would be liable for roughly half of the CSR amounts they would have had to provide if there was no BHP in place. Under the previous BHP payment methodology, if these premiums that already partially account for CSRs are used to calculate the BHP payment, we would increase the reference premium by 18.8 percent for the PAF, leading to an effective increase of 30.68 percent (1.188 multiplied by 1.10 minus 1). This is significantly larger than the 20 percent adjustment we determined as the basis for the PAF for States that have operated their BHP for more than 2 full program years.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage[21] and to avoid such an overpayment, we proposed the following changes to the PAF:

(1) If a State has fully implemented BHP and is using SLSCP premiums for a year in which the BHP was fully implemented, then the value of the PAF would remain 1.188, as described above.

(2) If a State is in the first year of implementing a BHP and the State chooses to use prior year SLCSP premiums to determine the BHP payment (for example, the 2025 premiums for the 2026 program year), we set the value of the PAF to 1.00. This is the same approach described in the 2023 final BHP Payment Notice.

(3) If a State is using SLCSP premiums from a year in which BHP was not fully implemented, then the PAF is calculated as follows:

First, the State must determine the CSR adjustment that QHP issuers included in the SLSCP premiums for individual market Exchange plans. The State should identify the SLSCP in each region, as defined for the Exchange. For each SLSCP, the State should determine the CSR adjustment that the QHP issuer included in the premium. This may be done by (1) reviewing any materials submitted by the QHP issuer describing the calculation of the premium; or (2) requesting that the QHP issuer provide the adjustment, or an estimate of the adjustment used in calculating the premium. Second, the State should report the CSR adjustments for the SLCSP for individual market Exchange

[19] See the *Federal Funding Methodology for Program Year 2023 and Changes to the Basic Health Program Payment Notice Process* at 87 FR 77722, 77731, 77737.

[20] Id. at 77731–32.

[21] Section 1331(d)(3)(A)(ii) of the PHS Act.

plans for each region in the State to CMS. Third, CMS will take this percentage adjustment and calculate the PAF as 1.20 divided by 1 plus the adjustment. For example, if the percentage adjustment for the CSR is 5 percent, the PAF would be (1.20 ÷ 1.05), or 1.143. The maximum value of the PAF would be 1.188, and the minimum value of the PAF would be 1.00.

We noted in the proposed rule (89 FR 82319) that this approach would apply based on the premium year, not necessarily the program year. If the State has fully implemented BHP but is using the prior year premiums and BHP was not fully implemented in that year, this modified approach would still apply. For example, if a State partially implemented BHP in 2026 and fully implemented BHP in 2027, when determining the BHP payments for 2027, we would then use 1.188 for the value of the PAF if the State elected to use 2027 QHP premiums to determine the payment; if the State elected to use the 2026 QHP premiums, then we would use the modified PAF calculation described in this section. CMS would make a determination of whether or not a BHP was fully implemented based on a review of the Blueprint and provide that determination to the State.

We also noted in the proposed rule (89 FR 82319) that we considered other approaches to the modified PAF. We considered whether or not CMS would collect data on the underlying CSR adjustment in the SLCSP premiums; however, we believe that such activities fall within States roles as BHP administrators and States are better able to work with QHP issuers to administer this data collection process. We also considered if States should survey all QHP issuers (not just those with the SLSCP premium). We believe that only using the CSR adjustment from individual market Exchange plans with the SLCSPs would be a more reasonable approach and would minimize the burden on States and QHP issuers by only requiring the State to work with one issuer in each region, as opposed to all issuers in each region. We also considered whether or not we should make further changes to the PAF, but we believe that this approach balances maintaining accurate BHP payments with stability and limited burden for BHP States. We requested comments on this approach or alternative approaches to calculating the PAF.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the approach to calculating the PAF as proposed. We summarize and respond to public comments received on the proposed change to the calculation of the PAF below.

Comment: Several commenters were supportive of the change to adjust the PAF for BHP in program years in which States have not fully implemented BHP.

Response: We appreciate these comments in support of the proposed change.

Comment: One commenter noted ''relying on silver CSR loads from 2018 in the development of the population adjustment factor may not reflect actual silver loads because these 2018 premiums are based on experience from a time when CSRs were fully funded,'' while also acknowledging there are other factors ''including state-specified loads, the impact of States' 1332 waivers, the effects of the COVID–19 pandemic and related Medicaid coverage policies, and other factors'' that may affect these adjustments in States.

Response: We acknowledge that there are limitations to relying on the 2018 CSR loads for calculation of the PAF. We also agree that other factors that may affect CSR loads and these factors complicate updating the PAF. We did not propose and are not making any changes to the standard calculation of the PAF in this final rule.

2. Technical Clarification for Calculation of BHP Payment Rates in Cases of Multiple Second Lowest Cost Silver Plan Premiums in an Area

The BHP payment rates are based on the second lowest cost silver plan premium among individual market QHPs operating on the Exchanges in each rating area (or county) in a State. This is the basis for the reference premium (or RP) in the BHP payment methodology.

In general, we expect that each county would have a unique second lowest cost silver plan premium, which is used to calculate the payment rates for residents of that county for the BHP payment. However, in some cases, we have found that States may have more than one second lowest cost silver plan within a county. This may occur in cases where the State has allowed QHPs to operate in only a portion of the county instead of the entire county on the Exchange.

In our previous BHP payment methodologies, we do not describe how such a case would be handled for calculating BHP payments. In our technical guidance to States,[22] we have instructed States to report the premiums for the second lowest cost silver plan operating in the largest part of the county as measured by total population.

Under the Secretary's general authority to account for all relevant factors necessary to determine the value of the premium and cost-sharing reductions that would have been provided to eligible individuals now enrolled in BHP coverage,[23] for the 2026 payment methodology and all subsequent years, we proposed to clarify that in cases where there are more than one second lowest cost silver plans in a county, the BHP payment would be based on the premium of the second lowest cost silver plan applicable to the largest portion of the county as measured by total population. We sought comment on this approach.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposed clarification of the correct premiums to use below.

Comment: Several commenters were supportive of the clarification for which second lower cost silver plan premiums to use in these cases for the purposes of calculating the Federal BHP payment.

Response: We appreciate these comments in support of the proposed change.

Comment: Two commenters noted that in one State that has operated a BHP, the State is using a different silver plan premium (the third lowest cost silver plan premium) in cases when there are two or more second lowest cost silver plan premiums in an area. Commenters noted that using the proposed approach would present operational challenges for the State. The commenters requested flexibility on this in the BHP payment methodology.

Response: We appreciate the comments and understand that there may be some operational issues; however, we believe that these issues can be easily addressed, and we note that other BHP States have been able to determine premiums in accordance with these requirements. In addition, we do not believe there is any basis to use any premiums other than the second lowest cost silver plans (even if there are two or more in an area) for the purposes of the BHP payment methodology.

[22] CMS. (September 15, 2023). *Basic Health Program; Federal Funding Methodology for Program Year 2024.* Accessed at: *https://www.medicaid.gov/federal-policy-guidance/downloads/cib091523.pdf.*

[23] Section 1331(d)(3)(A)(ii) of the PHS Act.

B. 45 CFR Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the ACA that transfers funds from issuers of lower-than-average risk, risk adjustment covered plans to issuers of higher-than-average risk, risk adjustment covered plans in the individual, small group markets, or merged markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program or have HHS do so on its behalf.[24] HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2025, the HHS-operated risk adjustment program is subject to the fiscal year 2025 sequestration.[25] The Federal Government's 2025 fiscal year began on October 1, 2024. Therefore, the HHS-operated risk adjustment program is sequestered at a rate of 5.7 percent for payments made from fiscal year 2025 resources (that is, funds collected during the 2025 fiscal year).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA),[26] as amended, and the underlying authority for the HHS-operated risk adjustment program, the funds that are sequestered in fiscal year 2025 from the HHS-operated risk adjustment program will become available for payment to issuers in fiscal year 2026 without further Congressional action. If the Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

Additionally, we note that the Infrastructure Investment and Jobs Act[27] amended section 251A(6) of the BBEDCA and extended sequestration for the HHS-operated risk adjustment program through fiscal year 2031 at a rate of 5.7 percent per fiscal year.[28]

One comment was received on this section of the proposed rule that acknowledges the fiscal year 2025 sequestration rate. Therefore, after consideration of this comment and for reasons outlined in the proposed rule and this final rule, the HHS-operated risk adjustment program will sequester payments made from fiscal year 2025 resources at a rate of 5.7 percent.

2. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as HCCs) producing a risk score. The State payment transfer formula[29] that is part of the HHS Federally certified risk adjustment methodology utilizes separate models for adults, children, and infants to account for clinical and cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year,[30] and prescription drug categories (RXCs) beginning with the 2018 benefit year.[31] Starting with the 2023 benefit year, we removed the severity illness factors in the adult models and added interacted HCC count factors (that is, additional factors that express the presence of a severity or transplant HCC in combination with a specified number of total payment HCCs or HCC groups on the enrollee's record) to the adult and child models[32] applicable to certain severity and transplant HCCs.[33]

Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR adjustment factor. The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score (PLRS)) within a geographic rating area is one of the inputs into the State payment transfer formula, which determines the State transfer payment or charge that an issuer will receive or be required to pay for that plan for the applicable State market risk pool for a given benefit year. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

a. Data for HHS Risk Adjustment Model Recalibration for the 2026 Benefit Year

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82320 through 82321), we proposed to recalibrate the 2026 benefit year HHS risk adjustment models with the 2020, 2021, and 2022 enrollee-level EDGE data. In the proposed rule, we noted the history of recalibrating the risk adjustment models, the transition to use of enrollee-level EDGE data for this purpose, and why we use 3 years of blended data for recalibration.[34] Given this history and reasoning, we proposed to determine coefficients for the 2026 benefit year based on a blend of separately solved coefficients from the 2020, 2021, and 2022 benefit years' enrollee-level EDGE data, with the costs of services identified from the data trended between the relevant year of data and the 2026 benefit year.[35] We sought

[24] See also 42 U.S.C. 18041(c)(1).

[25] OMB. (2024). OMB Report to the Congress on the BBEDCA 251A Sequestration for Fiscal Year 2025. *https://www.whitehouse.gov/wp-content/uploads/2024/03/BBEDCA_251A_Sequestration_Report_FY2025.pdf.*

[26] Public Law 99–177, 99 Stat. 1037 (1985).

[27] Public Law 117–58, 135 Stat. 429 (2021).

[28] 2 U.S.C. 901a.

[29] The State payment transfer formula refers to part of the Federally certified risk adjustment methodology that applies in States where HHS is responsible for operating the program. The formula calculates payments and charges at the State market risk pool level (prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year). See, for example, 81 FR 94080.

[30] For the 2017 through 2022 benefit years, there was a set of 11 binary enrollment duration factors in the adult models that decreased monotonically from 1 to 11 months, reflecting the increased annualized costs associated with fewer months of enrollments. See, for example, 81 FR 94071 through 94074. These enrollment duration factors were replaced beginning with the 2023 benefit year with HCC-contingent enrollment duration factors for up to 6 months in the adult models. See, for example, 87 FR 27228 through 27230.

[31] For the 2018 benefit year, there were 12 RXCs, but starting with the 2019 benefit year, the two severity-only RXCs were removed from the adult models. See, for example, 83 FR 16941.

[32] See Table 4 in the proposed rule for a list of draft factors in the adult models, and Table 5 in the proposed rule for a list of draft factors in the child models.

[33] See 87 FR 27224–28. Also see Table 6 in the proposed rule.

[34] See 89 FR 82308, 82320–21.

[35] As described in the *2016 Risk Adjustment White Paper* (*https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf*) and the 2017 Payment Notice (81 FR 12218), we subdivide expenditures into traditional drugs, specialty drugs, medical services, and preventive services and

comment on the proposal to determine 2026 benefit year coefficients for the HHS risk adjustment models based on a blend of separately solved coefficients from the 2020, 2021, and 2022 enrollee-level EDGE data.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the approach to use the 2020, 2021 and 2022 enrollee-level EDGE data to calculate the 2026 benefit year coefficients as proposed. We summarize and respond to public comments received on the proposed enrollee-level EDGE data to be used for HHS risk adjustment model recalibration for the 2026 benefit year below. Because we were unable to complete the calculations for the final coefficients in time to publish them in this final rule, we will publish the final 2026 benefit year coefficients in guidance after the publication of this final rule consistent with § 153.320(b)(1)(i). We will release this guidance by the spring of 2025, in time for rate setting for the 2026 benefit year.

Comment: A few commenters supported utilizing the 2020, 2021, and 2022 enrollee-level EDGE data to recalibrate the HHS risk adjustment models for the 2026 benefit year as proposed. Other commenters opposed or noted concern about using these years of enrollee-level EDGE data due to concerns about the potential impact of the COVID–19 PHE on 2020 and 2021 benefit year enrollee-level EDGE data.

Response: We are finalizing the use of the 2020, 2021, and 2022 enrollee-level EDGE data to recalibrate the 2026 benefit year HHS risk adjustment models as proposed. As described in the proposed rule (89 FR 82308, 82320) and detailed further below, our analyses found the 2020 and 2021 benefit year enrollee-level EDGE data is sufficiently similar to prior years of enrollee-level EDGE data such that exclusion of these data years from the risk adjustment model recalibration is not warranted.

We recognize that if a benefit year of enrollee-level EDGE data has significant changes that differentially impact certain conditions or populations relative to others or is sufficiently anomalous relative to expected future patterns of care, we should carefully consider what impact that benefit year of data could have if it is used in the annual recalibration of the HHS risk adjustment models.[36] This includes consideration of whether to exclude or adjust that benefit year of data to increase the models' predictive validity or otherwise limit the impact of anomalous trends. For this reason, as described in the 2026 Payment Notice proposed rule,[37] we conducted extensive analysis on the 2020 benefit year enrollee-level EDGE data to consider its inclusion in the recalibration of the 2024 benefit year risk adjustment models. For example, in the 2024 Payment Notice proposed rule [38] and final rule [39] we discussed our analysis of the 2020 benefit year data to identify possible impacts of the COVID–19 PHE.[40] Likewise, when we conducted recalibration of the 2025 benefit year risk adjustment models, we conducted similar analyses on the 2021 benefit year enrollee-level EDGE data as we did to the 2020 benefit year enrollee-level EDGE data to examine the potential impact of the COVID–19 PHE.[41] We did not find any notable anomalous trends, and determined that deviations identified in 2020 or 2021 benefit year data were within the expected level for any individual data year. Further, we believe the blending of the coefficients from the separately solved models for benefit years 2020 and 2021 with benefit year 2022 for purposes of the 2026 benefit year model recalibration sufficiently stabilizes any differences resulting from the COVID–19 PHE in the 2020 or 2021 datasets. As the 2020 and 2021 benefit years' enrollee-level EDGE data used to recalibrate the 2025 benefit year risk adjustment models are identical to the 2020 and 2021 enrollee-level EDGE data used to recalibrate the 2026 benefit year risk adjustment models, the analyses and conclusions discussed in prior rulemaking equally apply to the recalibration of the risk adjustment models for the 2026 benefit year.

Comment: One commenter noted decreases in the risk adjustment model R-squared values for the 2022 benefit year enrollee-level EDGE data relative to prior benefit years as presented in Table 10 of the proposed rule.[42] This commenter requested information regarding any analysis HHS has conducted concerning the reduction in this model performance statistic.

Response: First, as demonstrated by Table 10 of the proposed rule,[43] each individually solved model that contributes to the blended HHS risk adjustment models has an R-squared statistic within the expected range for concurrent claims-based risk scoring models [44] such as the models used for the HHS-operated risk adjustment program. Nevertheless, we are aware of and intend to continue monitoring the slight decrease in the R-squared values for the HHS risk adjustment models over the past few years of enrollee-level EDGE data which indicates that the models are explaining slightly less of the variation in plan liability for the 2022 benefit year enrollee-level EDGE data compared to prior benefit years of enrollee-level EDGE data. In our quality control assessments of the recalibration process for the proposed draft 2026 benefit year coefficients, we explored two possible explanations for this decrease in R-squared values—a shift in enrollment and the presence of outlier enrollees with very high costs in the enrollee-level EDGE data.

Our analysis found that the largest percentage decreases in R-squared values between the 2022 benefit year and the 2019 (or 2020) [45] benefit year of enrollee-level EDGE data for adult enrollees were for enrollees without HCCs, enrollees with only 1 month of enrollment, and new enrollees (that is, enrollees new to an issuer, whose system identifier was not present for the issuer in the prior year).[46] We interpret these results to be consistent with a hypothesis that new enrollees and a greater proportion of relatively healthier enrollees in 2022 were partially

determine trend factors separately for each category of expenditure. In determining these trend factors, we consult our actuarial experts, review relevant Unified Rate Review Template submission data, analyze multiple years of enrollee-level EDGE data, and consult National Health Expenditure Accounts (NHEA) data as well as external reports and documents published by third parties. In this process, we aim to determine trends that reflect changes in cost of care rather than gross growth in expenditures. As such, we believe the trend factors we used for each expenditure category for the 2026 benefit year models are appropriate for the most recent changes in cost of care that we have seen.

[36] Since the start of model calibration for the HHS risk adjustment models in benefit year 2014, the COVID–19 PHE has been the only such situation to date. Other events and policy changes have not risen to the same level of uniqueness or potential impact.

[37] 89 FR 82308, 82320.

[38] 87 FR 78214–18.

[39] 88 FR 25749–54.

[40] This analysis included assessing how the 2020 benefit year enrollee-level EDGE recalibration data compares to 2019 benefit year enrollee-level EDGE recalibration data.

[41] See the 2025 Payment Notice Final Rule, 89 FR 26218, 26236–37.

[42] 89 FR 82308, 82347.

[43] See 89 FR 82308, 82347.

[44] See Hileman, G., & Steele, S. (2016). Accuracy of Claims-Based Risk Scoring Models. Society of Actuaries. *https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf.*

[45] HHS was unable to incorporate an analysis of new enrollees for the 2019 benefit year of enrollee-level of EDGE data at the time of the analysis of R-squared changes. As such, R-squared changes for new enrollees only considered the difference between 2020 benefit year and 2022 benefit year R-squared values.

[46] Ibid.

responsible for a decrease in model R-squared values between the 2022 benefit year and the 2019 through 2021 benefit years of enrollee-level EDGE data, in that the R-squared value decreases are largest for subgroups that are likely to contain more new enrollees or are difficult to predict, for example, new enrollees to an issuer and enrollees without HCCs.

Likewise, our analysis found that the removal of outlier enrollees always resulted in an increase in R-squared values and the impacts were notably higher for 2020, 2021, and 2022 enrollee-level EDGE data than for 2019 enrollee-level EDGE data. We interpret these results to imply that recent data years have exhibited more influential high-cost enrollees. However, we do not see the presence of cost outliers in the enrollee-level EDGE data to be problematic at this time because we generally expect the number of cost outliers to vary from year to year, and we did not find evidence that suggests a clear data error exists related to any of these outliers.

In short, although we were able to identify likely contributing factors to the observed slight decrease in R-squared values and will continue to monitor the R-squared values in the future, the R-squared values for 2026 benefit year risk adjustment model recalibration remain high and within the expected range of R-squared values for the type of model used for the HHS-operated risk adjustment program. We remain confident the HHS risk adjustment models continue to operate effectively and appropriately predict plan liability for an average enrollee.

After consideration of comments and for the reasons outlined in the proposed rule, this final rule, the 2024 Payment Notice, the 2025 Payment Notice,[47] and our responses to comments above, we are finalizing this approach as proposed. However, to account for the incorporation of the human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) affiliated cost factor (ACF) with the generic drug exclusion and hierarchy specifications finalized in this rule, we were unable to complete the calculations for the final coefficients in time to publish them in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we are finalizing the use of the 2020, 2021 and 2022 enrollee-level data to calculate the 2026 benefit year coefficients and will publish the final coefficients for the 2026 benefit year in guidance after the publication of this final rule. We will release this guidance in time for rate setting for the 2026 benefit year.

b. Pricing Adjustment for the Hepatitis C Drugs

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82321), we proposed that beginning with the 2026 benefit year, we would begin phasing out the market pricing adjustment[48] to the plan liability associated with Hepatitis C drugs in the HHS risk adjustment models and start trending Hepatitis C drugs consistent with the other drugs[49] in the HHS risk adjustment models. Since the 2020 benefit year HHS risk adjustment models, we have included a market pricing adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing prior to solving for coefficients for the models.[50] The purpose of this market pricing adjustment was to account for significant pricing changes between the data years used for recalibrating the models and the applicable benefit year of risk adjustment as a result of the introduction of new and generic Hepatitis C drugs.[51] For the reasons and history described in the proposed rule, we proposed to adopt a multi-year phase out approach to transition the Hepatitis C drugs' trending to move away from the current unique market pricing adjustment for these drugs and align Hepatitis C drugs' trending with the trending approach for specialty drugs.[52] To begin this transition for the 2026 benefit year HHS risk adjustment models, we proposed to apply the specialty drug trend to 1 year of trending Hepatitis C treatment costs (that is, the trend from 2025 to 2026) for all 3 years of enrollee-level EDGE data used in recalibration (that is, 2020, 2021, and 2022 enrollee-level EDGE data). As such, 2026 benefit year recalibration data for Hepatitis C would reflect 1 year of growth in the cost of treatment at the same rate as other specialty drugs. To continue the transition of phasing out the Hepatitis C drug pricing adjustment in future benefit years' annual model recalibration, we proposed to annually increase the number of years for which we would use the specialty drug trend and decrease the number of years that would use the unique market pricing adjustment for Hepatitis C drugs. We proposed to continue this approach until such time as all enrollee-level EDGE data years used for the recalibration of the HHS risk adjustment models are from benefit year 2025 or later, at which time the specialty drug cost trend would be fully applied to Hepatitis C drug costs consistent with other specialty drugs in the HHS risk adjustment models and we would stop applying the separate market pricing adjustment for Hepatitis C drugs as part of the annual model recalibration.

We sought comment on our proposal to begin to phase out the Hepatitis C drugs market pricing adjustment and trend Hepatitis C drugs consistent with other specialty drugs starting with the annual recalibration of the 2026 benefit year HHS risk adjustment models.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposal to begin to phase out the market pricing adjustment for Hepatitis C drugs starting with the 2026 benefit year below.

Comment: Many commenters supported the proposal to begin to phase out the market pricing adjustment and trend Hepatitis C drugs consistent with other specialty drugs starting with the annual recalibration of the 2026 benefit year HHS risk adjustment models. Many of these commenters agreed with HHS' assessment that the cost trend for Hepatitis C drugs has begun to rise alongside the expected cost of other specialty drugs. A couple of commenters recommended close monitoring of costs and utilization of Hepatitis C drugs to ensure that access to these drugs is not interrupted for enrollees.

Response: We are finalizing the phasing out of the market pricing adjustment for Hepatitis C drugs starting with the 2026 benefit year as proposed. We agree with commenters that the cost

[47] See, supra, notes 22–24, and 26.

[48] For discussion relating to the Hepatitis C Pricing Adjustment for previous benefit years, *see,* for example, 89 FR 26218, 26237–38.

[49] See 81 FR 12204, 12218–19.

[50] The Hepatitis C drugs market pricing adjustment to plan liability is applied for all enrollees taking Hepatitis C drugs in the data used for recalibration.

[51] See Milligan, J. (2018). A perspective from our CEO: Gilead Subsidiary to Launch Authorized Generics to Treat HCV. Gilead. *https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv.* See also AbbVie. (2017). AbbVie Receives U.S. FDA Approval of MAVYRETTM (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1–6) in as Short as 8 Weeks. Abbvie. *https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.* See also Silseth, S., & Shaw, H. (2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States [White paper]. Milliman. *https://www.milliman.com/-/media/milliman/pdfs/2021-articles/6-11-21-analysis-prescription-drugs-treatment-hepatitis-c-us.ashx.*

[52] See 89 FR 82308, 82321–23.

trend for Hepatitis C drugs has changed and resulted in the need to reexamine the treatment of these drugs in the HHS risk adjustment models, including consideration of phasing out the market pricing adjustment for these drugs. We also note that the policy adopted in this final rule to phase out the market pricing adjustment for these drugs will allow Hepatitis C drug costs to increase as appropriate alongside other specialty drugs in the simulation of plan liability used for annual HHS risk adjustment model recalibration. Starting this transition beginning with the 2026 benefit year and appropriately accounting for price increases of Hepatitis C drugs in the HHS risk adjustment models alongside other specialty drugs in the simulation of plan liability responds to these observed emerging trends and will better reflect the actuarial risk of an issuer's population, especially for issuers that attract a large number of enrollees using Hepatitis C drugs, helping to prevent adverse selection and the associated perverse incentives. As such, we are finalizing the policy to begin phasing out of the Hepatitis C market pricing adjustment starting with the 2026 benefit year recalibration of the HHS risk adjustment models as proposed, but we will also continue to monitor costs and utilization of drugs, including Hepatitis C drugs, as part of our ongoing efforts to examine ways to continually improve the HHS risk adjustment models for future benefit years.

Comment: One commenter requested that HHS continue to review the costs associated with specialty drugs and consider whether market pricing adjustments may be warranted for GLP–1 drugs, gene therapies, or other unique, high-cost drugs that may drive the cost of treating a particular condition in a given benefit year significantly higher than those reflected in the enrollee-level EDGE data years used in recalibration for that benefit year. One commenter noted recently available expensive gene therapies for sickle cell disease as an example of this phenomenon and requested that HHS consider a market pricing adjustment for sickle cell disease treatments.

Response: We did not propose to change the treatment of high-cost drugs, such as GLP–1 drugs, sickle cell disease treatments, or other gene and cellular therapies, in the 2026 benefit year HHS risk adjustment models and are not finalizing such updates in this final rule. As we discussed in the 2022 Payment Notice [53] and 2025 Payment Notice,[54] we recognize that the data used to recalibrate the HHS risk adjustment models lag by several benefit years behind the applicable benefit year for risk adjustment and therefore may not account for the costs of new, expensive drugs, such as gene therapy drugs, that are expected to be available in the market by the applicable benefit year of risk adjustment. Thus, we continue to consider ways that we could better account for high-cost drugs in the risk adjustment models and, as part of this effort, analyze new data as they become available.

With specific regard to new gene therapies for sickle cell disease, when we were previously analyzing the changes to the sickle cell disorder related HCCs in the 2025 benefit year risk adjustment models,[55] we considered whether to add an RXC for existing high-cost sickle cell drugs and new gene therapy treatments, but determined that we need to continue to analyze the evolution and availability of drug treatments for sickle cell disease. Specifically, the new gene therapy drugs for sickle cell disease were not approved for the market until December 2023.[56] Therefore, the first full year of claims data in which these new sickle cell disease treatments may be reflected will not be available until the 2024 benefit year enrollee-level EDGE data is available. We therefore continue to find that we do not have enough information at the present time to account for these treatments in the HHS risk adjustment models because of the general lack of data on the utilization and cost of gene therapy drugs for sickle cell disease in the individual, small group, and merged markets. We are committed to continuing to analyze new data as they become available and, consistent with § 153.320(b)(1), we would propose the addition of any market pricing adjustments or other changes to the risk adjustment models to account for these treatments through notice-and-comment rulemaking, as appropriate. We also note that if an enrollee in an issuer's risk adjustment covered plan has claims for gene therapy, other high-cost drugs, or other expensive treatments, that enrollee would be eligible for the high-cost risk pool payments if claims for that enrollee are over $1 million.[57]

Considering the absence of adequate data, we did not propose and are not finalizing a new market pricing adjustment or other model adjustments for sickle cell gene therapy drugs for the 2026 benefit year. We intend to continue to assess sickle cell gene therapy drugs and other high-cost drugs to consider whether model updates for future benefit years are warranted.

We also intend to work with interested parties to continue to analyze plan liability for sickle cell disease and the impact of gene and cell therapy treatments, as well as explore the availability of alternative data sources that could be used to monitor utilization and costs outside of currently available enrollee-level EDGE data.

As explained in the 2025 Payment Notice (89 FR 26249), we also recently examined the treatment of GLP–1 drugs in the HHS risk adjustment models using the 2022 benefit year enrollee-level EDGE data and found that, at this time, a change was not warranted to the current mapping of GLP–1 drugs to RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only).[58] We understand GLP–1 drug utilization patterns are changing and will continue to assess these trends as additional benefit years of enrollee-level EDGE data become available for potential targeted refinements to the HHS risk adjustment models in future benefit years, as appropriate.

Comment: One commenter requested additional information on how HHS defines generic and specialty drugs and what trend assumptions HHS uses for each of these two categories, asserting that this information would help interested parties better evaluate the proposal to begin to phase out the Hepatitis C market pricing adjustment against costs experienced by issuers.

Response: Since the 2017 benefit year, we have subdivided expenditures into traditional drugs, specialty drugs, medical services, and preventive

[53] See 86 FR 24140, 24163.

[54] See 89 FR 26218, 26247–48.

[55] Ibid.

[56] See *https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease.*

[57] For example, the new sickle cell gene therapy treatments are expected to exceed the high-cost risk pool payment threshold. See, DeMartino P, Haag MB, Hersh AR, Caughey AB, Roth JA. A Budget Impact Analysis of Gene Therapy for Sickle Cell Disease: The Medicaid Perspective. JAMA Pediatr. 2021 Jun 1;175(6):617–623. doi: 10.1001/jamapediatrics.2020.7140. Erratum in: JAMA Pediatr. 2021 Jun 1;175(6):647. PMID: 33749717; PMCID: PMC7985816. Accessed at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7985816/.*

[58] As background, RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) is a pharmacotherapeutic class of drugs, which contains a broad array of anti-diabetic medications that vary in cost. RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) does not include all GLP–1 drugs currently on the market; drugs that carry an FDA indication for chronic weight management are excluded from RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only). The RXC 07 (Anti Diabetic Agents, Except Insulin and Metformin Only) coefficient in the HHS risk adjustment adult models is meant to reflect the average enrollee cost for individuals being treated by any of the drugs in this class.

services and determine trend factors separately for each category of expenditure.[59] In determining these trend factors, we consult our actuarial experts, review relevant URRT submission data, analyze multiple years of enrollee-level EDGE data, and consult NHEA data as well as external reports and documents [60] published by third parties. As described in the 2024 Payment Notice,[61] in this process, we aim to determine trends that reflect changes in cost of care rather than gross growth in expenditures. We believe the trend factors we used for each expenditure category for the 2026 benefit year are appropriate for the most recent changes in cost of care that we have seen in the market. We further note that, for the purposes of annual risk adjustment model recalibration activities, our definitions of what drugs qualify as either traditional (for example, low-cost and generic drugs) or specialty are also informed by consultations with actuarial experts and by reviewing price data for these drugs. Specific thresholds and criteria may vary according to the class of drugs or the conditions they are intended to treat, but we generally use the Part D specialty-tier cost threshold, which is updated periodically, to differentiate between traditional and specialty drugs.[62]

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments above, we are finalizing the proposal to begin phasing out the market pricing adjustment for Hepatitis C drugs starting with the 2026 benefit year, as proposed. However, to account for the incorporation of the PrEP ACF with the generic drug exclusion and hierarchy specifications finalized in this final rule, we were unable to complete the calculations for the final coefficients in time to publish them in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we will publish the final coefficients for the 2026 benefit year in guidance after the publication of this final rule. We will release this guidance in time for rate setting for the 2026 benefit year.

c. Inclusion of Pre-Exposure Prophylaxis (PrEP) in the HHS Risk Adjustment Adult and Child Models as an Affiliated Cost Factor (ACF)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82323), we proposed to incorporate human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) as a separate, new type of factor called an Affiliated Cost Factor (ACF) in the HHS risk adjustment adult and child models starting with the 2026 benefit year. As proposed, the change would reflect an evolution in our approach to defining the factors used in the HHS risk adjustment models to include a factor that is not indicative of an active medical condition and would change our current policy that models the costs of PrEP alongside other preventive services.

As explained in the proposed rule (89 FR 82324), as a general principle, we currently incorporate preventive services (including PrEP [63]) into the HHS risk adjustment models to ensure that 100 percent of the cost of those services are reflected in the simulation of plan liability. In the simulation of plan liability, services are only counted as preventive when they occur in the recommended circumstances (for example, age) to the extent we can identify such circumstances from enrollee-level EDGE data. In addition to PrEP drugs, like other preventive services,[64] ancillary services related to PrEP care (for example, HIV screenings) qualify as preventive services and as such are also currently calibrated at 100 percent plan liability in the recalibration of the HHS risk adjustment adult and child models.[65]

However, as a part of our commitment to consider ways to continually improve the HHS risk adjustment models, we continued to monitor and assess different ways to more accurately assess the actuarial risk and costs associated with PrEP in the HHS risk adjustment models. In this regard, we stated in the proposed rule (89 FR 82324) that because of PrEP's high costs relative to other preventive services, PrEP services can pose a unique risk of adverse selection to the extent that utilization of PrEP services differs between plans. Our analysis of 2022 benefit year enrollee-level data [66] found that the costs of PrEP services remained high, in contrast to our initial assumptions about expected pricing decreases as generics entered the market, and that there are statistically significant, substantial differences in PrEP prevalence between issuers in rating areas where PrEP use is most common, indicating that the addition of a PrEP factor in the adult and child risk adjustment models would be appropriate and would have a meaningful impact on risk adjustment State transfers. Our analysis also found that other considerations that helped inform the current approach (such as the expected decrease in costs as generics entered the market and gained market share) have not addressed the uniquely high costs of PrEP as a preventive service as we previously expected. For these reasons, we proposed to incorporate a non-RXC and non-HCC model factor for PrEP in the HHS risk adjustment adult and child models to capture differences in costs for PrEP utilizers relative to the average enrollee. To signify that the proposed new factor would not indicate the presence of a specific active medical condition, we referred to the proposed new type of factor as an ''affiliated cost factor'' (ACF), thereby distinguishing this new type of factor from RXCs and HCCs. Furthermore, we proposed a set of seven principles to guide our development of any new ACF variable.

We stated in the proposed rule (89 FR 82324) that in developing an ACF variable reflecting PrEP, we considered whether PrEP satisfies those principles and what approaches were necessary to appropriately balance all seven principles. As described in the proposed rule, a PrEP ACF would easily satisfy the principles of clinical meaningfulness and specificity,

[59] See 81 FR 12218. See also the 2016 Risk Adjustment White Paper, available at: *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf.*

[60] See, for example, ''How much is health spending expected to grow?'' by the Peterson-Kaiser Family Foundation, available at *https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow/.* See also ''Medical cost trend: Behind the numbers 2024'' by PwC Health Research Institute, available at *https://www.pwc.com/us/en/industries/health-industries/library/assets/pwc-behind-the-numbers-2024.pdf.* See also ''MBB Health Trends 2024'' by MercerMarsh Benefits, available at *https://www.marsh.com/na/services/employee-health-benefits/insights/health-trends-report.html.*

[61] See 88 FR 25740, 25754–55.

[62] For example, the specialty-tier cost threshold specified in the Contract Year (CY) 2023 Final Part D Bidding Instructions (available at: *https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf*) will be used to divide prescription drug claims into traditional versus specialty drugs for 2023 enrollee-level EDGE data when they become available.

[63] See 85 FR 28164, 29185–87.

[64] For example, colonoscopies typically require a combination of several services between the drugs needed for the colonoscopy and the professional and institutional claims for the visit and procedure itself. Likewise, contraception coverage often requires a doctor's visit to obtain a prescription for the contraception.

[65] See 86 FR 24140, 24164.

[66] Prior to the 2021 Benefit Year, Plan ID and Rating Area were not included as part of the enrollee-level data extracted from issuers' EDGE data submissions. As finalized in the 2023 Payment Notice (87 FR 27208, 27241–51), we now extract these fields as part of the enrollee-level EDGE dataset and are able to include them in our analyses. As such, this recent analysis reflects our earliest opportunity to reliably detect differences in prevalence within rating areas for any medical and prescription drug expenditures, including PrEP.

meaningful and predictable costs,[67] sufficient sample size, and low risk of inappropriate prescribing. However, we also stated in the proposed rule that that the creation of a PrEP ACF variable would require further careful consideration in assessing the other three proposed principles: specifically, the principles of hierarchical factor definitions, monotonicity, and mutually exclusive classification.

We stated in the proposed rule (89 FR 82327) that to address the HHS risk adjustment adult modeling concerns we identified regarding these three principles; we considered two alternative approaches. First, we could modify the current definition of RXC 1 (Anti-HIV Agents) by treating PrEP NDCs as RXC 1 NDCs in limited circumstances based on individual enrollee characteristics. Operationally, to capture these cases, the adult enrollees with a PrEP prescription claim would receive the RXC 1 flag instead of the ACF only in cases where the enrollee has both a PrEP prescription claim and an HIV diagnosis but does not have a typical RXC 1 prescription claim because the enrollee did not begin treatment for HIV, or because their treatment medication was provided at no cost to the issuer and therefore no claim was submitted to the issuer's EDGE server. Alternatively, we explained we could place the PrEP ACF in a hierarchy with RXC 1 but define no hierarchical restrictions between PrEP and HCC 1 (HIV/AIDS). This alternative would allow adult enrollees without RXC 1 to receive the PrEP ACF along with HCC 1 in cases where the enrollee has both a PrEP prescription claim and an HCC 1 diagnosis in their medical records for the benefit year. We solicited comments on addressing these hierarchy, monotonicity, and mutual exclusivity concerns, and both alternative approaches designed to address those concerns.

We also sought comment on our proposal to create a new ACF category of model factors for incorporation into the HHS risk adjustment models to account for unique medical expenses or services (such as PrEP) that do not meet the criteria to qualify as HCC or RXC factors, but impact the actuarial risk presented to issuers of risk adjustment covered plans. In addition, we sought comment on our proposal to modify the treatment of PrEP in the HHS risk adjustment adult and child models beginning with the 2026 benefit year, as well as how to methodologically define a potential ACF category of model factors that accounts for PrEP (or other unique medical expenses or services) and what other considerations should be part of the analysis and modeling for this proposed new category of model factors (such as the availability of drug rebates [68] or differences in medication adherence for PrEP). Furthermore, we sought comment regarding the principles to guide inclusion of potential ACF factors and the alternative approaches for defining a PrEP ACF's hierarchical relationship to HCC 1 and RXC1 to address the concerns related to hierarchical factor definitions, violations of monotonicity, and violations of mutually exclusive classification in the HHS risk adjustment adult models.

Additionally, we solicited comments on whether generic versions of PrEP medication should be excluded from the definition of the proposed ACF for PrEP. As we stated in the proposed rule (89 FR 82326), we found that a large disparity exists between the costs of generic PrEP medication and the costs of brand name PrEP medication.[69] We explained that due to this disparity, if we include all PrEP medications in the definition of an ACF, the estimated coefficient would likely lead to overprediction for enrollees receiving generic medications and underprediction for enrollees receiving brand name medications. Therefore, an exclusion of low-cost generics from the PrEP ACF could improve predictions for enrollees receiving either generic or brand name PrEP medication and has precedent in our adoption of other factors in the HHS risk adjustment models.[70]

Lastly, we sought comment concerning whether there are any similar medical expenses or services that we should consider for potential new ACFs alongside PrEP.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the addition of PrEP as an ACF in the HHS risk adjustment adult and child models, but are excluding generic versions of PrEP from the ACF at this time, and are placing the PrEP ACF in the adult models in a hierarchy below RXC 1 (Anti-HIV Agents) without defining any hierarchical relationship between the PrEP ACF and HCC 1 (HIV/AIDS). In the child models, which do not contain RXCs, we are finalizing the placement of the PrEP ACF in a hierarchy with HCC 1. We summarize and respond to public comments received on the proposed addition of PrEP as an ACF in the HHS risk adjustment adult and child models starting with the 2026 benefit year below.

Comment: Many commenters supported the proposal to add PrEP to the HHS risk adjustment adult and child models as an ACF. Many of these commenters noted agreement with HHS' determination that PrEP presents a unique risk of adverse selection among preventive services and that the addition of PrEP to the HHS risk adjustment adult and child models would mitigate perverse incentives for issuers to minimize their exposure to enrollees who can benefit from PrEP despite the mandate to cover preventive services with no enrollee cost sharing. Several commenters stated that this addition to the HHS risk adjustment adult and child models will better align issuers' incentives with the public health benefit of preventing HIV transmission. A few commenters acknowledged that PrEP may be appropriate to include in the HHS risk adjustment adult and child models but noted doubt that a new class of factors (that is, ACFs) was necessary.

Response: We agree with commenters that PrEP should be properly represented in the HHS risk adjustment adult and child models to mitigate the potential for adverse selection and appreciate the support for the addition of a new PrEP ACF to these models beginning with the 2026 benefit year. As explained in the proposed rule (89 FR 82308, 82323–24), we believe that creating a new class of factors is necessary and appropriate at this time to capture actuarial risks and costs that may contribute to adverse selection but are not indicative of an active medical condition, as is the case with PrEP, and therefore would not be reflected in the

[67] As discussed later in this section, it may be appropriate to remove generic drugs to ensure homogeneity of costs within a PrEP ACF.

[68] For example, we believe there are likely substantial rebates for Descovy that are not captured in issuers' EDGE data submissions. See, for example, Dickson, S., Gabriel, N., and Hernandez, I. Estimated changes in price discounts for tenofovir-inclusive HIV treatments following introduction of tenofovir alafenamide. AIDS. 2022 Dec 1;36(15):2225–2227. doi: 10.1097/QAD.0000000000003401. See, also, Krakower, D. and Marcus, J.L. Commercial Determinants of Access to HIV Preexposure Prophylaxis. *JAMA Network Open.* 2023;6(11):e2342759. doi: *10.1001/jamanetworkopen.2023.42759.* See, also, McManus, K.A., et al. Geographic Variation in Qualified Health Plan Coverage and Prior Authorization Requirements for HIV Preexposure Prophylaxis. *JAMA Network Open.* 2023;6(11):e2342781. doi: *10.1001/jamanetworkopen.2023.42781.*

[69] See, supra, note 53.

[70] We previously excluded generic drugs from RXC 9, Immune Suppressants and Immunomodulators, due to concern over patient access and health plan selection behavior. See the 2019 Payment Notice (83 FR 16942).

HCC and RXC factors used in the HHS risk adjustment models.

Although this new ACF class of model factors is guided by similar principles [71] for inclusion as the existing RXC class of model factors,[72] we feel that it is conceptually appropriate to distinguish between these two classes. As stated in the 2018 Payment Notice,[73] RXCs were specifically incorporated into the HHS risk adjustment models as separate factors from HCCs (which indicate the presence of a diagnosis directly) to impute a missing diagnosis or indicate severity of a diagnosis. Because the PrEP ACF (and any potential future ACFs) are not intended to be related to a diagnosis for any medical condition, we believe it is appropriate to distinguish such model factors from RXCs and HCCs.

Comment: One commenter opposed the proposal to add PrEP to the HHS risk adjustment adult and child models as an ACF on the basis that the commenter believes including PrEP in the HHS risk adjustment adult and child models is discriminatory, expressing a belief that risk adjustment and the assignment of risk scores to enrollees based on health conditions is discriminatory in general.

Response: HHS takes seriously our obligation to protect individuals from discrimination and generally disagrees that the use of factors based on enrollees' age, sex, and health conditions or utilization of services and treatments in risk adjustment is inappropriate. Consistent with section 1343 of the ACA, the HHS-operated risk adjustment program reduces the incentives for issuers to avoid higher-than-average risk enrollees, such as those with chronic conditions, by using charges collected from issuers that attract lower-than-average risk enrollees to provide payments to health insurance issuers that attract higher-than-average risk enrollees. The ACA limits issuers' ability to establish or charge premiums on the basis of age and prohibits issuers' ability to do so on the basis of sex or any individual health characteristic other than tobacco use.[74] However, the cost of care for and actuarial risk of enrollees is, in part, correlated with their age, sex, health conditions (or severity thereof), and likelihood to utilize services and treatments. As such, without the inclusion of factors related to age, sex, health conditions, and use of services and treatments in the HHS risk adjustment models, some issuers would be incentivized to design plans that are less attractive to potential enrollees whose age-sex category, health conditions, or use of services and treatments is predicted to create a higher liability for the issuer. The various factors in the HHS risk adjustment models help alleviate this incentive by ensuring that the actuarial risk of an issuers' enrollee population in a State market risk pool, including issuers that enroll a higher-than-average proportion of enrollees who fall into a high-cost age-sex category or are likely utilizers of high-cost preventive services (PrEP, for example), are appropriately assessed as part of the calculations under the State payment transfer formula. The use of factors associated with age, sex, health conditions, and the use of services and treatments (including expensive preventive services, such as PrEP) in the HHS risk adjustment models is therefore necessary, appropriate, and helps reduce the likelihood that discrimination based on any of these factors will occur with respect to health insurance coverage issued or renewed in the individual and small group (including merged) markets.

Comment: One commenter opposed the proposal due to concerns that the addition of ACFs would increase risk adjustment model complexity. A few commenters urged caution in implementing the proposal or requested that HHS implement the addition of the PrEP ACF on a pilot basis. A few commenters requested a technical paper be published on the ACF concept.

Response: We appreciate commenters' interest in carefully considering the impact of the addition of a PrEP ACF to the HHS risk adjustment adult and child models. We will continue to monitor the performance of the HHS risk adjustment models, including the impact of the new PrEP ACF. Although the HHS risk adjustment models are made more complex by the addition of any new model factor, we believe that the seven principles for considering new ACFs discussed in the proposed rule,[75] as well as the existing principles for consideration of HCCs [76] and RXCs,[77] are sufficient to ensure that new model factors are only added when appropriate. In particular, we note that the addition of the PrEP ACF satisfies the principles of clinical meaningfulness and specificity, meaningful and predictable costs, sufficient sample size, and low risk of inappropriate prescribing. Therefore, we determined that the addition of the PrEP ACF is likely to improve the predictive validity of the models with respect to the portion of the enrollee population that are eligible for PrEP. With the specifications finalized in this rule to address the principles of hierarchical factor definitions, monotonicity, and mutually exclusive factor definitions, we believe that the benefits of adding a new PrEP ACF outweighs the concerns about model complexity. In addition, our recent analysis of 2022 benefit year enrollee-level EDGE data confirmed there is sufficiently robust data to justify the addition of the PrEP ACF and calculate its coefficients for the HHS risk adjustment adult and child models beginning with the 2026 benefit year such that a pilot period for the PrEP ACF is unnecessary.

As always, as part of our ongoing efforts to continually improve the precision of the HHS risk adjustment models, we will seek input from interested parties through notice-and-comment rulemaking or other appropriate vehicles (including technical papers, as appropriate) on potential changes to the HHS risk adjustment models, including any potential new ACFs we may consider in the future. However, in light of the rationale and data discussed in the proposed rule, and in response to the comments in support of adding the PrEP ACF to the HHS risk adjustment adult and child models beginning with the 2026 benefit year, we do not believe a technical paper is warranted before finalizing the addition of the PrEP ACF to the HHS risk adjustment adult and child models.

[71] See 89 FR 82308, 82324–31.

[72] See 81 FR 94058, 94074–80. See also the 2016 HHS Risk Adjustment White Paper. Available at *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf*.

[73] Ibid. See also the March 31, 2016, *HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers.* June 8, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf*.

[74] See section 2701 of the Public Health Service Act (42 U.S.C. 300gg) as amended by section 1201 of the ACA. See also the Market Rules and Rate Review final rule (78 FR 13406, 13411–13).

[75] See 89 FR 82308, 82325–27.

[76] See the 2014 Payment Notice Proposed Rule (77 FR 73118, 73128) and the 2014 Payment Notice Final Rule (78 FR 15410, 15420). See also Kautter, J. et al (2014). The HHS–HCC Risk Adjustment Model for Individual and Small Group Markets under the Affordable Care Act. *Medicare and Medicaid Research Review, 4*(3). Available at: *https://www.cms.gov/mmrr/Downloads/MMRR2014_004_03_a03.pdf*. See also the 2016 HHS Risk Adjustment White Paper (available at: *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf*) and the 2021 RA Technical Paper (available at: *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf*).

[77] See the 2018 Payment Notice Proposed Rule (81 FR 61456, 61470–71) and the 2018 Payment Notice Final Rule (81 FR 94058, 94075–80).

Comment: Several commenters expressed a preference for excluding generic drugs from the definition of the PrEP ACF, noting the vast difference in prices between brand name and generic drugs. One commenter noted that their experience showed that prices for brand name PrEP drugs can be as much as 100 times the cost of generic PrEP drugs. A few commenters stated that excluding generics would better support patients as advances in PrEP come to market, with a few commenters specifically noting that newer branded forms of PrEP drugs that are more effective, more tolerable, and long-acting will likely be the predominant form of PrEP in the near future. Furthermore, a few commenters were concerned that including generics in the PrEP ACF definition would overcompensate plans that prescribe more generics than average or would otherwise contribute to adverse selection incentives.

Several other commenters noted a preference for generic drugs to be included in the definition of the PrEP ACF on the basis that excluding generics may incentivize prescription of brand name drugs and inefficient care patterns. A few of these commenters noted that issuers are likely receiving considerable manufacturer rebates for PrEP that may not be reflected in the enrollee-level EDGE data that HHS uses for risk adjustment model recalibration.

One commenter who supported the exclusion of generics requested that step-therapy requirements be instituted for PrEP drugs that have both a generic and brand name formulation. A few commenters noted an interest in splitting the PrEP ACF into two ACFs according to brand name/generic status or based on oral/injectable form.

Response: We appreciate the comments and agree with the position that the vast difference in costs between brand name and generic PrEP drugs warrants an exclusion for generic drugs from the definition of the PrEP ACF. Although excluding generic drugs from the definition of a model factor may, in many cases, encourage the prescription of brand name drugs over generic drugs and encourage inefficient care patterns, we do not believe this is especially likely in the case of PrEP due to the very large difference in price between the only generic form of PrEP available on the market and the multiple brand name forms available. Moreover, we are concerned that the inclusion of generic drugs would lead to an overpayment for coverage of generic drugs and an underpayment for coverage of brand name drugs, potentially incentivizing issuers to limit access to brand name drugs. Because there is presently only one form of generic PrEP available on the market (a daily oral regimen), barriers to accessing brand name drugs, including step-therapy requirements, would only limit access to newer and more tolerable formulations, including long-acting injectable forms of PrEP. Additionally, step-therapy requirements would be inconsistent with recently released guidance relating to coverage of preventive services under section 2713 of the PHS Act specifying that issuers must cover, without cost sharing, all three FDA-approved PrEP formulations (two oral and one injectable) and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.[78] As such, to further limit the influence of perverse incentives, to align with the recent guidance, and in recognition of the very large difference in price between generic and brand name forms of PrEP, beginning with the 2026 benefit year, we are finalizing the addition of the PrEP ACF to the HHS risk adjustment adult and child models with an exclusion of generic versions of PrEP medication from the definition of the PrEP ACF. We will continue to monitor the impact of the new PrEP ACF, as well as the cost and utilization of PrEP drugs in the market, and may consider alterations to the new PrEP ACF if the prices of generic and brand name forms of PrEP become more comparable, additional generic forms of PrEP enter the market, or we observe market distortions or other impacts resulting from the addition of the new PrEP ACF to the adult and child models that should be addressed.

We may also consider the potential addition of a separate generic drug PrEP ACF in the future, but would need to consider whether the inclusion of an ACF for generic drugs would satisfy the principles finalized in this rule to guide the adoption of potential additional ACFs in the future. In particular, we would need to consider whether a generic drug PrEP ACF would satisfy the principle of meaningful and predictable costs (Principle 2), as the cost of the generic version of PrEP currently available on the market is fairly low and may not produce a meaningful coefficient if incorporated into the HHS risk adjustment adult and child models. As part of this future analysis, we may also consider whether a distinction between oral and injectable PrEP is warranted. However, we note that the annual costs of brand name oral and injectable forms are currently similar and that the only generic form of PrEP currently available is an oral form. Therefore, the splitting of the PrEP ACF into oral and injectable forms may still necessitate the exclusion of generic PrEP due to the cost disparity between the generic and brand name oral forms, which would continue to lead to overprediction for the generic form, incentivizing issuers to use medical management techniques to direct individuals prescribed oral PrEP to utilize the generic oral formulation over other branded oral forms that may have fewer side effects or otherwise be more appropriate for the enrollee. We would seek input from interested parties through notice-and-comment rulemaking or other appropriate vehicles on any such potential changes.

Regarding the comments related to manufacturer rebates, we acknowledge that manufacturer rebates are common and may impact drug prices for a wide variety of prescription drugs.[79] We note that issuers are currently instructed that they do not need to adjust the reported Plan Paid Amount to reflect manufacturer rebates in the data made available to HHS through issuers' EDGE servers.[80] As such, using enrollee-level EDGE data to precisely account for manufacturer rebates for any prescription drugs in the HHS risk adjustment adult and child models may necessitate changes to issuers' data submission practices. We continue to consider these issues and different ways to potentially account for these rebates in the HHS risk adjustment models in future benefit years.

Comment: All commenters on the two hierarchy options set forth in the proposed rule preferred the alternative approach in which HHS would allow adult enrollees with HIV to receive credit for PrEP and place the PrEP ACF in the adult models in a hierarchy below RXC 1 (Anti-HIV Agents). Commenters noted that this approach is the most straightforward approach, that it maintains a strong adherence to the seven principles for developing a new ACF factor set forth in the proposed rule, and that it ensures that the HHS risk adjustment models can distinguish between preventive use of PrEP and treatment of active HIV infection, thus mitigating overlap issues and preserving the integrity of the classification system.

[78] See *https://www.cms.gov/files/document/faqs-implementation-part-68.pdf.*

[79] See, for example, Shepherd, Joanna. (2020). Pharmacy benefit managers, rebates, and drug prices: conflicts of interest in the market for prescription drugs. *Yale Law & Policy Review, 38(2),* 360–396. Available at: *https://heinonline.org/HOL/P?h=hein.journals/yalpr38&i=390.*

[80] See the EDGE Server Business Rules, Version 25 (December 2024). Available at: *https://regtap.cms.gov/reg_librarye.php?i=3765.*

One commenter suggested that if the ACF for PrEP is added to the HHS risk adjustment child models, RXC 1 (Anti-HIV Agents) should also be added to the child models with the same hierarchy specifications as the adult models. This commenter asserted that without this modification, it may be difficult to differentiate enrollees subject to the child models who are on PrEP from those who are taking antiretrovirals to manage active HIV infections.

Response: We agree that the alternative hierarchy approach for the adult models set forth in the proposed rule is straightforward and would appropriately address the hierarchy concerns identified in the proposed rule with regards to the adult models, namely the violations of the hierarchical factor definitions principle (Principle 4), the monotonicity principle (Principle 5), and the mutually exclusive classification system principle (Principle 6).[81] Because we are able to appropriately address these violations through the adoption of the alternative hierarchy approach, we also agree that the adult models will be able to appropriately distinguish between the preventive use of PrEP and the treatment of an active HIV infection. Therefore, in the HHS risk adjustment adult models we are finalizing the hierarchy option that places the PrEP ACF below RXC 1 in a hierarchy without defining any hierarchical relationship between the PrEP ACF and HCC 1 (HIV/AIDS). Under this approach, adult enrollees without RXC 1 will receive the PrEP ACF along with HCC 1 in cases where the enrollee has both a PrEP prescription claim and an HCC 1 diagnosis in their medical records for the benefit year. Further, under this approach, an adult enrollee with a PrEP prescription claim in their medical records for the benefit year who later tests positive for HIV in the same benefit year would have an increase in their risk score for that year as a result of the additional diagnosis, appropriately satisfying the principles of additivity (Principle 4) and monotonicity (Principle 5).

Regarding the comment requesting the addition of RXC 1 to the child models with the same hierarchy specifications as the adult models, we did not propose and are not finalizing the addition of any RXCs to the HHS risk adjustment child models. Currently, only the HHS risk adjustment adult models include RXCs. Determining whether it is appropriate to add any RXCs to the child models would require careful analysis and consideration, and we would want to solicit public comment on such analysis, which was not possible between the receipt of these comments and publication of this final rule. For example, similar to the development of the RXC–HCC pairs for the HHS risk adjustment adult models, we would need to work with clinicians to analyze, select, and tailor the RXCs that could be used to impute diagnoses and to indicate the severity of diagnoses otherwise indicated through medical coding as appropriate for the child models.[82] We would also need to propose and solicit comments on such potential draft factors in the applicable HHS notice of benefit and payment parameters.

However, we agree with the commenter that there is an important issue with the hierarchy specification(s) related to the addition of the PrEP ACF in the child models that needs to be addressed when finalizing these new factors for the models. To explain, we first note that because the HHS risk adjustment child models do not contain RXCs, the costs of HIV treatment (inclusive of the HIV treatment medication regimens captured in RXC 1 in the adult models) are accounted for in the HCC 1 coefficient in the child models. As such, in contrast to the adult models, where the RXC 1 coefficient is generally larger than the PrEP ACF or HCC 1 coefficient, with the HCC 1 coefficient having the smallest coefficient of the three adult model factors, the absence of RXC 1 in the child models generally results in a higher coefficient for HCC 1 than the PrEP ACF coefficient. As such, without a hierarchy specification limiting the application of the PrEP ACF in the child models, an enrollee subject to the child models who was on PrEP for part of a benefit year, but was later diagnosed with HIV (and would therefore likely be prescribed treatment for an active HIV infection instead) would receive a large increase to their risk score (approximately 3.993, per the draft silver coefficient for HCC 1 in the child models as reflected in Table 5 of the proposed rule)[83] because the enrollee would be receiving risk score components associated with both prevention and treatment of HIV. However, in the context of the adult model PrEP ACF and hierarchy specification finalized in this rule, a similar enrollee subject to the adult models who was on PrEP for part of a benefit year, but was later diagnosed with HIV and started to take an RXC 1 drug for treatment would receive a much smaller increase to their risk score (approximately 1.962 per the silver coefficients for the adult models as reflected in Tables 2 and 4 of the proposed rule)[84] because the enrollee's risk score would only reflect the difference in cost associated with treatment relative to prevention.

Pending further research and consideration on the impact of adding RXCs (such as RXC 1) to the child models, to better align the representation of risk between the adult and child models and more appropriately reflect the cost of enrollees who receive both PrEP and HIV treatment in the same benefit year in the child models, we believe that an appropriate approach would be to place the PrEP ACF below HCC 1 in a hierarchy in the child models. This would allow the risk score of an enrollee subject to the child models who was on PrEP for part of a benefit year but was later diagnosed with HIV to reflect only the difference in cost associated with treatment relative to prevention (approximately 2.719 per the silver coefficients for the child models as reflected in Tables 3 and 5 of the proposed rule)[85] rather than the whole cost of both treatment and prevention.

We are finalizing as proposed the addition of a new PrEP ACF to the child models and, in response to comments, we will place the PrEP ACF in a hierarchy below HCC 1 in the child models to ensure that child enrollees who have both a PrEP prescription claim and an HCC 1 (HIV/AIDS) diagnosis reflected in their medical records for a benefit year (and are therefore likely receiving active treatment) will receive an appropriate increase to their risk score relative to enrollees in the child models without an

[81] This alternative hierarchy approach satisfies the intent of Principle 6 (mutually exclusive classification) by using similar considerations and filtering steps to those we currently use in our simulation of plan liability for PrEP.

[82] For information on the development of the RXC–HCC pairs for the adult models, including the guiding principles and other considerations, see the 2018 Payment Notice Proposed Rule (81 FR 61456, 61470–71), the 2018 Payment Notice Final Rule (81 FR 94058, 94075–80), and the 2019 Payment Notice Final Rule (83 FR 16930, 16941–43). Also see Chapter 4, 2016 HHS Risk Adjustment White Paper, available at: *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf.*

[83] See 89 FR 82308, 82328–41. Note that these values are approximate and presented here only for illustrative purposes. We note that the proposed rule estimates included generic drugs in the definition of the PrEP ACF but in this rule we are finalizing that generic drugs will be excluded from PrEP ACF definition for both the adult and child models. As such, these values should be taken only as rough estimates of the impact of the hierarchy specification on the example enrollee.

[84] Ibid.

[85] Ibid.

HCC 1 diagnosis who have a PrEP prescription claim in their medical records for that year.

We will consider if any additional changes to the child models are necessary as we continue to monitor the impact of the new PrEP ACF and consider potential refinements to the ACF framework in future benefit years. As always, as part of our ongoing efforts to continually improve the precision of the HHS risk adjustment models, we will seek input from interested parties through notice-and-comment rulemaking or other appropriate vehicles on potential changes to the models in future benefit years.

Comment: Several commenters offered ideas for additional ACFs to be added to the HHS risk adjustment models in the future. These included ACFs for biologic drugs, GLP–1 drugs, and cellular and gene therapies. Other commenters' suggestions requested the use of the ACF framework to restructure how childbirth, organ transplants, end stage renal disease (ESRD), dialysis, respirator dependance, amputations, autism spectrum disorder, moderate forms of psychiatric illness, and prophylactic interventions such as prophylactic mastectomy are accounted for in the HHS-operated risk adjustment program.

A few commenters requested changes to the risk adjustment specifications for one or more of these conditions without specifying that the ACF framework was the proper vehicle for addressing their concerns.

Response: We did not propose and therefore are not finalizing the adoption of additional ACFs at this time. However, we are finalizing the adoption of the ACF framework and the proposed principles to guide any potential development of additional ACFs to the HHS risk adjustment models in the future. We appreciate the suggestions regarding other conditions or diagnoses for which it may be appropriate to leverage the ACF framework to restructure or refine the treatment of the other identified clinically meaningful enrollee characteristics in the HHS risk adjustment models. As we consider potential refinements to the ACF structure and other changes to the HHS risk adjustment models in the future, we may further consider these suggestions and the structure of related HCCs. As always, as part of our ongoing efforts to continually improve the precision of the HHS risk adjustment models, if we were to make changes to the ACF structure or other changes to the HHS risk adjustment models in the future, we will seek input from interested parties through notice-and-comment rulemaking or other appropriate vehicles on such potential changes.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments above, we are finalizing the addition of PrEP as an ACF in the adult and child risk adjustment models beginning with the 2026 benefit year. Furthermore, we are finalizing the exclusion of generic versions of PrEP from the PrEP ACF and are finalizing the placement of the PrEP ACF in the adult models in a hierarchy below RXC 1 (Anti-HIV Agents) without defining any hierarchical relationship between the PrEP ACF and HCC 1 (HIV/AIDS). In the child models, which do not contain RXCs, we are finalizing the placement of the PrEP ACF in a hierarchy below HCC 1. Additionally, we are finalizing the proposed ACF framework and principles used to determine whether it is appropriate to add a new ACF to the HHS risk adjustment models, and how the hierarchy structure associated with an ACF should be defined.

We were unable to complete the calculations for the final coefficients in time to publish them in this final rule because additional time is needed to complete the calculations needed to account for the incorporation of the PrEP ACF with the generic drug exclusions and hierarchy specifications finalized in this rule. Therefore, consistent with § 153.320(b)(1)(i), we will publish the final coefficients for the 2026 benefit year in guidance after the publication of this final rule. We will release this guidance by the spring of 2025 in time for rate setting for the 2026 benefit year.

d. List of Factors To Be Employed in the HHS Risk Adjustment Models (§ 153.320)

Consistent with § 153.320(b)(1)(i), we are finalizing the use of the 2020, 2021 and 2022 enrollee-level EDGE data to calculate the 2026 benefit year coefficients and will publish the final coefficients for the 2026 benefit year in guidance after the publication of this final rule, as we were unable to complete the calculations to finalize them in time to publish them in this final rule,[86] due to the additional calculations needed to account for the incorporation of the PrEP ACF with the generic drug exclusions and hierarchy specifications as finalized in this rule. The proposed 2026 benefit year HHS risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using 2020, 2021, and 2022 enrollee-level data are shown in Tables 2 through 9 of the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82328 through 46). As we have done for certain prior benefit years,[87] we will release the final 2026 benefit year coefficients in guidance after publication of this final rule by the spring of 2025 in time for rate setting for the 2026 benefit year. We received several comments requesting additional changes to the HHS risk adjustment models that we did not consider or propose in the proposed rule. We respond to these comments below.

Comment: One commenter suggested that HHS update the risk adjustment models to incorporate Tepezza and Graves Disease/Hyperthyroidism.

Response: We did not propose and are not finalizing changes to add an RXC to the HHS risk adjustment adult models for Tepezza, which treats thyroid eye disease, or to add a payment HCC for Graves Disease/Hyperthyroidism. We recently discussed the approach to the treatment of Tepezza and Graves Disease/Hyperthyroidism in the HHS risk adjustment models in the 2025 Payment Notice final rule,[88] explaining that thyroid eye disease (thyrotoxicosis) is currently categorized in a condition category (Other Endocrine/Metabolic/Nutritional Disorders) that is not a payment HCC in the HHS risk adjustment models. Further, all RXCs in the HHS adult risk adjustment models are associated with a payment HCC. We therefore generally have concerns about adding thyroid eye disease to the HHS risk adjustment models at this time as it is currently not categorized as a payment HCC and we would need to perform further analysis to consider whether it is appropriate and how best

[86] See 45 CFR 153.320(b)(1)(i).

[87] For example, the final 2018 benefit year HHS risk adjustment model coefficients were not published in the 2018 Payment Notice final rule (81 FR 94058, 81 FR 94084) but were instead published on the CMS website and are available at *https://www.cms.gov/cciio/programs-and-initiatives/premium-stabilization-programs/downloads/2018-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf*. See also, for example, the final 2021 benefit year HHS risk adjustment model coefficients, which were not published in the 2023 Payment Notice final rule (85 FR 29164, 29190) but were instead published on the CMS website and are available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/final-2021-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf*.

See also, for example, the final 2023 benefit year HHS risk adjustment model coefficients, which were not published in the 2023 Payment Notice final rule (87 FR 27208, 27235) but were instead published on the CMS website and are available at *https://www.cms.gov/files/document/2023-benefit-year-final-hhs-risk-adjustment-model-coefficients.pdf*.

[88] See 89 FR 26218, 26248–49.

to incorporate this condition into the models given these concerns. For these reasons, HHS did not propose and is not finalizing any changes with respect to the treatment of Tepezza for thyroid eye disease in the 2026 benefit year risk adjustment models. However, HHS intends to continue analysis of Graves Disease/Hyperthyroidism and thyrotoxicosis and the use of Tepezza as more data becomes available and consider potential changes to the treatment of this condition and drug in the HHS risk adjustment models for future benefit years.

Comment: A few commenters identified certain conditions that they believe are undercompensated in the risk adjustment models. These conditions included autism spectrum disorder, ESRD, and maternal and newborn care. These commenters requested that HHS reconsider how these conditions and their associated costs are accounted for in the HHS risk adjustment models. Additionally, one commenter requested that HHS revisit the analysis in the 2021 RA Technical Paper,[89] expressing concern that the risk associated with the lowest-risk enrollees remains underpredicted by the HHS risk adjustment models. One commenter recommended that HHS study the impact of calibrating the HHS risk adjustment models separately for the individual and small group markets due to differences in the characteristics of the enrollee population between the two markets. Furthermore, one commenter recommended that HHS consider ways to account for plan design generosity as more generous plans tend to attract enrollees with expensive chronic conditions.

Response: We appreciate the suggestions regarding conditions that commenters identified for review of how they are accounted for in the HHS risk adjustment models. Although we did not propose and are not finalizing changes to the treatment of the identified conditions in the 2026 benefit year risk adjustment models, we generally note that we consistently monitor the performance of the risk adjustment models, including through out-of-sample analysis of predictive ratios associated with each model factor, as additional years of enrollee-level EDGE data become available. Results of these monitoring activities were a key impetus for several risk adjustment model changes finalized in the 2023 Payment Notice [90] to address the adult and child models' underprediction for enrollees with many HCCs. Specifically, we finalized the interacted HCC counts and HCC-contingent enrollment duration factor model specifications to improve model prediction for higher risk enrollees and ensure that issuers are being accurately compensated for these enrollees. As such, the potential for underprediction or overprediction in the HHS risk adjustment models is an area that HHS is consistently monitoring and addressing as needed and will continue to monitor and address in the future as part of our ongoing efforts to continually improve the HHS risk adjustment models. We also note that the conditions or diagnoses identified in these comments show strong overlap with the conditions that some commenters identified as being appropriate to be addressed by the ACF framework and that, as stated in our response to comments about those conditions in that section of this final rule, we will take these comments into consideration as we consider potential refinements to the HHS risk adjustment models in future benefit years.

In regard to the request to revisit the analysis in the 2021 RA Technical Paper, we appreciate the commenter's concern. As noted in the 2023 Payment Notice,[91] our analysis of the addition of the interacted HCC counts factors in the adult and child models, the removal of the former adult model severity illness factors, and the replacement of the former enrollment duration factors with the HCC-contingent enrollment duration factors in the adult models found that the combined impact of these changes would significantly improve predictions across most deciles and HCC counts for the very highest-risk enrollees, as well as the lowest-risk enrollees without HCCs.[92] These model specification updates were implemented starting with the 2023 benefit year HHS risk adjustment models and we intend to monitor the impact of these updates as part of future benefit years' model recalibrations using additional years of available enrollee-level EDGE data.

As we consider potential refinements to the HHS risk adjustment models in the future, we will also continue to monitor the specific conditions identified by commenters, along with the structure of related model factors, and the impact of recent model specification updates on the ability of the models to predict risk across all subgroups of enrollees and enrollees with chronic conditions who are more likely to enroll in plans with more generous coverage. We also will continue to study whether differences in the characteristics of the enrollee population between the individual and small groups markets would warrant calibrating the HHS risk adjustment models separately for the individual and small group markets. As always, as part of our ongoing efforts to continually improve the precision of the HHS risk adjustment models, if we were to pursue changes to the risk adjustment models in the future, we will seek input from interested parties through notice-and-comment rulemaking or other appropriate vehicles.

Comment: Several commenters requested clarification regarding how medically administered injectable drugs are accounted for in the HHS risk adjustment models. These commenters were concerned that these drugs appear to be filtered out of enrollee claims data for the purpose of calculating risk scores.

Response: We appreciate commenters bringing this concern to our attention. Although not expressly stated by commenters, we believe these concerns stem from the commenters' interpretation of language in guidance document(s) such as the Risk Adjustment DIY Software Instructions.[93] To clarify, for RXC eligibility (including medically administered injectable claims), a professional or outpatient medical claim does not need to have a risk adjustment eligible service code or bill type code. Instead, the professional or outpatient claim simply needs to have a service code that maps to an RXC for selection and inclusion in enrollee claims data for purposes of calculating risk scores. We intend to update language in these guidance document(s) in future releases to clarify this point.

e. Cost-Sharing Reduction Adjustments

In the 2025 Payment Notice (89 FR 26252 through 26254), we finalized the updated CSR adjustment factors for American Indian/Alaska Native (AI/AN) zero-cost sharing and limited cost sharing CSR plan variant enrollees for the 2025 benefit year, and for all future benefit years, unless changed through notice-and-comment rulemaking. In the 2025 Payment Notice (89 FR 26252 through 26254), we also finalized maintaining the existing CSR

[89] See *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[90] 87 FR 27208, 27221–30.

[91] Ibid.

[92] Ibid. See also Figure 4.2. HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes. (2021, October 26). CMS. *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[93] For example, see the 2024 Benefit Year Risk Adjustment Updated HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software Instructions, available at: *https://www.cms.gov/files/document/cy2024-diy-instructions-09062024.pdf.*

adjustment factors for silver plan variant enrollees (70 percent, 73 percent, 87 percent, and 94 percent AV plan variants) [94] for the 2025 benefit year and beyond, unless changed through notice-and-comment rulemaking.

For the 2026 benefit year, we did not propose to change the CSR adjustment factors as finalized in the 2025 Payment Notice and we will maintain the existing CSR adjustment factors for the 2026 benefit year.[95] We summarize and respond to the public comments received on the CSR adjustment factors for the 2026 benefit year below.

Comment: We received a few comments asking that HHS revisit the CSR factors for Massachusetts wraparound plans, specifically for wrap-around plans with AVs above 94 percent. These commenters stated that the wrap-around plans with AVs above 94 percent warrant higher CSR factors than the current 1.12 values. One of these commenters compared the current CSR factor used for Massachusetts wrap-around plans with AVs above 94 percent to those used in Arkansas for plans the commenter identified as having similar AVs.

Response: For all plan liability risk score calculations under the State payment transfer formula, we use the CSR adjustment factor that aligns with the AV of the applicable plan for the enrollee. Thus, for unique State-specific plans, we apply the CSR adjustment factors that correspond to each plan's AV. As we identify unique State-specific plans that have higher plan liability than the standard plan variants, such as those in Massachusetts and Arkansas, we work with the relevant State Departments of Insurance and other relevant State agencies to identify the applicable CSR adjustment factor that corresponds to the unique State-specific plan's AV.

Regarding the comparison between Massachusetts' wrap-around plans and Arkansas' Medicaid expansion plans, Arkansas Medicaid expansion plans are identical to other 94 percent and 100 percent AV CSR plan variants offered on the Exchange and are distinguished from these identical plans only in their sources of funding and eligibility criteria. As such, we presently direct issuers in Arkansas who provide Medicaid expansion plans with AVs of 94 percent and 100 percent to use specified plan variant codes for their Medicaid expansion plans only to differentiate the sources of funding and to differentiate between populations eligible for the Medicaid expansion plans from those who are eligible for standard 94 percent and 100 percent AV CSR plan variants. In contrast, in Massachusetts, the higher cost sharing wrap-around plans are variations of lower cost sharing plans and do not have the same AVs as their comparable plans.

We will continue to follow this approach, working with the State to identify the applicable CSR adjustment factor that corresponds to that State's unique State-specific plan's AV. As of the release of this final rule, the Massachusetts Division of Insurance, which is the regulating body for the State, has not identified changes to the AVs of the State's wrap-around plans. As such, we are maintaining our general approach to determining the CSR factors for State-specific plans, including Massachusetts wrap-around plans, for the 2026 benefit year.

f. Model Performance Statistics

Each benefit year, to evaluate the HHS risk adjustment model performance, we examine each model's R-squared statistic and predictive ratios (PRs). The R-squared statistic, which calculates the percentage of individual variation noted by a model, measures the predictive accuracy of the model overall. The PR for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The PR represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a PR of 1.0. For each of the current and proposed HHS risk adjustment models, the R-squared statistic and the PRs are in the range of published estimates for concurrent HHS risk adjustment models.[96] Because we are finalizing a blend the coefficients from separately solved models based on the 2020, 2021 and 2022 benefit years' enrollee-level EDGE data, we publish the R-squared statistic for each model separately to verify their statistical validity. We will include the R-squared statistics for the final 2026 benefit year models when we publish the final coefficients for the 2026 benefit year in guidance after publication of this final rule. We will release this guidance by the spring of 2025, in time for rate setting for the 2026 benefit year.

We received one comment noting the decreases in the risk adjustment model R-squared values for the 2022 enrollee-level EDGE data relative to prior benefit years as presented in Table 10 of the proposed rule and provide a response to that comment in the section on Data for HHS Risk Adjustment Model Recalibration for the 2026 Benefit Year above.

3. Overview of the HHS Risk Adjustment Methodology: State Payment Transfer Formula

In part 2 of the 2022 Payment Notice (86 FR 24183 through 24186), we finalized the proposal to continue to use the State payment transfer formula finalized in the 2021 Payment Notice for the 2022 benefit year and beyond, unless changed through notice-and-comment rulemaking. We did not propose any changes to the formula in the proposed rule, and therefore, did not republish the formulas in the proposed rule. We therefore will continue to apply the formula as finalized in the 2021 Payment Notice (86 FR 24183 through 24186) in the States where HHS operates the risk adjustment program in the 2026 benefit year.

Additionally, as finalized in the 2020 Payment Notice (84 FR 17466 through 17468), we will maintain the high-cost risk pool parameters for the 2020 benefit year and beyond, unless amended through notice-and-comment rulemaking. We did not propose any changes to the high-cost risk pool parameters for the 2026 benefit year; therefore, we will maintain the $1 million threshold and 60 percent coinsurance rate.[97]

We did not receive any comments in response to the overview of the HHS risk adjustment methodology applicable to the 2026 benefit year.

4. Solicitation of Comments—Time Value of Money in HHS-Operated Risk Adjustment Program

In the HHS Notice of Benefit and Payment Parameters 2026 proposed rule (89 FR 82347, 82348), HHS solicited comments on the impact of the time value of money on the HHS-operated risk adjustment program, including the impact of the time value of money on issuers' assessment of actuarial risk and the incentives for adverse selection, and what possible solutions or mitigating steps we should consider to address the impact of the time value of money on

[94] See 83 FR 16930, 16953; 84 FR 17454, 17478–79; 85 FR 29164, 29190; 86 FR 24140, 24181; 87 FR 27208, 27235–36; 88 FR 25740, 25772–74; and 89 FR 26218, 26252–54.

[95] See CSR adjustment factors finalized in the 2025 Payment Notice at 89 FR 26252 through 26254.

[96] Hileman, G., & Steele, S. (2016). *Accuracy of Claims-Based Risk Scoring Models.* Society of Actuaries. *https://www.soa.org/4937b5/globalassets/assets/files/research/research-2016-accuracy-claims-based-risk-scoring-models.pdf.*

[97] See 81 FR 94058, 94081. See also 84 FR 17454, 17467.

the HHS-operated risk adjustment program in future rulemaking. HHS noted in the proposed rule that it received feedback in the past from some interested parties that issuers of risk adjustment covered plans were more impacted by the time value of money for benefit year 2023 than in any previous benefit years. Therefore, HHS solicited comment on the impact of the 8-to-10-month gap between the end of the benefit year when claims are incurred and the issuance of risk adjustment charges and allocation of payments for that benefit year. We thank commenters for their feedback and will take these comments into consideration in future rulemaking as applicable.

5. HHS Risk Adjustment User Fee for the 2026 Benefit Year (§ 153.610(f))

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82348), we proposed an HHS risk adjustment user fee for the 2026 benefit year of $0.18 PMPM. Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a State, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

For the 2026 benefit year, HHS proposed to use the same methodology used in the 2025 Payment Notice (89 FR 26218) to estimate our administrative expenses to operate the program. These costs cover development of the models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, interested parties training, operational support, and administrative and personnel costs dedicated to HHS-operated risk adjustment program activities. To calculate the risk adjustment user fee, we divided HHS' projected total costs for administering the program on behalf of States by the expected number of BMMs in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2026 benefit year.[98]

We estimated that the total costs for HHS to operate the risk adjustment program on behalf of States within the 2026 calendar year will be approximately $65 million, roughly the same as the amount estimated for the 2025 calendar year. Based on these costs and because we did not estimate increased enrollment in the 2026 benefit year beyond the 2024 benefit year level, we proposed an HHS risk adjustment user fee of $0.18 PMPM for the 2026 benefit year. We sought comment on the proposed HHS risk adjustment user fee for the 2026 benefit year.

After consideration of comments and updating our projections based on the most recent available data, which impacted our enrollment estimates, we are finalizing a risk adjustment user fee rate of $0.20 PMPM for the 2026 benefit year. We summarize and respond to public comments received on the proposed 2026 benefit year risk adjustment user fee rate below.

Comment: Several commenters supported the proposed 2026 benefit year risk adjustment user fee rate but noted that the user fee rate may require modification if enhanced premium tax credit (PTC) subsidies are not extended into the 2026 benefit year. A few commenters requested more information on the assumptions we made if enhanced PTC subsidies expire or are extended.

Response: We are finalizing an HHS risk adjustment user fee rate for the 2026 benefit year of $0.20 PMPM. We proposed a risk adjustment user fee rate of $0.18 PMPM for the 2026 benefit year based on our estimates at the time in the proposed rule (89 FR 82348), and we explained that we may modify the risk adjustment user fee rate in the final rule if there were events resulting in larger than expected enrollment growth or some other deviation from our expectations of current conditions that would significantly change our estimates around costs, enrollment projections or the finalization of the proposed risk adjustment policies between the proposed and final rule. The final 2026 benefit year risk adjustment user fee rate adopted in this final rule assumes that, consistent with current law, the enhanced PTC subsidies will expire at the end of 2025. Though we project a similar budget to operate the HHS-operated risk adjustment program, the final user fee rate reflects updates to enrollment projections in individual, small group, and merged market risk pools based on the latest data available that was not available at the time of the proposed rule, such as PY 2025 open enrollment data[99] and estimated health insurance coverage changes[100] due to the expiration of enhanced PTC subsidies. We explained the assumptions used when determining the risk adjustment user fee in the 2026 Payment Notice proposed rule (89 FR 82349).

As we noted in the proposed rule (89 FR 82348), similar to prior benefit years, we projected risk adjustment enrollment scenarios for the 2026 benefit year, considered the impact of the expiration of the enhanced PTC subsidies established in section 9661 of the ARP and extended in section 12001 of the IRA through the 2025 benefit year on enrollment in the individual, small group, and merged market risk pools for the 2026 benefit year of risk adjustment, and used those estimates to calculate the proposed 2026 benefit year HHS risk adjustment user fee rate. While our updated projections show a decrease in enrollment in risk adjustment covered plans in States where the HHS-operated risk adjustment program will apply in the 2026 benefit year, we continue to estimate that the total costs for HHS to operate the risk adjustment program on behalf of States within the 2026 benefit year will be approximately $65 million. Therefore, we are finalizing a risk adjustment user fee rate for benefit year 2026 of $0.20 PMPM to ensure adequate funding for the HHS-operated risk adjustment program.

6. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (HHS–RADV) (§§ 153.350 and 153.630)

HHS conducts risk adjustment data validation under §§ 153.350 and 153.630 in any State where HHS is responsible for operating the risk adjustment program.[101] The purpose of risk adjustment data validation is to ensure issuers are providing accurate high-quality information to HHS, which is crucial for the proper functioning of the HHS-operated risk adjustment program. HHS–RADV also ensures that risk adjustment transfers calculated under the State payment transfer formula reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor quality data, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to

[98] HHS did not receive any requests from States to operate risk adjustment for the 2026 benefit year. Therefore, HHS will operate risk adjustment in every State and the District of Columbia for the 2026 benefit year.

[99] See Marketplace 2025 Open Enrollment Period Report National Snapshot, as of December 4, 2024: *https://www.cms.gov/newsroom/fact-sheets/marketplace-2025-open-enrollment-period-report-national-snapshot-0.*

[100] See CBO June 2024 projections of health insurance coverage via *https://www.cbo.gov/system/files/2024-06/51298-2024-06-healthinsurance.pdf.*

[101] Since the 2017 benefit year, HHS has operated the risk adjustment program in all 50 States and the District of Columbia.

issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. HHS–RADV consists of an initial validation audit (IVA) and a second validation audit (SVA).

a. Initial Validation Audit (IVA) Sampling Methodology—Enrollees Without HCCs, Finite Population Correction, and Neyman Allocation (§ 153.630(b))

To better align the IVA sampling methodology with the HHS–RADV error estimation methodology that estimates HCC error rates and to improve overall sampling precision, in the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82349), we proposed to exclude enrollees without HCCs [102] from IVA sampling, to remove the FPC, and to replace the source of the Neyman allocation [103] data used for IVA sampling purposes with 3 years of available HHS–RADV data beginning with benefit year 2025 HHS–RADV.[104]

For a discussion of the background of the HHS–RADV IVA sampling methodology and the proposed changes to the IVA sampling methodology, see the proposed rule (89 FR 82308, 82349). We summarize and respond to public comments on each of these three IVA sampling methodology changes below.

1. Proposal To Exclude Enrollees Without HCCs From IVA Sampling

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82351), we proposed to modify IVA sampling to exclude stratum 10 enrollees, which would exclude enrollees that do not have HCCs nor RXCs, and adult enrollees in strata 1 through 3 that have RXCs only, from IVA sampling beginning with benefit year 2025 HHS–RADV. For a full discussion of the proposed changes to exclude enrollees without HCCs from the HHS–RADV IVA sampling methodology, see the proposed rule (89 FR 82308, 82351). We sought comment on this proposal to exclude enrollees without HCCs from IVA sampling.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposal to exclude enrollees without HCCs from IVA sampling beginning with benefit year 2025 HHS–RADV below.

Comment: Many commenters supported the proposal to exclude enrollees without HCCs from IVA sampling with several of these commenters suggesting that the proposal would enhance the accuracy of HHS–RADV. A few commenters agreed that excluding enrollees without HCCs would ensure that the IVA sample reflects enrollees who most directly impact risk scores and HHS–RADV error rates, and one commenter suggested that including only enrollees with HCCs in the IVA sample would streamline the IVA validation and medical record retrieval processes, making the IVA less resource intensive.

Other commenters agreed that excluding enrollees without HCCs would better align the IVA sampling methodology with the HHS–RADV error estimation methodology and the policies finalized in the 2024 Payment Notice to discontinue the use of the lifelong permanent condition (LLPC) list and non-EDGE claims in HHS–RADV. One commenter noted concern that stratum 10 enrollees were included under the current IVA sampling methodology and suggested that these enrollees have no variance of error and therefore cannot have Neyman allocation-calculated sample sizes.

Response: We are finalizing the exclusion of enrollees without HCCs from IVA sampling, which excludes stratum 10 enrollees that do not have HCCs nor RXCs and adult enrollees in strata 1 through 3 that have RXCs only, beginning with benefit year 2025 HHS–RADV as proposed. We agree with commenters that finalizing this change, in combination with the other IVA and SVA methodological changes finalized in this rule, will improve the accuracy of HHS–RADV results. Moreover, finalizing the exclusion of enrollees without HCCs will better align our IVA sampling methodology with the error estimation methodology established in the 2019 Payment Notice, which calculates HCC-associated error rates and applies these error rates to the HCC-related portion of issuers' plan liability risk scores. Finalizing this policy will also better align our IVA sampling methodology with the HHS–RADV policies finalized in the 2024 Payment Notice to discontinue the LLPC list and no longer allow non-EDGE claims beginning with the 2022 benefit year of HHS–RADV, which emphasize HHS–RADV's focus on validating enrollee HCCs on EDGE.[105] We also agree with commenters that excluding enrollees without HCCs will ensure that issuers, IVA Entities, and the SVA Entity (as applicable) focus audit resources on enrollees who have a more direct impact on Super HCC failure rates, issuers' group failure rates, and issuers' error rates in HHS–RADV.

We disagree with commenters' concerns about stratum 10 enrollees being included under the current IVA sampling methodology as stratum 10 enrollees have stratum sample sizes calculated with the Neyman allocation in the current HHS–RADV IVA sampling methodology.[106] The current methodology assumes that the variance of net risk score error for stratum 10 used in the Neyman allocation is equal to the variance of net risk score error for the low-risk strata, which is a non-zero variance. Moreover, if we were to remove this assumption, it would still be possible to calculate a non-zero variance of net risk score errors for these stratum 10 enrollees because net risk score error is measured as the difference between the enrollee's calculated risk score using the HCCs validated during audit and the enrollee's calculated risk score using HCCs on EDGE. Therefore, the proposed change to exclude enrollees in stratum 10 was not driven by being unable to calculate stratum 10's variance of net risk score error or sample size. Rather, the change was driven by the desire to continue to make incremental improvements to the HHS-operated risk adjustment program, including HHS–RADV, and make IVA sampling more targeted and efficient. As previously noted, this change also better

[102] As explained in the proposed rule, adult enrollees with only RXCs do not have any HCCs, and therefore would be excluded from IVA sampling under this policy. See 89 FR 82308 at 82351.

[103] Neyman allocation is a method to allocate samples to strata based on the strata variances. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See *http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml.*

[104] Activities related to the 2025 benefit year of HHS–RADV will generally begin in Spring 2026, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2025 benefit year. Changes to the IVA sampling methodology need to be finalized before HHS–RADV activities begin; therefore, we proposed these IVA sampling changes begin with 2025 benefit year HHS–RADV due to the timing of this rulemaking. For the most recently published annual HHS–RADV timeline, see the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* We note that there were delays in the 2023 Benefit Year HHS–RADV Activities Timeline in recognition of issuers facing challenges related to EDGE server operations after the Change Healthcare Cybersecurity Incident.

[105] See 88 FR 25790 through 88 FR 25798.

[106] In the initial years of HHS–RADV, we constrained the ''10th stratum'' of the IVA sample—that is, enrollees without HCCs selected for the IVA sample—to be one-third of the sampled IVA enrollees. In the 2020 Payment Notice, we finalized the extension of the Neyman allocation sampling methodology to the 10th stratum to improve sample precision and permit for a larger portion of the sample to be allocated to the HCC strata. See 84 FR 17494 through 17495.

aligns the IVA sampling methodology with the error estimation methodology and the policies finalized in the 2024 Payment Notice to discontinue the use of the LLPC list and no longer allow non-EDGE claims in HHS–RADV.[107]

Comment: Some commenters that supported the proposal to exclude enrollees without HCCs from the IVA sampling methodology suggested that HHS should not include enrollees without HCCs in IVA sampling because audits should investigate whether issuers are overstating sickness in their population and enrollees without HCCs do not have sickness reflected in their risk adjustment risk scores. Another commenter suggested that including enrollees without HCCs in the IVA sample advantages lower-risk issuers that have more enrollees without HCCs and will face less administrative burden in the medical record retrieval and review process. This commenter expressed concerns that these lower-risk issuers get more opportunities for HCCs to be found while also getting fewer opportunities to fail to validate HCCs under the current methodology, which could limit HHS–RADV's ability to identify lower-risk issuers that are engaging in upcoding and therefore undermine the accuracy of HHS–RADV adjustments to risk adjustment State transfers. Another commenter similarly suggested that the proposal to exclude enrollees without HCCs from IVA sampling would help prevent upcoding.

Response: The purpose of HHS–RADV is to ensure that issuers are submitting accurate, high-quality information to their EDGE servers to be used in the risk adjustment State transfer calculations. We recognize that lower-risk issuers may face less administrative burden than higher-risk issuers when performing HHS–RADV under the current IVA sampling methodology if these issuers have more enrollees without HCCs, and therefore more enrollees without medical records proportionately affecting the Neyman allocation and stratum 10's sample size. However, lower-risk issuers may continue to have less burden than higher-risk issuers under the revised IVA sampling methodology finalized in this rule that excludes enrollees without HCCs. This is because the Neyman allocation will continue to calculate the optimal number to be sampled from each stratum, proportional to each stratum's contribution to the total standard deviation of risk score error in the issuer's population. Each stratum's contribution to the total standard deviation of risk score error in the issuer's population is determined by the stratum's population size, mean risk score, and variance of net risk score error. Therefore, compared to lower-risk issuers, higher-risk issuers may still have relatively more enrollees selected for higher-risk strata if the higher-risk strata contribute relatively more to the total standard deviation of risk score error in the issuer's population. Conversely, lower-risk issuers may still have relatively more enrollees in their IVA samples from lower-risk strata with less HCCs to validate or medical records to review if the lower-risk strata contribute relatively more to the total standard deviation of risk score error in the issuer's population, and therefore would experience a lower burden than higher-risk issuers with respect to medical record retrieval and review. As we explain in more detail later in this final rule, we estimate that issuer burden will decrease on average across all issuers as a result of the finalized changes to the IVA sampling methodology.

In addition, we agree that excluding enrollees without HCCs from the IVA sampling methodology will further ensure that issuers are submitting accurate, high-quality information to their EDGE servers to be used in the risk adjustment State transfer calculations and disincentivize inaccurate coding practices, such as upcoding. However, we note that we have not seen conclusive evidence of upcoding on EDGE. We also believe that the HHS–RADV program serves as a safeguard against upcoding by auditing the issuer's EDGE data and reviewing the supporting medical records to validate enrollee health status. In addition, we note that there are risk adjustment model specifications to mitigate the potential for upcoding, such as the HCC coefficient estimation groups, which reduce risk score additivity within disease groups and limit the sensitivity of the risk adjustment models to upcoding,[108] and we have developed HHS–RADV's error estimation methodology to appropriately account for these model specifications (such as., the HCC coefficient estimation groups).[109]

Comment: Several commenters opposed the proposal to exclude enrollees without HCCs from IVA sampling and some commenters disagreed with or questioned whether the proposal would improve the accuracy of HHS–RADV results. Some of these commenters noted that enrollees without HCCs may be under-coded and HHS–RADV should validate appropriate coding by issuers for all diagnoses—including diagnoses that were not originally submitted to issuers' EDGE servers or supplemental files or HCCs that were not on EDGE—in the sampled enrollees' medical records to appropriately adjust issuers' risk scores. A few commenters suggested that the accurate assessment of a plan's risk score depends on sampling from the issuer's full population during HHS–RADV. One of these commenters noted that many enrollees in issuers' populations have no documented HCCs and noted concern that removing enrollees without HCCs would lead to greater volatility or even increase the number of outlier issuers. One commenter expressed concern that HHS–RADV was only validating HCCs and excluding other components of the risk score, such as RXCs, from validation. Another commenter suggested that removing enrollees without HCCs from HHS–RADV could encourage upcoding and inaccurate risk adjustment coding because issuers would not be able to get failure rate credit for diagnoses identified in HHS–RADV but unreported on EDGE. This commenter also suggested that HHS–RADV encourages coding to the industry average rather than coding with accuracy and noted that if issuers engage in upcoding at similar rates, industry failure rates will increase, coding accuracy will decrease, but HHS–RADV results could remain the same. Other commenters who opposed the proposal suggested that excluding enrollees without HCCs from the IVA sample could unfairly penalize or reward plans based on the risk profile of their high-cost patients and may be short-sighted, as HHS–RADV should help ensure that the actuarial risk and risk scores for both high-risk and low-risk plans are appropriately calculated

[107] See 88 FR 25790 through 88 FR 25798.

[108] See, for example, Section 2.3 of the Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program White Paper (June 17, 2019) available at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.* Note that ''HCC Group constraints'' is synonymous with ''HCC coefficient estimation groups.''

[109] The 2020 HHS–RADV Amendments Rule finalized a policy to ensure that HCCs that share a coefficient estimation group used in the risk adjustment models are sorted into the same failure rate groups by first aggregating any HCCs that share a coefficient estimation group into Super HCCs before applying the HHS–RADV failure rate group sorting algorithm beginning with benefit year 2019 HHS–RADV. See 85 FR 76984 through 76989. The 2023 Payment Notice finalized to extend the application of Super HCCs to also apply to coefficient estimation groups throughout the HHS–RADV error rate calculation beginning with benefit year 2021 HHS–RADV. See 2023 Payment Notice, 87 FR 27208, 27253 through 27256.

and reflected in risk adjustment State transfers.

Response: As explained in the proposed rule (89 FR 82308, 82351), we anticipate that excluding enrollees without HCCs from IVA sampling will improve the precision of issuers' group failure rates for any given sample size by increasing the number of observations used to make statistical inferences. The precision of group failure rates is important as we identify outliers in HHS–RADV based on whether their group failure rates are statistically different from the national benchmarks. As previously noted, the purpose of HHS–RADV is to ensure that issuers are submitting accurate, high-quality information to their EDGE servers as that data is used to calculate risk adjustment State transfers. While it is possible that enrollees without HCCs may be missing diagnoses, issuers are responsible for submitting data to EDGE in accordance with the EDGE Server Business Rules for the applicable benefit year by the established deadline.[110] [111] The validation of HCCs in HHS–RADV aligns with the policies in the EDGE Server Business Rules stating that a risk adjustment eligible diagnosis must be supported by appropriate medical record documentation and linked to a risk adjustment eligible claim accepted by the issuer's EDGE server to validate an HCC in HHS–RADV. Since we finalized discontinuing the use of the LLPC list and non-EDGE claims beginning with 2022 benefit year HHS–RADV, IVA and SVA Entities cannot abstract diagnoses that are not linked to an accepted risk adjustment eligible claim on issuers' EDGE servers. Therefore, it is unlikely that HHS–RADV would identify any missing HCCs for enrollees without HCCs if these enrollees remained in the IVA sample. Furthermore, we clarify that the changes finalized to the IVA sampling methodology in this rule will not affect the review of demographic and enrollment information, as we will continue to validate demographic and enrollment information for a subsample of up to 50 enrollees from the IVA sample, or RXC review, as the HHS–RADV requires review of RXCs for all adult enrollees in the IVA sample with at least one RXC, and we continue to assume that a review will be performed on approximately 50 RXCs per issuer.[112] As explained in the proposed rule (89 FR 82308, 82351), an analysis of available enrollee-level EDGE data from benefit years 2019 through 2022 shows that on average less than 12 percent of an issuer's adult enrollee population with RXCs has no HCCs. Therefore, the vast majority of adult enrollees with RXCs also have HCCs and will therefore still be captured in strata 1 through 3 in the IVA sample and eligible for inclusion in the HHS–RADV RXC validation.

Under the finalized methodology, any enrollees inappropriately coded with diagnoses that map to payment HCCs would fall within the population of enrollees with HCCs and may be selected in the IVA sample. Therefore, we believe this policy ensures that HHS–RADV remains focused on ensuring issuers submit accurate, high-quality information to their EDGE servers to be used in the risk adjustment State transfer calculations and further disincentivizes inaccurate coding practices, such as upcoding. However, as previously noted, we have not seen conclusive evidence of upcoding on EDGE and believe that the HHS–RADV program serves as a safeguard against upcoding by auditing the issuer's EDGE data and reviewing the supporting medical records to validate enrollee health status. In addition, while we acknowledge that issuers are compared to industry coding averages when comparing issuer group failure rates to national benchmarks, issuers with statistically significant group failure rates that are below these national benchmarks may receive negative group adjustment factors to calculate IVA sampled enrollees' adjusted risk scores in error estimation and may be assigned negative error rates such that their more accurate coding practices are reflected in their HHS–RADV results.[113] We therefore continue to believe that the HHS–RADV program encourages accurate coding in issuer EDGE data. In addition, we also believe that some variation and error should be expected in the compilation of data for risk scores, because providers' documentation of enrollee health status varies across provider types and groups, so it may not be reasonable to assume that issuers can achieve group failure rates equal to zero. As such, the primary purpose of identifying statistically meaningful differences between issuers' group failure rates and national benchmarks in HHS–RADV is to avoid the unwarranted application of risk score adjustments.

We also disagree that excluding enrollees without HCCs from the IVA sampling methodology would lead to unfair HHS–RADV results based on the risk profile of issuers' high-cost patients as enrollees with HCCs in the issuer-specific low-risk and medium-risk strata will continue to be sampled and included in the IVA. Moreover, we anticipate that the average proportion of issuers' IVA samples from low-risk strata will generally increase from finalizing the policy to use HHS–RADV data rather than MA–RADV data as the source for the Neyman allocation for IVA sampling.

Finally, we note that the refinements to the IVA sampling methodology, including the policy to exclude enrollees without HCCs, further advance program integrity goals of validating the actuarial risk of enrollees in risk adjustment covered plans to ensure that the HHS-operated risk adjustment program accurately assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. We therefore believe that HHS–RADV will continue to help ensure that the risk scores and risk adjustment State transfers for issuers of high-risk and low-risk plans are calculated consistent with the established methodology and

[110] As explained in 45 CFR 153.730, issuers of risk adjustment covered plans must submit data to be considered for risk adjustment payments and charges for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

[111] Issuers of risk adjustment covered plans remain responsible for ensuring the completeness and accuracy of the data submitted to their respective EDGE servers by the data submission deadline. CMS does not permit issuers to submit additional data or correct data already submitted to their EDGE servers after the applicable benefit year's data submission deadline.

[112] In the 2020 Payment Notice, we finalized piloting the incorporation of RXCs into the HHS–RADV process in the 2018 benefit year, which was the first year that RXCs were incorporated into the risk adjustment models. We also finalized incorporating RXC validation into HHS–RADV as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic, and enrollment errors discovered during HHS–RADV beginning with the 2019 benefit year. See 84 FR 17501. We later extended the pilot years of incorporating RXCs into HHS–RADV to the 2019 and 2020 benefit years of HHS–RADV to increase consistency between the operations of these benefit years' HHS–RADV and facilitate the combination of the HHS–RADV adjustments for these benefit years as we transitioned to a concurrent application of HHS–RADV results. See 85 FR 77002 through 77005.

[113] We also note that the 2020 HHS–RADV Amendments Rule adopted a negative failure rate constraint to mitigate the impact of adjustments that result from outlier issuers with negative failure rates that are driven by newly identified Super HCCs (rather than by high validation rates) beginning with 2019 benefit year HHS–RADV. See 85 FR 76994 through 76998. The 2023 Payment Notice expanded the application of the negative failure rate constraint to constrain the failure rate of any failure rate group in which an issuer is a negative failure rate outlier to zero when calculating the group adjustment factor, regardless of whether the outlier issuer has a negative or positive error rate, beginning with 2021 benefit year HHS–RADV. See 87 FR 27255 through 27256.

requirements based on the data made available to HHS by the applicable benefit year's deadline.

Comment: A few commenters requested clarification on how this change would impact the error rate calculation. One of these commenters requested HHS further investigate the impact of this policy as the commenters believed the impact would vary across issuers depending on the proportion of their enrollee population with HCCs. This commenter requested HHS apply the error rate such that only the plan liability risk score associated with enrollees with HCCs, and not with the total enrollee population, would be adjusted.

Response: Excluding enrollees without HCCs from the IVA sampling methodology does not impact the formula used to calculate issuers' HCC-associated error rates during error estimation. As described in the HHS–RADV protocols, HHS estimates an issuer's HCC-associated error rate using sampled enrollees' adjusted HCC-associated risk scores and HCC-associated EDGE risk scores.[114] Although enrollees without HCCs are currently included in issuers' audit samples, these enrollees have HCC-associated EDGE risk scores equal to zero and cannot have adjusted HCC-associated risk scores. Therefore, enrollees without HCCs are already excluded from the calculation of the HCC-associated error rate, which was explained as one of the reasons for implementing this IVA sampling change in the proposed rule (89 FR 82351).

However, we also note that excluding enrollees without HCCs from IVA sampling will have an impact on the steps in the error estimation methodology during which HCC-associated error rates are applied to adjust issuers' plan liability risk scores. Under the current error estimation methodology finalized in the 2019 Payment Notice[115] and the 2020 HHS–RADV Amendments Rule,[116] and as described in the HHS–RADV Protocols,[117] the HCC-associated error rate, which only describes the proportion of the HCC-related components of the risk score that are believed to be in error, is scaled to apply only to the HCC portion of an issuer's total plan liability risk score, which includes non-HCC and HCC components. To accomplish this, HHS uses the issuer's audit sample, which includes enrollees with and without HCCs under the current IVA sampling methodology, to calculate an HCC-associated PLRS weight and estimate how much of the issuer's plan liability risk score is HCC-related in the issuer population. Therefore, removing enrollees without HCCs from IVA sampling beginning with 2025 benefit year HHS–RADV implies that issuers' audit samples can no longer be used to calculate the appropriate HCC-associated PLRS weight according to the existing formula. As such, before 2025 benefit year HHS–RADV error estimation begins,[118] we intend to continue to consider the impact of the IVA sampling methodology changes in this rule on the HHS–RADV error estimation methodology and will seek comments from interested parties on potential modifications to the intermediate steps in the error estimation methodology to ensure that the HCC-associated error rate continues to apply to only the proportion of the total plan liability risk score that is associated with HCC-components of EDGE risk scores.

Comment: One commenter requested that HHS allot additional time for issuers to complete HHS–RADV, as excluding enrollees without HCCs from the IVA sample will require issuers to validate more HCCs and RXCs, impacting operational resources and capacity.

Response: We do not anticipate that excluding enrollees without HCCs from IVA sampling will prevent issuers from meeting the current timeline associated with HHS–RADV activities. Issuers have complied with the timeline for HHS–RADV activities under the current IVA sampling methodology and should be able to maintain compliance under the finalized IVA sampling methodology where issuer burden is estimated to decrease on average. As discussed in the proposed rule, under the revised IVA sampling methodology, we estimate that issuers will have to submit approximately 2 medical records per enrollee in the IVA sample for IVA review, which is a decrease from the current burden estimates under the existing IVA sampling methodology of 5 medical record requests per enrollee in the IVA sample. In addition, as explained in the Collection of Information section of this rule, we do not anticipate that these changes will affect RXC review, as HHS–RADV requires review of RXCs for all adult enrollees in the IVA sample with at least one RXC, and we continue to assume that a review will be performed on approximately 50 RXCs per issuer.[119]

2. Proposal To Remove the Finite Population Correction (FPC)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82351), we proposed to remove the FPC from the IVA sampling methodology such that, with the exclusion of enrollees without HCCs from IVA sampling, all issuers with at least 200 enrollees with HCCs in their enrollee population would have an IVA sample size of 200. Under this proposal, all issuers with fewer than 200 enrollees with HCCs would have an IVA sample size equal to their population of enrollees with HCCs. See the proposed rule (89 FR 82308, 82351) for a full discussion of the proposal to remove the FPC from the IVA sampling methodology.

As noted in the proposed rule (89 FR 82308, 82352), by including more enrollees with HCCs in these smaller issuers' IVA samples, we would increase these issuers' probability of meeting the 30 Super HCC constraint and improve the precision of group failure rates during error estimation, as well as improve the precision of net risk score error as discussed below. In addition, for small issuers that meet the 30 Super HCC threshold, this proposal would further allow these issuers' risk scores to be appropriately adjusted if they are identified as outliers, and it would allow them to gain additional insights from a richer set of data elements reported in their HHS–RADV results to improve coding practices and EDGE data submission procedures (as applicable). For these reasons, we proposed to remove the FPC beginning with 2025 benefit year HHS–RADV.

We sought comment on the proposal to remove the FPC from the IVA sampling methodology.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our

[114] See Section 13.3.1.3.3 Calculate Error Rates of the BY23 HHS–RADV Protocols available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[115] See the Notice of Benefit and Payment Parameters for 2019; Final Rule, 83 FR 16930 at 16961–16965 (April 17, 2018) (2019 Payment Notice).

[116] See the Amendments to the HHS-Operated Risk Adjustment Data Validation (HHS–RADV) Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program; Final Rule; 85 FR 76979 at 76998–77001 (December 1, 2020) (2020 HHS–RADV Amendments Rule).

[117] See Section 13.3.1.3.3 Calculate Error Rates of the BY23 HHS–RADV Protocols available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[118] Error estimation for 2025 benefit year HHS–RADV is anticipated to begin in Spring 2027 after IVA and SVA Entities submit audit findings for the 2025 benefit year.

[119] For more details on RXC validation, see Section 10.4 Validation of the BY23 HHS–RADV Protocols available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

responses to comments, we are finalizing this proposal as proposed. We summarize and respond to public comments received on the proposal to remove the FPC from the IVA sampling methodology beginning with 2025 benefit year HHS–RADV below.

Comment: Many commenters supported the proposal to remove the FPC from IVA sampling. Several of these commenters suggested that this proposal would contribute to improving sampling precision and the accuracy and integrity of HHS–RADV.

A few commenters were opposed the proposal to remove the FPC. One of these commenters expressed concern that the combined impact of this policy and the policy to exclude enrollees without HCCs from IVA sampling would significantly disadvantage smaller issuers. This commenter noted that smaller issuers are already burdened by a significantly higher per member per month audit cost than larger issuers and stated that these changes would not apply the same audit standard equitably and consistently across issuers. This commenter suggested that a smaller issuer with a total population of 600 enrollees with HCCs could end up with 33 percent of their enrollee population with HCCs sampled for audit by sampling 200 enrollees whereas a larger issuer in the same market might have a total population of 37,000 enrollees with HCCs and end up with less than 1 percent of their enrollee population of HCCs sampled for audit. Another commenter noted that the proposal would likely burden smaller issuers that currently have modified IVA sample sizes less than 200 enrollees by increasing the number of sampled enrollees and medical records.

Response: We are finalizing the proposal to remove the FPC from IVA sampling as proposed and anticipate that this policy will improve the precision of net risk score error and group failure rates. We disagree that the removal of the FPC, combined with the finalization of the proposals to exclude enrollees without HCCs from IVA sampling and replace the source of the Neyman allocation data, will disadvantage smaller issuers over larger issuers. While we recognize that smaller issuers incur costs to hire an IVA Entity and undergo the HHS–RADV, there are other HHS–RADV provisions intended to limit administrative and cost burden on small issuers. Specifically, at § 153.630(g)(1) and (2), we established exemptions from HHS–RADV for issuers with 500 or fewer billable member months (BMMs) Statewide and we established random and targeted sampling for issuers at or below a materiality threshold [120] for the benefit year being audited.[121] For issuers at or below the HHS–RADV materiality threshold, which is set at 30,000 total BMMs Statewide, these costs are only realized for the benefits years that the smaller issuer is selected for HHS–RADV, which is approximately once every 3 years (barring any risk-based triggers that would warrant more frequent audits) under the materiality threshold provision at § 153.630(g)(2).[122] Under the very small issuer exemption at § 153.630(g)(1), an issuer that has 500 or fewer BMMs of enrollment in the individual, small group, and merged market (as appliable) for the applicable benefit year, calculated on a Statewide basis, and elects to establish and submit data to an EDGE server is not subject to the requirement to hire an IVA Entity or submit IVA audits for that benefit year.[123]

To further explain, we adopted these policies in response to concerns regarding the regulatory burden and costs associated with HHS–RADV, particularly for smaller issuers. For example, we explained in prior rulemakings that HHS was adopting a materiality threshold for HHS–RADV to ease the burden of annual audit requirements for small issuers of risk adjustment covered plans.[124] We further explained that we believed this provision was appropriate because the fixed costs associated with hiring an IVA Entity and conducting the audit may be disproportionately high for smaller issuers, and may even constitute a large portion of their administrative costs.[125] Also, we estimated that issuers of risk adjustment covered plans at or below this threshold would represent less than 1.5 percent of enrollment in risk adjustment covered plans nationally, so the effect of the provision on HHS–RADV would not be material. We similarly explained that exempting very small issuers under § 153.630(g)(1) is appropriate because they will have a disproportionally high operational burden for compliance with HHS–RADV.[126] [127] These provisions remain applicable.

In addition, we believe the removal of the FPC will benefit smaller issuers by giving them a better opportunity to increase the count of Super HCCs reviewed in HHS–RADV and gain additional insights from more informative HHS–RADV results to improve coding practices and EDGE data submission procedures. As explained in the proposed rule, we found in recent years of HHS–RADV results that issuers with IVA sample sizes less than 200 enrollees are less likely to meet the 30 Super HCC constraint for outlier identification in a failure rate group. This constraint was first established in the 2021 Payment Notice [128] as standard statistical practice states that sample sizes below 30 observations could result in violations of the assumptions of statistical testing or lead to the detection of more apparent outliers than would be desirable. Because the requirements to participate in HHS–RADV do not depend on issuers' count of Super HCCs, issuers selected for HHS–RADV may incur the costs to participate without having sufficient Super HCCs to make statistical inferences. By increasing the count of Super HCCs, we

[120] Beginning with the 2022 benefit year of HHS–RADV, the materiality threshold under § 153.630(g)(2) was defined as 30,000 total BMMs Statewide, calculated by combining an issuer's enrollment in the individual non-catastrophic, catastrophic, small group, and merged markets (as applicable), in the benefit year being audited. See the 2024 Payment Notice, 88 FR 25740, 25788 through 25790.

[121] See § 153.630(g)(1) and (2). Also see 81 FR 94058 at 94104, 83 FR 16930, 16966, and 84 FR 17454, 17508.

[122] An issuer who meets the criteria and is exempt from the IVA requirements for a benefit year of HHS–RADV under the materiality threshold for random and targeted sampling may be required to make their records available for review and comply with an audit by the Federal Government under § 153.620.

[123] 45 CFR 153.630(g)(1).

[124] See the 2020 Payment Notice, 84 FR 17508 through 17511. Also see the 2019 Payment Notice, 83 FR 16966 through 19697, and the 2018 Payment Notice, 81 FR 94104 through 94105.

[125] See the 2020 Payment Notice, 84 FR 17510. Also see the 2018 Payment Notice, 81 FR 94104 through 94105, and the 2019 Payment Notice, 83 FR 16966 through 19697.

[126] See the 2019 Payment Notice, 83 FR 16966. Also see the 2020 Payment Notice, 84 FR 17508.

[127] These very small issuers who are eligible for the exemption under § 153.630(g)(1) are also not subject to random sampling under the materiality threshold, and therefore would continue to not be subject to the requirement to hire an IVA Entity or submit IVA results for that benefit year. See the 2020 Payment Notice, 84 FR 17508. Issuers who qualify for this exemption are not subject to enforcement action for noncompliance with HHS–RADV requirements and are not assessed the default data validation charge under § 153.630(b)(10) for the applicable benefit year.

[128] Under the outlier identification policy finalized in the 2021 Payment Notice, when HCCs were the unit of analysis of failure rates, an issuer could not be identified as an outlier in any failure rate group in which that issuer had fewer than 30 Super HCCs. See 85 FR 29196 through 29198. In the 2023 Payment Notice, when the unit of analysis of failure rates was altered to de-duplicated Super HCCs, we finalized the policy to not consider an issuer as an outlier in any failure rate group in which that issuer has fewer than 30 de-duplicated EDGE Super HCCs. Issuers with fewer than 30 de-duplicated EDGE Super HCCs in a failure rate group may still be considered an outlier in other failure rate groups in which they have 30 or more de-duplicated EDGE Super HCCs. See 87 FR 27254.

increase the precision of the group failure rates that are used to determine national benchmarks and the probability that issuers will be able to meaningfully compare their calculated group failure rates to the national benchmarks. More specifically, as noted in the proposed rule (89 FR 82308, 82352) we estimate that any issuers receiving the FPC under the current methodology and whose IVA sample sizes would increase under the finalized IVA sampling methodology would see a 35 percent increase in Super HCC count in their IVA samples and a 26 percent increase in group failure rate precision on average across all three failure rate groups.

We also recognize that because IVA sample sizes are limited to 200 enrollees, larger issuers will inherently have smaller proportions of their populations subject to audit, but we disagree that this creates an unequal application of audit standards across issuers. Given the variance in issuer size across issuers of risk adjustment covered plans, it would not be possible to audit equal proportions of issuers' populations. The IVA sampling methodology recognizes this by using the Neyman allocation to optimally allocate each issuer's IVA sample across strata. In addition, while it is possible that a smaller issuer may be burdened by an increased number of sampled enrollees under the finalized policy to remove the FPC, we estimate a decrease in aggregate issuer burden across all issuers as the total estimated number of medical records reviewed per sampled enrollee will decrease, and we note that sample size will not increase for all issuers currently subject to the FPC as some of these issuers have a smaller population of enrollees with HCCs than their previously assigned modified IVA sample sizes that included enrollees without HCCs. For example, an issuer with a total enrollee population of 1,000 would be assigned a sample size of 160 enrollees under the current methodology and using the FPC formula. If this issuer only has a population of 100 enrollees with HCCs, then, under the methodology being finalized in this rule, the issuer's IVA sample size would decrease to 100 enrollees. In addition, we anticipate that the vast majority of issuers who would see increased IVA sample sizes after the removal of the FPC are at or below the materiality threshold for random and targeted sampling and would therefore only be selected for audit approximately once every 3 benefit years (barring any risk-based triggers based on experience that will warrant more frequent audits).[129] [130] Therefore, we believe that the benefits a smaller issuer gains from increased group failure rate precision, as described above, outweigh potential increases in IVA sample size.

3. Proposal To Source the IVA Sampling Neyman Allocation With HHS–RADV Data

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82352), we also proposed to change the current IVA sampling methodology to replace the source of the Neyman allocation data with HHS–RADV data to determine IVA sample strata allocation. To do this, we proposed to no longer use MA–RADV data to calculate the standard deviation of risk score error($S_{i,h}$) for use in the Neyman allocation and instead use a 3-year rolling-window of available HHS–RADV data beginning with 2025 benefit year HHS–RADV.

As noted in the proposed rule, under this proposal, for a given benefit year of HHS–RADV, we would use the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin as the source data for the Neyman allocation and would continue to combine enrollees in each stratum across all issuers to create a national variance of net risk score error to calculate the standard deviation of risk score error ($S_{i,h}$).[131] [132] We proposed to continue calculating $S_{i,h}$ with a national variance of net risk score error, but to use a 3-year rolling window of HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation. Under the proposed approach, we would re-calculate $S_{i,h}$ during each benefit year of HHS–RADV to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before each benefit year's HHS–RADV activities begin. In the context of HHS–RADV, a 3-year rolling window would capture population changes that occur over time while promoting stability in the estimates of $S_{i,h}$ in HHS–RADV year over year.

In the proposed rule (89 FR 82353), we noted that the proposal to use HHS–RADV data rather than the MA–RADV data as the source data for the Neyman allocation would decrease burden on issuers and IVA Entities. More specifically, our analysis found that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data, and that using the HHS–RADV data rather than the MA–RADV data is likely to increase the proportion of the sample in the lower-risk groups and decrease the proportion of the sample in the high-risk group. The estimated change in sampled enrollees means that, under this proposal, issuers would have relatively fewer medical records to review because of the increase in the proportion of sampled enrollees in the lower-risk strata and the decrease in the proportion of enrollees in higher-risk strata. To further explain, this decrease in estimated medical record review would occur because higher-risk enrollees tend to have relatively more medical records to review than lower-risk enrollees. Issuers and their IVA Entities spend time and resources on retrieving, reviewing, and submitting medical records and documentation for HHS–RADV, so the estimated decrease in the average number of medical records reviewed per enrollee in the IVA sample that our analysis found would result from replacing MA–RADV data with HHS–RADV data is expected to lead to a decrease in issuer burden. We further address the estimated aggregate burden impact of all IVA sampling policies being finalized in section III.B.6.a.4 below and the Collection of Information section of this rule.

We sought comment on the proposal to replace the source of the Neyman allocation data for IVA sampling source with HHS–RADV data.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this proposal as proposed. We summarize and respond to public comments received on the proposal to replace the MA–RADV data used in the Neyman allocation for IVA sampling purposes with HHS–RADV data below.

[129] 45 CFR 153.630(g)(2).

[130] Beginning with the 2022 benefit year of HHS–RADV, the materiality threshold under § 153.630(g)(2) is defined as 30,000 total BMMs Statewide, calculated by combining an issuer's enrollment in the individual non-catastrophic, catastrophic, small group, and merged markets (as applicable), in the benefit year being audited. See the 2024 Payment Notice, 88 FR 25740, 25788 through 25790.

[131] A new benefit year of HHS–RADV activities generally begins in the spring the year following the applicable benefit year when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS–RADV for that benefit year. See, for example, the 2023 Benefit Year HHS–RADV Activities Timeline. *https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf*. We note that there were delays in the 2023 Benefit Year HHS–RADV Activities Timeline in recognition of issuers facing challenges related to EDGE server operations after the Change Healthcare Cybersecurity Incident.

[132] As an example, finalizing this policy as proposed, we anticipate using HHS–RADV data from benefit years 2021, 2022 and 2023 for the Neyman allocation for benefit year 2025 HHS–RADV.

Comment: Many commenters supported the proposal to replace the MA–RADV data used in the Neyman allocation for IVA sampling purposes with HHS–RADV data and suggested that the proposal would improve sampling precision or the accuracy of HHS–RADV. A few commenters agreed that using the HHS–RADV data for this purpose would lead to the stratum allocation shifts described in the proposed rule and suggested that the MA–RADV data may lead to oversampling enrollees from the high-risk score groups relative to other groups. One of these commenters stated that the shift to lower-risk strata will be more reflective of the true population and another commenter noted that this shift may reduce administrative burden for issuers with a greater volume of HCCs to validate in their IVA samples. One commenter suggested that this shift may incentivize issuers to focus chart reviews on enrollees with lower risk scores but also recognized that the timing of HHS–RADV may make it difficult for issuers to determine whether these are effective strategies for chart reviews. One commenter expressed general opposition to the proposal to replace the MA–RADV data with HHS–RADV data in the Neyman allocation for IVA sampling.

Response: We agree with commenters that replacing the MA–RADV data used to calculate the standard deviation of risk score error ($S_{i,h}$) in the Neyman allocation for IVA sampling with HHS–RADV data would increase sampling precision, and we are finalizing this change as proposed beginning with 2025 benefit year HHS–RADV. Under this new approach, for a given benefit year of HHS–RADV, we will use the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin to calculate a national variance of net risk score error and issuer's standard deviation of risk score error in the Neyman allocation for IVA sampling purposes. For example, for 2025 benefit year HHS–RADV sampling, we anticipate using the 2021, 2022 and 2023 benefit years of HHS–RADV data for this purpose as they would represent the 3 most recent consecutive years of HHS–RADV whose results would be released before that benefit year's HHS–RADV activities began.[133]

As explained in the proposed rule (89 FR 82308, 82350), we initially chose to use MA–RADV data when calculating a national variance of net risk score error and issuers' standard deviation of risk score error because HHS–RADV data was not available and the MA–RADV program utilizes a similar HCC-based methodology. We reconsidered the use of MA–RADV data in the IVA sampling methodology in the 2019 HHS–RADV White Paper, but we only had data from 1 year of non-pilot HHS–RADV at the time, and we determined that we would need to gather more data from future years of HHS–RADV to perform further analysis.[134] Now, as noted in the proposed rule, we have several years of HHS–RADV data and our recent analysis found that the MA–RADV data yields considerably different sample sizes for each stratum than the HHS–RADV data and using the HHS–RADV data would better capture the true variance in net risk score error in the risk adjustment population. The HHS–RADV data supports sampling low-risk strata more intensely than the MA–RADV data because the HHS–RADV data estimates a greater variance for these groups than the MA–RADV data, so a relatively smaller proportion of the IVA sample will be assigned to the higher-risk strata. Consequentially, we anticipate this change to the source data used for the Neyman allocation for IVA sampling would result in relatively fewer HCCs to validate and medical records to review per enrollee during the IVA for all issuers, on average. We also note that while the Neyman allocation optimizes strata sample size by sampling strata with greater variance more intensely, the number of enrollees sampled from each stratum also depends on each stratum's relative size in the issuer's population. Enrollees will continue to be sampled from low, medium and high-risk strata as we calculate non-zero national variances of net risk score error for strata 1–9.[135] Therefore, issuers should continue to focus on the appropriate coding of all enrollees regardless of enrollee risk score as the purpose of HHS–RADV is to ensure that issuers are providing accurate, high-quality information to their EDGE servers to be used in the risk adjustment State transfer calculations. While HHS sets the standards for HHS–RADV and validates IVA results through the SVA, issuers have different structures, systems and contracts with their IVA Entities which may determine how they prioritize chart retrievals and reviews.

Comment: A few commenters expressed concerns with difficulty retrieving documentation to validate newborn birthweight and noted that this may impact calculating the variance of net risk score error for infant strata in HHS–RADV. One of these commenters requested HHS to exclude the newborn birthweight HCCs when calculating the variance of error for infant strata.

Response: While we recognize commenters' concerns with retrieving documentation to validate newborn birthweight, issuers are required to have the appropriate documentation to substantiate any risk adjustment eligible diagnoses submitted to EDGE. Moreover, we disagree with excluding the newborn birthweight HCCs when calculating the variance of infant strata. The average number of infant enrollees selected in the IVA sample is relatively low and excluding birthweight HCCs could artificially reduce the variance in the infant low, medium and high-risk strata, which in turn would further reduce the representation of infant enrollees in the IVA sample. We believe that using HHS–RADV data to derive stratum variance without excluding any HCCs will ensure that issuers' IVA sample sizes best reflect the relevant risk adjustment population. We therefore decline to exclude the newborn birthweight HCCs when calculating the variance of error for infant strata.

Comment: One commenter who supported the general proposal to no longer use MA–RADV data and begin using HHS–RADV data opposed using a 3-year rolling average and requested HHS instead use the most recent year of HHS–RADV data. This commenter suggested that HHS–RADV policy goals should not aim to make HHS–RADV audits predictable year-to-year and using the most recent year of HHS–RADV data available would help identify any evolving data integrity issues before they lead to competitive disequilibrium. This commenter also stated that continuing to use the MA–RADV data in the Neyman allocation may reduce transfer accuracy and requested HHS to recalibrate IVA sampling using the HHS–RADV data as soon as possible rather than waiting to the 2025 benefit year of HHS–RADV.

[133] Activities related to the 2025 benefit year of HHS–RADV will generally begin in Spring 2026, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2025 benefit year. For the most recently published annual HHS–RADV timeline, see the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* Note that there were delays in the 2023 Benefit Year HHS–RADV Activities Timeline in recognition of the challenges some issuers were facing related to EDGE server operations after the Change Healthcare Cybersecurity Incident.

[134] See Chapter 2: HHS–RADV Initial Validation Audit (IVA) Sampling of the HHS Risk Adjustment Data Validation (HHS–RADV) White Paper (December 6, 2019).

[135] As noted above, we are also finalizing the proposal to exclude enrollees without HCCs from IVA sampling.

Response: We are finalizing the proposal to replace MA–RADV data as the source data for the Neyman allocation for IVA sampling and use of the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities to calculate the standard deviation of risk score error) in the Neyman allocation starting with the 2025 benefit year of HHS–RADV. As explained in the proposed rule (89 FR 82308, 82353), the purpose of using 3 years of HHS–RADV data is to capture population changes that occur over time while promoting stability in the estimates of the standard deviation of risk score error in HHS–RADV year over year and to ensure that all issuers, including smaller issuers that are at or below the materiality threshold at § 153.630(g)(2) that are generally subject to HHS–RADV approximately once every 3 years, are captured when estimating strata variance. The 3-year rolling average for sample design is not intended to make HHS–RADV predictable. Furthermore, using a rolling-window of the 3 most recent consecutive years of HHS–RADV data means that the set of 3 years informing the calculation of stratum variance would change from one benefit year of HHS–RADV to the next. Predicting these annually calculated stratum variance values years in advance would be more difficult under the finalized methodology than the current methodology, which relies on a static year of MA–RADV data to estimate the variance of net risk score error.[136] In addition, the stratum variance would continue to be calculated at a national level, so the impact of any one issuer's behavior on stratum variance is limited. Moreover, using this 3-year rolling-window should capture any new trends in variance that could reflect data integrity issues without immediately abandoning the trends in variance observed in the recent past.

While we anticipate the transition to HHS–RADV data in the Neyman allocation to better reflect the relevant risk adjustment population, we disagree with concerns that continuing to use the MA–RADV data before the 2025 benefit year of HHS–RADV will reduce transfer accuracy. Our analysis of the current HHS–RADV methodology supports acceptable levels of error rate precision, and we are finalizing improvements to the IVA sampling methodology in this final rule to further our program integrity goals of validating the actuarial risk of enrollees in risk adjustment covered plans to ensure that the HHS-operated risk adjustment program accurately assess charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. In addition, the finalized changes to use HHS–RADV data in the Neyman allocation for IVA sampling will require sufficient lead time for HHS to derive coding changes to calculate the national variance of net risk score error for each stratum and issuers' standard deviations of risk score error for each stratum, which are used as an input to the Neyman allocation formula, and to perform testing and quality reviews of the calculations. In addition, as we explained in the proposed rule (89 FR 82406), we considered implementing the change to use HHS–RADV data in the Neyman allocation without the other proposed IVA sampling modifications, and we found that making these modifications in combination would lead to greater improvements in sampling precision and would allow more than 95 percent of issuers to pass the 10 percent sampling precision target at a two-sided 95 percent confidence level. Therefore, we need sufficient lead time to build all changes to the IVA sampling methodology finalized in this rule before issuers' IVA samples can be generated under the methodology finalized in this rule. There would be insufficient time to complete these tasks and implement this change to generate 2024 benefit year IVA samples as 2024 benefit year HHS–RADV activities will generally begin in early 2025. We therefore are finalizing the proposed applicability date and will implement this change beginning with the 2025 benefit year HHS–RADV.

4. Impact of IVA Sampling Proposals

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82353) we noted that in preparation for these proposed changes to HHS–RADV IVA sampling, HHS conducted several analyses to evaluate the impact of these proposals. Our analyses revealed that the proposed modifications to switch data for the Neyman allocation to use the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities begin for the given benefit year, combined with the proposals to remove enrollees without HCCs from IVA sampling and to remove the FPC from the IVA sampling methodology, would improve our ability to reach the 10 percent sampling precision target for net risk score error for a greater proportion of issuers in HHS–RADV.[137] More specifically, when we evaluated the proposed IVA sampling methodology reflecting the changes outlined in the proposed rule, which excludes enrollees without HCCs, removes the FPC, and replaces the MA–RADV data with available HHS–RADV data as the source data for the Neyman allocation, using HHS–RADV data from the 2022 benefit year, we found that more than 99 percent of issuers met the 10 percent sampling precision target for net risk score error at a two-sided 95 percent confidence level.

Our analyses also focused on the impact of the policies on group failure rate precision. Under the proposed changes to the IVA sampling methodology in the proposed rule, our analysis found that approximately 91 percent of all issuers in HHS–RADV would meet the 10 percent group failure rate precision in all three Super HCC groups. Moreover, approximately 87 percent of issuers with IVA sample sizes less than 200 would also meet the 10 percent group failure rate precision target in all three Super HCC groups.

In addition, we anticipated that the proposed changes to the IVA sampling methodology in the proposed rule would result in an overall decrease in the number of medical records reviewed by IVA Entities. Although every enrollee sampled for the IVA would have HCCs, the proportion of enrollees sampled from strata 1 through 9 would change such that enrollees that generally have more medical records are sampled less intensely due to the replacement of MA–RADV data with HHS–RADV data for the Neyman allocation. As mentioned in the proposed rule, the median sample proportion of high-risk adult enrollees, who have more medical records to review on average, could decrease from 39 percent of the sample to 19 percent under the updated IVA sampling methodology reflecting the proposed changes in the proposed rule. We described our estimates of the proposed methodology on issuer burden in more detail in the Collection of Information section of the proposed rule.

As noted in the proposed rule (89 FR 82308, 82354), removing enrollees without HCCs and the FPC, and updating the source of the IVA sampling Neyman allocation data to use HHS–

[136] The HHS–RADV protocols include an estimate for the stratum variance calculated from MA–RADV data and used in the Neyman allocation. See, for example, Section 8.3.3 Validating the IVA Sample Generated by CMS in the 2023 Benefit Year HHS–RADV Protocols.

[137] The precision of net risk score error reflects the ability of the IVA sampling methodology to consistently estimate the percent difference between enrollees' audit risk scores and EDGE risk scores. We provided details on how the 10 percent sampling target was derived in the proposed rule. See 89 FR 82349 through 82350.

RADV data, leads to an IVA sample that improves sampling precision while decreasing burden on issuers and IVA Entities on average. Therefore, we proposed to exclude enrollees without HCCs from IVA sampling such that each enrollee in an issuer's IVA sample must have at least one HCC, remove the FPC, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to the 3 most recent consecutive years of HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin.

We sought comment on the estimated impact of all proposed changes to the IVA sampling methodology. After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments below and on the proposals to exclude enrollees without HCCs from IVA sampling, remove the FPC from the IVA sampling methodology, and replace the source of data in the Neyman allocation from MA–RADV data with HHS–RADV data, we are finalizing all proposed IVA sampling policies as proposed. We summarize and respond to public comments received on the estimated impact of these proposals below.

Comment: Several commenters suggested that the three proposed changes to the IVA sampling methodology would improve the overall accuracy and precision of HHS–RADV results. In addition, several commenters agreed that all proposed changes to the IVA sampling methodology would improve sampling and group failure rate precision. One of these commenters suggested that finalizing the proposed changes would provide a more accurate and inclusive threshold for outlier identification. Another commenter suggested that the IVA sampling proposals would improve the predictability of HHS–RADV.

Response: We appreciate these comments in support of the three proposed changes to the IVA sampling methodology and are finalizing all of these proposed changes as proposed to align sampling with the error estimation methodology and improve sampling precision. We anticipate that the changes will also improve the precision of group failure rates, the national benchmarks used to determine outlier status in each failure rate group, the net risk score error calculations, and will therefore improve the precision of HHS–RADV results used to adjust risk adjustment State transfers. Improving the precision of the IVA sampling methodology with the adoption of the changes finalized in this rule will also further promote the overall integrity of HHS–RADV and confidence in the HHS-operated risk adjustment program.

Comment: One commenter agreed with HHS' assessment that issuer and IVA Entity burden would decrease as a result of the proposed changes to the IVA sampling methodology. However, a few commenters questioned HHS' assessment of burden associated with the proposed changes. One of these commenters suggested that the proposals would unnecessarily increase the administrative burden for issuers and another commenter suggested that there would be a significant burden increase associated with collecting more records from enrollees in lower-risk strata as these enrollees will likely be more heavily sampled if the proposed changes are finalized. This commenter noted that enrollees in lower-risk strata are more likely to see providers who do not provide issuers with direct access to medical records, which could make it more burdensome for issuers to retrieve medical records for these enrollees, especially for smaller issuers. Another commenter noted concern that compliance with the added HHS–RADV audit requirements could place a greater burden on smaller issuers without clarity on how these proposed changes would help patients. One commenter urged HHS to monitor the impact of these changes on burden and consider future changes if there is an undesired impact on HHS–RADV adjustments to risk adjustment State transfers.

Response: As noted in the proposed rule, we estimate that the impact of finalizing all proposed modifications to the IVA sampling methodology will decrease issuer burden on average. Although every enrollee sampled for the IVA would have HCCs, the proportion of enrollees sampled from strata 1 through 9 would change such that enrollees with more medical records are sampled less intensely, and we estimate this would lead to an average decrease in the number of HCCs and medical records reviewed per enrollee. We recognize the commenter's concern that some providers for enrollees from lower-risk strata may provide issuers with less direct access to medical records, but we note that enrollees in lower risk strata are enrollees with fewer HCCs or relatively lower-risk HCCs, for whom issuers should be able to provide supporting medical records for risk adjustment eligible diagnoses submitted to EDGE as required by the EDGE Server Business Rules.[138] The principles for including an HCC in the risk adjustment models require that each HCC represents a well-specified, clinically significant, chronic or systematic medical condition, and therefore, any enrollees with HCCs, regardless of if they are in a lower-risk stratum or higher risk stratum, have conditions that should have supporting medical records.[139] Furthermore, if it is more burdensome to retrieve medical records for enrollees from lower-risk strata, any increase in burden from retrieving these medical records would be offset, at least in part, by the decrease in burden from retrieving fewer medical records for enrollees from higher-risk strata. We also note that enrollees from low, medium, and high-risk strata will continue to be sampled for the IVA and the actual number of enrollees sampled from each stratum will depend on that stratum's contribution to the total standard deviation of net risk score error in the issuer's population.

In addition, we estimate that smaller issuers whose IVA sample sizes may increase under the IVA sampling methodology finalized in this rule are also likely to see the greatest increases in Super HCC counts and group failure rate precision on average across all three failure rate groups. Overall, this contributes to more precise HHS–RADV results and ensures that risk adjustment State transfers reflect verifiable actuarial risk differences between issuers. Moreover, as explained in section III.3.B.6.a.2 above, we anticipate that the vast majority of issuers who would see increased IVA sample sizes after the removal of the FPC are at or below the materiality threshold for random and targeted sampling and would only be selected for audit approximately once every 3 benefit years (barring any risk-based triggers based on experience that will warrant more frequent audits). Therefore, we believe that the benefits a smaller issuer gains from increased group failure rate precision and the estimated overall average decrease in the number of HCCs and medical records reviewed per enrollee outweigh any potential increases in IVA sample size. We also clarify that HHS–RADV does not directly impact patients. The HHS–RADV program helps ensure the integrity of data used in the HHS-operated risk adjustment program to calculate risk adjustment State transfers. The risk adjustment program helps

[138] See, for example, the EDGE Server Business Rules (ESBR) Version 25.0 (December 2024) available at *https://regtap.cms.gov/uploads/library/DDC-ESBR-v25-5CR-120624.pdf*.

[139] See CMS. (2021). *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* Section 1.2.1 (Principles of Risk Adjustment). *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf*.

stabilize premiums across the individual, merged, and small group markets, and thereby helps provide consumers with affordable health insurance coverage options. As with any finalized modifications to HHS–RADV, we will monitor the implementation and impact of these policies. While these changes to the IVA sampling methodology could affect the adjustments to risk adjustment State transfers for an individual issuer, we anticipate that any changes to HHS–RADV adjustments will reflect more accurate actuarial risk differences between issuers.

Comment: One commenter requested HHS to apply the proposed IVA sampling methodology changes to the 2024 benefit year of HHS–RADV and stated that waiting to implement these changes until the 2025 benefit year would allow issuers to adjust their strategies in advance of the audit which would undermine the impact of the audit on data integrity. This commenter also suggested that the typical one-year delay between the year in which HHS–RADV changes are proposed and the applicable benefit year of HHS–RADV should not apply as HHS–RADV adjustments are not relevant to rate setting.

Response: We proposed the IVA sampling methodology changes to apply beginning with the 2025 benefit year of HHS–RADV to reflect the timeline for HHS–RADV activities and the anticipated time needed to test and implement these changes. We disagree that waiting to implement these changes beginning with 2025 benefit year HHS–RADV would undermine the impact of the audit on data integrity. While issuers and their IVA Entities may vary in how they choose to approach changes to HHS–RADV, we believe these policies maintain HHS–RADV's focus on ensuring issuers submit accurate, high-quality information to their EDGE servers to be used in the risk adjustment State transfer calculations. We also clarify that we are not delaying the implementation of these policies to benefit year 2025 because of issuers' timelines for rate setting. Rather, the finalized changes to exclude enrollees without HCCs and use HHS–RADV data in the Neyman allocation for IVA sampling will require sufficient lead time for HHS to derive coding changes to generate samples from EDGE server data that exclude enrollees without HCCs and coding changes to calculate the national variance of net risk score error for each stratum and issuers' standard deviations of risk score error for each stratum, which are used as inputs to the Neyman allocation formula. These IVA sampling changes will also require HHS to update the Audit Tool and perform testing before issuers' IVA samples can be generated under the IVA sampling methodology finalized in this rule. In addition, as we explained in Section III.B.6.a.3 above, we found that making the IVA sampling modifications to exclude enrollees without HCCs, remove the FPC, and replace the MA–RADV data used in the Neyman allocation in unison would lead to greater improvements in sampling precision. Therefore, we need sufficient lead time to build all changes to the IVA sampling methodology finalized in this rule before issuers' IVA samples can be generated under the methodology finalized in this rule. There would be insufficient time to complete these tasks and implement these changes to generate 2024 benefit year IVA samples as 2024 benefit year HHS–RADV activities will generally begin in early 2025. We therefore are finalizing the proposed applicability date and will implement this change beginning with the 2025 benefit year HHS–RADV.

b. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

To improve the sensitivity of the SVA pairwise means test, in the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82354), we proposed to modify the test, which currently uses a paired sample t-test methodology, to use a bootstrapping methodology, and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.[140]

As noted in the proposed rule (89 FR 82354), based on our experience operating HHS–RADV for the past several benefit years, we have reassessed the sensitivity of our pairwise means testing procedure, meaning the ability of the statistical test to identify statistically significant differences between IVA and SVA risk scores when they exist, to see whether changes are needed. Based on our reassessment, we noted that we believe the pairwise means testing procedure should be modified to use a 90 percent bootstrapped confidence interval, rather than a t-test with a 95 percent confidence interval, and to increase the initial SVA subsample level from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV to improve the sensitivity of the pairwise means test, improve the false negative rate and promote the integrity of HHS–RADV.[141] For a full discussion of the proposed changes to the SVA pairwise means test, see the proposed rule (89 FR 82308, 82354).

As we explained in the proposed rule (89 FR 82308, 82355), at a given SVA subsample level, the proposed pairwise bootstrapping methodology would perform 10,000 iterations of resampling with replacement from the enrollees in the issuer's SVA subsample at that level. The average difference between enrollees' IVA and SVA risk scores would be calculated for each resample to build an issuer-specific confidence interval for statistical testing of enrollee's IVA and SVA risk scores. Like the current pairwise means test, if the bootstrapped confidence interval contains zero, the bootstrapping procedure would show non-significant differences between IVA and SVA risk scores, and the issuer would pass pairwise means testing at that SVA subsample level and IVA results would be used in error estimation. If the bootstrapped confidence interval does not include zero, the differences between IVA and SVA risk scores identified would be statistically significant, and the issuer would fail pairwise means testing at that SVA subsample level. In these circumstances, the SVA subsample would be expanded and the pairwise means test conducted at that new SVA subsample level. If the issuer continues to fail the pairwise means test at the SVA 100-level, a precision analysis would be performed to determine whether the SVA audit results from the SVA 100 subsample can

[140] These changes to the SVA framework do not impact or change issuer or IVA Entity obligations or requirements; therefore, we proposed to implement the proposed changes to the SVA pairwise means test starting with the 2024 benefit year HHS–RADV. Activities related to the 2024 benefit year of HHS–RADV will generally begin in March 2025, when issuers can start selecting their IVA entity, and IVA entities can start electing to participate in HHS–RADV for the 2024 benefit year. The SVA typically starts the January 2 years after the applicable benefit year (January 2026 for the 2024 benefit year of HHS–RADV) once issuers' IVA results have been submitted. See HHS. (2024, March 27). For the most recently published annual HHS–RADV timeline, see the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* We note that there were delays in the 2023 Benefit Year HHS–RADV Activities Timeline in recognition of the challenges some issuers were facing related to EDGE server operations after the Change Healthcare Cybersecurity Incident.

[141] As explained in the proposed rule, ''false negatives'' are a detection error that occurs when there are significant differences between IVA and SVA results, but the statistical test does not identify a statistically significant difference between IVA and SVA enrollee risk scores. The conventional minimum power desired for most research settings is 80 percent, which implies a false negative rate of 20 percent. See Cohen, Jacob (1988). *Statistical Power Analysis for the Behavioral Sciences.* Routledge. ISBN 978–1–134–74270–7. pp. 25–27.

be used in error estimation or if the SVA sample needs to expand to the full IVA sample of 200 enrollees with the SVA 200 results used in error estimation.[142] [143] We sought comment on the proposal to modify the SVA pairwise means testing procedure to use a bootstrapped 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the modification to the SVA pairwise means test to use a bootstrapped 90 percent confidence interval and to increase the initial SVA subsample size to 24 enrollees beginning with the 2024 benefit year HHS–RADV as proposed. We summarize and respond to public comments received on modifying the SVA pairwise means testing procedure and increasing the SVA sample size below.

Comment: Several commenters supported the proposal to modify the SVA pairwise means test to use a bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees. Two commenters suggested these modifications would improve the accuracy and precision of HHS–RADV results. One of these commenters stated that the modelling assumptions under the proposed methodology would produce more accurate statistics when the underlying distribution is unknown. This commenter also recognized the effort to balance false negatives and false positives to increase the overall integrity of HHS–RADV.

Response: We agree with the comments in support of this proposal and are finalizing the proposal to modify the SVA pairwise means testing procedure to use a bootstrapped 90 percent confidence interval and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV to improve the sensitivity of the SVA pairwise means test, reduce the false negative rate, and further promote the overall integrity of HHS–RADV. We agree that building confidence intervals using bootstrapping rather than t-intervals is better suited for the SVA pairwise means test as issuers' population distribution of IVA and SVA risk score differences is unknown when conducting the test at any SVA subsample level. As noted in the proposed rule (89 FR 82308, 82355), there is a tradeoff between decreasing the false negative rate and the false positive rate when reducing the size of the confidence interval from 95 percent to 90 percent, but we believe that the benefits in achieving an acceptable rate of false negatives outweighs the potential impacts for any increase in the false positive rate. This is because the SVA methodology provides the opportunity for false positives to be addressed at a later stage of the SVA review process as an issuer failing the SVA pairwise at a given subsample size results in an incremental increase in that issuer's SVA subsample size for further review by the SVA Entity whereas false negatives result in the issuer passing the SVA pairwise test at the subsample size where no significant differences are detected between IVA and SVA results.

Comment: Some commenters opposed the proposed changes to the SVA pairwise means test. One commenter noted that the current SVA methodology has provided consistent results and noted concern that changing the methodology would create unpredictability in HHS–RADV. Another commenter stated that they could not appropriately evaluate the impact of the proposed changes because issuers and IVA entities have little transparency into SVA outcomes because issuers who pass pairwise do not receive SVA results. A few commenters also urged HHS to provide more transparency by releasing SVA results to issuers and their IVA entities when there is sufficient agreement between the IVA and SVA in the SVA pairwise means test. One of these commenters suggested that the current process prevents IVA entities from evaluating their own coding practices and specifically requested that HHS release calculated z-scores with SVA results so that issuers can understand where coding differences occurred that triggered additional levels of SVA review. A few commenters requested that HHS and interested parties take additional time to evaluate the impact of the IVA sampling methodology changes before pursuing changes to the SVA pairwise means testing procedure and sample size approach.

Response: We are finalizing the modifications to the SVA pairwise means test to use a bootstrapped 90 percent confidence interval and to increase the SVA subsample size from 12 to 24 enrollees beginning with benefit year 2024 HHS–RADV as proposed. In the proposed rule (89 FR 82355), we recognized that the increased sensitivity of the bootstrapping methodology could result in more issuers being expanded to larger SVA subsample sizes during pairwise means testing. However, issuers with IVA entities that continue to code according to the relevant coding guidelines and validate HCCs in accordance with the EDGE Server Business Rules and for whom the current pairwise test correctly identifies no significant differences between IVA and SVA results should continue to pass pairwise testing under the modified pairwise testing procedure and SVA subsample size approach finalized in this rule. We encourage all issuers to coordinate with their IVA Entities to study and learn from their HHS–RADV results and experience. In particular, issuers that fail pairwise testing should work with their IVA entities to review the IVA diagnosis abstraction and identify differences from SVA results.

Thus, we also disagree that issuers and IVA entities have insufficient transparency into SVA outcomes to evaluate the impact of the proposed changes to the SVA pairwise testing procedure or their own coding practices. In the proposed rule (89 FR 82308, 82355), we explained the impact of the proposed modifications to increase the initial SVA subsample size to 24 enrollees and use a bootstrapped 90 percent confidence interval on the false negative rate, false positive rate and the overall sensitivity of the pairwise means test, and we sought comment on these proposals. In addition, we disagree that issuers have insufficient transparency into SVA outcomes. HHS does not provide SVA results to issuers or IVA entities that pass pairwise testing because passing signifies that the SVA findings do not significantly differ from IVA findings and that the IVA findings, which issuers review and sign off on, can be used during error estimation as issuers' final accepted audit results.

[142] See Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[143] As explained in the proposed rule (89 FR 82308, 82354), all issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. Under the IVA policies finalized in this rule beginning with benefit year 2025 HHS–RADV, issuers with less than 200 enrollees with HCCs would continue to follow the standard SVA subsample sizes with a maximum SVA subsample size for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis is performed to determine whether the SVA audit results from that maximum SVA subsample size can be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

Issuers and IVA Entities that pass pairwise testing and do not receive an SVA findings report are still able to review key SVA findings, such as the most commonly miscoded HCCs for SVA reviewed sampled enrollees, from each benefit year of HHS–RADV in the results memo.[144] Issuers that do not pass pairwise testing receive SVA findings reports that include details on the enrollee-level HCCs that differed between IVA and SVA review.

Lastly, we note that in finalizing these changes to the SVA processes, we recognize that the paired t-test with a 95 percent confidence interval has been consistently used as the SVA pairwise testing procedure since we started conducting HHS–RADV, but we also note that the consistency or predictability of an issuer's SVA pairwise means test results from one benefit year to the next is not indicative of the effectiveness of the methodology. The SVA pairwise means test is intended to identify whether significant differences exist between an issuer's IVA and SVA results in a given benefit year of HHS–RADV and to determine which audit results should be used for that year's error estimation. We also further clarify that HHS does not calculate z-scores during the current SVA pairwise testing methodology as the current statistical test is a paired t-test.[145] HHS will not calculate z-scores under the finalized SVA pairwise testing methodology beginning with benefit year 2024 HHS–RADV as this statistical test will build bootstrapped confidence intervals.[146]

For these reasons, we disagree with delaying the finalization of changes to the SVA methodology after the finalized changes to the IVA methodology take place as the changes to the SVA methodology are intended to improve the sensitivity of the pairwise means test and the finalized changes to the IVA methodology are specific to IVA sampling and do not address the pairwise means test.

Comment: One commenter inquired about how the estimated costs and estimated improvement in the false negative rate were attributed to modifying the SVA subsample size as opposed to modifying the pairwise means testing procedure. This commenter noted concern that bootstrapping would not address underlying issues associated with smaller sample sizes or could create a false sense of precision at smaller sample sizes and stated that the current t-test is better suited to handle small sample size uncertainty. However, this commenter also suggested that bootstrapping may be appropriate if CMS observes that the rate of false negatives reliably decreases when switching from the t-test to bootstrapping and keeping the confidence interval and sample size constant.

Response: We estimate that approximately 20 percent of the estimated improvement in the false negative rate will be attributable to modifying the initial SVA subsample size to 24 enrollees and approximately 80 percent will be attributable to modifying to pairwise means test to a bootstrapped 90 percent confidence interval.[147] We also estimate that approximately 33 percent of the costs associated with making these changes in 2024 benefit year HHS–RADV will be attributed to transitioning from the current t-test pairwise means testing procedure to the bootstrapped procedure and coding the changes to test and execute the bootstrapping methodology, and the remaining costs will be attributed to increasing the initial SVA subsample size to 24 enrollees.

We are not concerned with a false sense of precision at smaller sample sizes because we are increasing the initial SVA subsample size from 12 to 24 enrollees and our analysis comparing the updated SVA pairwise means test to the current test indicates a lower incidence of false negatives at smaller sample sizes. Moreover, if there is an increase in false positives at smaller sample sizes, the incremental review structure of the SVA allows the opportunity for those false positives to be corrected and for issuers to pass SVA pairwise testing at larger sample sizes such that their IVA results could be used for error estimation.

c. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82356), we proposed to amend § 156.1220(a) to codify a new materiality threshold for HHS–RADV appeals, hereafter referred to as the materiality threshold for rerunning HHS–RADV results.[148] We proposed to amend § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to a successful appeal when the impact to the issuer who submitted the appeal (that is, the filer's) HHS–RADV adjustments to State transfers is greater than or equal to $10,000. We are finalizing these amendments as proposed; the discussion of comments pertaining to this proposal are below in part 156 (§ 156.1220).

C. Part 155—Exchange Establishment Standards and Other Related Standards

1. Solicitation of Comments—Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§ 155.210, 155.215, and 155.225)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82356), we solicited comment regarding how assisters who perform their assister duties in a hospital and hospital system may, within the bounds of the statute, refer consumers to programs designed to reduce medical debt. We thank commenters for their feedback and will take comments into consideration in future rulemaking.

[144] See, for example, Table 1 of the 2022 Benefit Year HHS–RADV Results Memo (May 14, 2024) available at *https://www.cms.gov/files/document/by22-hhs-radv-results-memo-appendix-pdf.pdf.*

[145] For more information on the paired t-test, see Section 11.6.2 Pairwise Means Test to Determine Accepted Results (IVA vs. SVA) of the 2023 Benefit Year PPACA HHS Risk Adjustment Data Validation (HHS–RADV) Protocols (June 4, 2024) available at *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[146] As explained above, the pairwise bootstrapping methodology would perform 10,000 iterations of resampling with replacement from the enrollees in the issuer's SVA subsample at that level. The average difference between enrollees' IVA and SVA risk scores would be calculated for each resample to build an issuer-specific confidence interval for statistical testing of enrollee's IVA and SVA risk scores. If the bootstrapped confidence interval contains zero, the issuer would pass pairwise means testing at that SVA subsample level. If the bootstrapped confidence interval does not include zero, the issuer would fail pairwise means testing at that SVA subsample level. More detail on the pairwise bootstrapping methodology will be provided in the applicable benefit year's HHS–RADV protocols.

[147] The rate of improvement in the false negative rate and how this is attributed to the initial SVA subsample size or the statistical methodology differs depending on the effect size, or the magnitude of the true difference between IVA and SVA results. For these estimates, we use the Cohen's D effect size measure and assume a small effect size. See Cohen, Jacob (1988). Statistical Power Analysis for the Behavioral Sciences. Routledge. ISBN 978–1–134–74270–7. pp 25–27.

[148] For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

2. Ability of States To Permit Agents and Brokers and Web-Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

a. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82357), we addressed our authority under § 155.220 to address misconduct or noncompliance occurring at an agency-level,[149] by undertaking compliance reviews of and enforcement action against an insurance agency's (agency's) lead agent(s), and discussed how we propose to utilize this authority to hold agencies accountable for misconduct or noncompliance with applicable HHS Exchange standards and requirements under § 155.220. We noted that the term lead agent generally refers to any person who registers or maintains a business within a State and/or any person who registers a business NPN with the Exchange, who typically is an executive or person with a leadership role within an agency.

Section 155.220 currently applies to an agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for APTC and CSRs for coverage offered through an Exchange. ''Web-broker'' is defined in § 155.20 as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in § 155.220(c)(3) or § 155.221.[150] Section 155.20 defines ''agent or broker'' as a person or entity licensed by the State as an agent, broker or insurance producer.

In the proposed rule (89 FR 82357), we did not propose amendments to our existing regulations to codify our approach to hold agencies, through their lead agents, accountable for misconduct or noncompliance with applicable standards and requirements in § 155.220 because they can reasonably be interpreted to apply to agencies that are involved in Exchange enrollment transactions, since agencies are entities licensed by a State as an agent, broker, or insurance producer. As such, agencies fall under the current definitions of ''agent or broker'' and ''web-broker'' under § 155.20.

We proposed to rely on the same authorities under § 155.220 to address misconduct or noncompliance occurring at an agency-level, by undertaking compliance reviews of and enforcement action against an insurance agency's lead agent(s). These authorities subject agents, brokers, and web-brokers to compliance reviews and enforcement actions under § 155.220, which allow HHS to periodically monitor and audit an agent, broker, or web-broker to assess their compliance with the applicable requirements of § 155.220.[151] This means that agencies, through their lead agents, would also be subject to section 155.220(g), which sets forth standards for suspension and termination of an agent's, broker's, or web-broker's Exchange Agreements for cause, which ends their participation in the FFEs.[152] These enforcement actions may be taken in three situations: (1) for specific findings or patterns of noncompliance,[153] (2) failure to maintain proper licensure in all States where the agent, broker, or web-broker is assisting consumers,[154] and (3) for engaging in fraud or abusive conduct.[155] Likewise, through their lead agents, agencies would be subject to section 155.220(k), which sets forth penalties other than suspension or termination of the agent's, broker's, or web-broker's Exchange Agreements for the current plan year. If an agent, broker, or web-broker fails to comply with the requirements of § 155.220, HHS may deny an agent, broker, or web-broker the right to enter into Exchange Agreements in future years[156] or impose a civil money penalty as described in § 155.285.[157]

Lastly, HHS may immediately impose a system suspension against an agent or broker if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems.[158] [159] We explained that under this proposal agencies, through their lead agents, would be subject to these enforcement actions too.

The NPN is a unique identifier for an agent, broker, web-broker, or agency that the National Association of Insurance Commissioners assigns during the State licensing application process. The NPN can be recorded as part of the consumer's Exchange eligibility application and is used to track which individual agents, brokers, or web-brokers and agencies assisted Exchange consumers. QHP issuers use the NPN to identify the agent, broker, web-broker, or agency for compensation purposes. Either the NPN of the individual agent, broker, or web-broker assisting the consumer, or the business NPN of the agency, may be listed on the consumer's eligibility application submitted to an FFE or SBE–FP. In the most recent Open Enrollment survey, approximately 4 percent of respondents attested to using a business NPN for all their enrollments.[160] That means at least 640,000 enrollments[161] contained an NPN that did not belong to an individual agent, broker, or web-broker. The NPN, when provided, is a key identifying element in any compliance review under § 155.220(c)(5) or enforcement action by HHS under

[149] For purposes of this policy, ''agency-level'' misconduct or noncompliance refers to misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 associated with an eligibility application or enrollment transaction that lists an agency's National Producer Number (NPN) or that the agency was involved in or facilitated the submission of, or misconduct or noncompliance with HHS Exchange standards and requirements under § 155.220 that involves the agency's lead agent(s) or that the agency endorsed or is otherwise involved in.

[150] The term also includes an agent or broker direct enrollment technology provider. See § 155.20.

[151] 45 CFR 155.220(c)(5).

[152] We notify State Departments of Insurance when we suspend or terminate the Exchange Agreement(s) of an agent, broker, or web-broker under § 155.220(g), per § 155.220(g)(6). We also maintain and publish the Agent and Broker Federally-facilitated Marketplace (FFM) Registration Termination List, which allows QHP issuers, consumers, and other interested parties to search for NPNs associated with agents, brokers, and web-brokers whose Exchange Agreement(s) have been terminated or suspended. See *https://data.healthcare.gov/ab-suspension-and-termination-list.*

[153] 45 CFR 155.220(g)(1).

[154] 45 CFR 155.220(g)(3)(ii).

[155] 45 CFR 155.220(g)(5).

[156] 45 CFR 155.220(k)(1)(i).

[157] 45 CFR 155.220(k)(1)(ii).

[158] 45 CFR 155.220(k)(3). HHS also authority to temporarily suspend the ability of a web-broker to make its non-Exchange website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction. See 45 CFR 155.220(c)(4)(ii).

[159] As detailed in III.C.2.b. of this rule, we are finalizing the proposal to amend § 155.220(k)(3) such that an agent's or broker's ability to transact information with the Exchange in instances in which HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

[160] Open Enrollment Survey, conducted between January 29, 2024, and February 14, 2024.

[161] Based on the PY 2024 enrollment total of 16 million consumers.

§ 155.220(c)(4)(ii), (g)(1), (g)(3)(ii), (g)(5), (k)(1)(i), (k)(1)(ii), and (k)(3).

Under the approach described in the proposed rule (89 FR 82358), when information suggests there is agency-level misconduct or noncompliance, an investigation or compliance review would occur, and enforcement action may be taken. Any such compliance review, or enforcement action would be directed at the agency's lead agent(s), and any other agent, broker, or web-broker who is discovered to be involved in the misconduct or noncompliant activity. When the misconduct or noncompliant activity is occurring at the agency-level, as stated in the proposed rule (89 FR 82358), we believe it is appropriate for the lead agents to be subject to the compliance review, or enforcement action, in addition to the agents, brokers, or web-brokers working at or for an agency that may have been involved in the misconduct or noncompliant activity, as those lead agents are the individuals responsible for directing and/or overseeing their employees' and contractors' behavior and activity. Engaging in compliance reviews and taking enforcement actions against lead agents in these circumstances would ensure that the individuals who are directing and/or overseeing the misconduct or noncompliance are held accountable.

We sought comment on these proposals. In particular, we solicited comments from States as to the specific or unique characteristics of their agency oversight policies and procedures, including how they define or describe the term ''lead agent,'' or whatever term of art each State uses to capture the same individuals who would fall under our definition of ''lead agent'' in this preamble, as well as suggestions from States for ways to enhance collaboration and alignment of our oversight and enforcement of agencies that assist consumers applying for and enrolling in QHPs through the FFEs and SBE–FPs. We also solicited comments from Classic DE and EDE partners, issuers, and other interested parties regarding whether we should consider an agent, broker, or web-broker that allows their NPN to be used by other agents, brokers, or web-brokers to be a lead agent and potentially held responsible for misconduct or noncompliant behavior or activities committed by another agent, broker, or web-broker using their NPN.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this approach as proposed. We summarize and respond to public comments received on the proposed approach to address misconduct or noncompliance occurring at an agency-level by undertaking compliance reviews of and enforcement action against agencies through their lead agents below.

Comment: Many commenters stated this change would protect consumers from noncompliant and fraudulent behavior and support the integrity of the Exchange.

Response: We agree with commenters that this change will better protect consumers and support the integrity of the Exchange. This change will allow HHS to undertake targeted actions—compliance reviews and enforcement actions—against lead agents to address misconduct or noncompliance occurring at an agency-level. Engaging in compliance reviews and taking enforcement actions against lead agents in these circumstances will ensure that the individuals who are directing and/or overseeing the misconduct or noncompliance are held accountable. This, in turn, will help protect consumers on the FFEs and SBE–FPs (Exchanges), reduce fraud and other misconduct and noncompliance on the Exchanges, and improve public trust in the Exchanges as a whole.

Comment: We received one comment noting that a single complaint of potential fraud or misconduct by an agent, broker, or web-broker should be enough to trigger an investigation.

Response: We agree with the commenter in that, depending on the nature of and facts underlying a complaint, one complaint of misconduct or noncompliance by an agent, broker, or web-broker could be enough to warrant an investigation and possible enforcement action under our existing authorities at § 155.220. We have also had conversations with interested parties, including State Departments of Insurance (DOIs), that share that view. We currently investigate and may take enforcement actions in situations where there was only a single complaint of misconduct or noncompliance by an individual agent, broker, or web-broker. For example, we use our authority under § 155.220(g)(3)(ii) to terminate the Exchange Agreements of agents, brokers, and web-brokers where there has only been one licensure complaint directed at them.[162]

We note that our proposal in the proposed rule concerned when we would engage in compliance reviews and take enforcement actions against lead agents for agency-level misconduct and noncompliance, as well as any other individual agents, brokers, and web-brokers involved in that agency-level misconduct and noncompliance. We refer readers to discussion in the proposed rule (89 FR 82358 through 82360) for a more detailed explanation of how we determine whether to engage in compliance reviews and take enforcement actions in these circumstances.

Comment: One commenter expressed concern about taking enforcement actions against lead agents and the implications this would have on downline agents, including downline agents' ability to receive commissions and complete enrollments. These commenters requested that CMS only engage in enforcement actions against lead agents when CMS is sure they were involved in the agency-level misconduct or noncompliance.

Response: We are mindful of the impact that enforcement actions under this proposal may have on an agency's downline agents.[163] We understand that there are different structures and relationships between agencies and their downline agents, brokers, and web-brokers, including single-level call centers, multi-level call centers, as well as agents, brokers, and web-brokers who work for multiple agencies, and that investigating and taking an enforcement action against a lead agent may disrupt some of these relationships.[164] Our goal is not to disrupt these structures, but we understand there may be impact on downline agents, brokers, and web-brokers, including single-level call centers, multi-level call centers, as well as agents, brokers, and web-brokers who work for multiple agencies, while we investigate and potentially suspend and terminate the Exchange Agreements of lead agents engaged in agency-level misconduct or noncompliance. However, as we explained in the proposed rule (89 FR 82357), we believe this enforcement framework is necessary to protect the integrity of the Exchanges, as well as to protect

[162] Sections 155.220(g)(3)(ii) and (l) allow HHS to immediately terminate the Exchange Agreements of an agent, broker, or web-broker for cause if they fail to maintain the appropriate license under State law as an agent, broker, or insurance producer in every State they actively assist consumers with applying for APTC or CSRs or with enrolling in QHPs through the Exchanges.

[163] In this context, ''downline agents'' refers to agents, brokers, and web-brokers who are working for, or with, a lead agent against whom we take an enforcement action, and who may be impacted by that compliance action.

[164] Such disruptions may include forcing an agent, broker, or web-broker to change agencies if the agency stopped working on the Exchanges due to a compliance action, or requiring an agent, broker, or web-broker to use their NPN on instead of an agency's NPN when actively assisting Exchange consumers with enrollment.

consumers from agency-level misconduct that threatens their PII, Exchange coverage, and trust in the Exchanges and the many compliant agents, brokers, and web-brokers who operate on them.

In addition, we note that even if we took enforcement action against an agency's lead agent(s) and terminated their Exchange Agreements, agents, brokers, and web-brokers employed by that lead agent's agency would still be able to assist consumers with Exchange enrollment using their own NPNs or their agency's NPN, assuming the licenses associated with those NPNs have not been suspended or revoked.

We appreciate the commenter's suggestion that we only take enforcement actions against lead agents when we are certain they were involved in the agency-level misconduct or noncompliance at issue. Under the approach we are finalizing, we will take enforcement action against a lead agent when we determine that the lead agent was involved in the misconduct or noncompliance at issue—whether by directing, overseeing, or otherwise participating in it. In addition, we will take enforcement action against a lead agent when we determine that there was agency-level endorsement of or involvement in the misconduct or noncompliance issue. We refer readers to the proposed rule (89 FR 82357) for discussion about why we believe it is appropriate to do so. In either case, we will only consider taking enforcement action against a lead agent when we have discovered information or evidence that indicates the lead agent's involvement in the misconduct or noncompliant behavior or activity at issue.

We will not permit a lead agent to engage in agency-level misconduct or noncompliant behavior or activity merely because there are downline agents or entities that may be impacted by their Exchange Agreement suspension or termination or other enforcement action against them. Doing so would run counter to the consumer protection and program integrity goals that underlie many of our agent, broker, and web-broker enforcement policies, including under § 155.220(g) and (k) in particular. See for example, the 2017 Payment Notice (81 FR 12259), which codified our ability to suspend and terminate an agent, broker, or web-broker's Exchange Agreements under § 155.220(g)(5)(i) ''in cases involving potential fraud or abusive conduct,'' and the 2020 Payment Notice (84 FR 17553), which codified our authority to system-suspend agents and brokers in instances where ''. . . there is a need to take immediate action to protect sensitive consumer data or Exchange systems and operations'' under § 155.220(k)(3). Similar to this proposal, we finalized these policies to protect consumers, their PII, and the integrity of the Exchanges.

Comment: A commenter recommended that CMS consider the volume of consumer complaints submitted to CMS about an agency relative to the volume of Exchange consumer enrollments that the agency is associated with before taking enforcement action against the agency's lead agent.

Response: We appreciate commenter's input. Under our approach, we will consider the volume and subject matter of consumer complaint(s) and other complaints that name or are directed at a lead agent as we determine whether to engage in enforcement action against or a compliance review of the lead agent. In particular, complaints that name an agency's lead agent(s), especially for unauthorized enrollments or other potentially fraudulent or noncompliant activity, could trigger a compliance review or enforcement action against the lead agent(s), as they could indicate agency endorsement of or involvement in misconduct or noncompliant behavior or activities, including inaction by the agency to try to curb the misconduct or noncompliant behavior or activities. We will also look to see if complaints against a lead agent are similar to complaints received against the agency's other agents, brokers, or web-brokers, which could indicate agency-level endorsement of or involvement in the misconduct or noncompliant behavior or activities. We refer readers to the proposed rule (89 FR 82357) for further discussion on the criteria we will consider as we determine whether to initiate a compliance review of or enforcement action against a lead agent and why we believe these criteria are appropriate.

With respect to considering the volume of complaints submitted against an agency relative to the volume of Exchange consumer enrollments the agency is associated with prior to investigating and taking compliance action against a lead agent, we decline to adopt this approach at this time. We currently investigate and take enforcement actions in situations where there was only a single complaint made about an agency or its agents, brokers, and web-brokers, including agencies associated with relatively few Exchange enrollments. We have consistently found that many of these cases involve serious risks to Exchange consumer coverage and PII and the integrity of the Exchange that require immediate action by CMS. We note that ignoring complaints against an agency because the volume of complaints is small relative to the agency's total book of business would be a disservice to consumers and not achieve our program integrity goals of promoting a safe and secure Exchange and reducing fraud and abuse. However, as we develop experience implementing this enforcement framework, we will further consider the commenter's recommendation in future rulemaking as applicable.

Comment: Some commenters expressed concern that we are no longer allowing agents, brokers, and web-brokers to assist consumers with enrolling in Exchange coverage and are allowing unlicensed persons to enroll consumers in Exchange coverage. These commenters were also concerned that we are eliminating the ability of an agent, broker, or web-broker to assist consumers with enrollment face-to-face. Commenters noted that agents, brokers, and web-brokers play a crucial role in helping consumers enroll in Exchange coverage and answering complicated health insurance questions consumers may have.

Response: We agree with commenters that agents, brokers, and web-brokers play a crucial role in helping to enroll consumers in Exchange coverage. Agents, brokers, and web-brokers guide consumers through the Exchange enrollment process, answer questions, and build personal relationships with consumers along the way. Accordingly, as we explain earlier in this final rule, our approach with respect to compliance review and enforcement actions against agencies through their lead agents will not limit the ability of an agent, broker, or web-broker to assist consumers with enrolling in Exchange coverage, including face-to-face whether through a DE pathway or the ''Exchange Pathway'' (whereby an agent, broker, or web-broker sits ''side-by-side'' to assist the consumer with enrollment using the *HealthCare.gov* website).

Instead, this approach clarifies that our current standards and requirements in § 155.220 can reasonably be interpreted to apply to agencies that are involved in Exchange enrollment transactions, since these agencies are entities licensed by the State as an agent, broker, or insurance producer and fall under the current definitions of ''agent or broker'' and ''web-broker'' in § 155.20. Addressing these issues in this rulemaking also clarifies and provides notice to interested parties that we will rely on those same authorities under § 155.220 to address misconduct or

noncompliance occurring at an agency-level by undertaking compliance reviews of and enforcement actions against an insurance agency's lead agent(s).

Similarly, this approach will not allow unlicensed persons to enroll consumers in Exchange coverage. Consistent with § 155.220(a) and the definitions of ''agent or broker'' and ''web-broker'' in § 155.20, agents, brokers, and web-brokers can assist consumers with enrolling in Exchange coverage in a manner that constitutes enrollment through the Exchange only if they are properly licensed in any State they are conducting business as an agent, broker, or insurance producer. Likewise, consistent with the definition of ''web-broker'' in § 155.20 and § 155.221(a)(2), web-brokers who are agents or brokers can only assist consumers with direct enrollment if they are properly licensed in any State they are conducting business as an agent, broker, or insurance producer in and meet the applicable requirements of §§ 155.220 and 155.221.[165] We will continue to monitor consumer enrollments on the Exchange to ensure that agents, brokers, and web-brokers who assist consumers with enrollment in Exchange coverage are properly licensed, and we will continue to leverage our authority under § 155.220(g)(3)(ii) to promptly terminate the Exchange Agreements of any such unlicensed individuals.

Comment: A commenter requested CMS expand the definition of ''lead agent'' to include any agent, broker or web-broker who willingly allows another agent, broker, or web-broker to use their NPN.

Response: We appreciate receiving this comment but have elected not to expand our proposed definition of ''lead agent'' to include agents, brokers, and web-brokers who allow another agent, broker, or web-broker to use their NPN at this time.

The definition of lead agent we are finalizing in this rule includes persons who register and/or maintains a business with a State and/or any person who registers a business NPN with the Exchanges. We developed this definition to identify agents, brokers, and web-brokers at an agency who are typically an executive or in a leadership role. We believe expanding the definition of lead agent as the commenter suggests will expand the pool of potential lead agents subject to compliance reviews and enforcement actions under this framework too greatly; we have observed that it is common for agents, brokers, and web-brokers to allow other agents, brokers, and web-brokers at their agencies to use their NPNs, such as where multiple agents, brokers, and web-brokers actively assist a consumer but use the NPN of the writing agent (one of the aforementioned agents, brokers, or web-brokers) on the eligibility application. Potentially subjecting such a high volume of lead agents to compliance reviews or enforcement actions to address agency-level misconduct or noncompliance may unduly interfere with agency operations and the ability of compliant agents, brokers, and web-brokers to assist consumers with Exchange enrollment, which would run counter to our goals of consumer protection and encouraging Exchange enrollment.

b. System Suspension Authority

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82360), we proposed to amend § 155.220(k)(3), which currently outlines our authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if we discover circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.[166] Specifically, we proposed to add language to reflect that § 155.220(k)(3) system suspensions may be imposed in instances in which we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260,[167] [168] until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. As stated in the proposed rule (89 FR 82360), we believe these amendments are necessary and appropriate Exchange program integrity measures to support the efficient administration of Exchange activities, reduce fraud and abuse, and protect Exchange applicant or enrollee's PII. We also explained in the proposed rule (89 FR 82361) that we were pursuing these amendments in the interest of transparency regarding when HHS may invoke this authority.

In the proposed rule (89 FR 82360), we stated that we continuously monitor for behaviors or activities related to Exchange operations or access to Exchange systems and Exchange enrollee or applicant PII that we believe, based on our experience overseeing agents and brokers on the FFEs and SBE–FPs, may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements. Our experience overseeing agents and brokers on the FFEs and SBE–FPs includes past completed agent, broker, and web-broker investigations and enforcement actions, and observations of behavior by agents and brokers that may not comply with the standards of conduct at § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and that could endanger the accuracy of Exchange eligibility

[165] This framework will not directly impact the existing abilities of issuer and direct enrollment entity application assisters to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. See 45 CFR 155.20. Those assisters remain subject to regulatory requirements at §§ 155.221(d) and 155.415(b). See also Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals final rule (78 FR 54074 through 54075, 54086 through 54087, and 54125 through 54126); and 2020 Payment Notice (84 FR 17525 through 17526).

[166] We did not propose to add a reference to web-brokers in § 155.220(k)(3) as part of these amendments because as DE entities, web-brokers are subject to the system suspension authority at § 155.221(e). See § 155.221(a)(2). As amended in this final rule, § 155.220(k)(3) will be similar to the authority captured at § 155.221(e) that applies to DE entities and permits HHS to immediately suspend the DE entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

[167] Section 155.220(d)(3) requires agents, brokers, and web-brokers to enter into a Privacy and Security Agreement pursuant to which they agree to comply with Exchange privacy and security standards adopted consistent with § 155.260. There are two Privacy and Security Agreements between CMS and the agent, broker, and web-broker for FFEs and SBE–FPs: (1) one is for the individual market FFEs and SBE–FPs, and (2) one is for the FF–SHOPs and SBE–FP–SHOPs.

[168] When consumers call the Marketplace Call Center to report unauthorized enrollments, we resolve their complaints through a combination of the following: (1) we review the complaint to verify that the consumer's plan switch was unauthorized and identify the plan that the consumer wants to be enrolled in; (2) we instruct the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The issuer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing; and/or (3) consumers receive information via an IRS Form 1095–A that is generated by HHS and which the enrollee may send to the IRS to prevent adverse tax implications as a result of the unauthorized plan switch activity.

determinations, applicant or enrollee PII, or Exchange operations or systems in a number of ways.

Consistent with the existing framework, in circumstances where we would impose a system suspension under the proposed amendments to § 155.220(k)(3), in the proposed rule, we explained that we would notify the agent or broker of the suspension and they would have an opportunity to submit evidence and information or to demonstrate that the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction to warrant lifting the suspension to reinstate their system access. We further noted that we would review such evidence and information submitted by the agent or broker to determine if the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to warrant lifting the suspension to reinstate their system access. For example, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers whose system access we would suspend under § 155.220(k)(3). If such evidence or information remedies or sufficiently mitigates the incident, breach, or noncompliance to our satisfaction, we explained that we would lift the suspension and reinstate Exchange system access for the agent or broker.

In cases where such evidence and information does not remedy or sufficiently mitigate the circumstances of the incident, breach or noncompliance to HHS' satisfaction (including situations where there is no response from the agent or broker), we explained that we would not lift the suspension under § 155.220(k)(3) to reinstate the agent's or broker's system access and would pursue a suspension or termination of the agent's or broker's Exchange Agreements under § 155.220(g). We also noted that agents and brokers whose ability to transact information with the Exchange is suspended under § 155.220(k)(3) remain registered with the FFEs and are authorized to assist consumers using the Exchange (or side-by-side) pathway and the Marketplace Call Center, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g).

We stated in the proposed rule (89 FR 82362) that we are pursuing these amendments at this time in light of recent increases in behavior and activity by agents and brokers that indicate potential violations of § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260 and endangers applicant or enrollee PII or Exchange program integrity in a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, enrollees, or Exchange information technology systems.

At the beginning of PY 2024 Open Enrollment, we saw an increase in complaints from enrollees, applicants, and other individuals and entities to the Agent/Broker Help Desk regarding enrollments submitted without enrollee or applicant consent, enrollee or applicant eligibility applications submitted with incorrect information and without enrollee or applicant review or confirmation of the eligibility application information, and changes to enrollee or applicant eligibility applications made without enrollee or applicant consent. These complaints continued to be submitted at a high volume until we implemented system changes targeted at preventing these issues.[169] A significant portion of these complaints have involved unauthorized changes to the plans in which enrollees or applicants were enrolled, impacting the ability of enrollees or applicants to utilize their desired coverage and access care.[170]

Unauthorized plan changes may harm enrollees or applicants by removing them from their selected plan and placing them in another plan that may not provide coverage that meets their needs (for example, different plans can have different formularies and provider networks). Unauthorized enrollments can also involve situations where individuals are enrolled in an Exchange plan without having an existing Exchange plan. Being enrolled in an Exchange plan, including in the case of an unauthorized enrollment, may impact a consumer's future ability to enroll in health insurance through the Exchange or enroll in Medicare or Medicaid, as a consumer generally may not enroll in more than one plan simultaneously. Unauthorized enrollments may also create premium costs for the consumer if the unauthorized enrollment is in a non-zero-dollar premium plan. Unauthorized plan changes and enrollments cost the consumer time to learn about and resolve the discrepancy and either (1) unenroll from a plan they did not want, or (2) change the plan to one that better meets their needs.

Additionally, submission of eligibility applications with inaccurate enrollee or applicant data, such as an incorrect income, may cause harm by providing the enrollee or applicant with an incorrect APTC amount. For example, an incorrect APTC amount can result in a consumer erroneously receiving a zero-dollar monthly premium. Because the consumer does not receive monthly billing notifications due to the zero-dollar premiums, they may not know they were enrolled or that their eligibility application information was incorrect. However, once the consumer files their taxes, a reconciliation may reveal that the consumer must repay the incorrect APTC amount they were receiving. By their nature, these unauthorized enrollments and plan changes, as well as inaccurate eligibility application information submissions, also involve the misuse of enrollee or applicant PII, and they threaten the efficient administration of the Exchange and the accuracy of Exchange eligibility determinations.

Our experience monitoring compliance with the new requirements in § 155.220(j)(2)(i), (ii), and (iii) has also shown that some agents, brokers, and web-brokers [171] are engaging in misconduct or noncompliant behavior or activities. For example, their consumer consent and eligibility application information review documentation often lacks the required content specified in § 155.220(j)(2)(ii) or (iii) that demonstrates the applicant or enrollee has taken an action to provide consent or confirm the accuracy of the eligibility application information prior to submission to the Exchange. For example, we have seen consent documentation that solely lists numbers

[169] CMS. (2024, July 19). *CMS Statement on System Changes to Stop Unauthorized Agent and Broker Marketplace Activity. https://www.cms.gov/newsroom/press-releases/cms-statement-system-changes-stop-unauthorized-agent-and-broker-marketplace-activity.*

[170] When consumers call the Marketplace Call Center to report unauthorized enrollments, we resolve their complaints through a combination of the following: (1) we review the complaint to verify that the consumer's plan switch was unauthorized and identify the plan that the consumer wants to be enrolled in; (2) we instruct the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The insurer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing; and/or (3) consumers receive information via an updated IRS Form 1095–A that is generated by HHS and which the enrollee may send to the IRS to prevent adverse tax implications as a result of the unauthorized plan switch activity.

[171] We did not propose to add a reference to web-brokers as part of the amendments to § 155.220(k)(3) because web-brokers are subject to the system suspension authority at § 155.221(e) applicable to DE entities. See § 155.221(a)(2).

that the agent, broker, or web-broker claims tie back to the consumer's IP address, which we cannot verify and does not meet the consent documentation requirements of § 155.220(j)(2)(iii). Additionally, we have received consent documentation that is merely a name, typed using a cursive script, with no indication or evidence demonstrating the consumer took an action to confirm their consent to the assistance provided by the agent, broker, or web-broker, such as a text message response, email response, or signature.[172] The proposed amendments to § 155.220(k)(3) to permit immediate system suspensions would support HHS' efforts to take immediate action to prevent further enrollee, applicant, Exchange operational, Exchange information technology, or Exchange program integrity harm caused by agents and brokers engaged in these types of misconduct or noncompliant behaviors or activities.

Though, as stated in the proposed rule (89 FR 82362), we believe our current authority in § 155.220(k)(3) allows HHS to implement system suspensions broadly based on circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems, in light of the increasing complaints about unauthorized enrollments, we proposed amendments to § 155.220(k)(3) to increase transparency concerning the reach and application of system suspensions and capture in regulation when HHS may invoke this authority. These proposed amendments would allow HHS to immediately respond to circumstances discovered by HHS that pose unacceptable risks to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems. They would also provide agents and brokers with an increased understanding of our approach to implement system suspensions. The proposed amendments would also better encapsulate the original intent of the § 155.220(k)(3) suspension authority, which included protecting against unacceptable risk to consumer Exchange data.

We noted in the proposed rule (89 FR 82363) that the types of misconduct or noncompliant behaviors or activities that could lead to a system suspension under § 155.220(k)(3) could also lead to an enforcement action under § 155.220(g). However, there are important distinctions between these authorities. For example, system suspensions under § 155.220(k)(3) allow HHS to immediately suspend an agent or broker's system access. These system suspensions differ from agreement suspensions or terminations under § 155.220(g) because system suspensions do not suspend or terminate the agent's or broker's Exchange Agreement(s).[173] Rather, system suspensions prevent agents or brokers from submitting Exchange applications and enrollments through the Direct Enrollment Pathways, whether Classic DE or EDE. However, while a system suspension is in place, the agent or broker remains registered with the FFEs, unless and until their Exchange Agreements are suspended or terminated under § 155.220(f) or (g). As such, a system suspension does not prohibit the agent or broker from assisting FFE and SBE–FP enrollees or applicants via the Marketplace Call Center on a three-way call with the enrollees or applicants or side-by-side with an enrollee or applicant on *HealthCare.gov* (also known as the ''Exchange Pathway'').[174] In cases where there is imminent danger to applicants' or enrollees' PII or to Exchange program integrity in such a manner that poses unacceptable risk to the accuracy of Exchange eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems from the misconduct or noncompliant behaviors or activities of agents or brokers, system suspensions under the proposed amendments to § 155.220(k)(3) would provide a more immediate action to protect applicants' or enrollees' PII and the efficient administration of the Exchange, as well as reduce potential fraud, abuse, and consumer harm.

In contrast, an enforcement action under § 155.220(g) to suspend or terminate an agent's, broker's, or web-broker's Exchange Agreement(s) results in the agent, broker, or web-broker no longer being registered with the FFEs.[175] When an agent's, broker's, or web-broker's Exchange Agreements are suspended, or following the termination of the agent's, broker's, or web-broker's Exchange Agreements, the agent, broker, or web-broker is also no longer permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE or SBE–FP, or assist individuals in applying for APTC and CSRs for QHPs. As such, these agents, brokers, and web-brokers cannot submit Exchange applications and enrollments through any of the available pathways—through Classic DE, EDE, the Marketplace Call Center, and/or through the Exchange pathway.

Though we would only initiate system suspensions under § 155.220(k)(3) against agents and brokers based on data or other information that suggest noncompliance or misconduct, we stated in the proposed rule (89 FR 82363) that we recognize that data or other information could suggest there is noncompliance or misconduct by a compliant agent or broker. For example, in some instances, this could occur if an agent or broker works largely or exclusively with a specific group of consumers, including those who live in low-income communities, communities where life changes necessitating eligibility application changes may be more common, or communities where some consumers may not have Social Security Numbers (SSNs) but are nonetheless eligible for Exchange coverage. Consistent with the existing framework, when pursuing system suspensions, agents and brokers would be notified of the system suspension and would have an opportunity to submit evidence or other information (such as documentation of consumer consent, or documentation demonstrating consumer review and confirmation of the accuracy of the eligibility application information

[172] A typed name using a cursive script, alone, makes it impossible for HHS to determine if the consumer, or their authorized representative, provided consent and typed the signature. In these situations, supplemental documentation is required for CMS to assess compliance with the consent requirements of § 155.220(j)(2)(iii).

[173] Consistent with § 155.220(d), there are currently three Exchange Agreements with CMS that extend to agents or brokers assisting consumers in the FFEs and SBE–FPs: (1) the Agent Broker General Agreement for Individual Market FFEs and SBE–FPs, (2) the Agent Broker Privacy and Security Agreement for Individual Market FFEs and SBE–FPs, and (3) the Agent Broker SHOP Privacy and Security Agreement. Web-brokers assisting consumers in the FFEs and SBE–FPs are required to sign the Web-broker General Agreement, and web-brokers who are primary Enhanced Direct Enrollment (EDE) entities that assist consumers in the FFEs and SBE–FPs are required to sign the EDE Business Agreement and the Interconnection Security Agreement. In addition, each individual agent or broker who wishes to include the business entity NPN on Exchange eligibility applications must also complete the annual registration process, take the required trainings, and sign the applicable Exchange Agreements with CMS for the applicable plan year using their individual NPN.

[174] In this pathway, registered agents and brokers help a consumer obtain an eligibility determination and select a plan directly on *HealthCare.gov.* The consumer creates an account, logs in to the *HealthCare.gov* website with a consumer account, and ''drives'' the process; the agent or broker does not log in to *HealthCare.gov.* Generally, the Exchange Pathway requires the agent or broker to be sitting side-by-side with the consumer because the consumer must sign in to *HealthCare.gov* without sharing their log-in credentials with the agent or broker.

[175] See § 155.220(g)(4) and (5)(iii).

that was created before the application was submitted to the Exchange that is compliant with § 155.220(j)(2)(ii) and (iii)) to demonstrate that the circumstances of the incident, breach, or noncompliance concerns are remedied or sufficiently mitigated to HHS' satisfaction to merit reinstatement of their system access. We noted that where there is clear evidence of compliance, compliant agents and brokers would be able to quickly respond to or otherwise remediate the risks identified by HHS that led to the system suspension under § 155.220(k)(3) such that their system access could be reinstated more swiftly than the lifting of a suspension or reinstatement of an agent's or broker's Exchange Agreement(s) following an enforcement action under § 155.220(g).

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the amendments to the system suspension authority under § 155.220(k)(3) as proposed. We summarize and respond to public comments received on these proposed amendments below.

Comment: Many commenters supported expanding § 155.220(k)(3) as it would reduce noncompliant behavior and protect consumers.

Response: We agree with commenters who supported these proposed amendments and agree it would help reduce noncompliant behavior and protect consumers. As we explained in the 2020 Payment Notice (84 FR 17517),[176] to promote information technology system security in the FFEs and SBE–FPs, including the protection of consumer data, we codified § 155.220(k)(3) to capture HHS' authority to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction. We explained this provision was necessary and appropriate to ensure that HHS can take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers, as well as take immediate action to protect sensitive consumer data.[177] Finalizing the proposed amendments to the system suspension authority in this final rule at § 155.220(k)(3) more closely aligns with this original intent and will better allow us to implement system suspensions in situations that pose unacceptable risk to consumer PII. The amendments to § 155.220(k)(3), which we are finalizing in this rule, will also allow HHS to impose a system freeze suspension in situations where there is noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii), or (iii) and the privacy and security standards under § 155.260, as well as when there is risk to the accuracy of Exchange eligibility determinations, operations, applications, enrollees, or information technology systems. Each of these different situations may cause consumer harm, impact the efficient administration of Exchange activities, and reduce public trust in the Exchange itself.

Comment: Some commenters suggested we consider changing the data metrics and analytics used to engage in system suspensions under § 155.220(k)(3), be more transparent in the process, and resolve these suspensions more quickly. Commenters also expressed concern about the impact our data metrics may have on minority groups and minority agents and brokers, citing potential equity issues and biases in the system.

Response: As explained in the proposed rule (89 FR 82361), we continuously monitor for behaviors or activities related to Exchange operations or access to Exchange systems and enrollee or applicant PII that we believe, based on our experience overseeing agents and brokers on the FFEs and SBE–FPs, may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements. In the interest of transparency, we also shared a non-exhaustive list of data that we currently use to monitor and identify behaviors or activities that may be indicative of misconduct or noncompliance with applicable HHS Exchange standards or requirements, which includes: (1) the number of Exchange transactions submitted to the FFEs or SBE–FPs to change enrollee or applicant eligibility application information or plan selections, (2) the volume of unsuccessful person search activities, (3) the number of submitted eligibility applications with missing SSNs, (4) the number of enrollments submitted within a specified time-frame, and (5) the volume of submitted eligibility applications with NPN changes. We also review and consider complaints from enrollees, applicants, and other individuals or entities concerning agent and broker activities.[178] While none of these items alone may ultimately indicate misconduct or noncompliant behavior or activities, each represents a piece of evidence that we currently utilize to identify behaviors or activities that may be indicative of misconduct or noncompliance and help decide whether a system suspension or other enforcement action is warranted in a particular circumstance. Furthermore, our history of investigations has revealed these data points are good indicators of noncompliant behavior and circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems. For example, a high volume of submissions made during a short timeframe is sometimes the result of scripting or automation, which is prohibited by regulation unless approved in advance by CMS.[179] Allowing agents or brokers to utilize scripting or automation may cause risk to the Exchange information technology systems. Unauthorized activity may cause the system to lag or present security risks to consumer PII. These same data points also offer good indicators of noncompliant behavior and circumstances that pose unacceptable risks to the accuracy of Exchange eligibility determinations, as well as Exchange applicants or enrollees. For example, a high volume of submissions made during a short timeframe may indicate unauthorized enrollments because it is not feasible to discuss this volume of enrollments with that many consumers during this period of time. This could lead to unauthorized enrollments for consumers or cause the consumer to incur future tax liabilities due to incorrect eligibility determinations and an incorrect APTC being applied to their application and enrollment. While the specific data points used would evolve over time in response to changes in the behaviors and activities that create circumstances that pose unacceptable risk to Exchange consumers, Exchange operations, and Exchange systems, we continue to believe that use of these types of data metrics and analytics are necessary and appropriate to protect consumers, reduce fraud and abuse, and support the efficient administration of Exchange activities.

Our experience monitoring and investigating agent and broker noncompliance on the Exchanges that use the Federal platform has shown that

[176] Also see the 2020 Payment Notice proposed rule, 84 FR 272.

[177] Ibid.

[178] Complaints may be submitted to the Marketplace Call Center. See *https://www.cms.gov/files/document/agent/broker-help-desks.pdf.*

[179] See 45 CFR 155.220(j)(2)(vi).

minority or disadvantaged groups are more likely to be targeted by agents and brokers engaged in misconduct or noncompliant activities, including in circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems. For example, noncompliant agents and brokers may target a population segment that does not speak English as a first language and use this language barrier to their advantage. This inevitably can lead to system suspensions against agents and brokers working with these groups.

We further note that we strive to resolve all system suspensions under § 155.220(k)(3) in a timely manner and are committed to expeditiously reviewing the response and information provided by agents and brokers to demonstrate compliance or explain the remedial or mitigation steps taken to address the circumstances identified by HHS that pose unacceptable risks. When a system suspension is imposed under § 155.220(k)(3), the agent or broker receives a notification outlining the circumstances and reasons for the system suspension, as well as offering details on how they may submit a response to remedy or mitigate the identified concerns. As with the existing framework, when pursuing system suspensions under § 155.220(k)(3), as amended, we would continue to notify an agent or broker if a system suspension is imposed and the notice would include information on the circumstances and reasons for the system suspension, as well as their opportunity to submit evidence or other information to remedy or mitigate the circumstances of the incident, breach, or noncompliance concerns. The agent or broker may then submit evidence and information (such as, for example, documentation of consumer consent and documentation of consumer review and confirmation of the eligibility application information that is compliant with § 155.220(j)(2)(ii) and (iii)) to HHS to show that the incident, breach, or noncompliance is remedied or sufficiently mitigated such that reinstatement of system access is warranted.

In addition, we expect that compliant agents and brokers would be able to quickly respond and provide compelling evidence that demonstrates compliance or otherwise offer information on remedial or mitigation steps that address the circumstances identified by HHS that pose the unacceptable risks that led to the system suspension under § 155.220(k)(3) such that their system access would be reinstated swiftly and the length of the system freeze suspension would be relatively short. We also encourage the timely submission of a response with evidence demonstrating compliance or offering information on the remedial or mitigation steps taken to address the circumstances identified by HHS that pose the unacceptable risks to help limit the length of the suspension period. We also remind readers that, as detailed above, system suspensions under § 155.220(k)(3) only restrict an agent's or broker's access to the Classic DE and EDE pathways and the system suspended agent or broker may still help enroll consumers in Exchange coverage using the Marketplace Call Center on a three-way call with the enrollees or applicants, or side-by-side with an enrollee or applicant on *HealthCare.gov.*

After consideration of comments, we are finalizing these amendments as proposed. We continue to believe that system suspensions under § 155.220(k)(3) are a necessary and appropriate program integrity measure that strikes the appropriate balance among the competing interests. Under this framework, the agent or broker has an opportunity to respond and can continue to assist FFE and SBE–FP consumers with the submission of Exchange applications and enrollments during the suspension period, and HHS has the ability to take immediate action to address circumstances that pose unacceptable risks to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems. This oversight and enforcement provision will be used to stop further FFE and SBE–FP enrollments through the Classic DE and EDE pathways to protect consumers and their data, as well as Exchange operations and systems.

Comment: Commenters suggested we allow agents and brokers to provide evidence prior to initiating system suspensions.

Response: We did not propose and decline to adopt changes to our system suspension process to allow an agent or broker to provide evidence prior to imposing a system suspension under § 155.220(k)(3) as that would defeat the purpose of this temporary enforcement measure that provides HHS the ability to immediately respond to circumstances HHS discovers that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems.

As previously explained, the original intent behind § 155.220(k)(3) was to promote Exchange information technology system security and protect consumer data. The proposed amendments, which we are finalizing in this rule as proposed, help further achieve these goals by allowing system suspensions to be immediately implemented when we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260.[180] [181]

Offering an opportunity to provide evidence prior to a system suspension being implemented would leave consumers and the Exchanges that use the Federal platform vulnerable in situations where HHS has identified circumstances that pose unacceptable risk to consumers and the Exchanges that use the Federal platform. System suspensions under § 155.220(k)(3) allow HHS to immediately suspend an agent's or broker's system access and prevents the agent or broker from utilizing the Classic DE or EDE pathways to assist with FFE and SBE–FP applications and enrollments. As previously explained, this program integrity measure offers an enforcement tool that permits HHS to immediately respond to circumstances HHS identifies that pose unacceptable risks as soon as they are discovered. While the option to assist FFE and SBE–FP consumers to apply for or enroll in Exchange coverage using the

[180] Section 155.220(d)(3) requires agents, brokers, and web-brokers to enter into a Privacy and Security Agreement pursuant to which they agree to comply with Exchange privacy and security standards adopted consistent with § 155.260. There are two Privacy and Security Agreements between CMS and the agent, broker, and web-broker for FFEs and SBE–FPs: (1) one is for the individual market FFEs and SBE–FPs, and (2) one is for the FF–SHOPs and SBE–FP–SHOPs.

[181] When consumers call the Marketplace Call Center to report unauthorized enrollments, we resolve their complaints through a combination of the following: (1) we review the complaint to verify that the consumer's plan switch was unauthorized and identify the plan that the consumer wants to be enrolled in; (2) we instruct the issuer offering the plan the consumer wants to be enrolled in to reinstate the consumer's enrollment in that plan as if it had not been terminated. The issuer is instructed to cover all eligible claims incurred and accumulate all cost sharing toward applicable deductibles and annual limits on cost sharing; and/or (3) consumers receive updated information via an IRS Form1095–A that is generated by HHS and which the enrollee may send to the IRS to prevent adverse tax implications as a result of the unauthorized plan switch activity.

Marketplace Call Center or *HealthCare.gov* would continue to be available to system suspended agents and brokers, these enrollment avenues have additional safeguards against misconduct and noncompliant behavior and activities, as the Marketplace Call Center requires the consumer to be on the call with the agent or broker and the agent or broker would need to be sitting with the consumer when using the Exchange pathway.

We believe our system suspension process is efficient, provides sufficient due process to the system suspended agent or broker, and strikes the appropriate balance by allowing the agent or broker to continue to assist FFE and SBE–FP consumers with the submission of Exchange applications and enrollments during the suspension period while also providing HHS authority to take immediate action to address circumstances HHS identifies that pose unacceptable risks to consumers and the Exchanges that use the Federal platform until the circumstances of the breach, incident, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. When a suspension under § 155.220(k)(3) is imposed, the agent or broker will receive a notice informing them of the suspension and providing information on the circumstances and reasons for the suspension, as well as the process for submitting evidence or other information to show that the circumstances of the incident, breach, or noncompliance concerns are remedied or sufficiently mitigated such that reinstatement of their system access is warranted. Our system suspension process is designed to be a narrowly tailored and temporary enforcement approach that stops further FFE and SBE–FP enrollments through the Classic DE and EDE pathways during the suspension period to protect consumers and their data, as well as Exchange operations and systems.

Comment: One commenter expressed concern that system suspensions are not a good enforcement method. The commenter explained that system suspending an innocent agent or broker would cause them harm even though enrollments are permissible using *HealthCare.gov* or by calling the Marketplace Call Center. The commenter further explained their concern was that it is more burdensome to work through these alternative enrollment channels.

Response: We recognize that working with a consumer using *HealthCare.gov* or by calling the Marketplace Call Center may require more coordination, time, and effort than the Classic DE and EDE pathways, however, we continue to believe this trade-off is necessary and appropriate in the context of system suspensions. Section 155.220(k)(3) is designed as a narrowly tailored and temporary enforcement approach that allows HHS in certain circumstances to take immediate action and stop further FFE and SBE–FP enrollments through the Classic DE and EDE pathways during the suspension period to protect consumers and their data, as well as Exchange operations and systems, until such time that the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. We continue to believe it is an important program integrity and consumer protection measure that strikes the appropriate balance between the agent's and broker's interests and desire to continue working with FFE and SBE–FP consumers, and HHS' interests in reducing fraud and abuse, protecting Exchange consumers and their data, and promoting Exchange information technology system security. In addition, as noted above, we expect that compliant agents and brokers would be able to quickly respond and provide compelling evidence that demonstrates compliance or offers information on how they addressed the circumstances identified by HHS that pose unacceptable risks that led to the system suspension under § 155.220(k)(3) such that their system access would be reinstated swiftly and the length of the system freeze suspension would be relatively short.

Comment: A few commenters expressed concern that allowing a noncompliant agent or broker to continue to assist FFE and SBE–FP consumers submit application and enrollments during the suspension period allows them to continue committing further misconduct or noncompliant behavior or activity using the Marketplace Call Center.

Response: We believe the system suspension framework under § 155.220(k)(3), which allows HHS to take immediate action in response to circumstances HHS identifies that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, is a necessary and appropriate program integrity approach that strikes the appropriate balance between the different interests involved. It is designed as a narrowly tailored and temporary enforcement approach that stops further FFE and SBE–FP enrollments through the Classic DE and EDE pathways during the suspension period to protect consumers and their data, as well as Exchange operations and systems, until such time that the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. While the option to assist FFE and SBE–FP consumers to apply for or enroll in Exchange coverage using the Marketplace Call Center or the Exchange pathway remains available to system suspended agents and brokers, these enrollment avenues have additional safeguards against misconduct and noncompliant behavior and activities. For example, the Marketplace Call Center requires the consumer to be on the call for the agent or broker to be able to assist the consumer with the Exchange application or enrollment. Similarly, the Exchange pathway requires the agent or broker to be working side-by-side with the consumer to assist with an Exchange application or enrollment. These enrollment avenues therefore do not pose the same risks to consumers and their data, the accuracy of the Exchange eligibility determinations, or Exchange operations and systems.

Comment: Several commenters stated we need to protect agents who report noncompliant behavior from being suspended themselves.

Response: We encourage any agent, broker, agency, or other entity to report fraud, abuse, and noncompliant behavior or activities that occurs with respect to applications or enrollments to *HealthCare.gov* Exchanges to the Agent and Broker Help Desk, as well as their State DOI, or its equivalent.[182] We take tips seriously and investigate claims of fraud, abuse, and noncompliant behavior or activities involving the *HealthCare.gov* Exchanges. We affirm that we do not engage in compliance actions against individuals for submitting such reports.

Comment: Some commenters stated we should leave all oversight and enforcement of agents and brokers to States and QHP issuers unless we have clear authority from Congress to conduct such oversight and enforcement.

Response: The proposed amendments to § 155.220(k)(3) that we are finalizing in this rule pertains to an agent's or broker's ability to use the Classic DE and EDE pathways to assist consumers with enrollments through the FFEs and SBE–FPs. These proposed amendments are rooted in the authority provided to HHS under the ACA, including section 1312(e), which provides HHS the

[182] The agent broker help desk email is: *FFMProducer-AssisterHelpDesk@cms.hhs.gov.*

authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through Exchanges and (2) assist individuals in applying for APTC and CSRs for QHPs sold through an Exchange. This enforcement tool and regulatory provision is also authorized by section 1313(a)(5)(A) of the ACA, which provides the Secretary with the authority to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the administration of the Exchanges, and section 1321(a) of the ACA, which provides the Secretary authority to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the ACA, including such other requirements as the Secretary determines appropriate. As previously detailed, we continue to believe the system suspension framework in § 155.220(k)(3), including the amendments finalized in this rule, is a necessary and appropriate program integrity measure for HHS to adopt and apply in Exchanges that use the Federal platform. It strikes the appropriate balance between the different interests involved and is narrowly tailored to protect consumers and their data, as well as Exchange operations and systems, until such time that the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. We affirm that it does not otherwise interfere with State authority to oversee or monitor compliance and take enforcement actions with respect to agents and brokers who are licensed to do business in their jurisdiction. However, HHS is responsible for protecting Exchange consumers and promoting Exchange information technology system security, which extends to ensuring compliance with applicable HHS Exchange standard and requirements by agents and brokers participating in the FFEs and SBE–FPs. We therefore generally disagree with the comments suggesting that we should leave all oversight and enforcement of agents and brokers to the States, but we intend to continue to conduct our investigations and enforcement related to the conduct of agents and brokers with respect to applications and enrollments submitted to the FFEs and SBE–FPs in coordination with States.

In response to the comment about QHP issuer responsibility with respect to their affiliated agents and brokers, we affirm that, consistent with § 156.340, each QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to the Exchanges. For QHP issuers participating in Exchanges that use the Federal platform, this includes being responsible for their downstream and delegated entities' compliance with the standards of § 155.220. Section 156.430(b)(5) also makes it clear that downstream and delegated entity are obligated to maintain Exchange-related records and comply with the relevant Exchange authority's demand to receive the entity's books, contracts, computers or other electronic systems relating to the QHP issuer's obligations in accordance with applicable Federal Exchange standards. Similar to our approach with the States, we intend to continue to coordinate with QHP issuers participating in Exchanges and share information, as appropriate, regarding our agent and broker enforcement and oversight activities.

Comment: Some commenters recommended that we should report system suspensions to State DOIs, QHP issuers, and the public. Commenters also recommended mandating that agents and brokers who are system suspended disclose this to consumers they are working with.

Response: We appreciate these comments and are committed to coordinating with the States and QHP issuers with respect to enforcement and oversight of agents and brokers, as well as sharing information with the public about these activities, as appropriate. Our regulations currently require HHS to notify to the State DOIs or equivalent State licensing authorities in cases of Exchange agreements suspensions or terminations under § 155.220(g).[183] Information on the status of an agent or broker's registration and Exchange Agreements is also made available to the public, updated on a monthly basis, and may be used or disclosed for certain limited purposes.[184] Our regulatory framework, however, does not currently provide for the sharing of information on system suspensions under § 155.220(k)(3).We further note that we currently work closely with State DOIs to coordinate our enforcement activities when we identify an agent's or broker's behavior or activities that poses unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants or enrollees, or Exchange information technology systems. Furthermore, if the agent or broker does not respond to our outreach or their response does not sufficiently mitigate the circumstances that led to the system suspension, we would likely move to terminate or suspend the agent's or broker's Agreements under § 155.220(g)(1) or (g)(5), respectively. If the issue is not resolved to HHS' satisfaction after sending the notice of intent to terminate under § 155.220(g)(1), or at the time we send the Exchange Agreement suspension or termination notice under § 155.220(g)(5), we would notify the State DOIs or other equivalent State licensing authorities as required by § 155.220(g)(6).

We respectfully disagree with commenters who believe agents or brokers who are system suspended should be required to disclose this fact to consumers. Requiring such disclosure at this point in the process may confuse consumers or cause unwarranted concerns. By system suspending the agent or broker, we have helped reduce the risk of noncompliant behavior by requiring the agent or broker to assist consumers working side-by-side through the consumer pathway on *HealthCare.gov* or via a three-way call with the Marketplace call center. We believe restricting access to the Classic DE and EDE pathways during the suspension period mitigates the concern sufficiently while we investigate the circumstances that led to the system suspension. Since these agents and brokers are still permitted to assist consumers with enrolling in coverage through the FFEs and SBE–FPs through the consumer pathway on *HealthCare.gov* and a three-way call with the Marketplace call center, it would be confusing for consumers to be notified about the system suspension. Furthermore, if the agent or broker does not respond to our outreach or their response does not sufficiently mitigate the circumstances that led to the system suspension, we would likely move to terminate or suspend the agent's or broker's Exchange Agreements under § 155.220(g)(1) or (g)(5), respectively. If the issue is not resolved to HHS' satisfaction after sending the notice of intent to terminate under § 155.220(g)(1), or at the time we send the Exchange Agreement suspension or termination notice under § 155.220(g)(5), we would notify the State DOIs or other equivalent State licensing authorities as required by § 155.220(g)(6).

Comment: We received comments stating that when an agent is system suspended under § 155.220(k)(3), we

[183] 45 CFR 155.220(g)(6).

[184] The Suspension and Termination List can be found here: *https://data.healthcare.gov/ab-suspension-and-termination-list.*

should ensure they are unable to utilize State Exchanges.

Response: We appreciate these comments and generally encourage State Exchanges that elect to operate a DE program, as part of their oversight of the agents and brokers assisting consumers in their respective States apply for and enroll in coverage in a manner that constitutes enrollment through their Exchange, to adopt a system suspension framework similar to § 155.220(k)(3). It is one of the important features of HHS' oversight of agents and brokers participating in the FFEs and SBE–FPs that protects consumers data, safeguards Exchange operations and systems, and helps reduce fraud and abuse. When HHS imposes a system suspension under § 155.220(k)(3), a system suspended agent or broker is unable to utilize the Classic DE or EDE pathways available in FFE and SBE–FP States to enroll consumers in coverage in a manner that constitutes enrollment through the Exchange. State Exchanges that do not use the Federal platform utilize their own systems and are responsible for overseeing and ensuring compliance by the agents and brokers assisting Exchange consumers in their State, including participation in any DE program the State Exchange elects to establish.[185] We therefore did not propose and are not finalizing the extension of the system suspension framework under § 155.220(k)(3) to State Exchanges that do not use the Federal platform; however, we continue to encourage adoption of a similar framework if a State Exchanges that does not use the Federal platform elects to establish a DE program.

Comment: Some commenters expressed concern that suspensions may prevent them from being paid commissions and that we should keep any withheld commissions in a trust that would be payable to the agent or broker upon the suspension being lifted.

Response: We appreciate these comments and generally note that the system suspensions implemented under § 155.220(k)(3) do not result in the suspension or termination of the agent's or broker's Exchange Agreements. As such, a system suspension by HHS under § 155.220(k)(3) should not have an impact on the agent's or broker's ability to receive commissions for FFE and SBE–FP enrollments. In addition, HHS does not set compensation levels or pay commissions to agents or brokers for assistance provided to Exchange consumers. Agents and brokers who participate in the Exchanges receive compensation directly from the QHP issuers they are affiliated with in accordance with their agreements with those issuers and any applicable State-specific requirements. Agents and brokers should work directly with their QHP issuers to resolve any questions or concerns with respect to commissions or other compensation they believe they are owed. We did not propose and decline to adopt an approach whereby we would start collecting and holding in trust commissions withheld by QHP issuers.

c. Model Consent Form Updates

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82363), we proposed to modify the model consent form that was created as part of the 2024 Payment Notice (88 FR 25809 through 25811).[186] Our proposed modifications included updating the model consent form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information under § 155.220(j)(2)(ii)(A)(1)–(2), as well as scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

Agents, brokers, and web-brokers are required to obtain consumer consent prior to assisting with and facilitating enrollment in coverage through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs. Until we finalized new requirements related to consumer consent in the 2024 Payment Notice, there was no mandate to document the receipt of consent of the consumer or their authorized representative, or to maintain such documentation. The absence of a consent documentation requirement led to disputes between consumers and agents, brokers, and web-brokers that were difficult for us to adjudicate because neither party had documentary proof of consent. In the 2024 Payment Notice (88 FR 25809 through 25811), we finalized regulations requiring receipt of consent of the consumer or their authorized representative to be documented.[187] Under these regulations, the consent documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(iii)(B) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(iii)(C). Our goal in codifying these consent documentation requirements was to minimize the risk of fraudulent activities, such as unauthorized enrollments, and help us resolve disputes and adjudicate claims related to the provision of consumer consent.

We also finalized regulations in the 2024 Payment Notice (88 FR 25804 through 25809) requiring agents, brokers, and web-brokers assisting with and facilitating enrollment in coverage through FFEs and SBE–FPs or assisting an individual with applying for APTC and CSRs for QHPs to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to application submission.[188] Under these regulations, this documentation must contain certain minimum elements as enumerated in § 155.220(j)(2)(ii)(A)(1) and must be retained by the assisting agent, broker, or web-broker for a minimum of 10 years and produced to HHS upon request in response to monitoring, audit, and enforcement activities pursuant to § 155.220(j)(2)(ii)(A)(2). Our goal in codifying these requirements was to minimize the risk of fraudulent activities, such as providing false information to the Exchange, help us resolve disputes and DMIs and adjudicate claims related to inaccurate eligibility information on submitted applications, and ensure consumers receive accurate eligibility determinations and do not receive incorrect APTC determinations, which may result in consumers owing money during tax reconciliation.

The model consent form[189] created and provided to agents, brokers, and

[185] In the 2025 Payment Notice, we finalized the extension of certain HHS minimum standards governing web-broker and DE entities across all Exchanges to newly apply them to State Exchanges that do not use the Federal platform. See 89 FR 26276 through 26298. The framework adopted in the 2025 Payment Notice also provided State Exchanges with continued flexibility and discretion to decide whether and how to structure their respective web-broker and direct enrollment programs. Ibid. It also affirmed the State Exchange's role with respect to oversight and enforcement with respect to the entities it permits to assist its consumers, and HHS' role overseeing the Exchange's compliance with the applicable Federal requirements. See 89 FR 26276 through 26298.

[186] CMS. (2022, December 14). CMS model consent form for Marketplace Agents and Brokers. PRA package (CMS–10840, OMB 0938–1438). *https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.*

[187] 45 CFR 155.220(j)(2)(iii).

[188] See § 155.220(j)(2)(ii).

[189] CMS. (2022, December 14). *CMS model consent form for Marketplace Agents and Brokers.* PRA package (CMS–10840, OMB 0938–1438). *https://www.cms.gov/files/document/cms-model-consent-form-marketplace-agents-and-brokers.pdf.*

web-brokers on June 30, 2023, has been used by agents, brokers, and web-brokers, either as is or as a starting point for creating their own consent documentation. However, no model consent form was created for agents, brokers, and web-brokers to use to meet the documentation of consumer review and confirmation of the accuracy of the eligibility application information requirements enumerated in § 155.220(j)(2)(ii)(A)(1). Since the 2024 Payment Notice requirements went into effect, agents, brokers, and web-brokers have asked us to provide a model documentation that they could use to meet these requirements under § 155.220(j)(2)(ii). In the proposed rule, (89 FR 82364), we proposed to update the model consent form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information in response to these requests. This addition to the model consent form is meant to provide clarity to agents, brokers, and web-brokers on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply with this regulation by providing a standardized form they may use to do so. Furthermore, we stated in the proposed rule (89 FR 82364) that we believe providing a clearly written model consent form would provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii).

Because the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) can be met via an audio recording, we also proposed (89 FR 82364) to create appendices to the model consent form that would contain scripts agents, brokers, and web-brokers may use to document compliance with these requirements via an audio recording. We stated in the proposed rule (89 FR 82364) that our goal is to provide agents, brokers, and web-brokers who assist consumers verbally with guidance on meeting the consent and eligibility application review documentation requirements contained in § 155.220(j)(2)(iii) and (j)(2)(ii)(A), respectively, similar to how the current model consent form helps agents, brokers, and web-brokers documenting consent via a physical document with handwritten signatures demonstrate compliance with the new consent documentation requirements.

In the proposed rule (89 FR 82364), we stated that the proposed scripts, to the extent they are utilized by agents, brokers, and web-brokers, would help ensure agents, brokers, and web-brokers are following the regulatory requirements when enrolling consumers. We further stated that we believe this would reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment. We also stated that we believe this proposal would clarify and simplify how regulated entities can meet regulatory requirements. The proposal did not involve any revisions to § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A) through (C). Lastly, we stated that if finalized as proposed, it would not be mandatory for agents, brokers, or web-brokers to use the amended model consent form or new scripts to comply with the requirements set forth in § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A) through (C).

We sought comment on these proposals.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the modifications to the model consent form as proposed. We summarize and respond to public comments received on the modifications to the model consent form below.

Comment: Some commenters supported updating the model consent form, stating this would provide clarity to agents, brokers, and web-brokers, and help ensure consumers' enrollment applications include correct information.

Response: We agree with commenters that these updates will provide more clarity and assurance to agents, brokers, web-brokers, and agencies on how to meet the applicable regulatory requirements and more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with the applicable regulatory requirements.

Comment: Some commenters stated that we should not mandate audio recording of enrollments and should not require agents, brokers, or web-brokers to use our scripts as this would be especially burdensome to smaller agents, brokers, web-brokers, or agencies.

Response: While agents, brokers, and web-brokers can meet the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) via an audio recording, this is just one type of documentation that is considered to be acceptable under these sections, and there is no mandate that an audio recording be used to meet these requirements. Agents, brokers, and web-brokers may use any method they wish to meet the consent documentation requirement and review and confirmation of the accuracy of eligibility application information requirement, provided the minimum information required by the regulations is captured in this documentation and the documentation can be maintained for a minimum of 10 years and produced to CMS upon request. In addition, as noted in the proposed rule (89 FR 82364), it would not be mandatory for agents, brokers, or web-brokers to use the amended model consent form or new scripts to comply with the requirements set forth in § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A) through (C).

Comment: A commenter requested clarification on whether the updated model consent form, if finalized, would invalidate consumer consent obtained and documented using the previous model consent form.

Response: If an agent, broker, or web-broker obtained consumer consent using the previously released model consent form, the consent and the documentation of such consent would still be valid if the consent documentation complies with the regulatory requirements at § 155.220(j)(2)(iii) and the consent has not expired or been rescinded.

3. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for 2 Consecutive Tax Years (§ 155.305)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (88 FR 82308 through 82411), we proposed changes and updates to the failure to file and reconcile (FTR) process at § 155.305(f)(4). Specifically, we proposed that all Exchanges, including State Exchanges, would be required to send notices to tax filers or their enrollees for the second, consecutive tax year in which they or their tax filer failed to reconcile APTC. This notice, when sent to the tax filer, would serve as an additional warning to inform and educate tax filers that they need to file their Federal income taxes and reconcile their APTC or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year. The notice, when sent to enrollees, would indicate the importance of filing Federal income taxes and reconciling APTC on Form 8962 in order to remain eligible for APTC, without disclosing tax information about an individual tax filer. We are finalizing this policy as proposed.

As part of the 2024 Payment Notice (88 FR 25814 through 25816), we changed the FTR process such that an Exchange may only determine enrollees

ineligible for APTC due to their FTR status after a tax filer (or a tax filer's spouse, if married) has failed to file a Federal income tax return and reconcile their APTC for 2 consecutive years (specifically, years for which tax data will be utilized for verification of household income and family size). In the 2025 Payment Notice (89 FR 26218 through 26426), we imposed a requirement for Exchanges to send direct or indirect notices for the first year in which the tax filer was determined to have failed to file and reconcile. A direct notice to the tax filer provides a warning to inform and educate the tax filer that they need to file and reconcile, or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year. An indirect notice, also sometimes referred to as a ''combined notice,'' contains general, broad language regarding FTR that complies with the prohibition on sending Federal tax information (FTI) in circumstances where the household contact or enrollee is not the tax filer. However, in the 2025 Payment Notice, we did not impose a requirement for Exchanges to send a direct or indirect notice enrollees or their tax filer about the second consecutive year that the applicable tax filer failed to file and reconcile. In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82364), we proposed to revise § 155.305(f)(4) to require Exchanges to send a direct or indirect notice to enrollees or their tax filer who have not filed their Federal income tax return and reconciled their APTC for 2 consecutive tax years.

Under the policy finalized in this rule, Exchanges on the Federal platform will continue to send notices to enrollees or their tax filers for the second consecutive tax year in which the tax filer has failed to reconcile APTC. State Exchanges that operate their own eligibility and enrollment platforms will be required to send either one of these notices and may send an indirect notice to the tax filer if desired. Our policy to codify this practice for Exchanges on the Federal platform and require State Exchanges to notify either an enrollee or their tax filer as described above, ensures that tax filers who have been determined to have FTR status for 2 consecutive tax years are adequately educated on the file and reconcile requirement, and have ample opportunity to file their Federal taxes and reconcile APTC before they lose APTC. This policy supports compliance with the filing and reconciling requirement under section 36B(f) of the Code and its implementing regulations at 26 CFR 1.36B–4(a)(1)(i) and (a)(1)(ii)(A), minimizes the potential for APTC recipients to incur large tax liabilities over time, and supports eligible enrollees' continuous enrollment in Exchange coverage with APTC by avoiding situations where enrollees become uninsured when their APTC is terminated because they were unaware of the requirement to file and reconcile. Additionally, this policy better aligns State Exchanges' FTR processes with that of the Exchanges on the Federal platform by ensuring that consumers will receive at least one FTR notice per year before being found ineligible for APTC. We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed at § 155.305(f)(4)(ii) to require all Exchanges to send direct notices to a tax filer alerting them of their FTR status, or to send informative indirect notices that do not contain FTI either to the enrollee or their tax filer, if through the income verification processes described in § 155.320, they have been found to have failed to reconcile their APTC for 2 consecutive tax years. Section 155.305(f)(4)(ii)(A) describes the requirements for sending the direct notice to the tax filer, including that Exchanges must send the notice consistent with the standards applicable to the protection of FTI. Section 155.305(f)(4)(ii)(B) describes the requirements for sending the indirect notice, which must not convey FTI. We summarize and respond to public comments received on the proposed policy below.

Comment: The majority of commenters supported the proposal requiring an Exchange to notify enrollees and their tax filers of their FTR status when they are identified as having failed to reconcile for 2 consecutive tax years. Several of these commenters cited its positive impact on continuity of coverage for consumers enrolled in Exchange coverage.

Response: We agree with commenters that the proposed FTR policy will have a positive impact on enrollee retention of APTC and Exchange coverage by ensuring enrollees and their tax filers are informed of the tax reconciliation requirement or of a potential FTR status.

Comment: A few commenters opposed the proposal requiring Exchanges to send FTR notices to enrollees who have a 2-year FTR status. These commenters believe that it is not the role of Exchanges, but rather of the Internal Revenue Service (IRS), to conduct FTR because the IRS has the ability to send direct notices that more specifically address a tax filer's FTR status. These commenters stated that indirect notices are less effective because they cannot disclose FTI.

Response: We disagree with commenters that the IRS is the correct agency to provide FTR notifications. Exchanges are well-suited to send FTR notices because they already send a variety of notices about Exchange coverage to QHP enrollees, both through mail and Exchange portals, including direct and indirect notices to enrollees or their tax filer who have failed to file and reconcile for 1 tax year. These notices sent by the Exchange have proven effective, as, historically, the majority of consumers identified in the failure to file and reconcile process have successfully filed and reconciled to prevent the loss of their APTC. State Exchanges are afforded the flexibility to choose to send direct notices in certain situations, but also can choose to send indirect notices in situations where sending a direct notice that protects FTI is not feasible.

Comment: A few commenters supported the proposal but stated that the FTR process overall is flawed, overly punitive to consumers by removing APTC, and a threat to continuity of coverage. They also stated that the IRS already has the adequate tax enforcement tools and, as such, these commenters recommended repealing the FTR process entirely.

Response: We acknowledge the concerns that commenters have raised that FTR is overly punitive to consumers. However, the changes that HHS has implemented in this rule, as well as the changes finalized in the 2024 Payment Notice and the 2025 Payment Notice, properly balance consumer protections and program integrity protections. Therefore, we maintain that we should continue to improve the FTR process rather than repeal FTR entirely.

Comment: A few commenters stated that HHS should fully repeal FTR processes because there is no statutory authority for it.

Response: We disagree with commenters that there is no statutory authority for Exchanges to conduct FTR. Consumers who receive APTC are required to file income taxes pursuant to § 6011(a) of the Code and regulations prescribed by the Secretary of Treasury. Section 36B(f) of the Code requires taxpayers to reconcile their APTC under section 1412 of the ACA with their PTC allowed under section 36B of the Code. FTR regulations, implemented pursuant to the Secretary's general rulemaking authority under section 1321(a) of the

ACA, facilitate compliance with those requirements.

Comment: A few commenters stated that requiring Exchanges to provide a direct FTR notification to their consumers would be overly burdensome.

Response: We understand the concern raised by commenters regarding increased burden for Exchanges to provide these FTR notifications. However, States have flexibility under § 155.305(f)(4)(ii)(B) to provide either a direct notice that discloses FTI or an indirect notice that does not disclose FTI to their consumers, and we are not requiring Exchanges to provide direct notices in this final rule.

Comment: One commenter requested that HHS provide technical guidance on developing indirect notices for Exchanges that do not want to store any FTI. In addition, the commenter also requested HHS to consider a phased implementation approach that accounts for varying State capabilities and resources.

Response: We are allowing Exchanges to choose whether they want to send direct or indirect notices and have provided Exchanges with technical guidance and sample notice for both types of notices. These are available at *https://www.cms.gov/marketplace/in-person-assisters/applications-forms-notices/notices.* Additionally, Exchanges have experience sending direct and indirect notices for consumers whose tax filer has failed to file and reconcile APTC for 1 tax year, so they should have the capability to send notices as required in this final rule. For these reasons, we have provided sufficient time for Exchanges to implement the notice required described in this final rule and will not be providing a phased implementation.

4. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies § 155.400(d)(1)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82365 through 82366), we proposed to add § 155.400(d)(1) to codify HHS guidance [190] that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as ''State Exchange issuer'') that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.[191]

In the proposed rule, we explained that, under existing rules, the State Exchange issuer must work with its State Exchange to ensure resolution of any inaccuracy impacting APTC payment. If a State Exchange issuer is directed by its State Exchange to submit inaccuracies directly to HHS, the State Exchange issuer should follow those submission instructions, but any information HHS shares in response to the submission is informational. If the inaccuracy remains unresolved, the State Exchange issuer must follow up with its State Exchange to identify and rectify the reason for non-resolution. In accordance with § 155.400(b), a State Exchange must submit all enrollment data that HHS then uses to calculate APTC payments to State Exchange issuers. Therefore, in instances when a State Exchange does not address State Exchange issuer data inaccuracies in a timely manner, HHS cannot directly assist the State Exchange issuer in addressing these data inaccuracies.

In accordance with this policy, the proposed rule (89 FR 82308, 82365 through 82366) proposed to codify the guidance titled *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs).* This guidance directs State Exchanges to review descriptions of data inaccuracies submitted by State Exchange issuers, resolve them, and submit to HHS a description of the resolution of the inaccuracies when the State Exchange issuer submits a description of a data inaccuracy within the 90-calendar day deadline, or reasonably after the 90-calendar day deadline but before the 3-year deadline pursuant to § 156.1210(b) and (c).[192] The guidance directs State Exchanges to submit the resolution of these inaccuracies to HHS via the State Based Marketplace Inbound File (SBMI) within 60 calendar days after receiving from a State Exchange issuer a description of a data inaccuracy that includes all the information that the State Exchange requires or requests to properly assess the inaccuracy.

We stated in the proposed rule (89 FR 82308, 82365 through 82366) that this proposed timeline for resolution of enrollment data inaccuracies would require State Exchanges to timely review and resolve enrollment data inaccuracies; clarify the resolution process for State Exchange issuers; and ensure the accurate payment of APTCs, as enrollment data is the basis of APTC payments to State Exchange issuers in the automated policy-based payments (PBP) system. We will monitor State Exchanges' efforts to implement the policy and continue to consider whether modifying the State-based Marketplace Annual Reporting Tool (SMART) to have State Exchanges outline their process for timely resolving data inaccuracies in accordance with the requirement may be appropriate for tracking State Exchanges' efforts to meet the 60-calendar day requirement for submission inaccuracies to HHS.

We sought comments on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the codification that, within 60 calendar days after a State Exchange receives a data inaccuracy from a State Exchange issuer that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.[193]

Comment: Some commenters supported the proposal, noting that enrollment inaccuracies impact consumers, and ensuring timely resolution of data inaccuracies will minimize impacts on consumers' APTC payments. Other commenters opposed the policy, expressing various operational and financial concerns for State Exchanges. These concerns

[190] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[191] OMB Control No: 0938–1312 and 0938–1341.

[192] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[193] OMB Control No: 0938–1312 and 0938–1341.

included: system restrictions and limitations; limited resources; the anticipated need to divert staff from essential functions like outreach, enrollment assistance, and plan certification; being held accountable for a timeframe based on required actions by issuers, which are outside of State Exchanges' direct control; increased risk of errors or incomplete reviews in resolving disputes resulting from rushed decision-making to meet the 60-calendar day requirement; and other unforeseen circumstances. Some commenters requested that this regulation be effective no earlier than PY 2026 and the 60-calendar day window restart when State Exchanges need additional information from issuers to resolve inaccuracies. Some commenters suggested that HHS allow extensions and in doing so sought clarification on the difference between responding to versus resolving data inaccuracies.

Response: We acknowledge commenters' concerns regarding operational and financial burdens such as system, human capital, procedural constraints, and other unforeseen circumstances. However, we do not believe codifying a timeliness standard represents a significant increase in operational and financial burden given this policy aligns with existing guidance [194] and, as stated in the proposed rule (89 FR 82365 through 82366), builds on the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. Further, because State Exchanges provide the enrollment data that HHS uses as the basis of APTC payments to State Exchange issuers, timely and accurate resolution between State Exchanges and State Exchange issuers is necessary for accurate payment of Federal dollars. This policy also provides certainty for State Exchange issuers by providing a timeline for State Exchanges to act upon enrollment data inaccuracies submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c). As such, we believe that any potential operational or financial burden faced by State Exchanges is outweighed by the benefits of ensuring more timely and more accurate APTC payments, and for these same reasons, we are finalizing this policy to be effective as of the effective date of this final rule.

Further, we are clarifying in this rule that there are generally no exceptions to the 60-calendar day window for State Exchanges to review, resolve, and submit data inaccuracies to HHS. However, as described in the proposed rule (89 FR 82365 through 82366) and in the guidance,[195] the 60-calendar day window begins after the receipt of a complete inaccuracy submission from a State Exchange issuer that includes all the information that a State Exchange requires or requests to properly assess the amount of APTC paid to the issuer.[196] If a State Exchange requires additional information needed to address the APTC payment or enrollment data inaccuracy after a State Exchange issuer reports the inaccuracy to the State Exchange or HHS (as required by the State Exchanges), the State Exchange may respond to the State Exchange issuer to request that information. The 60-calendar day window to review, resolve, and submit the data inaccuracy to HHS would start only after the State Exchange receives all necessary information. Resolving inaccuracies, as opposed to responding to inaccuracies, includes taking any warranted action to address the inaccuracy and submit to HHS as described in the guidance.[197] Because the 60-calendar day time period does not begin until the State Exchange has all the information it needs (that is, a complete inaccuracy submission), we have not identified any situations that warrant an extension of this deadline.

Comment: Some commenters sought clarification regarding the separate 90-calendar days for issuers to report inaccuracies and the 60-calendar day requirement in this rule for State Exchanges to address disputes.

Response: We clarify that these are two separate time frames. State Exchange issuers must submit enrollment data and APTC payment inaccuracies to the State Exchange or HHS (as required by the State Exchanges) within 90 calendar days after the date HHS sends a payment and collections report to State Exchanges and State Exchange issuers [198] or, in limited circumstances, within 15 calendar days of identifying the inaccuracy, within the 3-year period beginning at the end of the plan year to which the inaccuracy relates.[199] This timeframe is unaffected by this final rule. The policy being finalized in this rule requires State Exchanges to review and resolve data inaccuracies and send them to HHS within 60 calendar days after receipt of a complete inaccuracy submission from a State Exchange issuer. HHS reiterates the 90-calendar day window applies to issuers and the 60-calendar day window applies to State Exchanges.

5. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82366), we proposed to codify a provision related to the premium payment threshold policies under § 155.400(g) that would allow additional issuer flexibility to decide when amounts collected from an enrollee would be considered to satisfy their obligation to pay the enrollee-responsible portion of the premium for certain purposes. Specifically, this would provide issuers with additional flexibility to not place an enrollee in a grace period for failure to pay the full amount of their portion of premiums due, and to not terminate enrollment through the Exchange after the applicable grace period ends without outstanding premiums being paid in full. We stated in the proposed rule (89 FR 82366) that this proposal would reduce the number of coverage terminations for enrollees who owe only a small amount of premium within the threshold. Specifically, we proposed that issuers be permitted to set a fixed-dollar threshold of $5 or less, which would be adjusted for inflation by annual agency guidance. In the proposed rule (89 FR 82366), we stated that we were also considering permitting issuers to adopt a threshold that is based on the gross premium owed by the enrollee, rather than net premium. We also proposed to modify the threshold of the existing premium payment threshold policy at § 155.400(g) from a reasonable amount to 95% for clarity. We further proposed to allow issuers to adopt only one of the three thresholds. Finally, we proposed to limit application of the fixed-dollar premium payment threshold and gross premium-payment threshold to payments made after coverage is effectuated, so that it could not apply to the binder payment. Based on comments received, we are finalizing this policy with the following modifications: we are increasing the fixed-dollar threshold to $10, adjusted annually for inflation, from $5 as proposed; decreasing the gross premium percentage-based threshold to 98

[194] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[195] Id.

[196] Id.

[197] Id.

[198] 45 CFR 156.1210(a).

[199] 45 CFR 156.1210(c).

percent, from 99 percent as proposed; and allowing issuers to select a fixed-dollar threshold in tandem with one of the two percentage-based thresholds.

Currently, issuers have the option under § 155.400(g) to adopt a percentage-based premium payment threshold which allows issuers to effectuate coverage in accordance with binder payment rules at § 155.400(e) for enrollees who pay an amount of the enrollee-responsible portion of the premium that is less than 100 percent but within the threshold, provided that the level is reasonable and that the level and the policy are applied in a uniform manner to all enrollees (we have historically recommended a percentage equal to or greater than 95 percent).[200] This permits an issuer to avoid triggering a grace period for non-payment under § 156.270(d) or a grace period under State rules, and to avoid terminating enrollment for non-payment of premiums. Under this policy, if the total amount of premium owed by an enrollee (including aggregate amounts over multiple months) exceeds the threshold set by the issuer, the issuer is required to place the enrollee in a grace period: either the grace period for enrollees receiving APTC described at § 156.270(d), or a grace period under State authority, as applicable. Any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer.[201]

In the 2017 Payment Notice (81 FR 12271 through 12272), in which HHS established the option for issuers to implement a percentage-based premium payment threshold, we received a comment requesting that issuers be allowed to establish a flat dollar amount threshold. At that time, we stated that we did not consider implementing such a threshold because there may be cases in which even a low flat dollar amount may represent a large percentage of an enrollee's portion of the premium less APTC (81 FR 12272).

However, after implementation of the percentage-based threshold, we have realized that the percentage-based premium threshold policy does not always adequately enable enrollees who owe small amounts of premium to avoid triggering a grace period or termination of enrollment through the Exchange. For example, an enrollee whose portion of the premium was $1 after APTC, and who failed to make a premium payment, would be placed into a grace period even if the issuer had adopted a 95 percent payment threshold, despite being delinquent by only $1. In an analysis of Exchange data for PY 2023, we found that there were 81,383 total policies terminated for non-payment in which $5 or less was owed by the enrollee, representing approximately 5.4 percent of the total number of policies terminated for non-payment that year. In addition, 102,728 policies in which enrollees owed premiums of $5.01 to $10 were terminated for non-payment, representing approximately 6.84 percent of the total number of policies terminated for non-payment. Even though $5 may represent a large percentage of an enrollee's portion of the premium less APTC, we stated in the proposed rule (89 FR 82367) that we believe that triggering a grace period or terminating enrollment through the Exchange is too severe a consequence for non-payment of such limited dollar amounts.

In the proposed rule (89 FR 82367), we noted our concern about situations in which an issuer would be willing to avoid termination of enrollment through the Exchange if the enrollee owed only small amounts of premium but are prevented from doing so by the lack of flexibility in the current regulation. In addition, many of the enrollees who enter a grace period because they owe de minimis amounts of premium are likely low or moderate-income enrollees and thus might be especially hurt by disruptions in coverage. We stated in the proposed rule (89 FR 82367) that we recognize that issuers have historically implemented various premium payment thresholds, and we believe there is value in providing flexibility to issuers regarding whether to adopt a fixed-dollar payment threshold and the amount of the threshold.

We thus proposed to modify § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold of $5 or less, adjusted for inflation by annual agency guidance, under which they could provide additional flexibility to enrollees who fail to pay the full amount of their portion of premium owed. We proposed to limit the fixed-dollar premium threshold to $5 or less because, unlike the current percentage-based threshold, a fixed-dollar threshold would allow enrollees, in some cases, to pay $0 in premium without the issuer triggering a grace period or terminating enrollment through the Exchange. Such a limit would ensure that enrollees who owe large amounts of premium do not remain enrolled in coverage through the Exchange and would serve to limit the number of times an enrollee may fail to pay premium and avoid triggering a grace period or termination of enrollment through the Exchange. As we stated in the proposed rule (89 FR 82367), we believe that a limit of $5 is sufficiently large to enable issuers to allow enrollees who owe *de minimis* amounts of premium to remain enrolled, while ensuring that enrollees do not accumulate excessive amounts of premium owed prior to triggering a grace period or termination of enrollment through the Exchange. We also stated that we recognize that this amount might be lower than the threshold enrollees might be afforded under a percentage-based threshold. However, we also stated that we recognize that within a percentage-based threshold, the enrollee must pay a certain amount of their premium to avoid triggering a grace period or termination of enrollment through the Exchange, whereas with a fixed-dollar threshold, an enrollee may not have paid any other amount than the binder payment. Other factors such as the amount the enrollee has paid for their premium to date is not considered when applying the fixed-dollar payment threshold. We requested comment on whether this is a reasonable limit for the fixed-dollar threshold, or whether an alternative amount (such as $10) would be more appropriate and in line with our goal of enabling enrollees who owe small amounts of premiums, while avoiding excessive accumulation of premium debt, to avoid triggering a grace period or termination of enrollment through the Exchange. In the proposed rule (89 FR 82367), we stated that if adopted, we would publish annual updates through subregulatory guidance to this $5 limit to adjust for inflation, using the National Health Expenditure Forecast published annually by CMS' Office of the Actuary.[202]

Issuers that adopt such a policy could permit enrollees who owe less than the specified amount of premium to avoid triggering a grace period and termination of enrollment through the Exchange. However, we proposed to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment. Issuers have the option under the current percentage threshold policy at § 155.400(g)(1) of applying a percentage-based threshold

[200] See CMS. (2024, Aug. 19). *Federally-facilitated Exchange (FFE) Enrollment Manual.* Section 6.2, pp. 92–94. *https://www.cms.gov/files/document/ffe-enrollment-manual-2024-5cr-082024.pdf.*

[201] 2017 Payment Notice, 81 FR 12203, 12272.

[202] See CMS. (n.d.). National health expenditure data—Projected. *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected.*

to the binder payment, but under that policy, enrollees are required to pay some amount of premium, even if it less than the total. By contrast, under a fixed-dollar premium payment threshold, enrollees could have their coverage effectuated without making any payment if their portion of the binder payment is under the threshold amount. Due to concerns about program integrity, we stated in the proposed rule (89 FR 82367) that we believe it is important to ensure that, when a binder payment is required, enrollees must always pay some amount of premium to effectuate coverage as an important signal that the coverage is desired by the enrollee. In addition, as under the current policy (81 FR 12272), any amount that is unpaid but within the reasonable premium payment threshold established by an issuer remains an amount owed by the enrollee and cannot be forgiven by the issuer. This remains true whether the premium payment threshold is utilized for any of the following payments: binder payments, regularly billed payments, or amounts owed by an enrollee while in a grace period.

To illustrate how a fixed-dollar premium threshold would work, we provided the following example in the proposed rule (82368):

Example 1: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of $300, and the consumer is determined eligible for $299 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be $1. The QHP issuer has adopted a fixed-dollar premium payment threshold policy under which it will not terminate enrollment of enrollees who owe $5 or less of the enrollee-responsible portion of premium. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of $1 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer does not make a payment for February, March, April, May, or June, and, as a result, the enrollee owes $5 in outstanding premiums. Because the issuer has adopted a $5 premium payment threshold, the issuer would not put the consumer into a grace period, since the total amount owed does not exceed $5. However, the issuer would not be permitted to write off the $5 owed, and if the consumer does not pay the premium for July in full, the issuer must put the consumer into a 3-month grace period since the total amount of premium owed would exceed the threshold set by the issuer. However, if within the grace period the consumer paid the full amount owed or a portion of the full amount owed that brings the amount owed under $5, the issuer could terminate the grace period without terminating enrollment through the Exchange.

Finally, under the current percentage-based threshold policy, the percentage is calculated based on the percentage paid of the enrollee's portion of the premium (that is, the total premium minus any APTC). In the proposed rule (89 FR 82368), we stated that we were considering whether to further amend § 155.400(g) to also permit issuers to set a threshold that is a percentage of the policy's total premium and not just the enrollee's portion of premium, thus allowing APTC paid on the consumer's behalf to count toward the threshold.

In the 2017 Payment Notice (81 FR 12271 through 12272), we established the option for issuers to adopt a premium payment threshold based on net premium owed by the enrollee. At that time, we did not consider establishing a threshold based on gross premium, nor have we done so since then. We stated in the proposed rule (89 FR 82368) that we now recognize that this option may provide issuers with an alternative method of keeping consumers enrolled in coverage that issuers may prefer, either because it is simpler to implement or because it is percentage-based and therefore more similar to the premium payment threshold that is currently allowed under § 155.400(g).

Establishing an option for issuers to adopt a percentage threshold based on gross premium owed by the enrollee with APTC counting toward the threshold would, in some cases, allow enrollees to remain enrolled in coverage or avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of the enrollee-responsible portion of the premium. For example, an enrollee whose gross premium was $600, and was receiving $595 in APTC, could avoid triggering a grace period or termination of enrollment through the Exchange or termination of coverage even without paying the $5 enrollee-responsible portion of the premium if the issuer had adopted a 99 percent premium threshold based on gross premium because 99 percent of the gross premium ($594) would have been paid on the enrollee's behalf in the form of APTC. With the current 95 percent threshold based on net premium, by contrast, the enrollee would be required to pay at least $4.75 to avoid triggering a grace period or termination of enrollment through the Exchange. While historically we have not defined a specific threshold for the premium threshold based on net premium, we stated in the proposed rule (89 FR 82368) that we would implement a threshold for the premium threshold based on gross premium that is 99 percent or more of the gross premium. We stated that we believe the gross premium threshold should be higher than the net premium threshold to avoid the enrollee accumulating a much larger amount of premium debt, and to keep to a similar *de minimis* amount of premium owed as the net premium percentage-based and fixed-dollar thresholds allow. Because this threshold would also, in some circumstances, allow enrollees to temporarily avoid paying any premium, we also proposed to limit application of this threshold to premium payments made after coverage is effectuated, so that it could not apply to the binder payment (due to operational and program integrity concerns, as discussed earlier in this section).

A percentage threshold based on gross premium may be simpler to implement, since it is similar to the type of threshold issuers are already allowed to adopt. However, in the proposed rule (89 FR 82368), we stated that we recognize that there may also be drawbacks to this approach, including that enrollees could accumulate more than $5 in premium debt, which the enrollee would continue to owe even if coverage were eventually terminated due to non-payment of premiums. Based on our experience with the current, net premium-based payment threshold, we stated that we do not believe this would result in significant premium debts accumulated by enrollees, since we would be limiting the gross percentage-based threshold to be 99 percent or more of the gross premium. We further stated that we recognize that a gross premium amount higher than the average gross premium (which was $604.78 in February 2023) [203] might allow enrollees to accrue more than the $5 debt that could be accrued under the fixed-dollar threshold, but this is true under the existing net premium payment threshold as well. We also noted in the proposed rule (89 FR 82368) that issuers are prohibited from attributing premiums owed to prior debts and not to binder payments, and thus issuers may not refuse to enroll enrollees in coverage based on failure to

[203] See CMS (2024). *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average. https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.*

pay their binder payment by attributing binder payments to prior debts.

To illustrate how a premium threshold based on gross premium would work, we provided the following example in the proposed rule (89 FR 82368):

Example 2: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of $500, and the consumer is determined eligible for $495 in APTC and elects to receive the entire amount. The consumer's enrollee-responsible portion of premium will thus be $5. The QHP issuer has adopted a percentage-based premium payment threshold policy under which it will not trigger a grace period or termination of enrollment through the Exchange for enrollees who pay at least 99 percent of gross premium (including payments of APTC made on the enrollee's behalf), which here would be $5. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of $5 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer pays $1 in February and owes $4 in past due premium; because the consumer's payment is within the 99 percent threshold established by the issuer, the issuer would not place the enrollee in a grace period. The following month, the consumer does not pay any premium, and now owes $9 in past due premium. Since the $9 now owed after application of the $495 APTC paid on the consumer's behalf for March represents more than 1 percent of the $500 gross premium, the issuer must put the consumer into a 3-month grace period starting March 1. The issuer would not be permitted to write off the $9 owed, and the consumer must pay all outstanding premium owed before the end of the grace period (May 31) to avoid exhaustion of the grace period and remain enrolled in coverage.

We sought comments on this proposal. Specifically, we requested comment on whether a fixed-dollar threshold, as proposed, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period or termination of enrollment through the Exchange for owing small amounts of premium.

We also proposed changing the premium payment threshold based on net premium owed by the enrollee from being a ''reasonable'' standard to a specifically defined threshold of 95 percent or higher of the net premium. We stated in the proposed rule (89 FR 82369) that we believe this would provide clarity for issuers and Exchanges.

We also proposed limiting issuers to utilize one premium payment threshold, such that a fixed-dollar threshold cannot be adopted and utilized in tandem with a percentage-based policy, either net or gross. We stated in the proposed rule (89 FR 82369) that we believe that limiting this flexibility would allow issuers to choose and apply the threshold that works best for their payment operations but prevents complex situations that may arise from allowing multiple thresholds to be used simultaneously. We sought comment on whether we should allow issuers to adopt both a fixed-dollar and percentage-based threshold and requested commenters to consider the administrative feasibility of applying both thresholds, and how such a policy could be applied uniformly and consistently across enrollees.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy with the following modifications: we are increasing the fixed-dollar threshold to $10, lowering the gross premium percentage-based threshold to 98 percent, and allowing issuers to select multiple thresholds: a fixed-dollar threshold in tandem with one of the two percentage-based thresholds. We summarize and respond to public comments received on the proposed premium payment thresholds below.

Comment: Many commenters supported the proposal overall and stated that providing additional flexibilities to issuers would allow consumers who owe small premium amounts, especially those with lower incomes, to keep their coverage and prevent disruptions in care.

Response: We agree that the additional flexibilities would allow issuers to implement a premium payment threshold that meets the needs of their enrollees and allow enrollees to maintain their coverage when they owe minimal premium.

Comment: The majority of commenters supported the premium payment threshold but recommended that the fixed-dollar threshold be increased from the proposed $5 limit. Most recommended that it be increased to $10 and stated that the proposed $5 limit would be too low to afford consumers the desired protection from triggering a grace period or termination over a minor payment issue. One commenter stated that $10 was less than 2 percent of the average premium in their State, which operates a State Exchange, and that carriers in their State had higher fixed-dollar thresholds for non-Exchange plans. One commenter, an issuer, stated that a fixed-dollar threshold of $5 was too low as it translated to approximately 99.9 percent of their premiums, which they stated is a very high bar for underpayments.

Response: We agree with commenters that a fixed-dollar threshold of $10, adjusted for inflation by annual agency guidance, would provide more protection to consumers who owe small amounts of premium. We also note that $10 would represent less than 2 percent of the average monthly premium across all Exchanges. Based on FFE data from PY 2023, 102,728 policies in which enrollees owed premiums of $5.01 to $10 were terminated for non-payment, representing approximately 6.84 percent of the total number of policies terminated for non-payment. Increasing the maximum fixed-dollar threshold to $10 would allow more consumers to avoid termination of their coverage, while ensuring that most enrollees will still be required to pay the majority of their premium to maintain coverage. While we maintain that the fixed-dollar threshold should remain at a *de minimis* amount to prevent enrollees from accruing too much debt, based on comments received, we believe that the additional $5 an enrollee could accrue would not place them in substantially more debt.

Comment: Many commenters stated that the fixed-dollar threshold and gross premium percentage-based thresholds should also apply to the binder payment. Some commenters stated that expanding the proposal in this way would allow issuers to maintain enrollment for consumers, many of whom are living paycheck to paycheck. One commenter stated that applying the proposed policy to binder payments was unlikely to have a meaningful effect on the number of fraudulent enrollments: many plans already have a $0 premium for consumers at certain income levels, and a broker willing to engage in fraud could simply choose a plan and fabricate an income estimate to get a $0 enrollment. Another commenter suggested that the fixed-dollar and gross premium payment thresholds should be applied to the binder payment, but only for policies with an enrollee responsible amount, which would help maintain effectuation rates. Finally, one commenter supported our proposal to not apply the fixed-dollar and gross premium percentage-based thresholds to the binder payment and stated that enrollees should continue to be required to pay a premium to effectuate coverage.

Response: While we understand that some enrollees will have a difficult time paying the binder payment, we believe that when a premium is required, it is best practice to require consumers to pay some portion of it to indicate their desire to effectuate coverage to promote the integrity of the Exchanges and to reduce the potential for fraud and abuse. This policy may also minimize the opportunities for agents, brokers, and web-brokers to enroll consumers in an Exchange plan without their consent because all consumers who owe a premium would be required to pay some of their binder payment if the issuer adopted a net premium percentage-based threshold, or all of their binder payment if the issuer adopted a fixed-dollar or gross premium percentage-based threshold in order to effectuate coverage. We have found that some agents, brokers, and web brokers may target consumers who do not have to make a binder payment because it is harder for those consumers to detect the unauthorized enrollment when they do not have to pay to effectuate coverage. Given the pattern of unauthorized enrollments and our efforts to curb them,[204] we think it is prudent to further protect consumers and the Exchanges by making it harder for agents, brokers, and web-brokers to enroll consumers in Exchange coverage without their consent, to the extent possible. As such, at this time we are finalizing that the binder payment will be excluded from the fixed-dollar and gross premium-based thresholds.

Comment: Some commenters stated that issuers should be able to apply more than one threshold to improve continuity of coverage, as long as the issuer applied both thresholds consistently and in a non-discriminatory manner. Commenters also disagreed that allowing issuers to implement more than one threshold would introduce too much complexity for both issuers and consumers. Commenters stated that if an issuer was concerned about the complexity of implementing two thresholds, they have the option to only apply one threshold, or none at all. Lastly, some commenters noted that while consumers may be confused about the existence of multiple thresholds, the benefit of avoiding being put into a grace period would outweigh any potential confusion.

Response: We agree that allowing issuers to apply multiple thresholds would allow more consumers to avoid being placed into a grace period and thereby avoid termination of their coverage for owing nominal amounts of premium, which would increase the effectiveness of the proposed policy. We also agree that if an issuer is concerned about the complexity of implementing multiple thresholds, they have the option to only implement one threshold or none at all. As such, we are finalizing the option for issuers to implement multiple thresholds: a fixed-dollar threshold and either the net premium or gross premium percentage-based threshold. We would limit an issuer to only applying one of the percentage-based thresholds to ensure that the implementation and application of the premium payment threshold does not become too operationally complex for issuers and for CMS in reviewing audits of premium payment activity. To illustrate how a fixed-dollar and percentage-based threshold might be implemented, we are providing the following example: During the annual Open Enrollment Period, a consumer selects a QHP with a total monthly premium amount of $200. The consumer is determined ineligible for APTC and thus responsible for paying the full amount of the premium. The QHP issuer has adopted both a fixed-dollar premium payment threshold policy, under which it will not terminate coverage of enrollees who owe $8 or less of the enrollee-responsible portion of premium, and a net premium percentage-based threshold policy, under which it will not terminate coverage of enrollees who pay at least 95 percent of the enrollee-responsible portion of the premium. The issuer has set a binder payment deadline of January 30, and the consumer sends the binder payment of $200 ahead of the deadline and effectuates coverage effective January 1. Subsequently, the consumer makes a payment of $190 for February's premium, only 95 percent of the total amount owed. Although the remainder of the amount owed, $10, is above the issuer's fixed-dollar premium payment threshold of $8, it falls within the percentage-based threshold of 95 percent set by the issuer, and thus the enrollee's coverage would not be terminated. If the enrollee makes another payment of $190 for March's premium, the issuer would then terminate coverage, subject to a State's grace period if applicable, because the premium owed would exceed both the 95 percent and $8 thresholds.

Comment: Some issuers, while supportive of the premium payment threshold proposal, specifically opposed the gross premium percentage-based threshold and stated that it could be confusing for consumers who likely consider the premium payment to be the individual responsibility amount, rather than the premium amount owed before the application of APTC. One commenter stated that more time was needed to review the gross premium percentage-based threshold.

Response: While we agree that most consumers likely consider the net premium (their portion of the premium after APTC) to be their premium amount, we encourage issuers who adopt the gross premium percentage-based threshold to include the full premium amount and the applied APTC on member invoices so that the enrollee is made aware of the gross premium amount and whether they have paid enough of their portion due to avoid being placed into a grace period. Because establishment of a premium payment threshold is optional, issuers that are concerned about implementation of a gross premium percentage-based threshold could wait or opt not to implement one.

Comment: A few commenters opposed the premium payment threshold policy entirely. One commenter was concerned that implementation of the proposal may lead to unintended consequences, particularly if the threshold is set by the issuer, such as issuers undermining the rate review process and providing an incentive for issuers to take more credit risks and incorporate the additional costs into premiums. The commenter was also concerned that the fixed-dollar threshold could incentivize fraudulent activity directed at the most flexible premium payment threshold policies, and that a flexible threshold would also lead to brokers leveraging these unique carrier-specific policies as a marketing lever. One commenter was concerned that the proposal would modify the grace period because consumers would be allowed to continue coverage without making any of their premium payments, which the commenter stated would extend grace period coverage. Additionally, the commenter stated this would lead to a costly tax bill for consumers who expected their coverage to terminate for non-payment.

Response: We disagree that the additional flexibilities provided in the premium payment threshold proposal might drive issuers to take additional credit risks since all of the premium

[204] See CMS (2024). *CMS Update on Actions to Prevent Unauthorized Agent and Broker Marketplace Activity. https://www.cms.gov/newsroom/press-releases/cms-statement-system-changes-stop-unauthorized-agent-and-broker-marketplace-activity.* See also the revisions in this final rule to § 155.220, ''Ability of States to Permit Agents and Brokers and Web-Brokers to Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs.''

payment thresholds allow enrollees to owe a *de minimis* amount of debt. In addition, issuers that do not want to take on the risk associated with adopting a premium payment threshold would not have to, since the policy is optional. We also disagree that any premium payment threshold policy set by an issuer would undermine the rate review process, because there is already a current existing net premium percentage-based threshold which is optional for issuers to implement and must currently be set at a reasonable *de minimis* level, and which has not, to our knowledge, impacted the rate review process. We also disagree that the fixed-dollar threshold would incentivize fraudulent activity directed at the most flexible premium payment threshold policies and that a flexible threshold would lead to agents, brokers, or web-brokers leveraging these unique carrier-specific policies as a marketing lever. The commenter seems to suggest that agents, brokers, or web-brokers would be incentivized to enroll consumers in an Exchange plan with a generous premium policy threshold(s) to secure a commission. However, we are not convinced that consumers would be persuaded to enroll in an Exchange plan, or to enroll in a specific Exchange plan over another, because of a *de minimis* premium payment threshold, especially when any unpaid amounts remain a debt owed to the issuer. If the commenter is suggesting that an agent, broker, or web-broker might pay a binder payment on a consumer's behalf in order to secure an unauthorized enrollment, we note that the fixed-dollar and gross premium percentage-based thresholds will not apply to the binder payment, and that the current net percentage-based threshold, which does apply to the binder payment, has not, to our knowledge, induced unauthorized enrollments. With regard to the comment that the proposal would modify the grace period, we clarify that the premium payment threshold, which already exists as the net premium percentage-based threshold, would not extend the grace period. Per § 156.270(g), and issuer guidance, a consumer must pay the full amount due once they are placed into the grace period, and the grace period does not reset if partial payments are made.

Comment: Some commenters recommended a lower threshold for the gross premium percentage-based threshold.

Response: We agree that the gross premium percentage-based threshold should be lowered, and as such, we are finalizing a 98 percent or above threshold for the gross premium percentage-based threshold. Since we are also increasing the fixed-dollar threshold to $10, which is almost 2 percent of the average premium in the FFE, increasing the allowed gross premium percentage-based threshold would allow more consistency to the definition of a *de minimis* amount, though we note that any percentage-based threshold may be higher than $10 if the gross premium is higher than the average premium.

Comment: Several commenters stated that CMS should establish clear guidelines for issuers on how the premium payment threshold should be implemented uniformly across all plans.

Response: Issuers that select any threshold must apply it in the same manner to all enrollees in a plan. For example, an issuer may not impose a $10 threshold for some enrollees and a $5 threshold for others, even though both thresholds would be within the permitted fixed-dollar threshold of $10. We note that we already provide guidelines for implementing the current net premium percentage-based threshold through the *FFE Enrollment Manual* and will also do so for the fixed-dollar and gross premium percentage-based thresholds in the same manner in a future revision of the *FFE Enrollment Manual.*[205]

Comment: Some commenters requested clarification on whether State Exchanges would be limited to permitting only the premium payment threshold options specifically described in the proposed regulation, or whether State Exchanges have the authority to permit issuers in their State to offer additional flexibility.

Response: State Exchanges have the option to permit their issuers to implement only the flexibilities available after finalization of this rule. Similar to the current premium payment rules, State Exchanges would not be permitted to provide additional flexibility. Consistent with the current rules on premium payment thresholds, the FFE and SBE–FPs will provide the flexibilities specified in the regulation.

6. General Eligibility Appeals Requirements (§ 155.505)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82369), we proposed revising § 155.505(b) to codify an option for application filers to file appeals on behalf of applicants and enrollees on the application filer's Exchange application.

The Exchanges on the Federal platform allow application filers as defined under § 155.20 to file applications on behalf of an applicant. However, the appeals regulation at § 155.505(b) states that only applicants and enrollees may submit appeal requests to the HHS appeals entity or a State Exchange appeals entity. Appeal requests submitted online to the HHS appeals entity are linked to a consumer's *HealthCare.gov* account, which is controlled by the application filer. Thus, an application filer who has authority to apply for coverage through *HealthCare.gov* on behalf of an applicant under § 155.20, does not have parallel authority under § 155.505(b) to appeal a contested eligibility determination on behalf of that applicant through the same *HealthCare.gov* account.

In the proposed rule (89 FR 82369), we stated that this limitation under § 155.505(b) puts a burden on consumers, as appeals filed by application filers who are neither an applicant or enrollee are considered invalid based on lack of standing, requiring either that the applicant or enrollee resubmit their appeal or that they designate the application filer as an authorized representative in writing. These extra steps not only add unnecessary complications for the applicant or enrollee, but also serve to delay an appeal resolution that may grant or restore QHP coverage and financial assistance.

The proposed change would allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency throughout the application and appeals processes. In the proposed rule (89 FR 82369), we stated that we did not anticipate that this would impose any additional substantial burden on any Exchanges, including State Exchanges that operate their own platform, as this should not materially increase the number of appeals filed, or add complexity to appeals processes.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposed policy to allow application filers to file appeals on behalf of applicants and enrollees below.

[205] CMS. (2024, Aug. 19). *Federally-facilitated Exchange (FFE) Enrollment Manual.* Section 6.2, pp. 92–94. *https://www.cms.gov/files/document/ffe-enrollment-manual-2024-5cr-082024.pdf.*

Comment: The majority of commenters supported allowing application filers to file appeals on behalf of applicants and enrollees on the application filer's Exchange application. Several commenters noted that application filers have the authority to apply for coverage in the Exchange on behalf of applicants and that this change ensures operational consistency throughout the application and appeals process while reducing burden on appellants. One commenter noted that the change will particularly help reduce the burden on those appellants with disabilities and limited English proficiency who rely on household members to assist them. A few commenters stated that health center staff are already knowledgeable in navigating *HealthCare.gov* and the appeals process, and that this proposed change would benefit the patients they serve. Lastly, one commenter noted that the proposed regulation would support continuous health insurance coverage and prevent unnecessary gaps in coverage by removing administrative hurdles faced by applicants and enrollees.

Response: We agree that this change ensures operational consistency throughout the application and appeals process while reducing burden on consumers.

Comment: One commenter suggested that CMS clarify that the regulation applies only to FFEs, noting that if a consumer needs assistance filing an appeal with a State Exchange appeals entity, the appeal form provides a space in which the consumer can appoint an authorized representative. The commenter stated that allowing application filers to file appeals rather than attempting to resolve the appeal through customer support pathways may increase the number of appeals filed for issues that could be resolved without an appeal. The commenter also stated that appeals may be delayed in the State Exchange system if the system does not recognize application filer data.

Response: We clarify that the change to § 155.505(b) applies to State Exchanges as well. We agree that it is important to not make a change that may unnecessarily delay the appeals process for a consumer. However, we believe that the current process requiring the consumer to designate the application filer as an authorized representative in writing creates a burden that potentially delays adjudicating and resolving an appeal. We appreciate that a State Exchange may need to make adjustments to accommodate application filers, however we expect these adjustments to be minimal and ultimately in the best interest of the consumer and the efficiency of the appeals process. Finally, we acknowledge that State Exchanges may have multiple paths to resolve eligibility determination issues, but we note that this change should not hinder consumers' use of those alternative paths or incentivize consumers to pursue a formal appeal over an informal resolution.

Comment: One commenter suggested CMS include additional appeal consent language confirming that the applicant gives consent to have the application filer file an appeal on their behalf. The commenter noted concern that application filers may file appeals on behalf of applicants that do not wish to appeal.

Response: We acknowledge the concern that an application filer may file an appeal on behalf of an applicant who does not wish to appeal. However, Exchanges allow application filers, as defined under § 155.20, to file applications on an applicant's behalf and therefore it is consistent to allow an application filer to appeal an eligibility determination related to such application on the applicant's behalf. While there is a low risk that an application filer may submit an application for coverage or appeal the eligibility determination created in response to that application without the consumer's consent, the application and appeal request are both submitted under penalty of perjury to guard against any misuse of authority. We further believe that the benefit created for both the application filer and consumer in streamlining these processes and providing operational consistency outweighs such a risk.

Comment: One commenter suggested that CMS provide guidance on the scope and role of the application filer after filing an appeal and that CMS explore the ramifications of this change further before making it.

Response: As per the proposed regulation, the application filer would have the same standing to file an appeal and participate in the adjudicatory process as an applicant or enrollee. We have considered, but have not identified, any unintended consequences of this policy.

Comment: One commenter suggested that CMS expand the language to allow agents and brokers to file appeals on behalf of consumers, stating it would be consistent with other actions they perform.

Response: We clarify that an agent, broker, or web-broker would have authority to file an appeal on behalf of a consumer if the agent, broker, or web-broker has been designated as an authorized representative by the consumer (or if the agent, broker, or web-broker is acting in their personal capacity and otherwise meets the definition of application filer). Given our efforts to address misconduct and noncompliance by agents, brokers, and web-brokers, as described in more detail in section III.C.2. of this final rule, we decline to further extend the authority for agents, brokers, and web-brokers to file consumer appeals.

7. Certification Standards for QHPs (§ 155.1000)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82369), we proposed to amend § 155.1000 by adding a new paragraph (e) stating that an Exchange may deny certification of any health plan as a QHP that does not meet the general certification criteria at § 155.1000(c).

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the State.[206] In the Exchange Establishment Rule (77 FR 18310, 18404 through 18405), we codified the responsibilities of an Exchange to certify QHPs at § 155.1000 and, § 155.1000(b), required Exchanges to only offer health plans which have in effect a certification issued or are recognized as health plans deemed certified for participation in an Exchange as a QHP. In that final rule, we also codified general certification criteria, consistent with section 1311(e)(1)(A) and (B) of the ACA, at § 155.1000(c): an Exchange may certify a plan as a QHP if: (1) the health insurance issuer provides evidence during the certification process that it complies with the applicable minimum certification requirements outlined in subpart C, part 156 of our regulations; and (2) the Exchange determines that making the health plan available through the Exchange is in the interest

[206] Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

of qualified individuals and qualified employers.[207]

However, an Exchange's authority to deny certification is not explicitly referenced in 45 CFR part 155. Several regulations, including §§ 155.1000(c) and 155.1090, illustrate that an Exchange may deny certification of a health plan that does not meet the requirements of § 155.1000(c). Moreover, a plain reading of section 1311(e)(1) of the ACA makes clear that an Exchange, as the entity statutorily responsible for determining whether a plan meets the minimum QHP certification standards, has the implied authority to deny certification of plans that do not meet these standards. Any contrary read of section 1311(e)(1) of the ACA would mean that an Exchange does not have any statutory authority to take any action for plans that do not meet minimum certification standards, which is not a reasonable result and would be contrary to congressional intent.

We sought in the proposed rule (89 FR 82369) to revise our regulations so that they more fully and accurately reflect the discretion that Exchanges have to deny certification of any plan that does not meet the general certification criteria at § 155.1000(c). Accordingly, we proposed to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to add new paragraph (e) to § 155.1000 to formalize the implicit authority that an Exchange, including State Exchanges and SBE–FPs, may deny certification to any plan that does not meet the general certification criteria at § 155.1000(c). We proposed that an Exchange may deny certification if the issuer does not provide evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements (under § 155.1000(c)(1)), or if the Exchange determines that making the health plan available is not in the interest of the qualified individuals and qualified employers (under § 155.1000(c)(2)).

In the proposed rule (89 FR 82370), we stated that we were not proposing to require Exchanges, including State Exchanges and SBE–FPs, to implement any specific procedures or processes for the denial of a QHP certification application. We stated that we did not intend for this proposal to amend the existing, implied authority of an Exchange to deny certification. We stated that we only intended this proposal to make that authority more explicit in our regulations, which would provide greater certainty to Exchanges, issuers, and consumers on an Exchange's role, which we expected would only improve the efficiency of the Exchanges.

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposal to amend § 155.1000 below.

Comment: We received a small number of comments on the proposal, with most commenters supporting and agreeing with HHS that the proposal is consistent with the text of the ACA and that it provides a clear articulation of an Exchange's existing authority. These commenters noted the proposal is imperative to ensuring that plans that do not meet the certification criteria at § 155.1000(c) are denied certification.

Response: We appreciate these commenters' support of the proposal and of the rationale that we provided in the proposed rule.

Comment: One commenter opposed the proposal as unnecessary, stating the current regulations provide no uncertainty with respect to an Exchange's authority to not certify plans that do not meet the certification criteria at § 155.1000(c). This commenter maintains that HHS should not expand certification regulations without due cause and, in this case, current regulations have served all Exchanges well in providing authority to certify or not certify plans as QHPs. Finally, this commenter stated that the proposed regulatory text providing that an Exchange may deny certification ''if the Exchange determines that making the health plan available is not in the interest of the qualified individuals and qualified employers'' introduces subjectivity and therefore ambiguity for certification denial that does not currently exist in QHP certification criteria.

Response: We appreciate this commenter's position that the current regulatory text already encompasses the implied authority of an Exchange to deny certification of any plan that does not meet the general certification criteria at § 155.1000(c). To HHS' knowledge, no Exchanges have interpreted § 155.1000(c) to preclude them from denying certification to plans that do not meet the general certification criteria. The proposed rule (89 FR 82369) explained that this proposal is intended to codify an Exchange's existing and implicit certification denial authority. This revision is not without due cause, as it provides a reader of this regulatory text, including Exchanges, issuers, and consumers, greater certainty with respect to an Exchange's role, which we continue to expect will only improve the efficiency of the Exchanges. In addition, we disagree with this commenter's characterization that the proposal introduces subjectivity that does not currently exist in the QHP certification criteria with reference to the ''interest standard.'' This proposal did not seek to revise the QHP certification criteria at § 155.1000(c), which include a determination by the Exchange that making the health plan available is in the interest of the qualified individuals and qualified employers. Given this, we do not expect any change in an Exchange's approach in assessing whether plans meet certification criteria, including for States with an FFE.[208]

8. Request for the Reconsideration of Denial of Certification Specific to the FFEs (§ 155.1090)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82370), we proposed to amend § 155.1090 to revise the standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs.

Section 1311(e)(1) of the ACA grants an Exchange the authority to certify a health plan as a QHP if the health plan meets the requirements for certification promulgated by the Secretary under section 1311(c)(1) of the ACA, and the Exchange determines that making the plan available through the Exchange is

[207] In that rule, we outlined a number of non-exhaustive strategies an Exchange may employ to determine whether the offering of a health plan is in the interest of qualified individuals and qualified employers (77 FR 18406).

[208] *See* the discussion in the 2017 Payment Notice (81 FR 12289) for more information on HHS' approach for the denial of certification on the FFEs (stating ''HHS expects to continue to certify the vast majority of plans that meet certification standards. HHS will focus denials of certification in the FFEs based on the 'interest of the qualified individuals and qualified employers' standard on cases involving the integrity of the FFEs and the plans offered through them.'')

in the interests of qualified individuals and qualified employers in the State.[209] In the 2018 Payment Notice (81 FR 94137), we finalized § 155.1090 to allow an issuer to request the reconsideration of a denial of certification of a plan as a QHP for sale through an FFE.

HHS, as operator of the FFEs, is responsible for ensuring that health plans offered through the FFEs meet all Federal requirements for certification as QHPs under § 155.1000(c). Starting with PY 2014, HHS has certified numerous health plans as QHPs on the FFEs. During this time, HHS has also determined that a small number of applications submitted by issuers for the certification of health plans as QHPs on the FFEs did not meet minimum certification criteria under § 155.1000(c), and HHS denied certification to these plans. Some of these issuers submitted reconsideration requests to HHS under § 155.1090(a)(1). HHS ultimately sustained its denial determinations for these issuers' certification applications upon reconsideration review.

Based on our experience reviewing these certification application reconsideration requests, we stated in the proposed rule (89 FR 82370) that we believe that it would be appropriate to amend § 155.1090 to codify more structure for the FFEs' process for conducting a reconsideration of denial of certification. Accordingly, we proposed to use the authorities under section 1311(c) of the ACA (which gives HHS the authority to establish criteria for the certification of health plans as QHPs), section 1311(d)(4)(A) (which provides that Exchanges shall implement procedures for the certification, recertification, and decertification of QHPs consistent with the guidelines HHS develops under section 1311(c)), and section 1321(a)(1)(B) (which provides HHS with broad rulemaking authority to issue regulations setting standards for meeting the requirements under title I of the ACA (which includes section 1311) for the establishment and operation of Exchanges and the offering of QHPs through the Exchanges) to require that an issuer's reconsideration request meet a specified burden of proof. Specifically, we proposed revising § 155.1090(a)(2) to state that the burden is on an issuer that is denied certification to provide evidence that HHS' determination that the plan does not meet the certification criteria at § 155.1000(c) was in error.

As we stated in the Exchange Establishment Rule (76 FR 41891), offering only QHPs through an Exchange assures consumers that the coverage options presented through the Exchange meet certain minimum Federal standards. Given the voluntary nature of QHP certification, the FFEs utilize a process for QHP certification whereby the burden of proof is on issuers to provide sufficient evidence that they comply with those minimum Federal standards to obtain certification.[210] Consistent with this general approach towards QHP certification, we stated in the proposed rule (89 FR 82370) that we believe it is appropriate to propose formalizing that the burden of proof involved in a reconsideration request is also on issuers. Under this proposal, we stated that an issuer that is denied certification on an FFE would be responsible for submitting a request to HHS, as operator of the FFEs, for reconsideration of a denial determination.

In the proposed rule, we also proposed to revise § 155.1090(a)(2) to require that, as part of a reconsideration request, an issuer would be required to submit clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. We noted in the 2017 Payment Notice (81 FR 12289) that HHS expects to certify the vast majority of plans that meet the certification standards. To maximize this amount of time for health plans to prepare, submit, and revise QHP applications to the FFEs, HHS provides as much time as it can for issuers to demonstrate that they comply with the certification standards. In the proposed rule, we explained that the FFE's QHP certification timeline provides at least three opportunities for issuers to submit application materials to demonstrate that it meets minimum certification standards for a given plan year (four opportunities, if the issuer avails itself of an optional early bird submission). As such, by the time it issues a denial of certification, HHS will have typically already received substantial factual information from the issuer over the period of several months upon which it will have based its denial determination. It is unlikely that any additional evidence that the issuer would seek to provide upon reconsideration request that they had not already provided during the three or four rounds of application submissions would meaningfully weigh in favor of certification unless it clearly and convincingly establishes that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

In the proposed rule (89 FR 82370), we stated that under this proposal, we would expect evidence to be clear and convincing that HHS' determination was in error if the issuer demonstrates that HHS clearly misunderstood or misinterpreted facts or data already provided by the issuer in previously submitted application materials (such as network adequacy calculation errors). We stated that we would not expect evidence to be clear and convincing in this regard if it is substantially based on new information (such as the inclusion of new ECPs that the issuer did not include in previously submitted application materials) or is comprised of disputes of HHS' authority to ensure compliance with certification standards (such as a determination that making the plan available is not in the interest of the qualified individuals and qualified employers, under section 1311(e)(1)(B) of the ACA and § 155.1000(c)(2)) that would require HHS to perform de novo analysis before open enrollment.

Finally, we proposed to revise the title of § 155.1090 to state, ''Request for the reconsideration of a denial of certification'' and the subtitle of § 155.1090(a) to state, ''Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange.''

We sought comment on this proposal.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond to public comments received on the proposal to revise the standards for an issuer to request reconsideration of denial of certification as a QHP specific to the FFEs below.

Comment: We received a small number of comments on this proposal. Most commenters were in support, agreeing that the burden should be on the issuer receiving a denial of certification to provide HHS with ''clear and convincing'' evidence that its determination was in error.

Response: We are appreciative of these commenters' support of the proposal and of the rationale that we provided in the proposed rule.

[209] Section 1311(c)(1)(B) of the ACA and § 155.1000(c)(2) further provide that an Exchange may not exclude a health plan (i) on the basis that such plan is a fee-for-service plan, (ii) through the imposition of premium price controls, or (iii) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

[210] See § 155.1000(c)(1): ''The health insurance issuer provides evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156, as applicable.''

Comment: One commenter opposed the proposal due to the complexity of the QHP certification process and requirements and stated consumers are best served from increased issuer participation, and therefore, HHS should create more lenient certification standards to allow for the certification of plans with more innovative benefit designs.

Response: We agree with this commenter that increased issuer participation and innovation on the Exchanges serves consumers generally. However, the certification criteria are minimum requirements established by the ACA and CMS regulations for a plan to be offered on an Exchange, and innovation is not a substitute for compliance with these minimum requirements. Permitting issuers to offer Exchange plans that do not meet those requirements would run counter to our goal of ensuring that all QHPs provide essential health benefits, maintain reasonable cost-sharing limits, include adequate provider networks, and meet other requirements that help ensure Exchange consumers have access to a range of quality, affordable plans meeting their health needs.

With respect to the commenter's point that the QHP certification process is complex, the proposed rule noted that, in addition to providing robust technical guidance to issuers,[211] HHS provides as much time as it can for issuers to demonstrate that they comply with the certification standards. For example, HHS provides issuers with three separate opportunities to submit certification application materials to demonstrate that their plan meets minimum certification standards for a given plan year.[212] These opportunities have proven more than sufficient for issuers to demonstrate compliance with minimum certification requirements while still having the ability to innovate, as only a small number of issuers have been denied certification of all of the plans they submitted for certification on the FFEs since 2014. The denial of certification of a small fraction of plans that HHS has certified since 2014 has not had a material negative impact on consumers, as they had many other QHP options on the impacted FFEs to choose from that offered benefits comparable to the plans that were not certified.

9. General Program Integrity and Oversight Requirements (§ 155.1200)

We currently collect certain information and data from State Exchanges and SBE–FPs under § 155.1200 to monitor their performance and compliance. In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82369), we proposed under our authority under section 1321(a)(1)(D) of the ACA to promulgate appropriate requirements related to Exchanges, to also use this information and data to increase transparency into State Exchange operations and to promote program improvements.

Under § 155.1200, State Exchanges must report to HHS on certain Exchange-related activities and performance monitoring data. State Exchanges must also engage an independent qualified auditing entity which follows generally accepted government auditing standards (GAGAS) to annually compile a financial statement and conduct a financial audit and a programmatic audit.

To meet these requirements, under section 1313(a)(1) of the ACA, State Exchanges and SBE–FPs are required to submit a State Marketplace Annual Reporting Tool (SMART) to CMS, which CMS uses to monitor and evaluate State Exchange compliance with Exchange requirements under Title I of the ACA.[213] Through the SMART, State Exchanges and SBE–FPs attest to compliance with specific regulations, provide supporting documentation including, if applicable, a redetermination plan for the upcoming plan year, an oversight and monitoring plan with fraud, waste, and abuse policies and procedures, nondiscrimination policies and standards, and an operating budget with a financial statement. Additionally, the Exchanges submit the financial and programmatic audits with corrective action plans for any identified audit or findings. Following review, we provide State Exchanges and SBE–FPs with a SMART summary letter based on the observations and action items identified and monitor State Exchange completion of any open findings.

State Exchanges that operate their own eligibility and enrollment platform also report enrollment and Exchange activity data to CMS weekly during Open Enrollment and twice a year outside of Open Enrollment.[214] We publish Exchange Open Enrollment data annually.[215] We utilize the programmatic data received from State Exchanges to identify program risks and provide technical assistance to State Exchanges on corrective actions or strategies to mitigate risks, as well as to inform the development of new or updated policies as part of our annual rule-making processes to address known risks.

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule we explained our intention to use the information and data that State Exchanges and Exchanges on the Federal platform (SBE–FPs) submit to HHS under § 155.1200 to increase transparency into State Exchanges and to promote program improvements. Specifically, we described our plan to publicly release the State Exchange and SBE–FP annual State Marketplace Annual Reporting Tool (SMART) submitted to CMS annually and to expand on current Open Enrollment data reporting by publishing additional metrics on State Exchange operations and functionality that we currently collect from State Exchanges but do not currently report to external audiences. We also stated our intention that any public reporting of State Exchange operations and functionality would include the public release of comparable metrics for the FFE and SBE–FPs.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy with a modification. Commenters expressed support for increased transparency in Exchanges and agreement that any data released should include comparable data from the Exchanges on the Federal platform. State Exchange commenters raised challenges with posting the SMARTs since they contain non-public operational and business processes employed by Exchanges to maintain program integrity and combat fraud, such as procedures used for verifying consumer information. State Exchange

[211] See, for example, *https://www.qhpcertification.cms.gov/s/QHP.*

[212] The proposed rule (89 FR 82370) explained that issuers have four opportunities (instead of three) to submit certification application materials to demonstrate that their plan meets minimum certification standards if the issuer avails itself of an optional early bird submission opportunity. HHS is planning to enhance the application submission process in order to provide more contemporaneous results to issuers as soon as they submit their applications. As a result, HHS no longer intends to offer an early bird submission deadline in the certification process for PY 2026 or future plan years.

[213] *State-based Marketplace Annual Reporting Tool (SMART).* OMB Control Number: 0938–1244. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/smart_2017_5.pdf.*

[214] OMB Control Number: 0938–1119.

[215] See, for example, CMS. (2024, March 22). *2024 Marketplace Open Enrollment Period Public Use Files. https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files.*

commenters described the value the SMARTs provide as an oversight tool through which they are held to meeting Federal Exchange requirements but also receive technical assistance. They were concerned that restricting their responses to protect the release of sensitive operational issues would devalue the SMARTs and limit its effectiveness as an oversight mechanism. Commenters also questioned the value of indiscriminately releasing data in the format of individual SMARTs and instead encouraged us to identify standard metrics that could be presented to meaningfully compare across all Exchanges.

After further consideration, we will not release the SMARTs. Commenters raised valid concerns and we do not want to inadvertently expose Exchange system operations that could be susceptible to misuse or to constrain the efficacy of the SMARTs. We also recognize that there may be better ways to provide Exchange data than posting individual reports. For that reason, as proposed, we intend to expand our current Open Enrollment data reporting by publishing additional metrics on State Exchange operations and functionality. We intend, as resources permit, to proceed with preparing for the release of additional customer service data elements already described. Specifically, we will, at a minimum, publish the following data elements that we currently collect from State Exchanges but do not currently report to external audiences:

- Exchange actual expenditures on consumer marketing, education, and outreach for the most recent fiscal year available,
- Exchange actual expenditures on Navigator program, total allocation and per grantee,
- Exchange call center metrics during Open Enrollment:

++ Total number of incoming calls received by the call center.

++ The average wait time for each incoming call to the call center.

++ The number of incoming calls terminated while waiting to speak to a call center representative.

++ The average amount of time spent by call center representative on each individual call.

- Exchange website (eligibility and enrollment application and/or consumer) visitors during Open Enrollment:

++ Number of website and mobile application visits.

++ Number of unique visitors requesting the website and mobile application.

We will work with States in advance to evaluate the metric definitions and methodologies and provide technical assistance prior to publishing this data. We reaffirm that we will also publish reasonably comparable customer metrics from Exchanges on the Federal platform if data is available. This data will be released publicly by CMS.

We summarize and respond to public comments received on the proposed public release of Exchange data below.

Comment: Generally, all commenters supported increased transparency of Exchange operations; however, several commenters expressed concerns about the scope and breadth of the information to be published. Specifically, several State Exchanges cited concerns over potential fraud or security risks if certain operational data, particularly the information that is collected in the SMARTs, is made public.

Response: We agree that increased transparency is necessary to monitor the performance of Exchanges and promote program improvements. However, because of these concerns raised by State Exchanges, we will not be releasing the SMARTs.

Comment: Commenters were split on what data should or should not be included and how the data should be presented. Several commenters believed the data State Exchanges currently make public is sufficient for current oversight requirements. Many commenters, however, recommended identifying standard metrics across both State Exchanges and the Exchanges on the Federal platform to meaningfully compare across all Exchanges rather than indiscriminately releasing data we currently collect, and that any State Exchange information or data released should include comparable FFE data from Exchanges on the Federal platform. Many commenters recommended specific metrics that they would like to see reported by State Exchanges and the Exchanges on the Federal platform. A few commenters recommended ways CMS could display data including creating a centralized reporting website; developing an Exchange performance measurement tool to assess Exchange quality and consumer experience; working with interested parties to identify set metrics and publish a joint State Exchange/Exchanges on the Federal platform data report; and adding data elements to the current PUF files.

Response: We recognize that regulations exist requiring State Exchanges to make certain data public and that some State Exchanges offer data above and beyond the regulatory requirements in various formats. We believe, however, that releasing additional data metrics will increase the public's understanding of State Exchanges and provide more transparency into our compliance activities. We also appreciate the recommendations on what specific data metrics could be identified, and how we should present data to the public. We will take these recommendations into consideration when it is time to publish data in the future. Initially, we intend to post most data through public communication channels to be determined by CMS. We intend to release the metrics originally proposed, if data from the Exchanges on the Federal platform is also available, and we will work with States through technical assistance to further identify and refine the additional metrics for public reporting that will be released for both State Exchanges and Exchanges on the Federal platform.

D. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Solicitation of Comments—Reducing the Risk That Issuer Insolvencies Pose to the Integrity of the FFEs

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82371), we solicited comments on methods that HHS, as operator of the FFEs, could potentially employ, in partnership with State regulators, to reduce the risk that issuer insolvencies pose to the integrity of the FFEs. We will take comments received into consideration in future rulemaking.

2. FFE and SBE–FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82373), we proposed an FFE user fee rate of 2.5 percent of total monthly premiums and an SBE–FP user fee rate of 2.0 percent of total monthly premiums for the 2026 benefit year. We also proposed a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums and an SBE–FP user fee rate range between 1.4 and 1.8 percent of total monthly premiums, with each of these ranges to be set at a single rate in this final rule, if the enhanced PTC subsidies at the level currently enacted [216] or at a higher level are extended through the 2026 benefit year by March 31, 2025. We sought comment

[216] ARP, Public Law 117–2, 135 Stat. 4 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169, 136 Stat. 1818 (2022) and are scheduled to expire after the 2025 calendar year.

on whether March 31, 2025 would provide sufficient time and whether we should select an earlier or later date.

Section 1311(d)(5)(A) of the ACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the ACA directs HHS to operate an Exchange within the State. Accordingly, in § 156.50(c), we provide that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. OMB Circular A–25 established Federal policy regarding user fees and what the fees can be used for.[217] OMB Circular A–25 provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public.

a. FFE User Fee Rates for the 2026 Benefit Year

Section 156.50(c)(1) provides that, to support the functions of FFEs, an issuer offering a plan through an FFE must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE. As in benefit years 2014 through 2025, issuers seeking to participate in an FFE in the 2026 benefit year will receive two special benefits not available to issuers offering plans in State Exchanges: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2026 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit are not covered by the FFE user fee.

As discussed in detail in the proposed rule (89 FR 82373 through 82375), the proposed user fee rate reflected our estimates for the 2026 benefit year of costs for operating the FFEs, premiums, enrollment, and transitions in Exchange models from the FFE and SBE–FP models to either the SBE–FP or State Exchange models. We proposed a 2026 benefit year FFE user fee rate of 2.5 percent of total monthly premiums, which is greater than the 2025 benefit year fee rate of 1.5 percent of total monthly premiums. We noted that if any events occurred between the proposed rule and the final rule that significantly changed our estimated costs to operate the FFEs or the Federal platform or our projections of premiums or enrollment, we may finalize FFE and SBE–FP user fee rates that differ from the proposed rates to reflect those changes.

In addition to proposing a FFE user fee rate that assumed the expiration of enhanced PTC subsidies, we proposed a 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums, to be set at a single rate in this final rule, if the current level or a higher level of enhanced PTC subsidies is extended through the 2026 benefit year by March 31, 2025. We sought comment on the proposed 2026 benefit year FFE user fee rate of 2.5 percent of total monthly premiums and the alternative proposed 2026 benefit year FFE user fee rate range between 1.8 and 2.2 percent of total monthly premiums.

We refer readers to the proposed rule (89 FR 82373 through 82376) for further discussion of the proposed 2026 benefit year FFE user fee rate and the alternative proposed 2026 benefit year FFE user fee rate range, including the factors considered in developing the proposed user fee rates and the rationale for our proposals.

b. SBE–FP User Fee Rates for the 2026 Benefit Year

Section 156.50(c)(2) requires that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an SBE–FP. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions and enhance efficiency and coordination between State and Federal programs. The benefits provided to issuers in SBE–FPs by the Federal Government include use of the FFE information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the ACA, and QHP enrollment functions under 45 CFR part 155, subpart E. The user fee rate for SBE–FPs is calculated based on the proportion of total FFE costs associated with Federal activities that provide these benefits to the SBE–FP issuers.

To calculate the proposed SBE–FP rates for the 2026 benefit year, we used the same assumptions related to contract costs, enrollment, and premiums as we used for the proposed FFE user fee rates. Based on this methodology, we proposed a 2026 benefit year SBE–FP user fee rate of 2.0 percent of total monthly premiums, which is greater than the user fee rate of 1.2 percent of total monthly premiums that we established for the 2025 benefit year. As discussed in the proposed rule (89 FR 82373 through 82376), we also proposed an alternative SBE–FP user fee range between 1.4 percent and 1.8 percent of total monthly premiums, to be set at a single rate in this final rule, if the current level or a higher level of enhanced PTC subsidies is extended through the 2026 benefit year by March 31, 2025. We sought comment on the proposed 2026 benefit year SBE–FP user fee rate of 2.0 percent of total monthly premiums and the alternative proposed 2026 benefit year SBE–FP user fee rate range between 1.4 percent and 1.8 percent of total monthly premiums.

We refer readers to the proposed rule (89 FR 82373 through 82376) for further discussion of the proposed 2026 benefit year SBE–FP user fee rate and the alternative proposed 2026 benefit year SBE–FP user fee rate range, including the factors considered in developing the proposed user fee rates and the rationale for our proposals.

We are finalizing two sets of FFE and SBE–FP user fee rates accounting for the

[217] See OMB. (n.d.) Circular No. A–25 Revised. *https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.*

expiration and extension of enhanced PTC subsidies. If enhanced PTC subsidies expire as currently set forth in the IRA,[218] we are finalizing as proposed the 2026 benefit year user fee rate for all issuers offering QHPs through an FFE to be 2.5 percent of the monthly premium charged by the issuer for each policy under FFE plans, and the 2026 benefit year user fee rate for all issuers offering QHPs through an SBE–FP to be 2.0 percent of the monthly premium charged by the issuer for each policy under SBE–FP plans. If enhanced PTC subsidies at the level currently enacted [219] or at a higher level, are extended through the 2026 benefit year by July 31, 2025, we are finalizing an alternative set of 2026 benefit year FFE and SBE–FP user fee rates of 2.2 percent and 1.8 percent of total monthly premiums, respectively, which are both within the range set forth in the final rule. Both sets of user fee rates have been finalized after consideration of comments, and for the reasons outlined in the proposed rule and this final rule, including our responses to comments. The finalized, alternative user fee rates were informed by updates to our projected enrollment [220] and premium growth estimates based on the most recent data (along with our latest budget projections). Additionally, after consideration of the comments, we are finalizing July 31, 2025, as the date by which the enhanced subsidies must be extended in order to trigger the alternate user fees, instead March 31, 2025, as proposed.

We summarize and respond to public comments received on the proposed 2026 benefit year FFE and SBE–FP user fee rates below.

Comment: Most commenters supported the 2026 benefit year user fee rates, with several of these commenters supporting user fee rates that adequately fund Federal programs. Some commenters supported maintaining the 2025 user fee rates or lowering the proposed 2026 user fee rates. These commenters stated that a higher user fee rate could lead to increased premiums and affect competitiveness of Exchange plans compared to off-Exchange plans, thereby impacting the affordability of health insurance.

Many commenters also expressed concern about the impact of the expiration of enhanced PTC subsidies on user fees and Exchange enrollment, as well as specifically how the expiration may impact enrollment projections or other factors used to determine 2026 benefit year user fee rates. One commenter stated that the proposed 2026 benefit year user fee rates may be lower than required to sufficiently fund costs if enrollment declines more than expected as a result of the expiration of enhanced PTC subsidies.

Response: We are finalizing the 2026 benefit year FFE and SBE–FP user fee rates as proposed. While we acknowledge that FFE and SBE–FP user fee rates impact the costs of plans offered in the FFEs and SBE–FPs, and by extension may impact premiums, we continue to calculate and set these FFE and SBE–FP user fee rates annually in a manner that ensures sufficient funding for operations of the FFEs and SBE–FPs.

We recognize commenters' concerns about the expiration of enhanced PTC subsidies, and in the proposed rule (89 FR 82373 through 82376), we noted the uncertainty around the expiration or extension of these enhanced subsidies and the potential impact on enrollment and premium growth in the Exchanges. In the proposed rule (89 FR 82375), we explained that if enhanced PTC subsidies expire, we project that the total enrollment through FFEs and SBE–FPs would decrease, and in turn, issuers would likely rate for the uncertainty associated with the expected decreased enrollment in the risk pool and increased premiums for 2026. We maintain this projection, and anticipate a decrease in enrollment beginning in 2026, which may exert upward pressure on premiums. Despite this uncertainty, we must set user fee rates that will allow us to sufficiently fund and operate the FFEs and the Federal platform based on the latest budget projections. Our data suggests that the user fees being finalized in this rule—which account for the possibility that enhanced PTC subsidies may expire or be extended—would do so.

Comment: Commenters had mixed opinions regarding the proposed March 31, 2025 deadline to apply a set of alternative user fee rates if enhanced PTC subsidies are extended. Some of these commenters wanted final user fee rates to be known by or before March 31, 2025 to allow sufficient time for issuers to set premiums and comply with State and Federal filing deadlines. Other commenters suggested the deadline could be later than March 31, 2025, as all States do not need to submit 2026 benefit year rate filings until August 2025. One commenter suggested that HHS should put the user fee rates in guidance or allow for multiple rate filing submissions.

Response: After considering comments, we are finalizing a revised deadline of July 31, 2025, for determining whether the alternative FFE and SBE–FP user fee rates will apply. The alternative 2026 benefit year user fee rates finalized in this rule will only take effect if enhanced PTC subsidies are extended through the 2026 benefit year at the current level or a higher level by July 31, 2025. While we proposed a March 31, 2025, deadline to provide issuers sufficient time to request rates and States sufficient time to review rate requests, we agree with commenters that the proposed March 31, 2025 deadline could be later, as issuers can submit changes to their benefit year 2026 QHP Applications, including updated rate data in the Rates Table Template of an issuer's QHP Application, as late as August 13. In finalizing the July 31, 2025, deadline, we recognize that many States allow issuers to file multiple rate filings to justify proposed rate increases depending on the uncertainty of factors applicable to the filing under review. In addition, we have previously provided flexibility on filing deadlines to allow States to account for rating changes in response to uncertain circumstances. For example, when issuers of silver-level QHPs were facing increased liability for enrollees in cost-sharing reduction plan variations after HHS stopped making cost-sharing reduction payments to issuers, we accounted for this change in single risk pool rate setting by extending the issuer filing deadline for QHPs and non-QHPs. Similarly, to provide the latest possible deadline that would allow issuers sufficient time to account for the uncertainty surrounding the expiration of enhanced PTC subsidies and allow issuers and States to set and approve rates under the existing filing deadlines, we are finalizing this revised July 31, 2025, deadline to establish the

[218] ARP, Public Law 117–2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169 (2022) and are scheduled to expire after the 2025 calendar year.

[219] ARP, Public Law 117–2 (2021). These enhanced subsidies were extended under the IRA, Public Law 117–169 (2022) and are scheduled to expire after the 2025 calendar year.

[220] As described in the proposed rule (89 FR 82373 through 82376), user fee rates are based, in part, on projected enrollment during the 2025 open enrollment period and may change between the publication of the proposed rule and final rule. At the time of this final rule, more data is available about the 2025 open enrollment period and about the projected 2025 open enrollment numbers to determine user fee rates than we had for the proposed rule. Thus, after accounting for updated open enrollment data, we have finalized single FFE and SBE–FP user fee rates within the proposed ranges if enhanced PTC subsidies are extended at the level currently enacted or at a higher level and finalized the proposed FFE and SBE–FP user fee rates if enhanced PTC subsidies expire as enacted. See Marketplace 2025 Open Enrollment Period Report National Snapshot, as of December 4, 2024: *https://www.cms.gov/newsroom/fact-sheets/marketplace-2025-open-enrollment-period-report-national-snapshot-0.*

alternative user fee rates. We believe this deadline will also help reduce uncertainty, and by extension any upward pressure on premiums, and help ensure that we do not impose higher user fees than necessary to fund the operations of the FFEs and the Federal platform.

Comment: A few commenters suggested that HHS should adopt a PMPM user fee structure, stating that administrative costs do not track with premium changes and a PMPM user fee would avoid higher fee amounts based solely on premium increases.

Response: We did not propose any changes to the user fee structure; as such, the user fee rates will continue to be set as a percent of the premium. We note that we propose and finalize user fee rates each benefit year and can adjust the user fee rates to avoid higher fee amounts based solely on premium increases. However, we will continue to engage with interested parties regarding how the FFE and SBE–FP user fee policies can best support consumer access to affordable, quality health insurance coverage through the Exchanges that use the Federal platform.

Comment: One commenter requested increased transparency on user fees and wanted additional information on how user fee collections support HHS' policy goals for the Exchanges. The same commenter requested enumerated costs of providing Federal eligibility and enrollment platform service and infrastructure to each State.

Response: HHS collects user fees in accordance with Section 1311(d)(5)(A) of the ACA which permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. Therefore, our goal in collecting user fees is to collect user fees at a rate that will allow us to sustain the operations of the FFEs and SBE–FPs. In the proposed rule (89 FR 82373 through 82376, 82402), we provided information on the assumptions used to calculate the 2026 benefit year user fee rates.

3. CSR Loading (§ 156.80)

In response to the termination of CSR payments to issuers in 2017,[221] State DOIs generally permitted or instructed their issuers to increase premiums only, or primarily, on silver-level QHPs, to compensate for the cost of offering CSRs, since the vast majority of eligible enrollees receiving CSRs are enrolled in silver plans. The proposed rule (89 FR 82376) reiterated that practices to increase premiums to offset amounts of unpaid CSRs [222] that are permitted by State regulators are permissible under Federal law to the extent that they are reasonable and actuarially justified. We further stated that we were considering codifying this by amending the single risk pool regulations at § 156.80(d)(2)(i) to state that the plan-specific factors by which issuers may adjust the market-wide index rate include adjustments that reflect the costs associated with providing CSRs to the eligible enrollee population, to the extent that such adjustments are reasonable and actuarially justified. We sought comment on whether and how to codify this policy at § 156.80. We refer readers to the proposed rule (89 FR 82376 through 82377) for a detailed discussion, including the history of CSR payments to QHP issuers.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing amendments to § 156.80(d)(2)(i) to specify that the actuarially justified plan-specific factors by which an issuer may vary premium rates for a particular plan from its market-wide index rate include the actuarial value and cost-sharing design of the plan, including, if permitted by the applicable State authority, accounting for CSR amounts provided to eligible enrollees under § 156.410, provided the issuer does not otherwise receive reimbursement for such amounts. We summarize and respond below to public comments received on the amendments considered in the proposed rule.

Comment: Most commenters generally supported amending § 156.80(d)(2)(i) to explicitly note that plan-specific adjustments to the market-wide index rate that account for CSR loading, as permitted by State regulators, are permissible, stating that codifying this would promote market stability and provide greater clarity for issuers. One commenter supported the continuation of the practice of CSR loading but noted that codifying the allowability of this practice in regulation may not be necessary, as it is not altering the position that CMS has already provided in written guidance. In contrast, one commenter opposed codifying language regarding the practice of CSR loading in § 156.80(d)(2)(i), stating that CSR loading is a temporary measure that creates significant market distortions and increases Federal PTC spending.

Response: We agree with commenters that supported codifying language specifying in § 156.80(d)(2)(i) that CSR loading is permissible under Federal premium rating requirements. We agree that the practice of CSR loading has helped to promote market stability, as evidenced by the adoption of CSR loading in most States.[223] While we understand that many States intended to permit loading practices that specifically reimburse issuers for unpaid CSRs, we recognize that CSR loading practices vary and may not be critical to promoting market stability under all market conditions. For this reason, we have consistently deferred to States, as the traditional regulators of insurance and rating practices, to provide issuers with pricing guidance on how to account for unpaid CSRs in an actuarially-justified manner. This codification does not change our deference to States.

States have provided guidance to issuers absent express language in § 156.80(d)(2) for years. We have concluded that it is appropriate to codify language regarding CSR loading in regulatory text because such amendments will provide greater clarity. Since the cessation of CSR payments in 2017, States and issuers have requested that we clarify how the single risk pool rules at § 156.80 apply with regard to CSR loading. We released guidance responsive to such requests in 2018 [224] and have consistently repeated that the ACA permits States' rating practices for CSR loading, as long as the resulting rate adjustments are actuarially justifiable pursuant to § 156.80. Because we continue to receive questions about permissible CSR loading practices, we have determined it is appropriate to codify that CSR loading is permitted under Federal

[221] See discussion in the proposed rule of the history of CSR payments to QHP issuers (89 FR 82376). As discussed in the proposed rule, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 could not be used to fund CSR payments to issuers.

[222] Rating practices to increase premiums to offset amounts of unpaid CSRs are referred to as ''silver loading'' (if premiums are increased on silver-level plans only), ''broad loading'' (if premiums are increased on all plans in the relevant State market, not just silver-level plans), or ''CSR loading'' generally. For purposes of this preamble, we use the term ''CSR loading'' to refer to any rating practices to increase premiums to offset amounts of unpaid CSRs.

[223] Uccello, CE, American Academy of Actuaries, ''Considerations for Calculating Cost-Sharing Reduction Load Factors,'' Society of Actuaries Virtual Health Meeting Session 3C, available at *https://www.actuary.org/sites/default/files/2023-07/2023_SOA_Session_3C_Uccello.pdf.*

[224] *See,* CMS. (2018, Aug. 3). Center for Consumer Information & Insurance Oversight, Insurance Standards Bulletin Series—Information, Offering of plans that are not QHPs without CSR ''loading,'' *https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/offering-plans-not-qhps-without-csr-loading.pdf.*

rules, provided any such adjustments are actuarially justified and the issuer does not otherwise receive reimbursement for such amounts.

We also recognize that CSR loading leads to higher PTCs and other pricing impacts that can alter how markets function. However, in light of the continued absence of Congressional action to fund CSRs, CSR loading continues to promote market stability, and we are codifying Federal policy that permits such premium rating under Federal premium rating requirements.

Comment: Some commenters encouraged CMS to affirm deference to State regulators to determine if and how CSR loading practices exist in their State, and other commenters, while supporting amendments to § 156.80(d)(2)(i), recommended against adoption of any further requirements on State approaches to CSR loading. Several commenters that supported amending § 156.80 encouraged HHS to avoid language that may, inadvertently or otherwise, limit State flexibilities, roll back State progress in pursuing innovative solutions, or undermine State methodologies to lower the cost of care. One commenter was concerned that a strict interpretation of the changes discussed in the proposed rule may require States to make significant changes to their strategic health policy initiatives related to CSR loading, which may have a destabilizing impact on the individual market. That commenter sought clarification regarding whether HHS intends to impose a test of reasonableness or actuarial justification that may override existing CSR loading practices permitted by States. Another commenter requested that CMS amend regulations to recognize the existing authority of States to establish rating rules for their markets. One commenter, who appears to have interpreted the discussion in the proposed rule to suggest that HHS was considering codifying a requirement that issuers use CSR loading when setting rates,[225] noted concern that codifying the practice of CSR loading in Federal regulation would undermine State authority to regulate insurance and stated that unfunded CSRs should be addressed through a Congressional appropriation, not regulatory codification of a workaround.

Response: Recognizing States' traditional role in regulating insurance and rating practices, this final rule codifies longstanding statements that, in light of the continued absence of Congressional action to fund CSRs and given States' well-established role as the primary regulators of insurance, the ACA permits States' rating practices for CSR loading, as long as the resulting rate adjustments are actuarially justifiable and otherwise comply with the requirements in § 156.80. The final rule codifies this deference to State regulators to determine if and how CSR loading practices exist in their State by permitting CSR loading ''if permitted by the applicable State authority (as defined in § 144.103 of this subchapter).''

States may determine how to implement CSR loading in their State. However, there is no requirement for States to do so. Likewise, in those States that have an Effective Rate Review Program,[226] the State has the responsibility to determine whether an issuer's adjustments to the market-wide index rate for plan-specific factors (including accounting for CSR amounts) are actuarially justified.

Comment: Many commenters that supported the regulatory codification made recommendations regarding amendatory language in § 156.80(d)(2)(i). For example, some commenters suggested adding ''including cost-sharing reductions under subpart E of this part 156 if not paid for under § 156.430,'' while another commenter suggested adding ''including adjustments for CSRs if not otherwise reimbursed.'' One commenter, noting that HHS uses both ''CSR loading'' and ''actuarial loading'' to describe the premium loads arising due to the lack of Federal funding for CSRs, suggested that the term ''CSR loading'' is more appropriate because it is more specific. The commenter noted that ''actuarial loading'' could refer to a broader range of premium loads, including those related to new benefits or administrative expenses. Another commenter that supported the regulatory codification noted that current requirements for plan-level adjustments in § 156.80(d) require all such adjustments to be ''actuarially justified,'' but not ''reasonable,'' and therefore, urged HHS to define ''reasonable'' if included in amendments to § 156.80(d).

Response: Section 156.80(d)(2)(i) provides that an issuer may vary premium rates for a particular plan from its market-wide index rate for a relevant State market based on the actuarial value and cost-sharing design of the plan. We are finalizing amendments to § 156.80(d)(2)(i) specifying that adjustments related to the actuarial value and cost-sharing design of the plan may include, if permitted by the applicable State authority (as defined in § 144.103 of this subchapter), accounting for CSR amounts provided to eligible enrollees under § 156.410, provided the issuer does not otherwise receive reimbursement for such amounts. We note that these amendments do not use the shorthand terms ''CSR loading,'' ''silver loading'' or ''actuarial loading.'' With respect to the comments regarding the use of the term ''reasonable'' in regulatory text, § 156.80(d) requires all permitted plan-level adjustments to be ''actuarially justified'' and does not apply a separate ''reasonableness'' standard to permitted plan-level adjustments. We therefore have not included the word ''reasonable'' in the amendments to § 156.80(d)(2)(i). We note that States with an Effective Rate Review Program or CMS will continue to review rates to determine whether rate increases subject to review are unreasonable, pursuant to section 2794 of the PHS Act and 45 CFR part 154.

Comment: One commenter noted concern that the discussion in the preamble of the proposed rule could be read to require the portion of silver premiums associated with CSRs to be experience-rated. The commenter therefore requested that HHS clarify that however a State approaches CSR loading, metal-level pricing must meet single risk pool requirements, and rates for individual plans must be set using methods that are actuarially justified.

Response: Section 156.80(d)(2)(i), as amended, does not require States or issuers to follow a specific methodology when accounting for unpaid CSRs, so long as any such adjustments are actuarially justified. When we issued guidance regarding CSR loading in 2018, we confirmed that, under Federal law, States may allow or require their issuers to apply a premium load that would cover the cost of amounts of unpaid CSRs. We recognize that States have directed or permitted issuers to adjust rates to reflect unreimbursed CSRs using a range of methodologies.[227]

Comment: Some commenters recommended actions HHS should take in recognition of the absence of an appropriation to pay CSRs, the existence of the practice of CSR loading, and the attendant impact of CSR loading on the

[225] Nothing in this final rule requires a State to allow CSR loading.

[226] State authority to maintain an Effective Rate Review Program, including establishing rating rules for their markets, is codified in 45 CFR 154.210(b), 154.225(b) and 154.301.

[227] Uccello, CE, American Academy of Actuaries, ''Considerations for Calculating Cost-Sharing Reduction Load Factors,'' Society of Actuaries Virtual Health Meeting Session 3C, available at *https://www.actuary.org/sites/default/files/2023-07/2023_SOA_Session_3C_Uccello.pdf.*

level of APTC paid. For example, one commenter recommended further action, such as the authorization of a pooled CSR fund, to address market distortions. A few commenters recommended further consideration of how silver loading interacts with risk adjustment, including potential modifications to the risk adjustment State payment transfer formula to account for the impact of CSR loading. One commenter noted that CSR loading will result in higher APTCs and requested that CMS allow consumers to apply such higher APTC amounts toward adult and pediatric dental care when included in silver-level QHPs as well as premiums for stand-alone dental plans (SADPs).

Response: We appreciate commenters' recommendations. We lack a specific appropriation to create a pooled CSR fund to address market distortions as one commenter recommended.

We recognize that the HHS-operated risk adjustment program serves as an important market stabilizing tool, but we did not propose and are not adopting in this final rule any changes to the risk adjustment State payment transfer formula that applies in States where HHS is responsible for operating the program to account for the impact of CSR loading. Instead, we are continuing to study these issues and their impact on HHS-operated risk adjustment to consider whether potential updates are needed to risk adjustment, including changes to the State payment transfer formula and the CSR adjustment factors discussed in section III.B.2.e of this final rule. If any updates are needed, we would propose them through notice-and-comment rulemaking.

With respect to the comment regarding permitting consumers to use excess APTC to pay for dental benefits, this is permitted to the extent that dental care is an EHB.[228]

Comment: A few commenters requested that issuers no longer be required to notify the Secretary of any reduced CSR amounts for QHPs.

Response: In accordance with § 156.430(d), in the absence of an appropriation for HHS to make advance CSR payments to issuers, the submission of CSR data under § 156.430 is optional.

[228] Pediatric dental benefits are an EHB. Beginning in PY 2027, States can choose to make adult dental care an EHB when updating their EHB-benchmark plan. In States that update their EHB-benchmark plan to include adult dental care, it will be an EHB and therefore APTC can go towards that benefit. APTCs cannot go toward adult dental SADP premiums at this time.

4. Publication of the 2026 Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage in Guidance (§ 156.130(e))

As established in part 2 of the 2022 Payment Notice (86 FR 24238), for benefit years in which we are not making changes to the methodology to calculate the premium adjustment percentage, the required contribution percentage, and maximum annual limitations on cost sharing and reduced maximum annual limitation on cost sharing, we will publish these parameters in guidance annually starting with the 2023 benefit year. Therefore, because we did not propose to change the methodology for calculating these parameters for the 2026 benefit year, these parameters are not included in this rulemaking. Instead, on October 8, 2024, we published these 2026 benefit year parameters [229] in guidance in accordance with our 2022 Payment Notice regulations.

5. AV Calculation for Determining Level of Coverage (§ 156.135)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82377), we stated that we intend to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator.

Section 2707(a) of the PHS Act and section 1302 of the ACA direct issuers of non-grandfathered individual and small group health insurance coverage, including QHPs, to ensure that plans meet a level of coverage, or metal tier, specified in section 1302(d)(1) of the ACA. Each level of coverage corresponds to an AV calculated based on the cost-sharing features of the plan. On February 25, 2013, HHS published the EHB Rule (78 FR 12834), implementing section 1302(d) of the ACA, which requires at subsection (d)(2)(A) that, to determine the level of coverage for a given metal tier, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a), as finalized in the EHB Rule, provides that an issuer must use the AV Calculator developed and made available by HHS for the given benefit year to calculate the AV of a health plan, subject to the exception in paragraph (b).

In the 2015 Payment Notice (79 FR 13744), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years. We stated in the preamble of the 2015 Payment Notice that we intend to release a draft version of the AV Calculator and AV Calculator Methodology through guidance for public comment each plan year before releasing the final version. In that same rule, we noted that interested parties could submit feedback on changes to the AV Calculator, and that we would consult as needed with the American Academy of Actuaries and the National Association of Insurance Commissioners on changes to the AV Calculator.

In the 2017 Payment Notice (81 FR 12204), we reiterated this approach and amended § 156.135(g) to allow for additional flexibility in our approach and options for updating the AV Calculator each year, which include trend factor updates, algorithms changes, user interface changes, updates to the claims data and demographic distribution being used in the AV Calculator, and an update to the AV Calculator's annual limitation on cost sharing. We also stated that we intend to release the final AV Calculator for a respective plan year no later than the end of the first quarter of the preceding plan year.

Since this time, we have largely fulfilled this intention. However, we have received feedback that we should strive to release the final version of the AV Calculator even sooner, in anticipation of State filing deadlines. SBE–FPs have also provided feedback explaining that they could benefit from an earlier release of the final version of the AV Calculator to design standardized plan options that satisfy the AV de minimis ranges. We stated in the proposed rule that we believe these requests are reasonable and that we can accommodate them in most years when there are no material changes between the draft and final versions of an AV Calculator for a respective plan year.

Therefore, in the proposed rule (89 FR 82377), we stated that we intend to revise the current method whereby we release a draft version of the AV Calculator for a respective plan year through guidance for public comment and then release the final version of the AV Calculator for that plan year no later than the end of the first quarter of the preceding plan year after considering any comments received. We stated that we intend to only release the single, final version of the AV Calculator for a respective plan year. We noted that under this approach, we would still solicit public comments on the AV Calculator for a plan year generally, but we would only plan to incorporate this

[229] Available at *https://www.cms.gov/files/document/2026-papi-parameters-guidance-2024-10-08.pdf.*

feedback into the development and release of the following plan year's AV Calculator, rather than to specifically inform the potential revision of the final version of the upcoming plan year's AV Calculator. We noted that this approach would allow us to release the final AV Calculator sooner and that we anticipated issuers would have the final version of the AV Calculator 3 to 6 months sooner than the end of the first quarter of the preceding plan year.

We also noted that this approach would not sacrifice the quality of the AV Calculator. We stated that the stability and functionality of the AV Calculator has improved every year, and that we believe there are diminishing returns to receiving public comments on specific versions of it at this time. We noted that this is particularly evident given that we receive fewer than 10 comments on average each year on the draft AV Calculator. In addition, we noted that since the first AV Calculator was released for PY 2014, we have never made substantive changes in a final version of the AV Calculator for a plan year based on comments received on the draft version for that plan year, though this feedback is valuable to us and informs our decisions to update the AV Calculator in subsequent plan years. We added that this decision to not make substantive changes to the final version of the AV Calculator is also partly influenced by the limited timeframe we would have to make substantive changes to the final AV Calculator.

Thus, changes from the draft to the final version of the AV Calculator have historically only included non-substantive amendments to correct and clarify language in the AV Calculator Methodology or to add frequently asked questions to the AV Calculator User Guide. We stated that since these changes have historically been so minor, we believe the time delay required to effectuate those changes and release the final AV Calculator by the end of the first quarter of the preceding plan year is less valuable to issuers than releasing the final version sooner. We noted that under this approach, we would leave open the rare possibility that we could reissue another final version of the AV Calculator for a plan year if we discover the AV Calculator contains an error that materially impacts the functionality or accuracy of that version of the AV Calculator. We noted that although this has never happened to date, under the current framework of releasing both a draft and final version of the AV Calculator, if we had discovered a material error in the final version, we also would have reissued a corrected, final version.

We also noted that under this approach, we would still seek public comment on the AV Calculator for a plan year generally and would still consult with the American Academy of Actuaries, as well as the National Association of Insurance Commissioners. We further stated that we would consider this feedback for incorporation into the following year's AV Calculator.

In addition, we stated that to maximize the benefits of this approach, we intended to make this change effective starting with the release of the 2026 AV Calculator. We noted that we believe there would be minimal effect in effectuating this change with the 2026 AV Calculator because we intend to base the 2026 AV Calculator substantially on the final 2025 AV Calculator, and do not plan to make any material changes to it.

We sought comment on this approach.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this approach to release only the single, final version of the AV Calculator for a respective plan year. We summarize and respond to public comments received on this approach below.

Comment: Many commenters supported the approach to release only the single, final version of the AV Calculator for a respective plan year. These commenters noted that an earlier release of the final AV Calculator provides States and issuers with additional time to prepare plan designs ahead of rate and form filing deadlines. Several commenters mentioned that this earlier release will give Exchanges more time to finalize their State-specific standardized plan designs. A few commenters also noted that this revised approach is more efficient and reduces duplicative work and administrative burden for issuers.

Some commenters provided feedback on the timing of the release of the final AV Calculator. One commenter requested that the final AV Calculator be released in October in future years, on a similar timeline to this year. Other commenters requested that the final AV Calculator be released no later than 13 or 14 months before the applicable plan year, while several commenters requested that the AV Calculator be released as early as possible. Lastly, a commenter requested we clarify that once the final version of the AV Calculator is released, issuers and States will have certainty that it is the final version.

Response: We agree with commenters that finalizing this revised approach for releasing the AV Calculator will create efficiencies and reduce administrative burden for issuers, States, and Exchanges.

While we cannot commit to specific timeframes for the release of future final AV Calculators, we stated in the proposed rule (89 FR 82377) that we expect to release the final version of the AV Calculator 3 to 6 months sooner than when we have historically published the final AV Calculator for the forthcoming plan year. In connection with this rule, we released the final 2026 AV Calculator on October 16, 2024, more than 14 months before the plans that use it would become effective.

Once we release the final version of the AV Calculator for a particular plan year, issuers, States, and Exchanges can expect that, except in rare circumstances, we would not thereafter release a subsequent version of the AV Calculator for that plan year. As stated in the proposed rule (89 FR 82377 through 82378), we leave open the rare possibility that we could reissue another final version of the AV Calculator for a plan year if we discover the AV Calculator contains an error that materially impacts the functionality or accuracy of that version of the AV Calculator. However, this has never happened to date. Under the current framework of releasing both a draft and final version of the AV Calculator, if we had discovered a material error in the final version, we also would have reissued a corrected, final version, so this revised approach is in line with precedent.

Comment: A few commenters suggested that we could achieve the same goal of releasing the final version of the AV Calculator sooner by releasing the draft version earlier as well. One commenter specifically requested that the draft AV Calculator be released in the spring, while two others requested that the draft AV Calculator generally be released earlier to provide even more time to analyze changes to that plan year's AV Calculator.

Response: Releasing a draft version of the AV Calculator in the spring is not technically possible. As discussed in the 2015 Payment Notice (79 FR 13811), certain updates to the AV Calculator are dependent on the timeline of availability of the necessary data elements. These data elements are unavailable in the spring for the plan year 2 years in the future (for example, spring 2024 for PY 2026). This includes the trend factors based on data collected through the Unified Rate Review

Templates and the maximum annual limitation on cost sharing, published annually in the PAPI parameters guidance. Both these data elements are unavailable until late summer or early fall. So, we cannot release the draft AV Calculator in the spring or even the summer. The earliest we could release a draft AV Calculator is in the fall as we have in previous years. It is not technically possible for us to receive and analyze this data, incorporate it into the next build of the AV Calculator, perform quality assurance, release a draft version, solicit public feedback, and make revisions to the final AV Calculator based on that feedback and still release a final version 13 or 14 months before the plans that use it would become effective.

Comment: Many commenters noted the ongoing importance of collecting and incorporating public feedback on the AV Calculator, despite no longer releasing the draft version. A few commenters agreed with our rationale to condense this process since we have received fewer than 10 comments on average each year on the draft AV Calculator and agreed that eliminating the draft version to release the final version earlier is an acceptable tradeoff to gain access to the final AV Calculator earlier.

Several commenters provided feedback on the process to collect input on the AV Calculator. One commenter noted that this change will allow issuers to provide feedback throughout the year. Conversely, several commenters requested that HHS establish a formal AV Calculator comment period that does not overlap with the Payment Notice comment period. The commenters stated that establishing a comment period would ensure that we receive input from all interested parties before starting work on the next year's AV Calculator, and creating a comment period distinct from the Payment Notice comment period would give interested parties more time to thoughtfully prepare feedback. In addition, one commenter distinguished between minor updates to the AV Calculator, such as updating the maximum out-of-pocket limits, that may not necessitate a formal comment period, versus more material changes when a comment and response period would be more appropriate.

Response: Public feedback on the AV Calculator is essential to its accuracy and functionality. Under this revised approach, we will still solicit public comments on the AV Calculator but will only seek to incorporate this feedback into the development and release of the following plan year's AV Calculator, rather than into the development of the same plan year's AV Calculator. As we noted in the proposed rule (89 FR 82379), this revised approach is justified given that the stability and functionality of the AV Calculator has improved every year, and we believe there are diminishing returns to receiving public comments on a draft version for incorporation into a final version for a particular plan year. We also noted that we receive fewer than 10 comments on average each year on the draft AV Calculator. We agree that collecting and incorporating public feedback on the AV Calculator is valuable, and we encourage and welcome feedback from all interested parties on the 2026 final AV Calculator and future final AV Calculators.

Given this revised approach, we do not believe it is necessary to set a specific deadline by which public comments on a particular version of the AV Calculator must be submitted, so we will accept public comments on a continuous rolling basis until the following plan year's AV Calculator is released. Without a specific deadline, interested parties can review the final AV Calculator without a timing constraint or competing priorities, such as reviewing and commenting on that year's Payment Notice.

Comment: Some commenters noted significant concerns with eliminating the draft version of the AV Calculator as a mechanism to solicit feedback. Several of these commenters urged CMS to continue a formal process to solicit feedback on the AV Calculator. A few commenters opposed our implementation of this approach for the 2026 AV Calculator, stating it was inappropriate to go forward with this approach without first seeking public comment. Another commenter stated that this approach introduces a dangerous precedent if applied to other guidance.

One commenter stated that reviewing the draft version of the AV Calculator is the only opportunity to provide feedback. This commenter stated that the receipt of a small number of comments in prior years does not justify doing away with the draft version of the AV Calculator and that we ignored the comments on the draft version in prior years. This commenter also found the process of accepting rolling comments impractical and pointed out that the 2026 AV Calculator did not provide instructions on how to submit comments.

Response: We reiterate our commitment to collecting feedback from all interested parties on the AV Calculator. In fact, we adopted this revised approach directly in response to consistent feedback we have received over the years to provide issuers, States, and Exchanges with access to the AV Calculator sooner. Releasing only the final version of the AV Calculator fulfills this request without jeopardizing its accuracy or functionality.

We believe it is reasonable to move forward with this revised approach for the final 2026 AV Calculator given the AV Calculator's stability over the last few years. Considering the many process improvements in recent years, including the switch to the masked enrollee-level EDGE data starting with the 2025 AV Calculator and other changes to make the standard population more representative of the individual and small group markets, the AV Calculator has improved every year, so we believe it has achieved a mature state. Given this stability, the benefit of releasing a draft version of the AV Calculator no longer outweighs the corresponding delay to release the final AV Calculator after the draft version.

Although we will no longer receive feedback on a draft version to incorporate into the final AV Calculator, the same process to submit feedback on the AV Calculator remains available throughout the year. Since this process is the same as previous years when we have collected feedback on the AV Calculator, but without a specific deadline to submit comments, we disagree that accepting comments on the final AV Calculator on a rolling basis is impractical.

We disagree that it was inappropriate to move forward with this revised approach before seeking public comment, since this revised approach was in response to numerous public comments that we have received in the past. We also disagree that this revised approach introduces a dangerous precedent of no longer seeking public comment on draft versions of guidance. As stated, we revised the approach to release only a final version of the AV Calculator in response to specific feedback on the timing of the release of the AV Calculator, and as such, we clarify that this revised approach applies only to the AV Calculator and to no other guidance.

In addition, as we noted in the proposed rule (89 FR 82379), we believe there will be minimal effect in effectuating this change with the 2026 AV Calculator because we based the 2026 AV Calculator substantially on the final 2025 AV Calculator, and did not make any material changes to it.

We note that the 2026 AV Calculator Methodology erroneously omitted a contact method for interested parties to

submit comments on the final 2026 AV Calculator, but all prior draft AV Calculators have included the same contact information, which has remained available. We apologize for this oversight. Interested parties may submit comments to HHS via email at *PMPolicy@cms.hhs.gov.*

Comment: A few commenters mentioned other ideas for soliciting feedback on the AV Calculator, such as forming an advisory work group, seeking input from Navigators, community-based organizations, regulators, and patients, publishing a white paper and/or hosting a webinar, and reporting on how we incorporate feedback into future versions of the AV Calculator.

Response: We again emphasize that feedback on the AV Calculator from all interested parties is essential. We appreciate the commenters' suggestions on other strategies to solicit feedback on the AV Calculator. We note that we already share updates and invite discussion on the AV Calculator at several venues, including at an annual webinar hosted for issuers and at the annual American Academy of Actuaries meeting. We will continue to do so, as well as explore other avenues and meetings throughout the year to engage with interested parties. However, a white paper explaining changes to the AV Calculator would be duplicative of the AV Calculator Methodology already published. The AV Calculator Methodology describes in detail all changes to that year's AV Calculator, as well as changes that were considered but not made. We will continue to use the AV Calculator Methodology document to describe such changes and considerations.

Comment: Some commenters opposed the proposed approach, stating that eliminating the draft version of the AV Calculator would not provide enough time to prepare plan designs. They stated that having earlier access to the draft version of the AV Calculator enabled them to plan ahead, and eliminating the draft version would make it difficult to meet key deadlines.

Response: These commenters misunderstood the primary goal of this revised approach. We want to clarify that this revised approach will not shorten the time that users have access to the AV Calculator. Rather, the revised approach will enable earlier access to the final AV Calculator. It is our understanding that having the final AV Calculator 3 to 6 months sooner than we have historically released it will only benefit plan design preparation.

Comment: Several commenters provided technical feedback on the 2026 final AV Calculator.

Response: We thank commenters for providing this feedback on the 2026 final AV Calculator. We have noted this feedback and will consider it in the development of the 2027 AV Calculator.

6. Standardized Plan Options (§ 156.201)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82378), we proposed to exercise our authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to make minor updates to the standardized plan options for PY 2026. We also proposed to amend § 156.201 by adding paragraph (c) to provide that an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

In the proposed rule (89 FR 82378), we proposed minor updates to the plan designs for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level. We proposed to otherwise generally maintain continuity regarding the approach to standardized plan options finalized in the 2023, 2024, and 2025 Payment Notices. Our proposed updates to plan designs for PY 2026 were detailed in Tables 11 and 12 in the proposed rule.

We proposed to maintain this high degree of continuity in standardized plan options for several reasons. We stated that primarily, we believe maintaining a high degree of continuity will reduce the risk of disruption for all involved interested parties, including issuers, agents, brokers, States, and consumers. We further stated that we continue to believe that making major departures from the standardized plan option designs finalized in the 2023, 2024, and 2025 Payment Notices could result in significant changes that may create undue burden for interested parties.

We refer readers to the proposed rule (89 FR 82378 through 82382) for further discussion of the background and rationale regarding our proposed approach to standardized plan options, and to the preambles of the 2023, 2024, and 2025 Payment Notices discussing § 156.201 (87 FR 27310 through 27322, 88 FR 25847 through 25855, and 89 FR 26357 through 26362, respectively) for a detailed discussion regarding the approaches to standardized plan options finalized in those Payment Notices.

In addition, we proposed a meaningful difference standard for PY 2026 and subsequent plan years at § 156.201(c) because several issuers in recent years have offered indistinguishable standardized plan options, and we believe issuers may continue to do so in future plan years partly because the number of non-standardized plan options that issuers can offer is limited in accordance with § 156.202(b). We stated that we do not believe it benefits consumers for issuers to offer identical standardized plan options, or standardized plan options that do not differ in meaningful ways, within the same product network type, metal level, and service area. In addition, we noted that permitting issuers to offer identical standardized plan options or standardized plan options that do not differ in meaningful ways runs counter to our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process. We also stated that allowing issuers to offer duplicative standardized plan options could cause significant consumer confusion and unnecessary plan proliferation if the trend continues unabated.

As such, we stated that under this proposal, although issuers would continue to be permitted to offer multiple standardized plan options within the same product network type, metal level, and service area, these standardized plan options would be required to have meaningfully different benefit coverage, provider networks, and/or formularies. For the purposes of the proposed standard, for PY 2026 and subsequent plan years, we stated that we would consider a standardized plan option with a different product, provider network, and/or formulary ID to be meaningfully different, similar to the version of the standard from the 2017 Payment Notice (81 FR 12312 and 12331).

In the proposed rule (89 FR 82380), we stated that if an issuer submitted two standardized plan options within the same product network type, metal level, and service area both with the same product, provider network, and formulary IDs, we would not certify both of these plans. We explained that we anticipated we would seek feedback from the issuer regarding which plan to certify, assuming the issuer meets all other certification requirements. We also noted that for the purposes of the proposed standard, we would not consider differences in plan variant marketing names, the availability of different language access features, or the administration of the plan by different

vendors in determining whether two or more standardized plan options are meaningfully different, similar to the version of the standard from the 2017 Payment Notice.

We further stated that if this policy were finalized as proposed, we would monitor whether issuers are seeking certification of plans that technically meet this standard but are nearly identical. We noted that if we determined that issuers were attempting to circumvent this standard in this manner, we would consider proposing in future rulemaking a version of this meaningful difference standard that would require greater variation among plans beyond product, provider network, and/or formulary IDs. We noted that we were not proposing such a standard for PY 2026 and subsequent plan years at that time because, assuming issuers do not attempt to circumvent this standard as noted above, we believe that the proposed policy would likely be sufficient to ensure that issuers' standardized plan options continue to support our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

We refer readers to the proposed rule (89 FR 82378 through 82380) for further discussion of the background and rationale regarding our proposal to require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

We sought comment on our proposed approach to standardized plan options for PY 2026, including amending § 156.201 to add paragraph (c).

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TABLE 1: 2026 Standardized Plan Options Set One (For All FFE and SBE-FP Issuers, Excluding Issuers in Delaware, Louisiana, and Oregon)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.12%	70.01%	73.07%	87.04%	94.11%	78.04%	88.03%
Deductible	$7,500	$6,000	$3,000	$700	$0	$2,000	$0
Annual Limitation on Cost Sharing	$10,000	$8,900	$7,400	$3,300	$2,200	$8,200	$5,200
Emergency Room Services	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	50%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$15*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$50*	$60*	$50*
Specialty Drugs	$500	$350	$350	$250	$150*	$250*	$150*

*Benefit category not subject to the deductible.

TABLE 2: 2026 Standardized Plan Options Set Two (For Issuers in Delaware and Louisiana)

	Expanded Bronze	Standard Silver	Silver 73 CSR	Silver 87 CSR	Silver 94 CSR	Gold	Platinum
Actuarial Value	64.12%	70.01%	73.09%	87.07%	94.09%	78.02%	88.01%
Deductible	$7,500	$6,000	$3,000	$700	$0	$2,000	$0
Annual Limitation on Cost Sharing	$10,000	$8,900	$7,400	$3,300	$2,400	$8,300	$5,300
Emergency Room Services	50%	40%	40%	30%	25%*	25%	$100*
Inpatient Hospital Services (Including Mental Health & Substance Use Disorder)	50%	40%	40%	30%	25%*	25%	$350*
Primary Care Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Urgent Care	$75*	$60*	$60*	$30*	$5*	$45*	$15*
Specialist Visit	$100*	$80*	$80*	$40*	$10*	$60*	$20*
Mental Health & Substance Use Disorder Outpatient Office Visit	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Imaging (CT/PET Scans, MRIs)	50%	40%	40%	30%	25%*	25%	$100*
Speech Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Occupational, Physical Therapy	$50*	$40*	$40*	$20*	$0*	$30*	$10*
Laboratory Services	50%	40%	40%	30%	25%*	25%	$30*
X-rays/Diagnostic Imaging	50%	40%	40%	30%	25%*	25%	$30*
Skilled Nursing Facility	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Facility Fee (Ambulatory Surgery Center)	50%	40%	40%	30%	25%*	25%	$150*
Outpatient Surgery Physician & Services	50%	40%	40%	30%	25%*	25%	$150*
Generic Drugs	$25*	$20*	$20*	$10*	$0*	$15*	$5*
Preferred Brand Drugs	$50	$40*	$40*	$20*	$5*	$30*	$10*
Non-Preferred Brand Drugs	$100	$80	$80	$60	$10*	$60*	$50*
Specialty Drugs	$150	$125	$125	$100	$20*	$100*	$75*

*Benefit category not subject to the deductible.

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After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing our proposed approach with respect to standardized plan options, with several modifications to both sets of plan designs at the expanded bronze metal level.

In particular, for both sets of plan designs at the expanded bronze metal level, we reduced the coinsurance rate for all benefit categories that had coinsurance subject to the deductible as the form of cost sharing from 60 percent to 50 percent. We also reduced the copayments exempt from the deductible for the primary care visit benefit category from $60 to $50; for the urgent care benefit category from $90 to $75; for the specialist visit benefit category from $120 to $100; for the mental health and substance use disorder outpatient office visit benefit category from $60 to $50; for the speech therapy benefit category from $60 to $50; and for the occupational and physical therapy benefit category from $60 to $50. To counterbalance this subsequent increase in AV, we increased the annual limitation on cost sharing value from $9,200 to $10,000. Altogether, these modifications resulted in a reduction in AV from 64.42 percent in the proposed plan designs to 64.12 percent in the plan designs finalized in this rule.

We made these modifications primarily to maintain continuity in plan designs, to minimize the risk of coverage disruption and unexpected financial costs for consumers already enrolled in these plans, and to allow issuers to design standardized plans in a manner that conforms to State laws. We are otherwise finalizing the plan designs as proposed. There were no other modifications to any of the other benefit categories in either set of plan designs at the expanded bronze metal level. There were similarly no modifications to either set of plan designs at any of the other metal levels. Our finalized plan designs for PY 2026 are detailed in Tables 1 and 2 of this final rule.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are also finalizing, with minor modification, our proposal that an issuer that offers multiple standardized plan options

within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, and/or formularies.

In particular, we modified the language at § 156.201(c) to state that an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, included prescription drugs, or a combination of some or all these factors. For the purposes of this standard, a standardized plan option with a different product ID, provider network ID, drug list ID, or some combination of or all these factors, will be considered meaningfully different.

We modified the portion of the proposed standard stating that a difference in formularies (which is defined as a difference in formulary IDs) would constitute a meaningful difference to instead state that a difference in included prescription drugs (which is defined as a difference in drug list IDs) would constitute a meaningful difference. We made this modification to ensure that minor differences in prescription drug cost sharing (which would be reflected by differences in formulary IDs) would not constitute a meaningful difference under this framework, consistent with our goal of ensuring that standardized plan options differ in meaningful ways. This is similar to how differences in included benefits (which is defined as a difference in product IDs) would constitute a meaningful difference, but differences in the cost sharing for those medical benefits would not. Additionally, we made this modification to further clarify the flexibility that issuers are permitted.

We summarize and respond to public comments received on the proposed approach to standardized plan options below.

Comment: Many commenters supported continuing to require FFE and SBE–FP QHP issuers to offer standardized plan options. Some of these commenters described standardized plan options as helping to reduce consumer confusion by simplifying the plan selection process and by allowing consumers to draw meaningful comparisons between plan options more easily. Many commenters noted that consumers continue to risk experiencing plan choice overload as they navigate the plan selection process and that standardized plan options continue to play an important role in reducing the number of variables that consumers need to compare as part of the selection process. Other comments encouraged CMS to make further improvements to the *HealthCare.gov* shopping experience by refining tools that help consumers navigate and manage plan choices more easily, including by enhancing the differential display of standardized plan options. Some commenters also requested that CMS create a pathway for issuers to submit both English and Spanish marketing plan variant names for all plans to enhance accessibility for Spanish-speaking consumers using *CuidadoDeSalud.gov.*

Many commenters supported our approach to the design of these standardized plan options for PY 2026. Specifically, commenters supported taking a consistent approach to the design of standardized plan options and only making minor adjustments to ensure the plans continue to have AVs within the permissible *de minimis* ranges at each metal level, particularly because of the consistency this provides enrollees for anticipating their health care costs. Conversely, a few commenters opposed continuing to require issuers to offer standardized plan options. These commenters noted that continuing to subject issuers to these requirements reduces consumer choice and makes it harder for consumers to find plan options that best meet their individual health care needs.

Response: We agree that standardized plan options continue to serve as one important facet of our multifaceted strategy of reducing the rate of plan proliferation, the risk of plan choice overload, and the frequency of suboptimal plan selection. We are also engaged in ongoing work to improve consumers' decision-making through enhancing choice architecture and the user experience on *HealthCare.gov,* and we will consider additional ways to do so in the future.

For the comments requesting that we create a pathway for issuers to submit both English and Spanish marketing plan variant names for all plans to enhance accessibility for Spanish-speaking consumers using *CuidadoDeSalud.gov,* we note that we are currently working on modifications to *HealthCare.gov* to improve the user experience, including with respect to language accessibility. We also note that we will consider revising the submission website to allow issuers to submit plan variant marketing names in Spanish or other languages in future plan years. For the purposes of the meaningful difference standard that we are finalizing in this rule for PY 2026 and subsequent plan years, we reiterate our explanation in the proposed rule (89 FR 82380) that we would not consider differences in plan variant marketing names, the availability of different language access features, or the administration of the plan by different vendors in determining whether two or more standardized plan options are meaningfully different.

We agree that maintaining a high degree of continuity in our standardized plan options from year to year is desirable for several reasons. Specifically, we agree that having consistent year-to-year plan designs allows consumers enrolled in these plans to become better acquainted with these plans, increasing both consumer understanding and financial certainty. We also agree that drastically modifying the plan designs from year to year could potentially result in avoidable financial harm if the cost sharing for benefits that consumers depend upon increases unexpectedly, which could also result in consumers forgoing obtaining medical care. Although we believe that, today, the benefits that may arise from making major modifications to these plan designs are outweighed by the risk that doing so could result in undue burden for issuers and consumers, we may consider making major modifications to the design of these standardized plan options in future rulemakings if this assessment changes.

We disagree that continuing to require issuers in the FFEs and SBE–FPs to offer standardized plan options makes it harder for consumers to access plans that meet their unique health needs, even with the additional requirement we are finalizing in this rule for meaningfully differentiating standardized plan options when an issuer chooses to offer multiple standardized plan options within the same product network type, metal level, and service area. We note that, as clarified in section III.E.7 of this rule, issuers are permitted to offer two non-standardized plan options per product network type, metal level (excluding catastrophic plans), inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area, as well as additional non-standardized plan options per product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area, so long as these additional plans substantially benefit consumers with chronic and high-cost conditions and meet the other criteria for the exceptions process under § 156.202(d) and (e).

As we explained in the 2025 Payment Notice (89 FR 26367), we believe the fact that issuers continue to be permitted to offer these non-standardized plan options ensures that consumers will continue to have access to a sufficiently broad range of plan designs that meet their diverse needs and that issuers can continue to offer innovative plan designs. We further believe that continuing to require issuers to offer standardized plan options, as well as reducing the non-standardized plan option limit and implementing the exceptions process for this limit (as discussed in section III.E.7. of this rule), strikes an appropriate balance between limiting the risk of plan choice overload while simultaneously continuing to permit issuers a sufficient degree of flexibility to offer innovative plan designs.

Comment: Many commenters expressed support for various features of the proposed plan designs. In particular, commenters supported standardized plan options for improving affordability by providing greater access to pre-deductible coverage and requiring copayments instead of coinsurance rates for certain benefit categories. Commenters also noted that the use of copayments and pre-deductible coverage in standardized plan options promotes predictable and affordable cost sharing for essential care, thereby reducing barriers and enhancing access for these services.

However, some commenters recommended further reducing enrollees' out-of-pocket costs, such as by exempting additional drug tiers from the deductible, or by capping monthly out-of-pocket costs for particular prescription drugs. Several commenters recommended lowering the coinsurance rate for both sets of plan designs at the expanded bronze metal level from 60 percent to 50 percent in order to allow issuers to design plans compliant with State laws that prohibit coinsurance rates over 50 percent. Another commenter recommended including health savings account (HSA)-compliant high-deductible health plan (HDHP) designs in both sets of standardized plan options.

Response: We appreciate commenters' support for various features of the proposed plan designs. We acknowledge that a high annual limitation on cost sharing values, high deductibles, and limited pre-deductible coverage can sometimes act as barriers that prevent consumers, including those with chronic and high-cost conditions, from obtaining the health care they need. We also acknowledge that coinsurance rates, as well as subjecting particular benefit categories and prescription drug tiers to the deductible, can potentially increase consumer uncertainty regarding how much particular items and services may cost.

However, due to AV constraints arising from the permissible *de minimis* range restriction for each metal level in accordance with § 156.140(c)(2), we are unable to substantially lower the annual limitation on cost sharing or deductible values, expand pre-deductible coverage to include additional benefit categories, or include copayments as the form of cost sharing for a broader range of benefit categories without a corresponding increase in the AV of each plan. Making some combination of these modifications would increase the generosity of these plans, potentially to the point of each plan's AV exceeding the permissible *de minimis* range for its respective metal level. Furthermore, even if making some combination of these changes would result in an AV within the permissible *de minimis* range for each metal level, there would still be a corresponding increase in premiums that would render these plans costlier for consumers and potentially uncompetitive.

We further note that although it may be possible to make some combination of these modifications to these plan designs while maintaining an AV near the floor of the *de minimis* range for each metal level, doing so would require a corresponding increase in cost sharing for other benefits or subjecting additional benefits to the deductible to offset this increase in generosity. Since the benefits that we have exempted from the deductible as well as the benefits for which we have reduced cost sharing in the standardized plan options finalized in this rule are some of the most frequently utilized benefits, we believe that the disadvantages of subjecting these benefits to the deductible or increasing the cost sharing for these benefits would outweigh the benefit that may arise from exempting other benefits from the deductible or reducing cost sharing for other benefits. The disadvantages include the risk that these plans would become uncompetitive and that consumers would forego obtaining medical services covered by these frequently utilized benefits which would be newly subject to the deductible or have increased cost sharing.

We also note that we are not standardizing the cost sharing for additional benefit categories beyond those already included in these plan designs since EHB-benchmark plans vary significantly by State, and we do not wish to standardize the cost sharing for benefits that issuers may not be required to offer in particular States.

However, we agree with commenters who recommended reducing the expanded bronze plan coinsurance rate from 60 percent in both sets of plan designs, as proposed, to 50 percent in order to allow issuers to design plans in a manner that conforms with State laws and to maintain continuity with plan designs from previous years. Requiring issuers to offer standardized plan options that fail to conform with State laws may inadvertently lead issuers to become subject to State enforcement and other legal actions, which could endanger their licensure and ability to continue offering QHPs, and cause coverage disruptions for consumers enrolled in noncompliant standardized plan options that are terminated during the plan year. Accordingly, we have finalized coinsurance rates of 50 percent for all benefit categories subject to a coinsurance rate in the expanded bronze plan design in both sets of plan designs.

In addition to modifying the default coinsurance rates for both sets of plan designs at the expanded bronze metal level, we also reduced the copayments exempt from the deductible for the primary care visit benefit category from $60 to $50; for the urgent care benefit category from $90 to $75; for the specialist visit benefit category from $120 to $100; for the mental health and substance use disorder outpatient office visit benefit category from $60 to $50; for the speech therapy benefit category from $60 to $50; and for the occupational and physical therapy benefit category from $60 to $50. To counterbalance this subsequent increase in AV and help ensure both sets of plan designs at the expanded bronze metal level have AVs within the permissible *de minimis* range for that level, we increased the annual limitation on cost sharing value from $9,200 to $10,000. Altogether, these modifications resulted in a reduction in AV from 64.42 percent in the proposed plan designs to 64.12 percent in the plan designs finalized in this rule.

We made these changes primarily to maintain consistent year-to-year plan designs, which allows enrollees to become better acquainted with these plans, increasing both consumer understanding and financial certainty, similar to our approach in previous years and consistent with the goals outlined in the proposed rule (89 FR 82379), to minimize the risk of coverage disruption for consumers already enrolled in these plans, and to allow issuers to design standardized plans in a manner that conforms to State laws.

Finally, we note that we have not included an HSA-eligible HDHP in these sets of plan designs due to decreased enrollment in these plans in the last several plan years, which suggests they may be less competitive and in-demand than traditional health insurance plans. We thus declined to include HSA-eligible HDHPs in these sets of plan designs because, as we explained when we reintroduced standardized plan options in the 2023 Payment Notice (87 FR 27319), our approach is to design standardized plan options that reflect the most popular QHPs offered through the Exchanges. We also declined to include an HSA-eligible HDHP in these sets of plan designs because we have not included these types of plans in the sets of standardized plan options for PY 2023, PY 2024, or PY 2025, and we want to maintain a high degree of continuity with the standardized plan option policies and designs finalized in the 2023, 2024 and 2025 Payment Notices. However, we note that QHP issuers in the FFEs and SBE–FPs continue to be permitted to offer HSA-eligible HDHPs as non-standardized plan options, if so desired.

Comment: Many commenters supported the proposal to allow QHP issuers to offer more than one standardized plan option within the same product network type, metal level, and service area if the plans conform to the proposed meaningful difference standard. These commenters appreciated the effort to reduce duplicative plan offerings and to help consumers better understand included benefits, provider networks, and included prescription drugs when making plan selections and comparisons. They described the adoption of the meaningful difference standard as a critical step toward simplifying plan selection, preventing confusion, and promoting better consumer decision-making. Commenters noted that the adoption of the meaningful difference standard aligns with the broader aims of standardized plan options—reducing the number and complexity of the variables that consumers must consider when comparing plans.

Some commenters noted their approval of relying on product, provider network, and formulary IDs to determine whether standardized plan options are meaningfully different, while other commenters noted concern that the proposed standard would not be strict enough to reduce the risk of issuers offering duplicative standardized plan options. One such commenter recommended that CMS consider requiring a particular quantitative difference between the standardized plan options' provider networks and formularies to ensure plans are meaningfully different from one another. Many commenters similarly recommended making the meaningful difference requirement more stringent by reducing the number of factors that would qualify a plan as meaningfully different. Several commenters recommended applying the meaningful difference standard to the non-standardized plan options instead of standardized plan options. Some commenters encouraged CMS to monitor whether allowing issuers to offer multiple standardized plan options in the same service area would result in unnecessary complexity for consumers shopping for health plans.

Response: We agree that requiring issuers to meaningfully differentiate between multiple standardized plans within the same product network type, metal level, and service area will improve the consumer experience by increasing consumer understanding, simplifying the plan selection process, and limiting unnecessary plan proliferation. We share commenters' concerns about consumer confusion when comparing identical-appearing standardized plan options, and, as we explained in the proposed rule (89 FR 82380), we will monitor whether issuers are seeking certification of standardized plans that technically meet the meaningful difference standard but are nearly identical.

We note that, in this final rule, we are finalizing a modification to our proposed meaningful difference standard. Instead of providing that a difference in formularies (which is defined as a difference in formulary IDs) would constitute a meaningful difference, we are finalizing that a difference in included prescription drugs (which is defined as a difference in drug list IDs) will constitute a meaningful difference. We made this modification to ensure that minor differences in prescription drug cost sharing (which would be reflected by differences in formulary IDs) would not constitute a meaningful difference. This is similar to how differences in included benefits (which is defined as a difference in product IDs) would constitute a meaningful difference, but differences in the cost sharing for those medical benefits would not.

If we determine that issuers are attempting to circumvent this standard, or that it is otherwise not strict enough, we will consider proposing in future rulemaking a version of this meaningful difference standard that would require greater variation among plans beyond product ID, provider network ID, drug list ID, or a combination of some or all these factors. We did not propose such a standard for PY 2026 and subsequent plan years in the proposed rule because, assuming issuers do not attempt to circumvent this standard as noted above, we believe that this proposed policy would likely be sufficient to ensure that issuers' standardized plan offerings support our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process. We will monitor whether the standard we are finalizing in this rule effectively enhances the consumer experience, reduces plan proliferation, and encourages plan diversity in the individual market.

We appreciated comments that shared specific recommendations about how to craft this standard in a manner that would ensure that the standardized plan options offered under this standard yield meaningfully different plan design features for consumers—such as by requiring particular quantitative differences in provider networks or formularies. Again, if we determine that the standardized plan options that issuers are offering within the same product network type, metal level, and service area that have different product IDs, provider network IDs, drug list IDs, or a combination of some or all these factors, fail to yield meaningful and distinguishable differences in plans for consumers, we may consider proposing a quantitative version of the standard in a future plan year.

Comment: Several commenters requested clarification on how issuers could vary benefit coverage in standardized plan options within the same product network type, metal level, and service area under this proposed standard. Several commenters recommended relaxing this standard, such as by allowing plans to be considered meaningfully different based on differences in cost sharing for non-standardized benefit categories or differences in tiered provider networks (in addition to differences in product, provider network, and drug list IDs)—similar to the previous meaningful difference standard finalized in the 2018 Payment Notice. Another commenter recommended providing issuers with the opportunity to make their case for how two proposed, seemingly indistinguishable standardized plan options meaningfully differ from one another before CMS decides whether to not certify one of these plans (assuming the issuer meets all other certification requirements).

A few commenters opposed allowing issuers to offer multiple standardized plan options within the same product network type, metal level, and service area—regardless of whether they are deemed to be meaningfully different—primarily due to concerns regarding plan proliferation. These commenters explained that permitting issuers to offer multiple standardized plan options within the same product network type, metal level, and service area but with different included benefit coverage, provider networks, or included prescription drugs could cause confusion for consumers—since these standardized plan options would not be standardized in every regard.

Response: In response to the commenters who requested clarification regarding how standardized plan options can vary benefit coverage outside of the benefit categories with standardized cost sharing in order to satisfy the requirements of this standard, we note that issuers may differentiate their standardized plan options from one another by varying the included benefit coverage, such as non-EHBs, or in how the plan covers EHB, consistent with the EHB requirements in the applicable State. For example, when reviewing if two standardized plan options within the same product network type, metal level, and service area are meaningfully different, we will consider the plans to be meaningfully different from one another if they do not share the same product ID.

However, we note that varying non-standardized benefit category cost sharing parameters (such as for those benefit categories that do not have standardized cost sharing parameters specified in Tables 1 and 2 of this rule) would not constitute a meaningful difference for the purpose of this standard. This is because we do not believe that minute differences in cost sharing (such as a $5 difference in the copayment amount for a relatively infrequently utilized benefit) would provide a meaningful or discernible difference for consumers. The same is true for minor differences in cost sharing for prescription drugs (which would be reflected in differences in formulary IDs)—which is why we modified the standard we are finalizing to instead state that differences in included prescription drugs (which is defined as differences in drug list IDs) would constitute a meaningful difference.

Furthermore, permitting issuers to vary standardized plan options in this regard could increase the risk of circumvention of the standard (such as by permitting issuers to offer one standardized plan option with a $20 copayment for an infrequently utilized benefit, another with a $15 copayment for the same benefit, and another with a $10 copayment for the same benefit)—within the same product network type, metal level, and service area and with the same product, provider network, and drug list ID. Such an approach would exacerbate the risk of plan proliferation and choice overload.

In response to commenters who recommended that we allow standardized plan options to be considered meaningfully different based on tiered provider networks, similar to our stance when we reintroduced the requirement for issuers to offer standardized plan options in the 2023 Payment Notice (87 FR 27311), we reiterate that we continue to design these standardized plan options to be similar to the most popular QHPs in FFEs and SBE–FPs in terms of cost sharing parameters, annual limitation on cost sharing values, and deductibles in order to ensure these plans are similar to plans that most consumers are already currently enrolled in, thereby reducing the risk of disruption for both consumers and issuers.

Given that most consumers continue to not be enrolled in plans with tiered provider networks, we believe that permitting issuers to offer standardized plan options with tiered provider networks under this standard would unnecessarily increase the risk of plan proliferation for consumers. Permitting issuers to offer standardized plan options with tiered provider networks would also mark a departure from our aim of maintaining continuity in plan designs from year to year, since we have not designed such plans as standardized plans to date. Adopting such an approach would also increase the number of factors that consumers must consider when selecting a plan—which runs counter to our goal of simplifying the plan selection process to reduce the risks of consumer confusion and plan choice overload. We also note that issuers are permitted to offer non-standardized plan options with tiered provider networks, if they so desire.

In response to the commenter who recommended that we provide issuers with an opportunity to make their case that their two proposed, seemingly indistinguishable standardized plan options are meaningfully different from one another before deciding not to certify one, we refer the commenter to discussion on this point in the proposed rule (89 FR 82380). In particular, in the proposed rule, we explained that, if an issuer submitted two standardized plan options within the same product network type, metal level, and service area, both with the same product, provider network, and formulary IDs, we would not certify both of these plans. We explained that before deciding which plan to certify, assuming the issuer meets all other certification requirements, we would seek feedback from the issuer regarding which plan to certify. Under the standard finalized in this rule, we will consider the issuer's explanation of how the plans differ based on their benefit coverage, provider networks, included prescription drugs, or a combination of some or all these factors, as part of this process.

We appreciate the concern of commenters who opposed allowing multiple standardized plan options within the same product network type, metal level, and service area due to this approach increasing the risk of plan proliferation. We acknowledge that this standard could permit issuers to offer multiple standardized plan options where consumers struggle to discern how the plans differ. However, as we explained in the proposed rule (89 FR 82380), we believe this is unlikely, and we will monitor whether issuers seek certification of standardized plan options that technically meet the meaningful difference standard but are nearly identical.

Further, if we determine that issuers are attempting to circumvent this standard in this manner, we will consider proposing in future rulemaking a version of this meaningful difference standard that would require greater variation between plans beyond requiring differences in product, provider network, and drug list IDs. As we explained in the proposed rule (89 FR 82380), we did not propose such a standard for PY 2026 and subsequent plan years because, assuming issuers do not attempt to circumvent this standard as noted above, we believe that the proposed policy would likely be sufficient to ensure that issuers' standardized plan options support our goals of enhancing the consumer experience, increasing consumer understanding, and simplifying the plan selection process.

Finally, we acknowledge the concern that allowing standardized plan options to have varied benefit coverage, provider networks, and included prescription drugs could potentially increase the risk of consumer confusion—since these standardized plan options would not be standardized in every regard. However, we note that that we wish to permit issuers a sufficient degree of flexibility to design plans that accommodate a broad and

diverse range of unique health care needs, which we do by permitting issuers to offer a range of standardized plan options, subject to the meaningful difference standard, as well as non-standardized plan options.

The benefit categories that we standardize within these plans are the most frequently utilized—and they are all required to be offered by QHP issuers as EHB. We do not wish to standardize the cost sharing for every possible benefit category within these plans since there are benefit categories that are less frequently utilized—as well as benefit categories that may not be required to be offered as EHB in particular States—and we do not wish to give the impression that such benefit coverage must be included in these plans even if they are not EHB in particular States. We further believe the standard we are finalizing in this rule will ensure that issuers that offer multiple standardized plan options within a product network type, metal level, and service area will yield meaningful differences in coverage for consumers while still providing a sufficient degree of standardization and minimizing the risk of consumer confusion. At the same time, we want to take steps to simplify and streamline the plan selection process for consumers, which, for the reasons explained in this final rule and in the proposed rule, we believe this policy does.

Altogether, we believe that requiring issuers to offer these standardized plan options, reintroducing this meaningful difference standard, limiting the number of non-standardized plan options that issuers can offer, and permitting exceptions to the non-standardized plan option limit for plans that have specific design features that would substantially benefit consumers with chronic and high-cost conditions strikes an appropriate balance between allowing issuers to innovate in plan designs, maintaining a sufficient degree of choice for consumers, and simplifying and streamlining the plan selection process to reduce the risk of choice overload.

7. Non-Standardized Plan Option Limits (§ 156.202)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82382), we proposed to exercise our authority under sections 1311(c)(1) and 1321(a)(1)(B) of the ACA to amend § 156.202(b) and (d) to properly reflect the flexibility that issuers have operationally been permitted since the introduction of non-standardized plan option limits to vary the inclusion of distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage categories under the non-standardized plan option limit in accordance with § 156.202(c)(1) through (3).

Section 1311(c)(1) of the ACA directs the Secretary to establish criteria for the certification of health plans as QHPs. Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the ACA, which includes section 1311, for, among other things, the offering of QHPs through such Exchanges.

In the 2024 Payment Notice (88 FR 25855 through 25865), we finalized requirements under § 156.202(a) and (b) limiting the number of non-standardized plan options that issuers of QHPs can offer through Exchanges on the Federal platform (including SBE–FPs) to four non-standardized plan options per product network type (as described in the definition of ''product'' at § 144.103), metal level (excluding catastrophic plans), inclusion of dental and/or vision benefit coverage, and service area for PY 2024, and two non-standardized plan options for PY 2025 and subsequent years.

In the 2025 Payment Notice (89 FR 26362 through 26375), we finalized an exceptions process under § 156.202(d) and (e) permitting FFE and SBE–FP issuers to offer more than two non-standardized plan options per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area for PY 2025 and subsequent plan years, if issuers demonstrate that these additional non-standardized plans offered beyond the limit at § 156.202(b) have specific design features that would substantially benefit consumers with chronic and high-cost conditions and meet certain other requirements.

In the 2025 Payment Notice (88 FR 26365 through 26366), we also clarified that the example included in the 2024 Payment Notice that illustrated issuers' flexibility to vary the inclusion of dental and/or vision benefit coverage in accordance with § 156.202(c) under the non-standardized plan option limits at § 156.202(a) and (b) failed to properly distinguish between the adult and pediatric dental benefit coverage categories.

In particular, in the 2024 Payment Notice (88 FR 25858), we stated that for PY 2025, for example, an issuer would be permitted to offer two non-standardized gold HMOs with no additional dental or vision benefit coverage, two non-standardized gold HMOs with additional dental benefit coverage, two non-standardized gold HMOs with additional vision benefit coverage, and two non-standardized gold HMOs with additional dental and vision benefit coverage, as well as two non-standardized gold PPOs with no additional dental or vision benefit coverage, two non-standardized gold PPOs with additional dental benefit coverage, two non-standardized gold PPOs with additional vision benefit coverage, and two non-standardized gold PPOs with additional dental and vision benefit coverage, in the same service area.

However, in the 2025 Payment Notice, we clarified that in PY 2024, issuers had the ability to vary the inclusion of dental and/or vision benefit coverage (including varying the inclusion of the distinct adult and pediatric dental benefit coverage categories), such that issuers could offer plans in the manner reflected in Table 3, instead of in the more limited manner reflected in the incomplete example in the 2024 Payment Notice.

In the 2025 Payment Notice, we affirmed that issuers continued to retain this flexibility for PY 2025 and subsequent years. We thus noted that under the non-standardized plan option limit of two for PY 2025 and subsequent years, if an issuer desired to offer the theoretical maximum number of non-standardized plans, and if that issuer varied the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage in these plans in accordance with the flexibility provided for at § 156.202(c)(1) through (3), that issuer could offer a theoretical maximum of 16 plans in a given product network type, metal level, and service area in the manner demonstrated in Table 3. Furthermore, we noted that if an issuer offered QHPs with two product network types (for example, HMO and PPO), that issuer could offer a theoretical maximum of 32 plans in a given metal level and service area in the manner demonstrated in Table 3.

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TABLE 3: Issuer Flexibility Under the Non-Standardized Plan Option Limit of Two for PY 2025 and Subsequent Years

Plan	Network Type	Cost Sharing Structure	Adult Dental	Pediatric Dental	Adult Vision
1	HMO	A			
2	HMO	A	Covered		
3	HMO	A		Covered	
4	HMO	A			Covered
5	HMO	A		Covered	Covered
6	HMO	A	Covered		Covered
7	HMO	A	Covered	Covered	
8	HMO	A	Covered	Covered	Covered
9	HMO	B			
10	HMO	B	Covered		
11	HMO	B		Covered	
12	HMO	B			Covered
13	HMO	B		Covered	Covered
14	HMO	B	Covered		Covered
15	HMO	B	Covered	Covered	
16	HMO	B	Covered	Covered	Covered
17	PPO	C			
18	PPO	C	Covered		
19	PPO	C		Covered	
20	PPO	C			Covered
21	PPO	C		Covered	Covered
22	PPO	C	Covered		Covered
23	PPO	C	Covered	Covered	
24	PPO	C	Covered	Covered	Covered
25	PPO	D			
26	PPO	D	Covered		
27	PPO	D		Covered	
28	PPO	D			Covered
29	PPO	D		Covered	Covered
30	PPO	D	Covered		Covered
31	PPO	D	Covered	Covered	
32	PPO	D	Covered	Covered	Covered

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In the proposed rule, we proposed to amend the regulation text at § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since we introduced non-standardized plan option limits to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3) for PY 2025 and subsequent plan years.

In particular, we proposed to amend § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE–FP, for PY 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

Consistent with our proposed amendment of § 156.202(b), we further proposed a conforming amendment to § 156.202(d) to provide that, for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and/or adult vision benefit coverage, and service area.

In the proposed rule, we stated that we proposed these modifications to align the regulation text of § 156.202(b) and (d) with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment Notice.[230]

We sought comment on these proposed modifications. After consideration of comments, and for the reasons outlined in the proposed rule and in this final rule, including our responses to comments, we are finalizing these provisions as proposed, with one minor modification. In particular, we are modifying the language at both § 156.202(b) and (d) to state that issuers may vary the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, *and* adult vision benefit coverage, instead of adult dental benefit coverage, pediatric dental benefit coverage, *and/or* adult vision benefit coverage—to enhance clarity and minimize risk of confusion.[231] We summarize and respond below to public comments received on the proposed modifications to § 156.202(b) and (d).

Comment: Several commenters supported the modifications to clarify the permissibility of varying the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage categories under the non-standardized plan option limit and the associated exceptions process. These commenters stated that clarifying that flexibility would ensure that issuers have a clearer understanding of the operational parameters of the existing non-standardized plan option limit and exceptions process and establish more uniform market rules for all issuers in FFE and SBE–FP States that are subject to the policy.

Many commenters expressed general support for continuing to limit the number of non-standardized plan options that issuers can offer. These commenters noted that in recent years, consumers have been confronted with too many health plan choices and thus may be more likely to make suboptimal plan selections. In some instances, commenters noted that consumers run the risk of forgoing enrollment altogether in instances where they cannot easily identify a plan that meets their needs due to choice overload. Several of these commenters also noted the chilling effect that choice overload can have on consumers with chronic and high-cost conditions or other significant health care demands.

Similarly, several commenters expressed general support for continuing to allow issuers to offer additional non-standardized plan options under the exceptions process so that they can provide targeted coverage specifically for populations with chronic and high-cost conditions. Commenters noted that permitting issuers to offer these additional non-standardized plan options continues to support health equity and allows for more targeted innovation by issuers, while still simultaneously achieving the reduction in plan proliferation HHS has sought. Many of these commenters noted that individuals with chronic and high-cost conditions are especially price sensitive, and that these individuals often encounter significantly higher out-of-pocket costs associated with the higher rates of utilization of the benefits required to treat these conditions.

Response: We agree that clarifying how the non-standardized plan option limit and exceptions process are operationalized enhances issuer understanding of the policy. We reiterate that we are not permitting issuers a novel flexibility to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage categories—nor are we permitting a novel flexibility in the exceptions process with the conforming modification to the regulation text language. Instead, we are amending § 156.202(b) and (d) to clarify the flexibility that issuers have been operationally permitted since we implemented the non-standardized plan option limit in PY 2024, as we explained in greater detail in the 2025 Payment Notice (89 FR 26365 through 26366). Thus, in PY 2026 and subsequent plan years, issuers will continue to retain that same flexibility.

We also agree that providing additional clarity in our regulations helps to educate issuers about their existing options for designing their product and plan offerings within and—when justified—above the non-standardized plan option limit. Ensuring issuers understand their non-standardized plan design flexibility may encourage more coverage of vision and dental benefits by non-standardized plans and more uniform plan offerings by issuers across States.

We also agree that the number of plan choices available to consumers continues to complicate the plan selection process, and that plan proliferation and the risk of plan choice overload persist. We further agree that this increased risk of plan choice overload also increases the risk of suboptimal plan selection and unexpected financial harm for those least able to afford it. Thus, we agree that continuing to limit the number of non-standardized plan options that issuers can offer in conjunction with permitting issuers to offer additional non-standardized plan options that facilitate the treatment of chronic and high-cost conditions under the exceptions process continues to reduce plan proliferation and the risk of choice overload while simultaneously permitting issuers a sufficient degree of flexibility to innovate.

We continue to recognize the advantages that innovation imparts upon consumers by supporting the ability of QHP issuers to offer them a diverse range of plan offerings from which to select. We also continue to believe that excepted non-standardized plans that reduce cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions can significantly reduce the out-of-pocket costs for consumers with these conditions experience and ultimately increase treatment adherence and improve health outcomes.

Comment: Some commenters opposed continuing to limit the number of non-standardized plan options that issuers can offer. Some commenters suggested that the market conditions that may necessitate a restriction on the number of non-standardized plan options may not apply uniformly across all States. These commenters explained that States differ in their rates of issuer participation and the unique needs of each State's population, among other factors.

Several of these commenters further suggested that that individual FFE and SBE–FP States themselves should be given the ability to exercise discretion on how best to address issues of plan proliferation and choice overload. Some of these commenters suggested that States could then choose how best to structure a non-standardized plan option limit or pursue an alternative approach altogether. One commenter suggested that all SBE–FP States should be exempted from the non-standardized plan option limit. Another commenter suggested allowing SBE–FP States to seek blanket exceptions for individual

[230] CMS. (2024, April 10). 2025 Final Letter to Issuers in the Federally-facilitated Exchanges. *https://www.cms.gov/files/document/2025-letter-issuers.pdf.*

[231] Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 125 (2012) (collecting ''experts'' that ''warn against'' use of the ''hybrid'' and/or); Kenneth A. Adams, *Know Your Enemy: Sources of Uncertain Meaning in Contracts,* Mich. B.J. 40, 42 (Oct. 2016) (discussing the ''ambiguity of the part versus the whole'' presented by the words ''and'' and ''or'').

issuers in their State to be exempted from the non-standardized plan option limit.

Some commenters opposed allowing issuers to offer excepted plans beyond the non-standardized plan option limit, citing concerns that additional exceptions could exacerbate the risk of plan choice overload and suboptimal plan selection. These commenters noted that the intent of the non-standardized plan option limit is to mitigate the risk of uncontrolled plan proliferation that leads to consumer confusion, and that to permit each issuer the opportunity to receive exceptions to the numerical limit counteracts this intent.

Response: We reiterate that we did not propose and are not finalizing any changes to the applicability of the non-standardized plan option limit or exceptions process under § 156.202(b) and (d). Instead, we are only making modifications to those regulations to more clearly align their text with the flexibility that issuers have been operationally permitted since we implemented the non-standardized plan option limit. As we previously noted in the 2024 Payment Notice (88 FR 25856 and 25864), we continue to believe it is appropriate to apply the non-standardized plan option limit equally to issuers in FFE and SBE–FP States given their shared platform. We also reiterate that States with SBE–FPs that do not wish to be subject to these requirements may investigate the feasibility of transitioning to a State Exchange. We continue to believe the financial and operational burden to HHS outweighs the benefit of changing the platform to permit distinction on this policy between FFEs and SBE–FPs.

We also acknowledge that different States and counties have differing rates of issuer participation, and thus, differing numbers of available plans. We still believe the limit of two non-standardized plan options and the permissible exceptions strike an appropriate balance in reducing the risk of plan choice overload and preserving a sufficient degree of consumer choice, even for consumers in counties with lower rates of issuer participation. For a more detailed example of the number of plan choices that we described as a likely scenario for consumers who have access to one QHP issuer where they live, we refer readers to the 2024 Payment Notice (88 FR 25862 through 258623). Except for the modifications we are making in this final rule, we are maintaining the non-standardized plan option limit and accompanying exceptions process and the applicability of these requirements as previously finalized.

We also recognize the potential concerns associated with an uncontrolled exceptions process. However, as we explained in the 2025 Payment Notice (89 FR 26363 through 26364), we did not set a numerical limit on the permitted exceptions per issuer, product network type, metal level, inclusion of dental and vision benefit coverage, and service area (for example, allowing exceptions for only two such plans) to ensure that issuers are not restricted in the number of innovative plans they can offer. We noted that this approach would help ensure that a greater portion of consumers with chronic and high-cost conditions have access to plans that reduce barriers to access to care for services critical to the treatment of their conditions.

We continue to believe the exceptions process finalized in the 2025 Payment Notice (alongside the modification we are finalizing in this rule to clarify the flexibility associated with varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage) that limits issuers to one exception per chronic and high-cost condition in each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area sufficiently mitigates the risk of contributing to choice overload.

Furthermore, similar to what we explained in the 2025 Payment Notice (89 FR 26364), although issuers are not limited in the total number of exceptions they may be granted from the non-standardized plan option limit (provided all such exceptions meet the criteria at § 156.202), we continue to anticipate that most issuers would determine that the burden of creating and certifying additional non-standardized plan options intended to benefit a comparatively small population of consumers would outweigh the benefit of doing so. In PY 2025, we certified only 120 plans as excepted plans, and we do not expect that those plans' availability on *HealthCare.gov* will create a colorable risk of plan proliferation or choice overload.

Additionally, we continue to believe that limiting the total number of excepted non-standardized plan options issuers can offer could harm consumers who have a comparatively less common chronic and high-cost condition that issuers may choose to not target with this exceptions process, which would hinder efforts to advance health equity.

Comment: Several commenters noted general support for the existing flexibility, clarified in the proposed rule, that issuers are permitted to offer additional plans within the non-standardized plan option limit by varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage. These commenters noted that the flexibility allows issuers the opportunity to design a sufficient number of plan offerings that cater to the individualized needs of consumers on the Exchange while maintaining guardrails on the rate of plan proliferation.

Some commenters also noted specific support for the benefit coverage categories that are subject to the existing flexibility afforded to issuers under the non-standardized plan option limit, namely adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage. These commenters further noted that ensuring that issuers' plan offerings include a variety of these dental and vision benefits encourages consumer access to these services and ensures that these services are integrated into the marketplace in a way that benefits both consumers and issuers.

Conversely, several commenters opposed the existing flexibility allowing issuers to offer non-standardized plans beyond the plan limit by varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage. Some commenters cited concerns that the flexibility to offer non-standardized plans beyond the plan limit by varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage could result in additional plan proliferation and ultimately exacerbate existing concerns with plan choice overload. One commenter noted that the existence of plans with variations solely based on dental or vision benefit coverage could complicate plan selection and the consumer shopping experience.

Response: We reiterate that the flexibility afforded to issuers to offer non-standardized plans within the plan limit by varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage has been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment Notice. In this final rule, we are maintaining continuity across all operational requirements associated with the non-standardized plan option limit for PY 2026, including that we are only finalizing modifications to align

the regulation text of § 156.202(b) and (d) with that existing flexibility.

We agree that the flexibility given to issuers to offer non-standardized plan options within the plan limit by varying the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage affords them the opportunity to design their non-standardized plan options enough to cater to the individualized needs of consumers while keeping the overall number of plans low.

In the 2024 Payment Notice (88 FR 25862), we expressed our belief that this combination of limiting issuers' non-standardized plan options and allowing flexibility to vary adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage within non-standardized plans within the limit strikes a sufficient balance between minimizing the extent of plan proliferation and maximizing choice of plans among distinguishable plan options.

We also agree that the vision and dental benefits are appropriate for distinguishing among non-standardized plan options within the existing flexibility offered under the non-standardized plan option limit opposed to other additional benefits. As previously noted in the 2024 Payment Notice (88 FR 25959), issuers have frequently offered dental and vision as additional benefits in otherwise identical plan options. Furthermore, when two plans are offered by the same issuer in the product network type, metal level, and service area with different product IDs, the plans are most often distinguished by their coverage of vision or dental benefits.

We share commenters' concerns about the negative consumer impact of plan proliferation. However, we note that nothing compels issuers to offer nearly identical plans that vary solely by the plans' coverage of vision and dental benefits. In our experience, we have found that issuers often choose to offer non-standardized plan options that vary in terms of more parameters (such as the plans' formularies or provider networks, among other factors)—in addition to the inclusion of dental and vision benefit coverage—within the limit of two non-standardized plan options per product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area.

We disagree with commenters who suggested that the flexibility permitting issuers to vary the inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage would result in issuers offering virtually indistinguishable plans that may confuse consumers and render them unable to make meaningful comparisons when attempting to select a plan that best meets their needs. This is because the inclusion of dental and vision benefit coverage represents meaningful coverage variations for consumers.

Comment: Several commenters suggested other modifications to the non-standardized plan option limit. Some commenters recommended expanding the criteria considered under the limit beyond those already included under § 156.202(b) to further relax the standard and allow issuers to vary plans along a greater number of parameters. Some commenters suggested adopting a meaningful difference standard for non-standardized plan options in conjunction with the non-standardized plan option limit to ensure that any two plans are not duplicative across all plan parameters, taking into account differences such as differences in product packages, differences in cost sharing (including whether particular services are available pre-deductible), differences in provider network (such as if there is a reasonable difference in the size of each plan's network), differences in provider network ID, differences in product network type, and differences in whether a plan is an HSA-eligible HDHP.

Response: Similar to our stance in the 2024 Payment Notice (88 FR 25863), we continue to believe that the current structure of the non-standardized plan option limit (as well as the criteria currently considered under the limit) strikes an appropriate balance that allows for issuers to innovate across a sufficiently broad number of plan attributes (including but not limited to provider network, benefit coverage, and benefit cost sharing) while further preventing the likelihood of unabated plan proliferation and plan choice overload. Furthermore, similar to our stance in the 2024 Payment Notice (88 FR 25864), we continue to believe that directly limiting the number of non-standardized plan options issuers can offer under the non-standardized plan option limit is a more effective mechanism than applying a meaningful difference standard at this particular time to reduce plan proliferation and the risk of plan choice overload.

We note that the current structure of the non-standardized plan option limit does not restrict issuers' ability to innovate by differentiating plans on the basis of parameters that are not explicitly identified in the limit—which allows issuers to vary non-standardized plan options' included benefit coverage, cost sharing parameters, and provider networks, among other factors, while still complying with the limit. Additionally, we note that the harm of identical or near-identical plans to the consumer experience is particularly salient for standardized plan options since there is no limit on the maximum allowable number of standardized plan options that an issuer can offer. However, we believe this harm is sufficiently mitigated for non-standardized plan options due to the existence of the non-standardized plan option limit. This is because under the limit, issuers are incentivized to offer plans with meaningful differences to consumers to attract a broader portion of the market. Offering duplicative plans under the non-standardized plan option limit would result in an issuer targeting the same market segments with two different plans.

As we explained in the preceding section addressing standardized plan options, we will monitor whether issuers seek certification of nearly identical plans, including by assessing whether there are plans that would appear identical to consumers shopping on *HealthCare.gov*. If we observe this kind of plan proliferation, we may consider proposing stricter standards in future rulemaking.

Comment: Several commenters also suggested modifications to the current exceptions process. They suggested considering additional metrics beyond cost sharing on which issuers might choose to innovate as grounds for granting an exception, such as deductibles, additional benefit coverage, provider networks, formularies, telehealth availability, or HSA-eligibility.

Response: While we agree that different benefit packages, deductibles, provider networks, formularies, the inclusion of telehealth services, and HSA-eligibility are all important factors that pertain to the treatment of chronic and high-cost conditions, we maintain that restricting eligibility for this exceptions process based solely on a reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions is the most appropriate approach. We continue to believe that the inclusion of any additional factors, including the aforementioned factors and HSA-eligibility, may compromise how precisely tailored the current standard is in ensuring that excepted plans indeed target the unique health care needs of consumers with high-cost and chronic conditions. As we explained in the 2025 Payment Notice (89 FR 26371), one of

our goals with the exceptions process is to ensure that excepted plans substantially benefit consumers with chronic and high-cost conditions.

Specifically, considering these additional criteria in determining eligibility for an exception may allow issuers to offer excepted plans that only slightly vary included provider networks, formularies, deductible amounts, the inclusion of telehealth services, HSA-eligibility, or additional benefits unrelated to the unique health care needs of consumers with high-cost and chronic conditions. This could result in excepted plans differing slightly but failing to provide meaningfully different coverage between excepted plans or failing to provide coverage that is tailored to meet the health care needs of consumers with high-cost and chronic conditions. We maintain that including one different provider in a plan's network, for example, should not result in that plan being permitted an exception on that basis alone.

We reiterate that such an approach would weigh against our goals of reducing plan proliferation, choice overload, and consumer confusion. We refer readers to the 2025 Payment Notice (89 FR 26368) for additional discussion about why we believe that restricting eligibility for this exceptions process based solely on a reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions remains the most appropriate approach.

8. Essential Community Provider Reviews for States Performing Plan Management (§ 156.235)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82385), we proposed, under § 156.235, to conduct Essential Community Provider (ECP) certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026.[232]

Section 1311(c)(1)(C) of the ACA directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to include within health insurance plan networks those ECPs, where available, that serve predominately low-income, medically-underserved individuals. Federal ECP standards were first detailed in the Exchange Establishment Rule (77 FR 18310) and codified at § 156.235. ECP certification reviews under § 156.235 ensure medical QHP and stand-alone dental plan (SADP) issuers include in their provider networks a sufficient number and geographic distribution of ECPs, where available.

HHS has relied on State ECP certification reviews for the certification of QHPs in FFEs in States that perform plan management functions since PY 2015 due to system limitations in the Systems for Electronic Rates & Forms Filing (SERFF),[233] which does not have unique network and service area IDs reliably associated with issuers' ECP data. From PY 2015 to PY 2024, prior to HHS' implementation of the user interface logic for ECPs in the Health Insurance Oversight System (HIOS) Marketplace Plan Management System (MPMS),[234] HHS received ECP data via the ECP/Network Adequacy (NA) Template[235] and SERFF. The ECP/NA Template was an Excel template created by HHS to provide to FFE issuers for collection and submission of both ECP and NA data. While issuers in FFE States would submit the ECP/NA Template with ECP data to HHS directly, issuers in FFEs in States performing plan management functions would not use the ECP/NA Template, but rather submit the ECP data to SERFF.[236] Since there was no reliable mechanism for HHS to convert ECP data received from SERFF back into the ECP/NA Template for review and analysis of the data, HHS could not conduct ECP reviews for issuers in FFEs in States performing plan management functions and therefore relied on States to perform those ECP certification reviews. In the SERFF data, each plan has its own ECP template with its own set of ECPs and networks. The SERFF data does not allow HHS to conduct accurate ECP evaluations of each issuer's networks because multiple networks can share the same sequence of numbers (sometimes referred to as ''sequence numbers'') within the SERFF data, making them indistinguishable from each other in the issuer's SERFF binder. For example, since network IDs are not required to be unique across binders, an issuer may have a multiple network ID 001; then when SERFF data is transferred to HHS, it is not possible to distinguish if ''Network 001'' is applied to the issuer's individual market QHPs or small business health option program (SHOP) SADPs. Initially, HHS designed a workaround to merge the SERFF issuer templates across each plan and remove duplicate entries to allow HHS to conduct the review at the plan level; but this workaround still did not allow for independent evaluation of each issuer's provider networks that share the same sequence number or network IDs.

As we stated in the proposed rule (89 FR 82385), as a result of HHS' system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in States performing plan management functions, enabling HHS to conduct ECP evaluations of each issuer's network. Starting with certification reviews for PY 2025, all issuers seeking certification of plans as medical QHPs and SADPs in FFEs, including in States performing plan management functions, can now enter their ECP data in the HIOS MPMS using the ECP user interface. We noted that because ECP data can now be collected directly in MPMS from all issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, HHS will now be able to independently review the ECP data for such issuers.

In addition, we noted that now, the MPMS ECP user interface also allows issuers in FFEs, including in States performing plan management functions, to validate data before submission to their States, improving data submission to the State as well as providing HHS with each issuer's provider network. We stated that, therefore, HHS will now be able to assess validated ECP data, improving the accuracy and efficiency of the QHP certification process.

We further noted that it was always HHS' intent to implement operational capabilities that would allow for more efficient and accurate ECP reviews. As a result, we proposed to harness the flexibilities afforded by MPMS to conduct Federal ECP certification reviews of medical and dental plans for which issuers submit QHP certification applications in FFEs in States that perform plan management functions beginning with certification reviews for PY 2026. We stated that this proposal would allow HHS to review, evaluate, analyze, and compare provider networks across various FFE States. We added that HHS would also consider challenges FFE issuers face across

[232] Twelve FFEs operate in States performing plan management functions: Delaware, Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

[233] Systems for Electronic Rates & Forms Filing (SERFF) is a portal utilized by States for form submittal, document management, and review.

[234] HIOS MPMS is a web application where users can validate plan data as well as submit their QHPs and SADPs to CMS for annual review and certification.

[235] OMB Control Number 0938–1415: Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification (CMS–10803).

[236] For PY 2025 there were 13 FFEs that operate in States performing plan management functions: Delaware, Hawaii, Illinois, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

various provider networks and ECP categories, such as provider shortages or facility closures. As proposed, issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, would be evaluated against the same requirements and standards. We stated that FFE issuers in States with limited plan management staff or resources would be given the same ECP support, guidance, and monitoring of ECP deficiencies as other FFE issuers.

We noted that this proposal would provide more consistent oversight of ECP data across all FFEs. We further noted that Federal ECP reviews would help ensure all medical QHP and SADP issuers applying for certification of plans as QHPs in FFEs, including in States performing plan management functions, include sufficient provider networks. We stated that this proposal would allow HHS to strengthen ECP data integrity in the FFEs by validating all ECP data before they are submitted and displayed on the FFEs, thereby supporting consumer access to vitally important medical and dental services and health equity for low-income and medically underserved consumers.

We sought comment on this proposal. After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond below to public comments received on the proposed policy to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions beginning in PY 2026.

Comment: Many commenters supported this proposal to conduct ECP certification reviews of plans submitted by QHP issuers in FFEs in States performing plan management functions, expressing that this proposal would allow greater consistency, improve data integrity, streamline data transfers that result in an overall operational improvement, and improve consumer access to ECPs. One commenter that supported this proposal asked that we extend this review to SADPs as these plans are also subject to the ECP requirement under the ACA.

Response: We agree that conducting ECP certification reviews for QHPs, both medical QHPs and SADPs, in all FFEs, including in States performing plan management functions, would allow greater consistency, improve data integrity, and support consumer access to qualified ECPs. We clarify that QHPs include medical QHPs and SADPs, and ECP certification reviews include medical QHPs and SADPs for which issuers submit QHP certification applications in FFEs, including in States performing plan management functions.

Comment: A few commenters opposed the proposal to expand Federal ECP review to certification applications submitted by issuers in FFE States performing plan management functions. These commenters stated that CMS does not have the authority to conduct these reviews as written in the Payment Notice.

Response: Although we have relied on the State for ECP certification review of QHPs in FFEs in States that perform plan management functions since PY 2015 due to system limitations in SERFF, these issuers are still applying for QHP certification in FFEs. We remind commenters that Section 1311(c)(1)(C) of the ACA, part of Title I of the statute, directs HHS to establish by regulation certification criteria for QHPs, including criteria that require QHPs to include within health insurance plan networks those ECPs, where available, that serve predominately low-income, medically-underserved individuals. In addition, Section 1321(a)(1)(B) of the ACA directs the Secretary to issue regulations setting standards for meeting the requirements of Title I with respect to the offering of QHPs through the Exchanges.

Comment: A few commenters submitted comments related to the use of MPMS for the purpose of providing ECP data to HHS via the ECP user interface. One of the commenters was confused by HHS' explanation of the associated network ID and service area ID data within SERFF prior to MPMS and asked, ''What is a 'sequence' number? Is it by a different name in the templates?'' Another commenter expressed concern over the level of personal information required to be disclosed for the multifactor identification for MPMS registration for users and the administrative burden on issuers. Another commenter suggested HHS provide year-round access to the ECP user interface and encouraged HHS to continue to provide transparent communications regarding timeframes for ECP reviews in MPMS and the frequency of updates made to the ECP list in MPMS.

Response: In response to the questions about sequence numbers, we clarify that the term ''sequence numbers'' was used to reference multiple provider networks that may share the same number sequence within SERFF data. Furthermore, we add that issuers in FFEs, including in States performing plan management functions, are not required to provide a unique sequence of numbers for their network IDs across SERFF binders. A SERFF binder submitted by an issuer contains a collection of various templates and plan data,[237] and an issuer may have multiple binders in SERFF. However, since an issuer could submit multiple SERFF binders for different types of plans (*e.g.,* SHOP SADPs, individual market medical QHPs, etc.) with potentially identical network IDs, this made it difficult for HHS to distinguish and evaluate how a network was applied to the issuer's plan. We used a workaround to merge the SERFF data at a plan level, but this workaround still did not allow for independent evaluation of each issuer's provider networks; therefore, we relied on States to certify ECP review results. Due to variations in ECP data transfers across SERFF submitting States, this network ID barrier to evaluating ECP data may not have applied to all SERFF submitting States.

In response to concerns about MPMS' registration requirements, we note that the implementation of the MPMS ECP user interface was the start of our efforts to drive innovation and tackle challenges during QHP certification. We continue to provide technical enhancements to help reduce burden on issuers while providing a secure environment to protect the sensitive data provided by MPMS users to HHS. By using HIOS to access a CMS system, MPMS, users are accessing a Federal Government information system which has system requirements that ensure only authorized/registered users can access protected information and systems through the CMS Enterprise Portal. New users are required to complete the Remote Identity Proofing process, which requires users to answer questions related to their personal information; as well as Multi-Factor Authentication (MFA), which requires users to provide more than one form of verification in order to access the CMS Enterprise Portal. Once an MFA device is registered for their account, users must use this device to log into the CMS Enterprise Portal. All users must complete this registration process, but we will continue to enhance our operational processes to minimize duplicative administrative steps for issuers.

We appreciate the suggestion that we provide year-round access to the ECP user interface. At this time, the ECP user interface is available for QHP certification; but issuers can access the Final PY 2025 ECP List or the HHS

[237] *https://login.serff.com/Appendix%20II.pdf.*

Rolling Draft ECP List year-round to view the current list of available ECPs. We will continue to provide issuers with technical support and communication around QHP certification timeframes and provide the frequency of updates to the ECP list through our published guidance and other communications.

9. Quality Improvement Strategy (§ 156.1130)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82385), we proposed to share aggregated, summary-level Quality Improvement Strategy (QIS) information publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period. We did not propose any revisions to the regulation text to codify this proposal.

Section 1311(c)(1)(E) of the ACA specifies that to be certified as a QHP for participation on an Exchange, each health plan must implement a QIS described in section 1311(g)(1) of the ACA. Section 1311(g)(1) of the ACA describes this strategy as a payment structure that provides increased reimbursement or other incentives for improving health outcomes of plan enrollees, and the implementation of activities to prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities. Section 1311(g)(2) of the ACA requires the Secretary to develop guidelines associated with the QIS in consultation with health care quality experts and interested parties, including periodic reporting to the applicable Exchange of the activities that the plan has conducted to implement the QIS, as described in section 1311(g)(3) of the ACA. In the 2016 Payment Notice (80 FR 10844 through 10845), we issued regulations at § 156.1130(a) and (c) to direct eligible QHP issuers to implement and report on their QIS for each QHP offered in an Exchange, and to submit data annually to evaluate compliance with the standards for a QIS in a manner and timeline specified by the Exchange, respectively.[238] In addition, in the Exchange Establishment Rule (77 FR 18324 and 18415), we finalized regulations at § 155.200(d) that direct Exchanges to evaluate each QIS, and § 156.200(b)(5) that direct QHP issuers to implement and report on a QIS consistent with ACA section 1311(g) standards as QHP certification criteria for participation in an Exchange.

The CMS National Quality Strategy,[239] launched in 2022, builds on previous efforts to improve quality across the health care system. As we noted in the proposed rule (89 FR 82386), we continue to use a variety of levers across the agency, including but not limited to quality measurement, public reporting, and quality improvement programs, to improve health care quality for all. One of the four priority areas of the CMS National Quality Strategy is to promote alignment and coordination across programs and care settings and to improve quality and health outcomes across the care journey.[240] We stated that by developing aligned approaches across quality programs, we can improve coordination and comparisons across programs and across the continuum of care and build the evidence base for quality interventions to support identifying disparities in care. We noted that across Medicare, Medicaid, and Exchange quality programs and initiatives, we promote sharing health care quality information with consumers, providers, researchers and others using different methods, such as program experience reports. Specifically, for the Quality Rating System (QRS) program, we share a summary of quality ratings for each plan year in an annual Results at a Glance report.[241] Additionally, we share information pertaining to both the QRS and QHP Enrollee Experience Survey programs with the public annually through the same report.[242] We noted that our proposal to share aggregated, summary-level QIS information publicly is consistent with the goal of these Marketplace Quality Initiatives (MQIs) to share information publicly and is in alignment with agency efforts to drive innovation and advance quality improvement across the Exchanges.

Since 2017, we have been collecting QIS information from QHP issuers on the FFEs. We stated in the proposed rule (89 FR 82386) that over the years, we have received feedback from issuers, States, and Technical Expert Panel (TEP) representatives about the benefits of sharing QIS data more broadly to promote transparency, improve engagement of best practices across QHP issuers, and provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs. Therefore, recognizing the general interest in this information, and consistent with the general authority set forth in section 1701(a)(8) of the PHS Act,[243] we proposed to release annually, in a report format, the following aggregated, summary-level QHP issuer data: (1) value-based payment models used in QHPs offered by the issuer; (2) QIS topic area; (3) QIS market-based incentive types; (4) clinical areas addressed by QIS; (5) QIS activities; and (6) QRS measures used in QIS. We stated that we do not receive QIS data from State Exchanges or SBE–FPs and would not collect QIS data from State Exchanges or SBE–FPs or their respective issuers under this proposal. As such, we stated that the report would provide information on QIS programs adopted by issuers offering QHPs in the FFEs.

We noted that we believe this proposal would promote transparency of data and drive innovation and quality improvement across Exchanges. We stated that sharing QIS data publicly would also strengthen alignment across CMS quality reporting and value-based incentive programs, including the MQI programs, and would encourage learning to inform best practices for quality improvement across Exchanges, QHP issuers, researchers, and health care quality communities. Additionally, we stated that we believe this proposal would increase accountability for QHP issuers through transparency of quality improvement goals, encourage State Exchanges to share QIS information from their State Exchange issuers publicly, and support HHS' mission to achieve optimal health and well-being for all individuals.

We acknowledged there may be concerns related to the potential sharing of proprietary and/or confidential information. However, we stated that we do not intend to share confidential or proprietary information from a QHP issuer and would only share QIS data that is de-identified and in summary and aggregate form. We further stated that we would maintain compliance with CMS privacy policies, and to address potential confidentiality concerns, we would carefully redact and omit confidential data when data are released aggregately and in a summary format.

[238] Refer to OMB control number 0938–1286.

[239] The CMS National Quality Strategy for Quality Improvement in Health Care available at *http://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[240] Id.

[241] See, for example, Health Insurance Exchanges Quality Rating System (QRS) for Plan Year (PY) 2024: Results at a Glance, available at *https://www.cms.gov/files/document/health-insurance-exchanges-qrs-program-plan-year-2024-results-glance.pdf.*

[242] Id.

[243] Section 1701(a)(8) of the PHS Act, codified at 42 U.S.C. 300u(a)(8), provides general authority to the Secretary of HHS to foster exchange of health-related information to consumers and others.

We sought comment on this proposal. In particular, we sought comment on the types of QHP issuer QIS data to release in an annual report, on the proposed approach and timeline for release of a QIS summary report with aggregated QIS data, and other potential mechanisms to present QIS information publicly in a manner that is informative to issuers and consumers.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing this policy as proposed. We summarize and respond below to public comments received on our proposal to share aggregated, summary-level QIS information publicly on an annual basis beginning on January 1, 2026.

Comment: Many commenters supported the proposal to release aggregated, summary-level QIS information publicly in a report format beginning in 2026. Specifically, these commenters noted support for releasing aggregated, summary-level QIS data and our goals of promoting transparency and encouraging learning to inform best practices for quality improvement across Exchanges, health plan issuers, researchers, and health care quality communities, which they stated will provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs.

Response: We appreciate commenters' support of the proposal to publicly share aggregated, summary-level QIS information annually in a report format. As noted in the proposed rule (89 FR 82386), this policy is in alignment with the goal of the MQIs to share information publicly and is in alignment with agency efforts to drive innovation and advance quality improvement across Federal programs including Medicare, Medicaid as well as the Exchanges.

Comment: Several commenters recommended we develop specific formats for data collection and reporting to ensure consistency, reliability of the data, and to reduce issuers' reporting burden. Other commenters encouraged CMS to develop a uniform standardized reporting format sample for use by QHP issuers in both the FFEs and the State Exchanges, to allow QHP issuers operating in State Exchanges to submit their data for inclusion in the summary-level QIS data CMS plans to share publicly. One commenter recommended we add demographic data to the aggregated, summary-level QHP issuer data we proposed to release annually, while another commenter suggested we add consensus-based entity endorsed measure information, if applicable. One commenter requested additional clarification with respect to what ''summary level data'' includes.

Response: We appreciate the feedback and suggestions regarding the format for QIS data collection and reporting. We intend to leverage data collected from QHP issuers in FFEs through the current QIS forms for the annual aggregated, summary-level QIS data and will consider opportunities to improve the consistency and reliability of data that is included in the aggregated, summary-level QIS data that we will release publicly. This will not increase issuer burden since issuers are already submitting this information on their current QIS forms. Prior to release of the first annual public report of QIS data, we plan to seek feedback from our TEP and will provide definitions, a summary, and clarifications to existing data elements in the associated technical guidance documents. As we stated in the proposed rule (89 FR 82386), we do not currently receive QIS data from State Exchanges or SBE–FPs and do not intend to collect QIS data from State Exchanges or SBE–FPs or their respective issuers under this proposal. We stated in the proposed rule (89 FR 82386) that over the years, we have received feedback from issuers, States, and TEP representatives about the benefits of sharing QIS data more broadly to promote transparency, and the types of data to release in an annual report to provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs. We will also consider and gain input from our TEP regarding adding demographic data and endorsement data, which refers to measure data that has been reviewed using a standard set of evaluation criteria by the Consensus-Based Entity. We clarify that we anticipate the summary-level QIS data we share publicly will be similar to the summary-level data contained in the QRS Results at a Glance report. Summary-level QRS data includes high-level overviews of health plan quality information such as percent and number of reporting units that scored three stars or more in their overall rating. Summary-level QIS data may include the percent and number of reporting units that used a specific market-based incentive type, addressed a specific clinical topic area, or used a QRS measure(s). We believe sharing such data allows consumers, researchers and policymakers to assess key trends, performance, and comparisons across QHP issuers.

Comment: A few commenters provided recommendations on specific approaches for release of an annual report with aggregated, summary-level QIS data. These commenters suggested we share a sample of an annual report for issuer review and feedback prior to the release of an official report, so that plans have an opportunity to review and comment to ensure QIS data is consistent across all plans, on which data points are made available to the public, and how the data will be presented and displayed. One commenter suggested that the publicly reported information be available in digital formats and physical formats to ensure access to information.

Response: We appreciate commenters' feedback, and consistent with section 1311(g)(2) of the ACA, which requires consultation with experts in health care quality and interested parties, we intend to seek feedback on approaches for the public display of the aggregated, summary-level QIS data, including meeting with TEP representatives and engagement with interested parties. We will take the comments summarized above into consideration in doing so. Although we do not routinely publish MQI sample reports solely for issuer review and feedback, we intend to gain thorough input from interested parties including representatives from issuer organizations, State Exchanges, the health care quality community, and consumer advocates. We will adhere to our processes of utilizing the TEP and above-mentioned parties to seek feedback on the timing of the report being released, types of data for inclusion, and approaches to sharing the data. We will also request input from our TEP as to the feasibility of reporting the QIS data in physical and digital formats.

Comment: A few commenters suggested that CMS allow for one full year of data collection prior to release of an annual report with aggregated, summary-level QIS data or limit the included data to a specific timeframe, to allow issuers to use information from the Healthcare Effectiveness Data and Information Set (HEDIS®) and any related QRS metrics in issuers' reporting. A few commenters recommended that CMS limit its public reporting to the information included in the QIS implementation plans submitted in the first year because different health plans may be operating on different timelines, and this may lead to ambiguity if data on plan performance is combined for reporting purposes. One commenter recommended CMS delay the public release of aggregated, summary-level QIS data until 2027 and use the interim period to clarify reporting requirements and release more detail on what data will be released. These commenters

stated that these steps will allow issuers to align their data submission processes with a standardized format fostering uniformity in the reporting of the data across issuers while avoiding duplication, and ensuring clear, consistent public information on QHP quality improvements.

Response: We appreciate the feedback and note the timeline being finalized will allow for one full year of data collection prior to release of the first annual report. One full year of data collection will ensure that issuers can capture comprehensive and reliable information from relevant sources such as HEDIS® and QRS metrics. One full year of data collection also ensures that the data used for reporting reflects a complete cycle of care and improvements. With a year of data, issuers can compare their performance against industry standards, which can identify areas for improvement. With respect to the comment related to the use of data from the QIS Implementation Plan form, CMS will extract and aggregate a majority of data fields from the Implementation Plan form, and may supplement information from an issuer's Modification Summary Supplement form, as needed. CMS may extract the performance measures from an issuer's Modification Summary Supplement form if that issuer has modified their measures. We currently do not aggregate nor publicly report data collected via Progress Report forms due to the timing of QIS data collection, which may result in unvalidated data. We are finalizing in this rule that aggregated, summary-level QIS information will be shared publicly on an annual basis beginning on January 1, 2026, with information QHP issuers submit during the PY 2025 QHP Application Period. We believe that January 1, 2026, is the appropriate time to begin sharing this QIS data publicly because, for the reasons stated above, we need one full year of data collection prior to the release of the annual report. QHP issuers have been submitting QIS data to HHS since 2017 and since that time, we have received feedback from issuers, States, and TEP representatives about the benefits of sharing QIS data more broadly. We intend to leverage data collected from issuers through current QIS reporting tools and believe that sharing the QIS data publicly beginning in 2026, instead of 2027, allows opportunities for interested parties to understand trends and potential issues by viewing interim data. Sharing interim data promotes transparency and helps foster trust even if the data is not yet complete. The collaborative approach from interested parties on review of the data can improve the quality of the final report. Additionally, regular data sharing can address quality improvement efforts where enhancements need to be made to processes throughout the year. Specifically, best practices in quality improvement activities across QHP issuers can be made apparent, improving engagement of QHP issuers to potentially refine approaches to their QIS, and provide consumers with useful information about quality improvement efforts by QHP issuers on the FFEs. We will continue to assess and enhance the public-facing report to help ensure that clear, consistent QIS information is being provided. Since we intend to use QIS information already submitted by QHP issuers on the FFEs through current, annual reporting tools, there would be no duplication of information.

Comment: One commenter suggested we ensure plain language experts review the QIS information that is publicly displayed to make this data accessible to a wider audience, which will empower interested parties to make informed decisions. One commenter recommended that the data be published in a manner that is simplified for consumers to easily understand and in multiple languages. Another commenter suggested we comply with ADA accessibility standards when presenting data. One commenter suggested the report be housed on the QIS website instead of *HealthCare.gov* because it will be most meaningful to policymakers and researchers with expertise in quality work and value-based care, and likely will be too much information and detail for a consumer. Another commenter recommended HHS disseminate publicly diverse sets of educational resources including webinars, fliers, and FAQs relevant to the aggregated, summary-level QIS data that will be publicly shared.

Response: We will make efforts to incorporate plain language and ensure that the QIS information that will be publicly shared complies with ADA standards. We will also consider making MQI reports, including the annual QIS report, available in multiple languages and align them as consistently as possible with other quality initiatives. We acknowledge the recommendation to post the QIS report on the QIS website as well as the recommendation regarding dissemination of information relevant to the aggregated, summary-level QIS information that will be publicly shared through various educational resources. As noted above, we intend to conduct activities to receive feedback for the public display of the information, including meeting with interested parties pursuant to section 1311(g) of the ACA.

Comment: Several commenters noted concern regarding the confidentiality of the aggregated, summary-level QIS information that will be displayed publicly on an annual basis because of accidental data breaches. One commenter suggested that we include de-identified data to address information security and privacy concerns.

Response: We acknowledged in the proposed rule (89 FR 82386) that there may be concerns related to the potential sharing of proprietary and/or confidential information. However, as we stated in the proposed rule, we do not intend to share confidential or proprietary information from a QHP issuer and will only share QIS data that is de-identified and in summary and aggregate form. We will maintain compliance with CMS privacy policies, and to address potential confidentiality concerns, we will carefully redact and omit confidential data when data are released aggregately and in a summary format.

10. HHS–RADV Materiality Threshold for Rerunning HHS–RADV Results (§ 156.1220(a)(2))

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82386), we proposed to amend § 156.1220(a) to codify a new materiality threshold for HHS–RADV appeals,[244] hereafter referred to as the materiality threshold for rerunning HHS–RADV results.[245] We stated that this proposal would codify a standard for when HHS would take action to rerun HHS–RADV results and adjust HHS–RADV adjustments to State transfers in response to a successful appeal. We proposed to make amendments to § 156.1220 to add a new paragraph (a)(2)(i) to provide that HHS would rerun HHS–RADV results in response to an appeal when the impact to the filing issuer's (that is, the issuer who submitted the appeal) HHS–RADV adjustments to State transfers is greater than or equal to $10,000, and we

[244] For the purposes of this proposal, ''appeals'' refers to all three steps of the administrative appeals process as listed in § 156.1220, which includes the request for reconsideration, informal hearing, and review by the Administrator of CMS.

[245] For purposes of this proposal, rerunning HHS–RADV results involves recalculating all national program benchmarks and issuers' error rate results, reissuing issuers' error rate results, conducting discrepancy reporting and appeal windows for the reissued results, applying the reissued error rates to the applicable benefit year's State transfers, and invoicing, collecting, and distributing any additional changes to the HHS–RADV adjustments to State transfers.

proposed to apply this new materiality threshold for rerunning HHS–RADV results beginning with the 2023 benefit year HHS–RADV.[246]

We noted that this materiality threshold would promote the stability of HHS–RADV and avoid considerable expenditures to rerun HHS–RADV results in situations where the filing issuer only accrues a very minor financial benefit (in this case defined as less than $10,000), if any, and where there is a non-material impact on State transfers in a State market risk pool. As we stated in the proposed rule (89 FR 82387), we believe the adoption of this additional materiality threshold to codify a standard for when HHS would rerun HHS–RADV results is necessary and appropriate because HHS–RADV is unique in comparison to other ACA financial programs, such as APTC, where the outcome of a successful appeal only impacts the filing issuer because an issuer's amount of APTC does not impact other issuers.[247] We noted that instead, an HHS–RADV appeal has the potential to impact all issuers nationwide who participated in the applicable benefit year's HHS–RADV.[248]

We refer readers to the proposed rule (89 FR 82386 through 82388) for further discussion of the background and rationale for this proposal.

We solicited comments on the proposed materiality threshold for rerunning HHS–RADV results, including the proposed dollar amount for the materiality threshold and whether that dollar amount should be higher or lower or subject to an annual inflation adjustment amount, as well as the proposed applicability of this threshold beginning with 2023 benefit year HHS–RADV.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing, as proposed, the amendments to add § 156.1220(a)(2)(i) to codify a new materiality threshold for rerunning HHS–RADV results such that we will not rerun HHS–RADV results if the appeal's financial impact on the filing issuer was less than $10,000, beginning with the 2023 benefit year of HHS–RADV. For purposes of this new materiality threshold, ''appeals'' refers to all three steps of the process in § 156.1220, which includes the request for reconsideration, informal hearing, and review by the Administrator of CMS. We summarize and respond below to public comments received on the proposed materiality threshold for rerunning HHS–RADV results.

Comment: A few commenters supported the proposal to codify a dollar threshold to specify when HHS would rerun HHS–RADV results based on a successful appeal. A few commenters noted that the proposal would improve predictability and ensure that adjustments to State transfers as the result of a successful HHS–RADV appeal are limited to situations with significant impacts on HHS–RADV adjustments to risk adjustment transfers. One commenter noted that the policy would limit the burden that rerunning HHS–RADV results has historically disproportionately placed on smaller issuers.

Response: We agree with commenters that this new materiality threshold to rerun HHS–RADV results, which we are finalizing as proposed in this final rule, will ensure appeals are limited to situations with significant State transfer impacts. We also agree that this materiality threshold will improve predictability and limit the administrative burden associated with HHS–RADV, including for smaller issuers.

Comment: A few commenters suggested that the proposed threshold of $10,000 was too low, with one suggesting an alternative threshold of $100,000. These commenters noted concern that a low threshold would result in HHS rerunning HHS–RADV results too frequently. Another commenter suggested that the threshold be set at a certain percentage of statewide average premium.

Response: We are finalizing the proposed materiality threshold for rerunning HHS–RADV results in response to a successful appeal such that we will not rerun HHS–RADV results if the appeal's financial impact on the filing issuer was less than $10,000. We are finalizing this $10,000 threshold because the current materiality threshold applicable to risk adjustment discrepancies set forth in § 153.710(e) is $100,000, and we have found based on our years of experience with HHS–RADV that the magnitude of HHS–RADV adjustments is generally at least one order of magnitude smaller than that of risk adjustment transfers calculated by HHS under the State payment transfer formula, as HHS–RADV adjustments are adjustments to the original risk adjustment State transfer amounts for a benefit year. For these reasons, we believe the proposed lower materiality threshold of $10,000 is roughly proportional to the risk adjustment discrepancy materiality threshold of $100,000.[249] Therefore, we maintain that this is an appropriate materiality threshold for rerunning HHS–RADV results in response to a successful appeal.

As for setting a materiality threshold based on a percentage of statewide average premium, we are concerned that this approach would be overly complex for the purposes of rerunning HHS–RADV results in response to a successful appeal as all issuers would be held to different dollar thresholds under the percentage of statewide average premium standard. While this would ensure a consistent proportional threshold by State market risk pool to account for the correlation of State transfers and statewide average premium, we note that it would likely advantage issuers whose risk adjustment State payments or charges were a larger percent of statewide average premium in meeting the materiality threshold and disadvantage issuers whose State transfers were a lower proportion of the statewide average premium. In this situation, two issuers with the same dollar impact could have their appeals treated differently based on different statewide average premiums. Use of a percentage of statewide average premium could also lead to more frequent re-running of national HHS–RADV results in response to a successful appeal, with associated burden but minimal impact on national results, based on appeals in smaller States with lower statewide average premium. Therefore, in the interest of ensuring that HHS–RADV appeals

[246] The appeal window for 2023 benefit year HHS–RADV is expected to open in July 2025, after the publication of the Summary Report of 2023 Benefit Year HHS–RADV Adjustments to 2023 Benefit Year Risk Adjustment Transfers, which is tentatively scheduled for release in July 2025. See the *2023 Benefit Year HHS–RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* Therefore, we proposed to adopt and apply the materiality threshold for rerunning HHS–RADV results in response to a successful appeal beginning with the 2023 benefit year HHS–RADV.

[247] The EDGE data discrepancies that can arise in States where the HHS-operated risk adjustment program applies have a more limited reach and only impact the State market risk pool with the discrepancy.

[248] The impact of successful HHS–RADV requests for reconsideration or appeals on HHS–RADV results and HHS–RADV adjustments to risk adjustment State transfers on all participating issuers also differs from that of high-cost risk pool audits, discrepancies, and appeals. Any high-cost risk pool funds HHS recoups as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals are used to reduce high-cost risk pool charges for that national high-cost risk pool in the next applicable benefit year for which high-cost risk pool payments have not already been calculated. See the 2023 Payment Notice (87 FR 27253).

[249] Please note that the risk adjustment discrepancy materiality threshold is the lesser of either $100,000 or 1% of State risk pool transfers.

measure the impact to HHS–RADV adjustments at a certain dollar threshold, we did not propose and decline to finalize a materiality threshold based on a percentage of statewide average premium at this time.

Comment: One commenter noted that the proposed threshold may impact the accuracy of the HHS–RADV results if HHS identifies a methodological error and limits recalculation and reissuance of the HHS–RADV results only to situations where the filing issuer meets the proposed materiality threshold. This commenter requested HHS clarify that the Department would recalculate and reissue HHS–RADV results in response to a successful appeal when an HHS error impacting many or all issuers is identified, regardless of how the error was identified.

Response: While we will not rerun HHS–RADV results in response to a successful appeal resulting in an impact of less than $10,000 to a filing issuer's HHS–RADV adjustments to State transfers, the materiality threshold finalized in this rule does not prevent HHS from taking appropriate action, outside of an individual appeal, which could include recalculation and reissuance of HHS–RADV results for a given benefit year, as a result of an identified HHS methodological error. With the adoption of § 156.1220(a)(2)(i), we aim to balance the importance of having accurate HHS–RADV results with the administrative burden of rerunning HHS–RADV when the impact on the filing issuer's HHS–RADV adjustments to transfers is not material.

Comment: One commenter suggested that as an alternative to a materiality threshold, HHS could reduce the broad impact of HHS–RADV successful appeals by limiting the application of the result of a successful appeal to the State market risk pool in which the appeal is filed, or adopt a policy to not make changes to group failure rate classifications or bounds if appeals are submitted after HHS–RADV adjustments to State transfers for a given benefit year are posted.

Response: We did not propose and are not finalizing the alternatives suggested by this commenter. We believe that the materiality threshold for determining when we will rerun HHS–RADV results in response to a successful appeal that we are finalizing in this final rule will best mitigate the administrative burden associated with re-running HHS–RADV results when there is a small financial impact both inside and outside of the State market risk pool in which the appeal was filed, and that the finalized materiality threshold to rerun HHS–RADV results ensures appeals are limited to situations with significant program impacts relative to the burdens incurred by issuers and HHS in rerunning HHS–RADV results.

We disagree that we could limit the scope of an HHS–RADV appeal to the applicable State market risk pool. HHS–RADV appeals have national impacts in that successful appeals can affect and change the national confidence intervals and group failure rates used to calculate issuers' error rates. This process cannot be disaggregated from the calculation of HHS–RADV adjustments, which applies issuers' error rates to all plan level risk scores and recalculates risk adjustment transfers at the State market risk pool level. We also do not believe this approach would be methodologically justifiable as disaggregating the processes of recalculating error rates from the application of error rates for HHS–RADV adjustments to State market risk pool level risk adjustment transfers would imply using two different sets of HHS–RADV results for a single benefit year.

We also do not agree with the comment that we should not make any changes to the group failure rates or confidence interval bounds in response to appeals submitted after the publication of the Summary Report of HHS–RADV Adjustments to Risk Adjustment State Transfers. First, all appeals occur after the publication of the Summary Report of HHS–RADV Adjustments to Risk Adjustment State Transfers. Second, this approach would not take into consideration the true impact of any successful appeal as appeals can result in necessary and methodologically justifiable updates to the group failure rates or confidence interval bounds. Lastly, due to the budget neutrality of risk adjustment transfers, a change to one issuer's risk score error rate or HHS–RADV adjustment due to a successful appeal impacts all other issuers' HHS–RADV adjustments in the filing issuer's State market risk pool; therefore, we do not believe the suggested approach to develop a policy that ignores the impact of a successful appeal on group failure rates and confidence interval bounds is a reasonable option.

E. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82388), we proposed to amend § 158.103 by adding a definition of ''qualifying issuer.'' See subsection E.2 below for the discussion of this proposal.

2. Reimbursement for Clinical Services Provided to Enrollees (§§ 158.140, 158.240)

In the HHS Notice of Benefit and Payment Parameters for 2026 proposed rule (89 FR 82308, 82388), we proposed to amend § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year (MLR reports due in 2027). We also proposed to amend § 158.240(c) to add an illustrative example of how qualifying issuers would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, as well as to make a conforming amendment to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers.

Section 2718 of the PHS Act and the implementing regulations at 45 CFR part 158 require health insurance issuers offering group or individual health insurance coverage to submit an annual report to the Secretary of HHS concerning their MLR and issue an annual rebate to enrollees if the issuer's MLR is less than the applicable MLR standard established in sections 2718(b)(1)(A)(i) and (ii) of the PHS Act. Under section 2718 of the PHS Act, an issuer's MLR is defined as the ratio of (a) incurred claims and quality improvement activity expenses, to (b) premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the ACA. The statute also defines the total amount of an issuer's annual rebate as an amount equal to the product of the amount by which the applicable MLR standard exceeds the issuer's MLR, multiplied by the issuer's premium revenue after subtracting taxes and licensing and regulatory fees and accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the ACA.

In contrast, section 1342(c) of the ACA provides that allowable costs shall be reduced by any risk adjustment payments in the numerator of the risk

corridors calculation.[250] To preserve consistency between these two programs, we finalized an approach in the 2014 Payment Notice (78 FR 15504) that accounted for all premium stabilization program [251] amounts, other than reinsurance contribution fees, in a way that would not have a net impact on the adjusted earned premium revenue used in the calculation of the MLR denominator as defined in § 158.130. Specifically, in the 2014 Payment Notice, we noted that to account for premium stabilization program amounts as an adjustment to earned premium under § 158.130(b)(5), net risk adjustment program receipts, net risk corridors program receipts, and reinsurance program payments would be added to total premium and then subtracted from adjusted earned premium. Section 158.140(b)(4) also provided that premium stabilization amounts, other than reinsurance contribution fees, must adjust incurred claims in the numerator of the MLR calculation defined in § 158.221, in a manner similar to the adjustment of allowable costs in the risk corridors formula set forth in § 153.500. As stated in the 2014 Payment Notice, we found that this approach adhered to the statutory construct of the MLR formula in section 2718 of the PHS Act, which we believe provides flexibility as to whether to account for the effects of collections or receipts for the premium stabilization programs in determining revenue (the denominator) or costs (the numerator) of the MLR formula, while also aligning with the treatment of risk adjustment transfer amounts and reinsurance payments in the calculation of risk corridors payments and charges under section 1342 of the ACA.

In the proposed rule (89 FR 82389), we noted that while many complex factors influence an issuer's underwriting position, our internal analysis suggests that issuers with unusual business models characterized by ratios of risk adjustment payments to earned premium that are approximately 50 percent or higher may owe disproportionately large MLR rebates that could impact solvency. We stated that in these circumstances, we believe that the way the current MLR methodology functions is misaligned with one of the primary statutory goals of the program, which is to ensure that consumers receive value for their premium dollars, as issuers with especially high-risk populations spend a significant proportion of their revenue paying medical claims and may nonetheless also owe rebates that make continued operation in their current markets untenable. Consistent with section 2718(c) of the PHS Act, the standardized methodologies for calculating an issuer's MLR ''shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.'' We stated that we believe modifying the treatment of risk adjustment transfer amounts in the MLR and rebate calculations for these issuers such that these amounts have a net impact on the MLR denominator rather than on MLR numerator would mitigate the solvency and stability concerns for this small subset of issuers that offer different types of plans with unique business models, namely the issuers that focus on underserved communities with significant rates of serious health conditions and that may disproportionately rely on risk adjustment payments, as opposed to premiums, for revenue.

Therefore, we proposed to exercise our authority to account for the special circumstances of this small subset of issuers. Specifically, we proposed to amend § 158.103 to add a definition of ''qualifying issuer'' to mean an issuer whose ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums, prior to accounting for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs (as described in § 158.130(b)(5)) in a relevant State and market, is greater than or equal to 50 percent. We also proposed to modify § 158.140(b)(4)(ii) to no longer apply net risk adjustment receipts as an adjustment to the incurred claims amount that is used to calculate the MLR numerator defined in § 158.221(b) for such qualifying issuers. We did not propose to make any changes to the definition of premium revenue in § 158.130.

We stated in the proposed rule (89 FR 82390) that under this proposal, we would modify the calculation of the MLR denominator and rebates as described in the 2014 Payment Notice such that for qualifying issuers, earned premium would account for net risk adjustment receipts by simply adding these net receipts to total premium, without subsequently subtracting them from adjusted earned premium. We noted that the effect of the proposed changes would be to remove these offsetting adjustments (the addition and the subtraction that offset each other) to earned premium in the MLR denominator and rebate calculations, such that these qualifying issuers' risk adjustment transfer amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively. We also proposed to make a conforming amendment to § 158.240(c) to clarify that the existing illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers, and to add an illustrative example in a new paragraph (c)(3) of how qualifying issuers would determine the amount of rebate owed to each enrollee, to accurately reflect how qualifying issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers.

In summary, we proposed that for qualifying issuers, risk adjustment transfer amounts would be a net adjustment to the denominator, rather than the numerator, of the MLR calculation as follows:

If (ra/p) > or = 50%;

Adjusted MLR = [(i + q − s + nc − rc)/{(p + s − nc + rc) − t − f − (s − nc + rc) − na + ra}] + c

Where,

i = incurred claims
q = expenditures on quality improving activities
p = earned premiums
t = Federal and State taxes
f = licensing and regulatory fees including transitional reinsurance contributions
s = issuer's transitional reinsurance receipts
na = issuer's risk adjustment related payments
nc = issuer's risk corridors related payments
ra = issuer's risk adjustment related receipts
rc = issuer's risk corridors related receipts
c = credibility adjustment, if any

For a qualifying issuer whose MLR falls below the minimum MLR standard in a State and market, we proposed to calculate the MLR rebate in § 158.240(c) as follows:

If (ra/p) > or = 50%;

Rebates = (m − a) * [(p + s − nc + rc) − t − f − (s − nc + rc) − na + ra]

Where,

m = the applicable minimum MLR standard for a particular State and market
a = issuer's MLR for a particular State and market.

We proposed that these amendments would be applicable beginning with the 2026 MLR reporting year (MLR reports

[250] Section 1342 of the ACA and the implementing regulations at 45 CFR part 153 established a temporary risk corridors program applicable to QHP issuers in the individual and small group (or merged) markets for the 2014, 2015, and 2016 benefit years.

[251] The premium stabilization programs refer to the reinsurance, risk corridors, and risk adjustment programs established by the ACA. See section 1341 of the ACA (transitional reinsurance program), section 1342 of the ACA (risk corridors program), and section 1343 of the ACA (risk adjustment program).

due in 2027), to enable issuers that are, or may be able to meet the definition of, a qualifying issuer to reflect the amendments in their premium rates. We requested comment on all aspects of the proposal, including the definition of ''qualifying issuer'' and whether issuers should satisfy additional criteria to qualify for this flexibility, whether the proposed MLR and rebate methodologies would create any inappropriate incentives for issuers that are unable to accurately price their products or reduce administrative costs, as well as impacts to other issuers that are not ''qualifying issuers'' and potential market distortions that may arise if the proposed flexibility for MLR and rebate calculations is not extended to all issuers in applicable markets.

We also considered an alternative approach that would modify the treatment of net risk adjustment transfer amounts such that these amounts would have a net impact on the MLR denominator and rebate calculations in § 158.221(c) and § 158.240(c), respectively, instead of the MLR numerator defined in § 158.221(b), for all issuers subject to MLR requirements, rather than only for qualifying issuers. We noted that we did not propose this alternative approach as we believe that the more narrow, tailored proposal to provide this flexibility only for qualifying issuers is sufficient to maximize availability of coverage options while remaining consistent with the statutory objective of section 2718 of the PHS Act, which is to ensure that consumers receive value for their premium dollars. We stated that the more narrow, tailored proposal would also produce a smaller reduction in rebate payments to consumers than the alternative approach and would cause less disruption to the industry. We requested comment on all aspects of this alternative approach, including on ways that this alternative approach could potentially influence issuers' rebate positions, plan composition, and pricing decisions, and potential impacts of this alternative approach on consumers.

We refer readers to the proposed rule (89 FR 82388 through 82391) for further discussion of our proposal as well as the alternative approach we considered.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing our proposal, with modification, effective beginning with the 2026 MLR reporting year. First, we are finalizing our proposed amendment to § 158.103 to add a definition of ''qualifying issuer,'' with a modification to clarify that the new definition of ''qualifying issuer'' is based on an issuer's 3-year aggregate ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums as defined in § 158.130, but prior to and excluding the adjustments in § 158.130(b)(5) that account for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs, in a relevant State and market. Second, we are finalizing our proposed amendment to § 158.140(b)(4)(ii) to allow qualifying issuers to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes, with a modification to specify that we are allowing qualifying issuers to modify the treatment of risk adjustment transfer amounts in the manner described above at their option, rather than making this change mandatory for qualifying issuers. Finally, we are finalizing our proposed amendments to § 158.240(c) to (1) add an illustrative example at § 158.240(c)(3) of how qualifying issuers that choose to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii) would calculate the amount of rebate owed to each enrollee to accurately reflect how such issuers would incorporate the net risk adjustment transfer amounts into the MLR and rebate calculations differently from other issuers, with a modification to clarify that qualifying issuers ''opt'' to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii), and (2) to clarify that the current illustrative example in § 158.240(c)(2) would apply to issuers that are not qualifying issuers or that are qualifying issuers that do not opt to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii). We summarize and respond to public comments received on our proposal below.

Comment: We received several comments of general support for the proposal.

Response: We thank commenters for their support of the proposal.

Comment: Several commenters supported the proposal's applicability to only the narrow subset of qualifying issuers, on the basis that doing so would minimize any rebate reduction that would be a result of the proposal and would avoid harming issuers whose premium rates are relatively low in proportion to the coverage provided and that incur risk adjustment program payments.

Response: We agree with these commenters and thank them for their support of the proposal.

Comment: One commenter requested CMS to clarify whether, when determining if an issuer is a ''qualifying issuer,'' the issuer should use a single year, or 3-years' aggregate ratio of net risk adjustment payments to earned premiums. Another commenter requested CMS to state more clearly and explicitly that the definition of ''qualifying issuer'' is based on billed premium, rather than premium that reflects the impact of risk adjustment transfer amounts.

Response: We confirm that the definition of ''qualifying issuer'' at § 158.103 is based on an issuer's 3-year aggregate ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums as defined in § 158.130, but prior to and excluding the adjustments in § 158.130(b)(5) that account for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs, in a relevant State and market. We are modifying the proposed definition of ''qualifying issuer'' at § 158.103 accordingly.

Comment: One commenter suggested that we allow all issuers that receive risk adjustment payments to reflect these amounts in the MLR denominator, while continuing to allow issuers that make risk adjustment payments (pay risk adjustment charges) to reflect these amounts in the MLR numerator. The commenter stated that they believe this approach eliminates any potential incentive to misprice premiums, is straightforward to implement, and is fair and equitable for all issuers, regardless of their share of claims from high- and low-risk enrollees.

Response: We decline to adopt this commenter's suggestion as the statute does not provide for a different means of accounting for risk adjustment payments and receipts in the MLR calculation. This approach is also inconsistent with generally accepted accounting principles that provide for a consistent accounting of transfers regardless of their direction. Additionally, the suggested approach would significantly reduce total net rebates to consumers without a justifiable benefit, contrary to the goals of the MLR program.

Comment: One commenter recommended making the proposal optional for qualifying issuers.

Response: We appreciate the comment and agree that qualifying issuers should have the option to elect whether to take advantage of modifying the treatment of risk adjustment program transfer amounts in their MLR and rebate calculations. Making the modification optional will allow issuers

that are part of a holding company system, and that operate in many States and markets, to maintain the consistent MLR reporting practices that they have implemented across companies. Such companies might find having one reporting approach to be simpler than determining which issuers, and in which States and markets, in the holding company system are ''qualifying issuers'' and changing their MLR reporting process only for those issuers. Additionally, issuers that meet the definition of a ''qualifying issuer'' but do not owe MLR rebates may not want to change their established reporting processes when the change would not create any benefit for them.

We are modifying the amendments to § 158.140(b)(4)(ii) and § 158.240(c)(2) and (3) to give qualifying issuers the option to elect whether to take advantage of modifying the treatment of risk adjustment program transfer amounts in their MLR and rebate calculations.

Comment: One commenter suggested that we add a maximum threshold of 25,000 enrollees in order for an issuer to qualify as a qualifying issuer, to serve as a guardrail to ensure that the proposal targets the specific issuers whose risk adjustment payments exceed 50 percent of their earned premium and does not cause unintended consequences for other issuers.

Response: While we appreciate the commenter's suggestion, we decline to adopt a maximum enrollment threshold of 25,000 enrollees, as we believe that it is possible for an issuer to have a unique business model and corresponding challenges targeted by this policy even if its enrollment exceeds 25,000. Based on our estimates that extremely few issuers would meet the definition of a qualifying issuer and also owe rebates, we do not believe that proposal, as finalized, is likely to cause unintended consequences for other issuers.

Comment: A few commenters declined to offer support or opposition to the proposal, but pointed out the potential benefits of, as well as noted concerns with, the proposal. A few commenters requested that if CMS does finalize the proposal, that it carefully monitor the impact on the affected enrollees in underserved communities. These commenters noted that the proposal could potentially benefit enrollees with chronic conditions by stabilizing their issuers, reducing premium increases, and promoting consistent access to care. On the other hand, commenters noted that the proposal could result in lower rebates, and that limiting the proposal to only qualifying issuers could result in market imbalances and lead to higher costs or fewer coverage options. These commenters noted concern that the proposal could unintentionally incentivize issuers to reduce their costs by reducing benefit quality.

Response: We appreciate the commenters' perspectives and agree that the policy will have a number of beneficial impacts. We agree that the policy could benefit enrollees in underserved communities, particularly those with chronic conditions and those with lower incomes that are served by issuers that receive large risk adjustment payments in proportion to their revenue. We believe that allowing qualifying issuers the flexibility to account for risk adjustment transfers in the denominator of the MLR calculation will enable them to continue to serve these communities and provide continuity of care to enrollees. We intend to monitor the impact of the finalized policy to the extent resources are available. While we acknowledge commenters' concern that the finalized policy could reduce rebates, we note that any rebate reduction is expected to come from issuers whose business models put them at risk of being financially unviable and unable to continue to provide coverage or pay any rebates, and thus any rebate reduction would be outweighed by the benefit to enrollees of being able to continue their current health coverage, or access higher quality health coverage that might not otherwise be available. We do not agree that the policy would incentivize issuers to reduce benefit quality, raise costs, or reduce coverage options as such coverage changes would not attract higher-risk enrollees for which the issuer would receive risk adjustment payment. For the reasons described in more detail in the response to the comment below, we also do not believe that the rule is likely to cause significant market imbalances or precipitate issuer insolvencies. However, we intend to monitor and analyze the impact of this provision after it is implemented for the 2026 and later MLR reporting years to evaluate whether it operates as intended and continues to be appropriate.

Comment: One commenter requested that CMS provide the number of impacted issuers as well as additional data on the impact of the proposal to enable interested parties to fully evaluate the proposal.

Response: As noted in the Regulatory Impact Analysis section of this final rule, since the proposal as finalized is not mandatory for qualifying issuers, CMS cannot, at this time, provide the number of impacted issuers. However, based on 2023 MLR data, we estimate that fewer than half a dozen issuers would meet the new definition of ''qualifying issuer'' and, if all of them choose to modify the treatment of risk adjustment transfer amounts in the manner described and finalized in this rule, would experience a total combined reduction in rebates of approximately $35 million, out of approximately 180 issuers that owed approximately $946 million in combined total rebates for 2023.

Comment: Several commenters opposed the proposal. The majority of these commenters advocated for the alternative approach described in the proposed rule that would apply the risk adjustment transfer amounts in a manner that has a net impact on the MLR denominator instead of numerator for all issuers, rather than only ''qualifying issuers.'' In contrast, a few commenters who opposed the proposal stated that if CMS nevertheless did finalize the proposal, they would prefer the proposed narrow approach, rather than the alternative approach, as it would be less harmful. These commenters were particularly concerned with the potential negative impacts of the alternative approach on the lower-cost issuers that tend to offer more affordable plans designed to target low utilization, generally owe risk adjustment payments, and sometimes face solvency concerns of their own. One commenter opposed both the proposal and the alternative approach. Several commenters noted concern that the proposal would exacerbate pricing uncertainty and market distortion for non-qualifying issuers. One commenter stated that they were unable to conclusively determine whether risk adjustment should be reflected in the MLR numerator or denominator, while two commenters stated they consider payments or receipts related to the HHS-operated risk adjustment program to be more appropriate as an adjustment to premium rather than claims, as this would be consistent with both generally accepted accounting practices and State statutory accounting.

Response: Given the wide range of views among commenters, including conflicting views regarding whether payments or receipts related to the risk adjustment program are generally more appropriate as an adjustment to premium in the MLR denominator or claims in the MLR numerator, we are declining to adopt the alternative approach described in the proposed rule and are finalizing the narrower proposal that applies the changes only to ''qualifying issuers,'' rather than all issuers, with the modification discussed

above to allow qualifying issuers to opt into taking advantage of modifying the treatment of risk adjustment transfer amounts in their MLR and rebate calculations. We agree with commenters who favored limiting this option to qualified issuers as a means of reducing the possibility of an adverse impact on issuers that owe risk adjustment charges and that may have lower administrative costs and premiums. Given the very small number of issuers that we estimate will meet the definition of a ''qualifying issuer'' and also owe rebates, we believe that finalizing the narrower proposal will have minimal possibility of disrupting the market and exacerbating pricing uncertainty, and we share some commenters' concerns regarding the potential negative impact of higher MLR rebates under the alternative approach on issuers that owe risk adjustment payments.

Comment: Some commenters who opposed the proposal stated that the proposed 50 percent threshold to become a ''qualifying issuer'' is arbitrary, inequitable, and would create an unlevel playing field. These commenters stated that the proposal could incentivize issuers to set inadequate rates to meet the new definition of a qualifying issuer, and that if actual risk adjustment receipts were to be lower than expected, an issuer could face both inadequate premium and risk adjustment revenue, as well as have to pay higher than expected rebates, which could ultimately increase, rather than prevent, market instability and issuer insolvencies.

Response: We acknowledge commenters' concerns. However, we believe that this hypothetical scenario, under which an issuer that is close to the threshold of ''qualifying issuer'' and close to or under the MLR rebate threshold would purposely and significantly underprice, would greatly increase the risk of insolvency, and is therefore unlikely. Our analysis of 2023 MLR data shows that fewer than half a dozen additional issuers have aggregate ratios of risk adjustment receipts to premium between 20 and 50 percent. Further, our analysis of 2023 MLR data also shows that very few issuers nationwide would currently meet the threshold to qualify as a ''qualifying issuer'' and also owe rebates, and thus it is unlikely that providing the option for these issuers to modify the treatment of risk adjustment transfer amounts in the manner described and finalized in this rule would cause significant or widespread market uncertainty, distortion, or instability that would outweigh the benefits of codifying this narrow flexibility for qualifying issuers that opt to utilize it. For the same reason, we disagree that the 50 percent threshold is arbitrary or would create an uneven playing field, as it was chosen to capture a small number of issuers that are clear outliers relative to the prevalent positioning in the industry, and whose risk adjustment transfer amounts and premium revenue indicate business models that are fundamentally different from those of most issuers.

Comment: One commenter noted skepticism that the proposal validly asserts that risk adjustment overcompensates issuers whose premiums are below statewide average premium and that they should be entitled to retain that overcompensation. One commenter also noted that the proposal is unnecessary since any issuer whose risk adjustment program payments are large enough to result in it owing MLR rebates is being overcompensated by the risk adjustment program for its enrollees, depriving those enrollees of an MLR rebate.

Response: The policy being finalized in this final rule is designed to target issuers that rely on risk adjustment receipts for revenue to such a disproportionate degree that it distorts the results of the MLR and rebate calculations, and that are consequently also unable to reduce enrollees' premiums any further without jeopardizing solvency. Therefore, we do not agree that the policy would enable such issuers to be overcompensated or that it would improperly deprive their enrollees of the benefit of MLR rebates.

Comment: A few commenters urged CMS to explore alternative vehicles other than MLR to address the stated policy concerns, such as addressing issues with the HHS-operated risk adjustment program or focusing on other policies that directly impact issuers' long-term financial stability and actuarily sound pricing practices.

Response: We appreciate the commenters' suggestions. We have analyzed the HHS risk adjustment methodology in numerous white papers, have refined the HHS risk adjustment methodology as new data become available, and have finalized modifications and improvements to it as necessary, including in this final rule. However, the modifications we are finalizing in part 158 do not impact the HHS-operated risk adjustment program, and the comment regarding changes to the HHS-operated risk adjustment program to address issuers' financial stability and pricing practices is out of scope of this proposal. As stated in the proposed rule, the change to the MLR and rebate calculations is intended to specifically address concerns that, for certain issuers with risk adjustment payments that are greater than half of their premium revenue, these calculations might require large rebate payments that impact solvency—a scenario that we believe is contrary to the goals of the MLR program. As such, we believe that finalizing the proposed change to the MLR and rebate calculations for qualifying issuers, at their option, is appropriate.

Comment: One commenter supported making the proposal effective beginning with the 2026 MLR reporting year.

Response: We thank the commenter for their support of the proposed effective date and are finalizing this proposal, with modification, effective beginning with the 2026 MLR reporting year.

Comment: One commenter suggested CMS postpone finalizing the proposal to study its potential impact in greater depth and to receive additional feedback from interested parties.

Response: While we appreciate the commenter's suggestion, we decline to postpone finalizing the proposal. We received many detailed and thorough comments from interested parties that addressed the full spectrum of the potential benefits and drawbacks of the proposal, and that are sufficient to inform the decision to finalize the proposal. However, as noted above, we intend to monitor and analyze the impact of this policy after it is implemented for the 2026 and later MLR reporting years to evaluate whether it operates as intended and continues to be appropriate.

Comment: One commenter urged CMS to investigate how issuers and PBMs are using vertically integrated systems to circumvent the intent of the MLR reporting and rebate rules by shifting profits from an issuer to an affiliated entity that is not subject to the MLR requirements, or inflating clinical reimbursement payments to affiliated providers. One commenter recommended that we change the definition of a ''health plan'' to include stand-alone dental coverage.

Response: While we appreciate the commenters' recommendations, these comments are out of scope of this proposal.

F. Severability

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this final rule in addressing them independently, HHS generally intends this rule's provisions to be severable from each other. For example, the final rule outlines payment parameters and

provisions for the HHS-operated risk adjustment and risk adjustment data validation programs, 2026 user fee rates for issuers in these programs, and changes to the BHP payment calculations. It includes modifications to the initial and second validation audit processes that are part of the HHS–RADV program and addresses HHS' authority to take enforcement action against lead agents at insurance agencies for violations of HHS' Exchange standards and requirements. The rule also addresses certification standards, ECP reviews, public sharing of aggregated, summary-level QIS information on an annual basis, and revisions to the MLR reporting and rebate requirements for qualifying issuers that meet certain standards. It is HHS' 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, the rule shall be construed so as to continue to give maximum effect as permitted by law. In the event a provision is found to be utterly invalid or unenforceable, HHS intends that that provision to be severable.

IV. Waiver of Delay in Effective Date

We ordinarily provide a minimum 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which usually requires a 30-day delayed effective date, and the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)), which usually requires a 60-day delayed effective date for major rules. However, we can waive the APA and CRA delay in effective date requirements for good cause (5 U.S.C. 553(d)(3) waiver available when ''provided by the agency for good cause found and published with the rule''; 5 U.S.C. 808(2) (waiver available when ''an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued that notice and public procedure thereon are impactable, unnecessary, or contrary to the public interest''). The Secretary has determined that it is appropriate to issue this final rule effective immediately from the date this rule appears in the **Federal Register**. The provisions are necessary to address imminent threats to the health and safety of Exchange enrollees presented by unauthorized changes to a consumer's health coverage.

Prompt action is necessary to provide for certain critical changes to our monitoring of agents and brokers for 2025 to protect consumers, insurers, and agents and brokers from non-compliant actors. Over the past year, HHS has observed inappropriate behavior by a small population of agents and brokers in the Exchanges that significantly impacts and endangers consumers. The non-compliant actions of these agents and brokers have placed the health and safety of consumers at risk, led to consumer financial harm, and undermined trust in the Exchanges and the healthcare system.

HHS has observed enrollment practices where agents and brokers switch individuals' plans without their consent or enroll them in a plan without their consent. This has led to dangerous gaps in coverage that kept consumers from obtaining medications for chronic conditions and placed at risk their ability to receive medically necessary procedures and services because of the disruption to their coverage. Making this final rule effectively immediately will help to mitigate the significant health and safety risk that consumers will go without necessary medical care and services due to gaps in coverage that are no fault of their own.

As reported, from January to August of 2024 there were 90,863 unauthorized plan switches and 183,553 unauthorized enrollments attributed to agent and broker misconduct.[252] Such actions not only harm consumers, but also place sensitive consumer information at risk, disrupting the integrity of the Exchanges. The oversight policies in this final rule are integral to combatting agent and broker misuse of sensitive consumer information. Privacy violations pose a significant risk, as unauthorized use or sharing of personal consumer information can lead to identity theft and other privacy breaches. In response to the proposed rule, interested parties requested speedy changes in oversight to protect consumers from noncompliant and fraudulent behavior to protect consumers and maintain the integrity of the Exchanges.

Consumers also have faced financial harm after being inappropriately lured into a plan by misleading agent/broker advertisements that promise non-existent cash benefits, as well as concerning behavior involving the use of high-pressure sales tactics. Such tactics have caused consumers to enroll in QHPs with no premium responsibility when they are already enrolled in Medicaid or employer sponsored coverage that qualifies as minimum essential coverage that disqualifies them from receiving APTCs to support QHP premium payments. This has exposed affected consumers to liability to repay APTCs once they discover they were enrolled in a plan without their knowledge or consent.

Prompt action is also necessary to provide for certain critical changes to our programs for 2025—including a policy to allow issuers to voluntarily adopt multiple premium payment thresholds to support continuous coverage of consumers; an amendment to the medical loss ratio (MLR) calculation to account for risk adjustment; updates to user fees for issuers offering qualified health plans (QHPs) through an FFE or SBE–FP and those participating in the HHS–RADV program; amendments to adjust the premium adjustment factor (PAF) in the Basic Health Program (BHP); a clarification to the BHP payment methodology to address ambiguities when multiple second lowest cost silver plans exist in one county; risk adjustment data validation policies that remove enrollees without HCCs from the IVA sampling methodology and remove the finite population correction (FPC) factor; and timeliness standards for State Exchanges to review and resolve enrollment data inaccuracies. We seek an immediate effective date to allow issuers ample time to prepare for the 2025 plan year and help stabilize the Exchanges for issuers and consumers. We believe consumers' confidence in the Exchanges is especially important this time of year when they are making enrollment decisions, with Open Enrollment in the individual market ongoing and the Medicare General Enrollment period about to begin on January 1. States, issuers, and other interested parties have also requested that this rule become effective earlier to establish rates for 2026 in a timely fashion.

HHS has determined that implementation of these changes beginning early in 2025 is necessary to protect against imminent threats to the health and safety of Exchange applicants and enrollees, maintain robust participation on the Exchanges, and to encourage affordability of coverage for enrollees and the continuity of care that is supported by the continued availability of plans on the Exchanges. HHS has therefore found good cause to waive the APA's and CRA's delayed effective date requirements and determined that the rule will become effective immediately

[252] CMS, *CMS Update on Actions to Prevent Unauthorized Agent and Broker Marketplace Activity, https://www.cms.gov/newsroom/press-releases/cms-update-actions-prevent-unauthorized-agent-and-broker-marketplace-activity#:~:text=consumers%20who%20believe%20they%20may,resolve%20any%20coverage%20issues%20promptly.* Oct. 17, 2024.

on the date this rule appears in the **Federal Register** January 15, 2025.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide a 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. 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 comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of the 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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The public comments and our responses appear in this section, and in the applicable ICR sections that follow.

A. Wage Estimates

To derive wage estimates, we generally use data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for the cost of fringe benefits and overhead) for estimating the burden associated with the ICRs.[253] Table 4 presents the median hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 4: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Median Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Business Operations Specialists, All Other	13-1199	38.26	38.26	76.52
Health Information Technologists and Medical Registrars	29-9021	30.28	30.28	60.56
Compliance Officer	13-1041	36.38	36.38	72.76

B. ICRs Regarding the Initial Validation Audit (IVA) Sample—Enrollees Without HCCs, Removal of the FPC, and Neyman Allocation (§ 153.630(b))

Beginning with the 2025 benefit year of HHS–RADV, we are finalizing under § 153.630(b) excluding enrollees without HCCs from the IVA sampling methodology, removing the FPC from IVA sampling,[254] and replacing the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before HHS–RADV activities for the benefit year begin. Specifically, these amendments will exclude enrollees without HCCs (stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, remove the FPC such that issuers with 200 or more enrollees in strata 1 through 9 will have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 will have IVA sample sizes equal to their population of enrollees with HCCs, and change the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to HHS–RADV data. By removing enrollees without HCCs from IVA sampling, the Neyman allocation will only apply to enrollees with HCCs in strata 1 through 9 in the IVA sample.

These amendments are intended to improve the validity of our IVA sampling assumptions and sampling precision and will decrease aggregate burden across all issuers when implemented in combination. As noted in section III.B.6.a of this final rule, the finalized changes to the IVA sampling methodology will result in increased sample sizes for some smaller issuers that are subject to the FPC and currently assigned modified IVA sample sizes less than 200 enrollees under the current methodology. However, sample size is not necessarily indicative of issuer burden in HHS–RADV, as the driving factor of burden is the number of enrollee medical records that must be retrieved and reviewed for the IVA sample. Overall, the amended IVA sampling methodology in this final rule alters the allocation of strata sample sizes within the IVA sample, ultimately resulting in relatively smaller proportions of enrollees from high-risk strata, who generally have more medical records to review, being selected for the IVA sample, on average. Consequently, with these amendments, the average number of medical records reviewed per enrollee in the IVA sample and the average number of medical records reviewed per issuer will decrease.

The currently approved information collection (OMB Control Number 0938–1155) for conducting the IVA takes into account that the issuer must review the IVA sample and determine which enrollees will require medical records to validate their HCCs and details the processes the issuer must undertake to obtain medical records for their enrollees selected for the IVA sample. In the currently approved information

[253] See Department of Labor. (2024, April 3). Bureau of Labor Statistics, Occupational Employment *and Wage* Statistics, *May 2023 Occupation Profiles. https://www.bls.gov/oes/current/oes_stru.htm.*

[254] In the current IVA sampling methodology, a Finite Population Correction factor is used to calculate a target IVA sample size less than 200 enrollees for issuers with less than 4,000 enrollees.

collection, we estimate an upper limit of 650 issuers submitting samples of 200 enrollees for HHS–RADV for any given benefit year, five medical record requests per enrollee in the IVA sample size and three HCCs to be reviewed by a certified medical coder per enrollee with HCCs, which leads to an aggregate burden of conducting IVAs of approximately 1,663,729 hours and $116,963,821.[255] Given the changes to the IVA sample under the policies in this final rule and recent HHS–RADV data, we estimate an upper limit of 600 issuers submitting samples of 200 enrollees for HHS–RADV for any given benefit year.[256] We estimate an approximate average of two medical records reviewed and two HCCs reviewed per enrollee in the IVA sample under the revised IVA sampling methodology.

For our monetary and hourly burden estimates, we are incorporating labor and wage costs from the most recent premium stabilization programs information collection, ''Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals'' (OMB Control Number 0938–1155). Based on an analysis that applies the amendments to remove enrollees without HCCs from IVA sampling, remove the FPC, and use HHS–RADV data as the source for the Neyman allocation beginning with 2025 benefit year HHS–RADV, approximately 200 enrollees in an issuer sample will require medical records to validate HCCs, with approximately two medical record requests per enrollee (approximately 400 medical record requests per issuer).[257] We estimate it will take a business operations specialist (occupation title ''Business Operations Specialists, All Other'' at an hourly wage rate of $76.52) approximately 1 hour to complete, review, and conduct follow-up on each medical record request (20 minutes each to complete each medical record request, review the response to each medical record request, and to conduct further follow-up on each medical record request). For each issuer, we anticipate the burden will be approximately 400 hours at a cost of $30,608. For an estimated 600 issuers required to submit samples for HHS–RADV for any given benefit year, we anticipate that the aggregate burden of completing medical record reviews will be approximately 240,000 hours and $18,364,800.

Based on a review of enrollee-level EDGE data for the 2017–2022 benefit years and the finalized changes to the IVA sampling methodology in this final rule, we have determined that for enrollees with HCCs, the average number of HCCs to be reviewed by a certified medical coder per enrollee will be approximately two HCCs. Additionally, based on HHS–RADV audit experience, we estimate that it may cost approximately $272.52 ($60.56 per hour for 4.5 hours on average) for a certified medical coder to review the medical record documentation for one enrollee with roughly two HCCs. For 200 enrollees with HCCs in an issuer's IVA sample, the total cost to each issuer will be $54,504 (for 900 hours). In some cases, a secondary review by a senior certified medical coder (occupation title ''Health Information Technologists and Medical Registrars'' at an hourly wage rate of $60.56 per hour) will be needed to re-review approximately one-third of the medical record documentation required during the first review. Thus, a senior certified medical coder will need to review medical documentation for the equivalent of approximately 66 enrollees with HCCs in an issuer sample. We estimate that the total cost to each issuer will be approximately $17,986.32 ($60.56 per hour for 4.5 hours per enrollee). For this review and secondary review, the total cost to each issuer will be approximately $72,490.32 (1,197 total hours).

These changes will not affect the review of demographic and enrollment information, as we will continue to validate demographic and enrollment information for a subsample of up to 50 enrollees from the audit sample, or the RXC review, as the audit entity must review RXCs for all adult enrollees in the audit sample with at least one RXC, and we continue to assume that a review will be performed on approximately 50 RXCs per issuer. As such, we are only changing our burden estimates of demographic and enrollment or RXC review to use the most recent median hourly wage estimates. We estimate that it may cost approximately $20.19 per enrollee ($60.56 per hour for 20 minutes) to validate demographic information for 50 enrollees in each audit sample totaling $1,009.33 per issuer. Similarly, we estimate that RXC validation for 50 enrollees will cost approximately $20.19 per RXC ($60.56 per hour for 20 minutes), totaling $1,009.33 per issuer. In addition, for each issuer, we expect it will require a compliance officer working 40 hours at $72.76 per hour, and two operations managers working a total of 80 hours at $97.38 per hour to make available to external medical coders associated with the IVA entity claims documents for review of demographic information and RXC review (120 hours at a combined cost of $10,701).

For each issuer submitting audit findings for HHS–RADV in a given benefit year, the total burden for reporting, coding, and administration will be approximately 1,750.33 hours at a cost of $115,817.79 per issuer. For an estimated 600 issuers required to submit audit findings for HHS–RADV for any given benefit year, we anticipate that the aggregate burden of conducting IVAs will be approximately 1,050,200 hours and $69,490,672 beginning in 2025. This reflects an aggregate burden decrease of 613,529 hours and $47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and $116,963,821.

We sought comment on these assumptions.

We did not receive any comments in response to the proposed burden estimates for this policy. We received comments on the general impacts of this policy on issuer and IVA Entity burden and respond to those comments in section III.B.6.a. and the Regulatory Impact Analysis section of this rule. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

C. ICRs Regarding Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

This finalized policy addresses HHS' authority to engage in compliance reviews of and take enforcement action against lead agents of insurance agencies in both FFE and SBE–FP States for misconduct or noncompliant activity

[255] OMB Control No: 0938–1155 (exp. April 30, 2025). *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202308-0938-015.*

[256] A total of 605 issuers participated in the HHS-operated risk adjustment program for the 2023 benefit year. However, some of these issuers are subject to exemptions from HHS–RADV under 45 CFR 153.630(g) and would not submit IVA samples for HHS–RADV. For example, any issuers at or below the materiality threshold for random and targeted sampling only participate in HHS–RADV approximately once every 3 years. Therefore, we use 600 issuers as a conservative upper limit of the number of issuers that could participate in a given benefit year of HHS–RADV. See the Summary Report on Individual and Small Group Market Risk Adjustment Transfers for the 2023 Benefit Year (July 22, 2024) available at *https://www.cms.gov/cciio/programs-and-initiatives/premium-stabilization-programs/downloads/ra-report-by2023pdf.*

[257] This estimate is a decrease from the estimate of medical record requests per enrollee in the currently approved information collection because the finalized changes to the IVA sampling methodology in this rule will generally result in relatively fewer enrollees sampled from higher-risk strata, which are generally composed of enrollees with more medical records, thereby reducing our estimated number of medical records for review.

at the agency level. We did not propose any amendments to our existing regulations as the current regulatory framework and definitions supports this approach. Furthermore, this finalized policy only envisions collecting agency-level documentation, including, but not limited to, training manuals, onboarding material, and marketing materials, from lead agents, in addition to the existing documentation collection [258] for agents, brokers, or web-brokers, to investigate potential misconduct or noncompliant behavior or activities. Therefore, this collection will fall under 5 CFR 1320.4(a)(2), stating collections of information ''. . . during the conduct of an [. . .] investigation'' are exceptions to the ICR requirements.[259] The documentation that will be collected will solely relate to investigations of potential misconduct or noncompliant behavior or activities such that this exception will apply.

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR, and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions for this policy as proposed.

D. ICRs Regarding Agent and Broker System Suspension Authority (§ 155.220(k))

We are finalizing an amendment to expand HHS' authority to suspend system access for agents and brokers under § 155.220(k)(3) in instances in which we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii), or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. Since this amendment will entail providing an opportunity for agents and brokers to submit evidence and information to demonstrate that the circumstances of the incident, breach, or noncompliance have been remedied or sufficiently mitigated to HHS' satisfaction, it will involve collecting documents from agents and brokers participating in the FFEs and SBE–FPs whose system access has been suspended. Depending on the circumstances leading to the system suspension, we anticipate receiving documentation of consumer consent and/or review and confirmation of the accuracy of the Exchange eligibility application information and assessing whether the documentation complies with § 155.220(j)(2)(ii) and (iii) for consumers cited in the suspension notice from agents and brokers we system suspend under § 155.220(k)(3). The system suspension authority in § 155.220(k)(3) is part of HHS' oversight and enforcement framework applicable to agents and brokers who participate in the FFEs and SBE–FPs. Therefore, this collection will fall under 5 CFR 1320.4(a)(2), stating collections of information ''. . . during the conduct of an [. . .] investigation'' are exceptions to the ICR requirements.[260] The documentation that will be collected will solely relate to investigations and responses to system suspensions, meaning this exception would apply.

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR, and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions for this policy as proposed.

E. ICRs Regarding Updating the Model Consent Form (§ 155.220)

We are finalizing amendments to the model consent form created as part of the 2024 Payment Notice (88 FR 25809 through 25811). The existing model consent form only provides a template for meeting the consent documentation and retention requirements of § 155.220(j)(2)(iii)(A)–(C). We are finalizing an update such that the model consent form will also include a template to meet the requirements under § 155.220(j)(2)(ii), which requires agents, brokers, and web-brokers to document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or their authorized representative prior to submission of the application to the FFE or SBE–FP. This amendment will only update the optional model consent form that was created as part of the 2024 Payment Notice and adopted on June 30, 2023. The 2024 Payment Notice (88 FR 25890 through 25891) considered the additional time it would take the assisting agent, broker, or web-broker to process and submit each consumer's eligibility application, and those assumptions remain valid and are unchanged. We believe these assumptions remain valid as none of the regulatory requirements established by the 2024 Payment Notice are being changed and no new requirements are being added with this amendment. Therefore, this finalized policy will not impart extra time or costs to the assisting agent, broker, or web-broker. Agents, brokers, and web-brokers are already required to meet the requirements of § 155.220(j)(2)(ii) and (iii), meaning the time required to gather the documentation required by the 2024 Payment Notice is already a part of every agent's, broker's, and web-broker's enrollment process. We do not believe the updated model consent form will impose any additional burden on agents, brokers, web-brokers, or consumers, because usage of this model consent form remains optional and this updated model consent form is simply intended to provide a useable example of how agents, brokers, web-brokers, and agencies may compliantly meet the documentation requirements already required by the 2024 Payment Notice. If agents, brokers, agencies, or web-brokers elect to use this form, we do not anticipate that the updated model consent form will take any longer to fill out than agent, broker, web-broker, or agency-created forms or other methods being already being utilized currently, as the requirements for documentation are not changing from the documentation requirements that agents, brokers, agencies, and web-brokers are already required to meet in their current agent, broker, web-broker, or agency-created forms or methods.

The amended model consent form will also include scripts agents, brokers, and web-brokers can utilize to meet the consumer consent and eligibility application review requirements finalized in the 2024 Payment Notice when assisting consumers via an audio recording. The scripts will ensure agents, brokers, and web-brokers having verbal, recorded conversations with consumers discuss all the regulatory requirements with consumers. We do not anticipate these scripts will increase burden on any assisting agent, broker, web-broker, or consumer as no regulatory requirements have been changed. As agents, brokers, and web-brokers should already be complying with these requirements, no additional costs will be borne by the agent, broker, or web-broker if using the updated model consent form scripts. The scripts are merely meant to provide agents,

[258] This includes documentation of consumer review and confirmation of the accuracy of eligibility application information in compliance with 45 CFR 155.220(j)(2)(ii)(A)(2) and consumer consent documentation in compliance with 45 CFR 155.220(j)(2)(iii)(c).

[259] 5 CFR 1320.4(a)(2).

[260] Id.

brokers, and web-brokers with guidance and clarification on how the consent documentation and eligibility application review documentation requirements can be met when having a verbal, recorded conversation with a consumer. The scripts in the updated model consent form are not mandatory and are not intended to limit or otherwise impact the agent, broker, or web-broker's ability to answer consumer questions about plan selection or other matters.

Finally, there is no anticipated increase in documentation collection burden on HHS based on the updated model consent form. We currently request documentation of consumer consent and eligibility application review for compliance reviews and, assuming agents, brokers, and web-brokers use the updated model consent form, that will not meaningfully impact the documentation collection or review by HHS.

The updated model consent form discussed in this section will be submitted for OMB review and approval in the amended PRA package (OMB Control No. 0938–1438/Expiration date: June 30, 2026).

We sought comment on these assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these assumptions for this policy as proposed. We summarize and respond to public comments received on the proposed assumptions below.

Comment: Some commenters stated we should not mandate audio recording of enrollments and should not require agents, brokers, or web-brokers to use our scripts as this would be especially burdensome to smaller agents, brokers, web-brokers, or agencies.

Response: While agents, brokers, and web-brokers can meet the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) via an audio recording, this is just one type of documentation that is considered to be acceptable under these sections, and there is no mandate that an audio recording be used to meet these requirements. Agents, brokers, and web-brokers may use any method they wish to meet the consent documentation requirement and review and confirmation of the accuracy of eligibility application information requirement, provided the minimum information required by the regulations is captured in this documentation and the documentation can be maintained for a minimum of 10 years and produced to CMS upon request. In addition, as noted in the proposed rule (89 FR 82364), it would not be mandatory for agents, brokers, or web-brokers to use the amended model consent form or new scripts to comply with the requirements set forth in § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C).

Comment: Numerous commenters noted concern that this proposal would impose more burdens on agents, brokers, and web-brokers, especially smaller entities. Commenters stated that agents, brokers, and web-brokers would have less time to spend with each consumer, people would be deterred from enrolling, and agents and brokers would be deterred from participating in the Exchange.

Response: We respectfully disagree with commenters that this proposal will require an agents, broker, or web-broker to spend more time with each consumer, that smaller agents or agencies will be impacted more severely, or that agents, brokers, web-brokers, or consumers will stop participating in the Exchange.

The proposal to update the model consent form does not involve a regulatory change or add requirements to the current enrollment process. The proposal expands the model consent form to include means to meet requirements that were established in the 2024 Payment Notice, namely, the requirement to document the consumer reviewed and confirmed their eligibility application information. The proposal also provides scripts an agent, broker, or web-broker may utilize to meet these requirements, along with the consent documentation requirements, if working with a consumer via a spoken method.

The requirements established in the 2024 Payment Notice remain in effect and are unchanged. Therefore, we do not anticipate any new burden or impact to consumers', agents', brokers', or web-brokers' participation in the Exchange that will be associated with the updated model consent Form and use of this form will remain optional.

F. ICRs Regarding Notification of 2-Year Failure To File and Reconcile Population (§ 155.305)

We are finalizing an amendment to current regulation at § 155.305(f)(4) under which an Exchange needs to provide notification to either an enrollee or their tax filer (or both) who have been identified as having failed to file their Federal income taxes and reconcile their APTC after 2 consecutive tax years. This notification provides an additional opportunity to educate the enrollee or their tax filer of their responsibility to file their Federal income taxes and reconcile their APTC and that they are at risk for losing their eligibility for APTC. This finalized rule will ensure that State Exchanges will provide notifications, similar to how Exchanges on the Federal platform currently do, and that tax filers with a 2 year FTR status on State Exchanges receive adequate education on the requirement to file and reconcile. It will also impact State Exchanges' FTR processing notices for PY 2026 and subsequent years, although HHS-published guidance has already recommended States implement noticing procedures for PY 2025 similar to what is being required in this final rule. We anticipate that the finalized amendment will not impact the information collection (OMB Control Number 0938–1207) burden for Exchanges because, in practice, the majority of Exchanges are already sending notifications to consumers who have been identified as at risk for losing APTC due to failing to file their Federal income taxes and reconcile their APTC for 2 consecutive years, as discussed in further detail in section VI.C.9 of this final rule and section V.C.9 the proposed rule.

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

G. ICRs Regarding General Program Integrity and Oversight Requirements (§ 155.1200)

As discussed in the preamble of this final rule, we proposed to increase transparency into Exchange operations by publishing annual State Exchange and SBE–FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment data reports. We are finalizing this proposal with a modification to not publish the SMARTs. We estimate that there will be no additional costs or burdens on Exchanges associated with this finalized policy since this data is already collected through the Blueprint application (OMB Control No.: 0938–1172), SMART (OMB Control No.: 0938–1244), and Enrollment Metrics PRA packages (OMB Control No.: 0938–1119).

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

H. ICRs Regarding Essential Community Provider Certification Reviews (§ 156.235)

The finalized policy to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions effective beginning in PY 2026 continues our ECP data collection as permitted under the currently approved information collection (OMB Control No.: 0938–1187/Expiration date: June 30, 2025).

To satisfy the ECP requirement under § 156.235, medical QHP and SADP issuers must complete and submit ECP data as part of their QHP application, in which they must list the names and geographic locations of ECPs with whom they have contracted to provide health care services to low-income, medically underserved individuals in their service areas. These issuers must contract with a certain percentage, as determined by HHS, of the available ECPs in the plan's service area. This finalized policy will not significantly change the burden currently approved under OMB Control No. 0938–1415,[261] because the ECP data collected remains the same. Only the format in which the ECP information is submitted will be different. As described in the preamble of this final rule, issuers in FFEs, including in States performing plan management functions, can now submit ECP data to HHS via MPMS. As a result of HHS system design enhancements via MPMS, HHS is now able to collect ECP data directly from issuers in FFEs in States performing plan management functions, enabling HHS to conduct independent ECP evaluations of each issuers' network.

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

I. ICRs Regarding Quality Improvement Strategy Information (§ 156.1130)

There is no information collection associated with this finalized policy and no changes were proposed to the QIS data collection requirements applicable to QHP issuers. QIS data collection from QHP issuers to the Exchange has been approved under OMB Control Number 0938–1286.

J. ICRs Regarding Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We are finalizing adding a definition of ''qualifying issuer'' to § 158.103, with certain clarifications, amending § 158.140(b)(4)(ii) to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes for, and at the option of, qualifying issuers, making conforming amendments to the rebate calculation example in § 158.240(c)(2), and adding § 158.240(c)(3) to provide a rebate calculation example for qualifying issuers that choose to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii). To the extent issuers currently report their risk adjustment transfer amounts on their Annual MLR Reporting Form(s), we do not expect there to be any impact on the reporting burden, as the affected issuers will continue to report the same risk adjustment transfer amounts but will include them on different lines of the MLR Annual Reporting Form. The burden related to this information collection is currently approved under OMB Control No.: 0938–1164.

We sought comment on these assumptions.

We did not receive any public comments regarding this ICR and the assumptions made. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

K. Summary of Annual Burden Estimates for Finalized Requirements

TABLE 5: Final Annual Recordkeeping and Reporting Requirements

Regulation Section(s)	OMB Control Number	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($)	Total Cost ($)
45 CFR 153.630(b)	0938-1155	600	600	-1,022.55	-613,529	-$47,473,149	-$47,473,149
TOTAL		600	600		-613,529	-$47,473,149	-$47,473,149

L. Submission of PRA-Related Comments

We have submitted a copy of the final rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the finalized proposed collections discussed above, please visit CMS' website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation programs, as well as 2026 user fee rates for issuers offering QHPs through FFEs and SBE–FPs. This final rule also includes finalized requirements related to modifications to the calculation of the BHP payment, changes to the IVA sampling approach and SVA pairwise means test for HHS–RADV, as well as finalized compliance reviews of and enforcement action against lead agents, updates to the model consent form, and the authority for HHS to suspend agent and broker access to Exchange systems. Additionally, this rule includes finalized policies related to consumer notification requirements, standards for an issuer to request the reconsideration of denial of certification as a QHP specific to the FFEs, changes to the approach for conducting ECP certification reviews of plans for which issuers submit QHP certification

[261] OMB Control No. 0938–1415: Essential Community Provider-Network Adequacy (ECP/NA) Data Collection to Support QHP Certification (CMS–10803).

applications in FFEs in States performing plan management functions, and revisions to the MLR reporting and rebate requirements for qualifying issuers. Lastly, this final rule includes finalized amendments to specify that the actuarially justified plan-specific factors by which an issuer may vary premium rates for a particular plan from its market-wide adjusted index rate include the actuarial value and cost-sharing design of the plan, including, if permitted by the applicable State authority, accounting for CSR amounts provided to eligible enrollees under § 156.410, provided the issuer does not otherwise receive reimbursement for such amounts.

B. Overall Impact

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), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, 94 Stat. 1164), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4, 109 Stat. 48), 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). Executive Order 14094 [262] amends section 3(f) of Executive Order 12866 and defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of OMB's 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) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the 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 significant rules. OMB's OIRA has determined that this rulemaking is ''significant'' as measured by the $200 million threshold under section 3(f)(1). We have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these regulations, and the Department has provided the following assessment of their impact.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf*), we have prepared an accounting statement in Table 6 showing the classification of the impact associated with the provisions of this final rule.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in Exchanges. We are unable to quantify all the benefits and costs of this final rule. The effects in Table 6 reflect qualitative assessment of impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annual monetized transfers described in Table 7 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers.

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[262] Office of the White House. (2023, April 6). *Executive Order on Modernizing Regulatory Review. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/.*

TABLE 6: Accounting Table

Benefits:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$39 million	2025	2 percent	2025-2029
Quantitative: • Cost savings of $47,473,149 annually for issuers for conducting IVAs due to IVA sampling methodology changes reducing the estimated number of medical records for review beginning with the 2025 benefit year of HHS-RADV. • Total cost savings of $1,778,545.44 annually for the 12 FFE States currently performing plan management functions associated with reduced administrative burden as finalized since they will no longer be responsible for ECP data review. • Reduced Federal costs by approximately $75,000 per year associated with the HHS-RADV materiality threshold policy, as this policy will eliminate situations wherein HHS is required to reissue HHS-RADV results for all issuers when the impact is less than $10,000 beginning in 2025.				
Qualitative: • Decreased risk of adverse selection with respect to coverage of PrEP users, resulting in an increase in health equity among this population due to the policy to incorporate PrEP in the HHS risk adjustment adult and child models as a new, separate type of model factor. • Improved education of tax filers and enrollees regarding the new 2-tax year FTR requirements. • Improved processing by State Exchanges of enrollment data inaccuracies, which benefits consumers by ensuring accurate payment of APTCs by finalizing HHS' timeliness standard for reporting enrollment data inaccuracies and for the State Exchange to resolve them. • Reduced enrollment barriers, particularly for low-income enrollees who would be disproportionately impacted by disruptions in coverage, associated with the policy to allow issuers to implement a fixed-dollar premium payment threshold and a gross premium percentage-based payment threshold.				

- Streamlined appeals processes and improved operational consistency between Exchanges on the Federal platform and appeals entities as a result of the finalized policy to allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application.
- Increased compliance with AV de minimis ranges associated with the approach to release the AV Calculator earlier.
- Increased transparency in Exchanges by publishing additional metrics on Exchange operations and functionality, including actual expenditures on consumer marketing, education, and outreach; actual expenditures on Navigator programs; call center metrics during Open Enrollment; and website visitors during Open Enrollment.

Costs:	Estimate	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	$3 million	2025	2 percent	2025-2029

Quantitative:

- Cost increase for the Federal Government associated with the HHS-RADV SVA medical record review of approximately $1.5 million annually due to initial SVA subsample size increase beginning with the 2024 benefit year of HHS-RADV.
- Annual cost increase of $500,000 to the Federal Government for increases to SVA medical record review due to the finalized SVA pairwise means testing procedure resulting in more SVA subsamples being expanded for review beginning with the 2024 benefit year of HHS-RADV.
- One-time cost of $250,000 to the Federal Government for coding modifications to test and execute the HHS-RADV SVA pairwise means test bootstrapping methodology beginning with the 2024 benefit year of HHS-RADV.
- Annual costs of $292,000 to the Federal Government to send initial direct FTR notices to the 2-tax year FTR population starting in benefit year 2025.
- Annual costs of $92,400 to State Exchanges for FTR notices for the 2-tax year population.
- Regulatory review costs of $3,336,300 for interested parties to review and analyze this final rule.

Qualitative:

- Not a significant increase in administrative burden or financial impact on the Federal Government for ECP data review due to the policy to conduct ECP certification reviews for plans offered by issuers in FFEs in States performing plan management functions beginning in PY 2026, due to using existing system infrastructure for the FFEs.

Transfers:	Estimates	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($/year)	Low: $1.442 billion	2025	2 percent	2025-2029
Annualized Monetized ($/year)	High: $1.511 billion	2025	2 percent	2025-2029

Quantitative:

- Increase in risk adjustment user fee transfers from issuers to the Federal Government of $6.6 million annually beginning in 2026 associated with the finalized risk adjustment user fee of $0.20 PMPM.
- An estimated annual transfer of APTC of $817,571,843 from the Federal Government to enrollees whose coverage would otherwise be terminated for non-payment as a result of the policy to establish an optional fixed-dollar premium payment threshold and gross premium percentage-based payment threshold.
- Increase in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $732 million for benefit year 2026 compared to if the user fee rates from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $937 million in 2027, $958 million in 2028, and $997 million in 2029 if the finalized 2026 user fee rates were maintained in subsequent years. Under the alternate FFE and SBE-FP user fee rates, which reflects the latest assumptions, we estimate increases in FFE and SBE-FP user fee transfers compared to if the 2025 benefit year user fee rates were maintained for 2026 and beyond from issuers to the Federal Government of $620 million in 2026, $854 million in 2027, $885 million in 2028, and $918 million in 2029 if the alternate user fee rates were maintained in subsequent years.
- Annual cost of $8,155 associated with ECP enforcement action is transferred from the States with FFEs in States performing plan management functions to the Federal Government in accordance with the policy for HHS to conduct ECP reviews for Exchanges in these States.
- Reduced rebates paid by issuers to consumers or increased premiums collected by issuers from consumers of approximately $35 million annually beginning with the 2026 MLR reporting year associated with the policy to allow "qualifying issuers" to no longer adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes.

TABLE 7: Estimated Federal Government Outlays and Receipts for the Risk Adjustment and Reinsurance Programs from Fiscal Year 2026-2030, in billions of dollars[263]

Year	2026	2027	2028	2029	2030	2026-2030
Risk Adjustment and Reinsurance Program Payments	9	10	10	10	10	49
Risk Adjustment and Reinsurance Program Collections	-10	-10	-10	-10	-10	-50

Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time. Source: Congressional Budget Office. Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2023 to 2033. Table A-2. September 2023. *https://www.cbo.gov/system/files/2023-09/59273-health-coverage.pdf.*

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1. BHP Methodology Regarding the Value of the Premium Adjustment Factor (PAF) (42 CFR Part 600)

The aggregate economic impact of the finalized changes to the BHP payment methodology is estimated to be $0 in transfers for calendar year 2026 and all subsequent years. For the purposes of this analysis, we have assumed that two States will operate BHPs in 2026 since currently only two States operate BHPs, and we do not assume any more States will do so.

For the States currently operating BHPs, we do not anticipate these finalized changes to the payment methodology will affect future payments. We expect that these States will have fully implemented programs by 2026, and thus these changes will not change the value of the PAF used in the payment methodologies for these States in 2026 and beyond. If other States implement a BHP and do so on a partial basis, the finalized changes would be expected to reduce Federal BHP payments compared to what they would be under current law. The changes in payments would depend on the number of people enrolled in BHP in the State, the QHP premiums in the State, and the level of adjustments added to the premiums to account for the CSRs.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

2. Incorporation of PrEP Affiliated Cost Factor (ACF) in the HHS Risk Adjustment Adult and Child Models (§ 153.320)

We are finalizing the incorporation of PrEP into the HHS risk adjustment adult and child models as part of a new class of factors that reflect the costs associated with care that is not related to active medical conditions. This finalized class of factors, called the Affiliated Cost Factors (ACFs), which are detailed in the preamble discussion under 45 CFR part 153, will not result in any additional reporting burden for issuers. Because it will have some impact on risk adjustment State transfers, some issuers' State transfers will be impacted, either in a positive or in a negative manner, consistent with the budget-neutral nature of the HHS-operated risk adjustment program. As HHS is responsible for operating the risk adjustment program in all 50 States and the District of Columbia, we do not expect these policies to place any additional burden on State governments. The finalized model specifications in this final rule result in limited changes to the number and type of risk adjustment model factors; therefore, we do not expect these changes to impact issuer burden beyond the current burden for the HHS-operated risk adjustment program. This change will help mitigate risk of adverse selection and issuers' associated perverse incentives for coverage of PrEP users, resulting in increased health equity among this population.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

3. Initial Validation Audit (IVA) Sampling Methodology Changes (§ 153.630(b))

We are finalizing several changes to the IVA sampling methodology. Beginning with the 2025 benefit year of HHS–RADV, we are finalizing under § 153.630(b) excluding enrollees without HCCs (enrollees in stratum 10 without HCCs nor RXCs and RXC-only enrollees in strata 1 through 3) from IVA sampling, removing the FPC such that issuers with 200 or more enrollees in strata 1 through 9 would have IVA sample sizes of 200 enrollees and issuers with less than 200 enrollees in strata 1 through 9 would have IVA sample sizes equal to their EDGE population of enrollees with HCCs, and changing the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA–RADV data to the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV.

Although issuers are already required to provide the IVA Entities with all documentation necessary to complete HHS–RADV, these finalized changes to the IVA sample will ensure all enrollees in the IVA sample have at least one HCC on EDGE and therefore will have associated medical records that will need to be submitted. In the Collection of Information section of this final rule, we estimate the aggregate decrease in administrative burden that will result from the finalized policies to modify the IVA sample as the average number of medical records reviewed per enrollee in the IVA sample and the average number of medical records reviewed per issuer will decrease. We estimate that the aggregate burden of conducting IVAs will be approximately 1,050,200 hours and $69,490,672 beginning with 2025 benefit year HHS–RADV, which is an aggregate burden decrease of 613,529

[263] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.

hours and $47,473,149 from the existing aggregate burden estimate of approximately 1,663,729 hours and $116,963,821. We believe that these finalized changes to the IVA sampling methodology will result in more precise HHS–RADV results which are used to adjust risk scores and associated risk adjustment State transfers.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: A few commenters agreed that the proposed changes to the IVA sampling methodology would contribute to reduced administrative burden among issuers and IVA entities. One commenter specifically suggested that administrative burden could decrease for issuers with a greater volume of HCCs to validate in their IVA samples if the proposed changes to the IVA sampling methodology were finalized. However, a few commenters questioned HHS' assessment of burden associated with the proposed changes to the IVA sampling methodology. Some commenters suggested that the proposals would increase administrative burden for issuers, specifically for smaller issuers or lower-risk issuers with more enrollees without HCCs in their population. One commenter suggested that issuers' operational resources and capacity will be significantly impacted because issuers will have to perform more HCC and RXC validations under the proposed IVA sampling methodology. Another commenter noted that smaller issuers that currently have modified IVA sample sizes of fewer than 200 enrollees under the FPC factor would be burdened by increasing the number of sampled enrollees and medical records. Another commenter suggested that there would be a significant burden increase associated with collecting more records from enrollees in lower-risk strata as these enrollees are more likely to see providers who do not provide issuers with direct access to medical records, which could make it more burdensome for issuers to retrieve medical records for these enrollees, especially for smaller issuers. Another commenter suggested concern that compliance with the added HHS–RADV audit requirements could place a greater burden on smaller issuers without clarity on how these proposed changes would help patients. One commenter requested HHS to monitor the impact of these changes on burden and consider future changes if there is an untenable increase in burden or an undesired impact on HHS–RADV adjustments to risk adjustment transfers.

Response: As explained in section III.B.6.a of this rule, we are finalizing the proposed changes to the IVA sampling methodology to exclude enrollees without HCCs, remove the FPC, and use the 3 most recent consecutive years of HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin to calculate the standard deviation of risk score error ($S_{i,h}$) in the Neyman allocation as proposed to align sampling with the error estimation methodology and improve sampling precision. We anticipate that these changes will also improve the precision of group failure rates, the national benchmarks used to determine outlier status in each failure rate group, the net risk score error calculations, and will therefore improve the precision of HHS–RADV results used to adjust risk adjustment State transfers. Improving the precision of the IVA sampling methodology with the adoption of the changes finalized in this rule will also further promote the overall integrity of HHS–RADV and confidence in the HHS-operated risk adjustment program.

As explained in the section III.B.6.a of this final rule, we anticipate a decrease in the aggregate average burden associated with conducting IVAs as the average number of medical records reviewed per enrollee in the IVA sample and the average total number of medical records reviewed per issuer will generally decrease. We disagree that all issuers will have to perform more HCC and RXC validations under the IVA sampling methodology finalized in this rule that incorporates all three of the proposed changes and, as described in the proposed rule and in section III.B.6.a of this final rule, we estimate an approximate average of two medical records reviewed and two HCCs reviewed per enrollee in the IVA sample under the revised IVA sampling methodology, which is a decrease from the previous burden estimates under the existing IVA sampling methodology of an approximate average of five medical record requests per enrollee in the IVA sample size and three HCCs to be reviewed by a certified medical coder per enrollees with HCCs. In addition, as explained in section III.B.6.a. and the Collection of Information section of this rule, we do not anticipate that these changes will affect RXC review, as HHS–RADV requires review of RXCs for all adult enrollees in the IVA sample with at least one RXC, and we continue to assume that a review will be performed on approximately 50 RXCs per issuer.[264]

We recognize that the IVA sampling methodology finalized in this rule will result in increased sample sizes for some smaller issuers that are currently subject to the FPC and assigned modified IVA sample sizes of fewer than 200 enrollees under the current IVA sampling methodology. However, we note that sample size will not increase for all issuers currently subject to the FPC as some of these issuers have a smaller population of enrollees with HCCs than their previously assigned modified IVA sample sizes that included enrollees without HCCs. For example, an issuer with a total enrollee population of 1,000 would be assigned a sample size of 160 enrollees under the current methodology and using the FPC formula. If this issuer only has a population of 100 enrollees with HCCs, then, under the revised IVA sampling methodology being finalized in this rule, the issuer's IVA sample size would decrease to 100 enrollees. In addition, based on an analysis of historical HHS–RADV data, we estimate that the vast majority of issuers who would see increased IVA sample sizes after the removal of the FPC are at or below the materiality threshold for random and targeted sampling and would therefore only be selected to participate in HHS–RADV approximately once every 3 benefit years (barring any risk-based triggers based on experience that will warrant more frequent audits).[265] [266]

We also recognize the commenter's concern that some providers of enrollees from lower-risk strata may provide issuers with less direct access to medical records for enrollees from lower-risk strata, but we note that that enrollees in lower-risk strata are enrollees with fewer HCCs or relatively lower-risk HCCs, for whom issuers should be able to provide supporting medical records for risk adjustment eligible diagnoses submitted to EDGE as required by the EDGE Server Business

[264] For more details on RXC validation, see Section 10.4 Validation of the BY23 HHS–RADV Protocols available at: *https://regtap.cms.gov/uploads/library/HHS-RADV_2023_Benefit_Year_Protocols_v1_5CR_060424.pdf.*

[265] 45 CFR 153.630(g)(2).

[266] Beginning with the 2022 benefit year of HHS–RADV, the materiality threshold under § 153.630(g)(2) is defined as 30,000 total billable member months Statewide, calculated by combining an issuer's enrollment in the individual non-catastrophic, catastrophic, small group, and merged markets (as applicable), in the benefit year being audited. See the 2024 Payment Notice, 88 FR 25740, 25788 through 25790.

Rules.[267] The principles for including an HCC in the risk adjustment models require that each HCC represents a well-specified, clinically significant, chronic or systematic medical condition, and therefore, any enrollees with HCCs, regardless of if they are in a lower-risk stratum or higher-risk stratum, have conditions that should have supporting medical records.[268] Furthermore, if it is more burdensome to retrieve medical records for enrollees from lower-risk strata, any increase in burden from retrieving these medical records would be offset, at least in part, by the decrease in burden from retrieving fewer medical records for enrollees from higher-risk strata. We also note that enrollees from low, medium, and high-risk strata will continue to be sampled for the IVA and the actual number of enrollees sampled from each stratum will depend on that stratum's contribution to the total standard deviation of net risk score error in the issuer's population.

Moreover, as explained in section III.B.6.a of this rule, we estimate that any smaller issuers receiving the FPC under the current methodology and whose IVA sample sizes would increase under the finalized IVA sampling methodology would see a 35 percent increase in Super HCC count in their IVA samples and a 26 percent increase in group failure rate precision on average across all three failure rate groups. Therefore, we believe that the benefits a smaller issuer gains from increased group failure rate precision and the estimated overall average decrease in the number of HCCs and medical records reviewed per enrollee outweigh any potential increases in IVA sample size.

We also clarify that while HHS–RADV does not directly impact patients, HHS–RADV is an issuer audit that helps ensure the integrity of data used in the HHS-operated risk adjustment program to calculate risk adjustment State transfers. The risk adjustment program helps stabilize premiums across the individual, merged, and small group markets, and thereby helps provide consumers with affordable health insurance coverage options.

HHS will continue to monitor the impact of the finalized changes to the IVA sampling methodology once implemented. While these changes to the IVA sampling methodology could affect the adjustments to risk adjustment State transfers for an individual issuer, we anticipate that any changes to HHS–RADV adjustments will reflect more accurate actuarial risk differences between issuers.

4. Second Validation Audit (SVA) Pairwise Means Test (§ 153.630(c))

We are finalizing modifications to the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS–RADV. Because issuers are already required to provide the IVA and SVA Entities with all documentation necessary to complete the audits, the finalized changes to the pairwise means test that will increase the initial SVA subsample size to 24 enrollees and transition to a bootstrapping methodology using a 90 percent confidence interval will not directly increase burden on issuers. We believe that these changes will increase the burden and costs to the Federal Government of conducting the SVA. We estimate that increasing the initial SVA sample size from 12 to 24 enrollees will increase the annual costs of SVA medical review by approximately $1.5 million and that transitioning from the current t-test pairwise means testing procedure to a bootstrapped procedure will increase the annual cost of SVA medical review by approximately $500,000 as more issuers will be expanded to larger SVA sample sizes under a more sensitive pairwise means testing procedure. In addition, there will be a one-time cost of approximately $250,000 to code these modifications to the existing SVA pairwise means test in the Audit Tool. Any increase in SVA costs will increase the costs to the Federal Government associated with HHS–RADV program activities, which are covered through the risk adjustment user fees that are charged to issuers. While issuers will indirectly cover these costs through the risk adjustment user fee, we do not anticipate that this policy alone will increase the risk adjustment user fee as the costs are relatively small compared to the entirety of the budget to operate the HHS-operated risk adjustment program. We believe that the benefits from improving the SVA process for validating the IVA results and determining the appropriate audit results to use in error estimation will outweigh the increased costs to the Federal Government and better ensure the integrity of the risk adjustment program.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: One commenter requested how the estimate costs and estimated improvement in the false negative rate are attributed to modifying the SVA subsample size as opposed to modifying the statistical methodology. Another commenter stated that they could not appropriately evaluate the impact of the proposed changes because issuers and IVA entities have little transparency into SVA outcomes as issuers who pass pairwise do not receive SVA results.

Response: As previously noted in section III.B.6.b of this rule, we estimate that approximately 20 percent of the estimated improvement in the false negative rate will be attributable to modifying the initial SVA subsample size to 24 enrollees and approximately 80 percent will be attributable to modifying the pairwise means test to a bootstrapped 90 percent confidence interval.[269] We also estimate that approximately 33 percent of the costs associated with making these changes in 2024 benefit year HHS–RADV will be attributed to transitioning from the current t-test pairwise means testing procedure to the bootstrapped procedure and coding the changes to test and execute the bootstrapping methodology, and the remaining costs will be attributed to increasing the initial SVA subsample size to 24 enrollees.

We disagree that issuers and IVA entities have insufficient transparency into SVA outcomes to evaluate the impact of the proposed changes to the SVA pairwise testing procedure. In the proposed rule (89 FR 82308, 82355), we explained the impact of the proposed modifications to increase the initial SVA subsample size to 24 enrollees and use a bootstrapped 90 percent confidence interval on the false negative rate, false positive rate and the overall sensitivity of the pairwise means test, and we sought comment on these proposals. As explained in section

[267] See, for example, the EDGE Server Business Rules (ESBR) Version 25.0 (December 2024) available at: *https://regtap.cms.gov/uploads/library/DDC-ESBR-v25-5CR-120624.pdf*.

[268] See CMS. (2021). *HHS-Operated Risk Adjustment Technical Paper on Possible Model Changes.* Section 1.2.1 (Principles of Risk Adjustment). *https://www.cms.gov/files/document/2021-ra-technical-paper.pdf.*

[269] The rate of improvement in the false negative rate and how this is attributed to the initial SVA subsample size or the statistical methodology differs depending on the effect size, or the magnitude of the true difference between IVA and SVA results. For these estimates, we use the Cohen's D effect size measure and assume a small effect size. See Cohen, Jacob (1988). Statistical Power Analysis for the Behavioral Sciences. Routledge. ISBN 978–1–134–74270–7. pp 25–27.

III.B.6.b of this final rule, we are finalizing the proposed modifications to the SVA pairwise means testing procedure beginning with 2024 benefit year HHS–RADV to improve the sensitivity of the SVA pairwise means test, reduce the false negative rate and promote the integrity of HHS–RADV. In addition, we disagree that issuers have insufficient transparency into SVA outcomes. HHS does not provide SVA results to issuers or IVA entities that pass pairwise testing because passing signifies that the SVA findings do not significantly differ from IVA findings and that the IVA findings, which issuers review and sign off on, can be used during error estimation as issuers' final accepted audit results for that benefit year of HHS–RADV. Issuers and IVA Entities that pass pairwise testing and do not receive an SVA findings report are still able to review key SVA findings, such as the most commonly miscoded HCCs for SVA reviewed sampled enrollees, from each benefit year of HHS–RADV in the results memo.[270] Issuers that do not pass pairwise testing receive SVA findings reports that include details on the enrollee-level HCCs that differed between IVA and SVA review.

5. HHS Risk Adjustment User Fee for the 2026 Benefit Year (§ 153.610(f))

For the 2026 benefit year, HHS will operate risk adjustment in every State and the District of Columbia. As described in the 2014 Payment Notice (78 FR 15416 through 15417), HHS' operation of risk adjustment under section 1343 of the ACA on behalf of States is funded through a risk adjustment user fee. For the 2026 benefit year, we are finalizing using the same methodology to estimate our administrative expenses to operate the HHS risk adjustment program as was used in the 2025 Payment Notice (89 FR 26218).

We expect that the finalized risk adjustment user fee for the 2026 benefit year of $0.20 PMPM would increase the amount transferred from issuers of risk adjustment covered plans to the Federal Government by approximately $6.6 million compared to maintaining the 2025 benefit year risk adjustment user fee of $0.18 PMPM. We continue to estimate that the total costs for HHS to operate the risk adjustment program on behalf of all States and the District of Columbia within the 2026 calendar year will be approximately $65 million, roughly the same as the amount estimated for the 2025 calendar year, and are finalizing the risk adjustment user fee for the 2026 benefit year at $0.20 PMPM to sufficiently fund these costs.

6. Engaging in Compliance Reviews and Taking Enforcement Actions Against Lead Agents for Insurance Agencies (§ 155.220)

As discussed in the preamble to this final rule, we address our authority to investigate, engage in compliance reviews of, and take enforcement actions against lead agents of insurance agencies who are engaging in potential misconduct or noncompliant behavior or activities in FFE and SBE–FP States. This will better align our oversight and enforcement approach with how States regulate agencies. This will also ensure enhanced consumer protections from agency-level misconduct or noncompliance facilitated at the agency level, which similarly impacts consumers negatively as misconduct or noncompliance by individual agents, brokers, and web-brokers. This finalized policy is also designed to reduce consumer harm associated with unauthorized enrollments or bad-acting agents, brokers, or web-brokers entering incorrect income information on eligibility applications which may cause harm by providing the enrollee or applicant with an incorrect APTC amount. For example, an incorrect APTC amount can result in a consumer having a zero-dollar monthly premium. Because the consumer does not receive monthly billing notifications due to the zero-dollar premiums, they may not know they were enrolled or that their eligibility application information was incorrect. However, once the consumer files their taxes, a reconciliation may reveal that the consumer must repay the incorrect APTC amount they were receiving. By their nature, these unauthorized enrollments and plan changes, as well as inaccurate eligibility application information submissions, also involve the misuse of enrollee or applicant PII, and they threaten the efficient administration of the Exchange and the accuracy of Exchange eligibility determinations.

This finalized policy is also designed to reduce consumer harm associated with unauthorized enrollments or unauthorized plan switches which can lead to the consumer receiving a DMI. Upon application submission, certain consumer data is checked against trusted data sources to ensure a match between what is in the application submission and the information HHS receives from the trusted data source(s). If the trusted data source does not have the consumer data or the data is inconsistent with the information provided on the application, a DMI is generated. A non-exhaustive list of DMIs include the Annual Income DMI, Citizenship/Immigration DMI, and American Indian/Alaskan Native Status DMI. Certain DMIs may lead to loss of Exchange coverage, including a Citizenship/Immigration DMI, which occurs when the consumer is unable to verify an eligible citizenship or lawful presence status.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: We received comments that we should remove or limit the 150 percent SEP and implement pre-enrollment SEP verification that are vulnerable to fraud, such as income.

Response: While this comment touches on issues that potentially relate to noncompliant agents and brokers or fraudulent behavior, these comments are outside the scope of this proposal.

Comment: We received comments stating this change would protect consumers from noncompliant and fraudulent behavior and maintain the integrity of the Exchange.

Response: We agree with commenters that this change would better protect consumers. This change would allow HHS to take targeted action against lead agents found to be involved in noncompliant or fraudulent behavior. Removing noncompliant individuals and entities from the Exchanges that use the Federal platform reduces fraud and improves public trust of these Exchanges as a whole. We continue to encourage State Exchanges that do not use the Federal platform to adopt a similar enforcement approach to enable it to also take immediate action when circumstances that pose unacceptable risk to their Exchange operations.

7. Agent and Broker System Suspension Authority (§ 155.220(k))

We believe the impact related to the finalized changes to § 155.220(k)(3) will be positive. These changes will allow HHS to take swift action for misconduct and noncompliance with existing standards and requirements by expanding the bases on which § 155.220(k)(3) system suspensions may be implemented. This finalized policy will enhance consumer protection and

[270] See, for example, Table 1 of the 2022 Benefit Year HHS–RADV Results Memo (May 14, 2024) available at *https://www.cms.gov/files/document/by22-hhs-radv-results-memo-appendix-pdf.*

promote program integrity by allowing HHS to immediately suspend an agent's or broker's access to Exchange systems when HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii), or (iii) or the privacy and security standards at § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction. This will help reduce future consumer harm by allowing HHS to quickly suspend system access for agents or brokers who are engaged in misconduct or noncompliant behavior that impacts Exchange consumers, operations, and systems. This finalized policy will also increase transparency by informing agents and brokers of the full suite of HHS enforcement actions that may be leveraged in response to noncompliance or misconduct, which may help curb such activities and behaviors. We do not anticipate negative feedback from the entities impacted by this, such as agents and brokers, as these changes are meant to more quickly system suspend bad-acting agents and brokers. This will help build consumer trust in compliant agents and brokers who work with consumers on the FFEs and SBE–FPs.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: Commenters suggested we allow agents and brokers to provide evidence to us prior to initiating system suspensions.

Response: We do not agree with commenters that we should change our system suspension process to allow for agent or broker response prior to engaging in a system suspension.

The purpose of § 155.220(k)(3) is to maintain the integrity of the Exchange and individual consumers. Adding language to allow system suspensions to be implemented when we discover circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under § 155.220(j)(2)(i), (ii) or (iii) or the privacy and security standards at § 155.260,[271] helps achieve these goals.

Providing an opportunity to provide evidence prior to a system suspension being implemented would leave consumers vulnerable to potential harm as the agent or broker would have full use of all avenues to enroll consumers. System suspensions allow HHS to ''immediately'' prevent an agent or broker from utilizing the DE/EDE pathways, protecting consumers. The use of the word ''immediate'' in § 155.220(k)(3) means this enforcement tool is intended to reduce risk of noncompliance as soon as it is discovered. Allowing an agent or broker to respond prior to implementing the system suspension would defeat the intention of the regulation. While the option to enroll using the call center or *HealthCare.gov* exists, these are safer options for the consumer as the call center requires the consumer to be on the call and the agent or broker would need to be sitting with the consumer if using *HealthCare.gov.*

We believe our process allowing an agent or broker to respond to a system suspension is efficient and provides sufficient due process to the system-suspended agent or broker. Agents or brokers may respond with exculpatory evidence immediately after receiving a system suspension, which would reduce the amount of time the system suspension is in place, provided the submitted evidence mitigates the situation to HHS' satisfaction.

Furthermore, we do not engage in compliance actions, such as system suspensions, without reviewing all the evidence at our disposal and determining there is a high likelihood the agent or broker has been engaging in noncompliant behavior.

Comment: We received comments in support of expanding § 155.220(k)(3) as it would reduce noncompliant behavior and protect consumers.

Response: We agree with commenters who supported this proposal and agree it would reduce noncompliant behavior and protect consumers.

The original intent of § 155.220(k)(3) included protecting against unacceptable risk to consumer Exchange data. Clarifying this in regulatory text will allow us to implement system suspensions in situations involving consumer PII while making agents and brokers aware of this authority. We believe violations of the standards of conduct under 155.220(j)(2)(i), (ii), or (iii), risk to the accuracy of Exchange eligibility determinations, operations, applications, enrollees, or information technology systems all warrant system suspensions as each may cause consumer harm or reduce public trust in the Exchange itself.

8. Updating the Model Consent Form (§ 155.220)

We are finalizing an update to the model consent form to include a section for documentation of consumer review and confirmation of the accuracy of their Exchange eligibility application information under § 155.220(j)(2)(ii)(A)(1)–(2), as well as scripts agents, brokers, and web-brokers could use when meeting the requirements codified at § 155.220(j)(2)(ii)(A) and (j)(2)(iii)(A)–(C) via an audio recording.

These finalized policies will update the optional model consent form that was created as part of the 2024 Payment Notice and adopted on June 18, 2023. The 2024 Payment Notice (88 FR 25890 through 25892) considered the additional time it would take to process and submit each consumer's eligibility application and those assumptions remain valid and are unchanged. We believe these assumptions remain valid because we are not changing the regulatory requirements established by the 2024 Payment Notice, we are not adding requirements with this finalized policy, and we are not making the use of the model consent form mandatory. The time required to gather the documentation required by the 2024 Payment Notice requirements is already a part of every agent's, broker's, and web-broker's enrollment process. We do not believe the updated model consent form will impose any additional burden on agents, brokers, web-brokers, or consumers. We do not anticipate that the updated model consent form will take any longer to fill out than agent, broker, web-broker, or agency-created forms already being utilized. The use of the updated model consent form will not be mandatory. Therefore, this finalized policy will not impart extra time or costs to the assisting agent or broker.

This updated model consent form will provide agents, brokers, and web-brokers with clarity on how to meet the regulatory requirements under § 155.220(j)(2)(ii) and help them comply

[271] Section 155.220(d)(3) requires agents and brokers to enter into a Privacy and Security Agreement pursuant to which they agree to comply with Exchange privacy and security standards adopted consistent with § 155.260. There are two Privacy and Security Agreements between CMS and the agent, broker, and web-broker for FFEs and SBE–FPs: (1) one is for the individual market FFEs and SBE–FPs, and (2) one is for the FF–SHOPs and SBE–FP–SHOPs.

with this regulation by providing a standardized form they may use to do so. Furthermore, we believe providing a clearly written model consent form will provide more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with § 155.220(j)(2)(ii). The finalized scripts, to the extent they are utilized by agents, brokers, and web-brokers, will help ensure they are following the regulatory requirements when enrolling consumers. We believe this will reduce consumer harm by reducing unauthorized enrollments, which can result in financial harm if a consumer receives an improper APTC amount upon enrollment, and DMIs, which may lead to cancellation of coverage if the DMIs are not resolved in a timely manner. We also believe this finalized policy will clarify and simplify how regulated entities can meet regulatory requirements.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing these impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: Some commenters stated we should not mandate audio recording of enrollments and should not require agents or brokers to use our scripts as this would be especially burdensome to smaller agents, brokers, web-brokers, or agencies.

Response: While agents, brokers, and web-brokers can meet the requirements of § 155.220(j)(2)(ii)(A) and (j)(2)(iii) via an audio recording, this is just one type of documentation that is considered to be acceptable under these sections, and there is no mandate that an audio recording be used to meet these requirements. Agents, brokers, and web-brokers may use any method they wish to meet the consent documentation requirement and review and confirmation of the accuracy of eligibility application information requirement, provided the minimum information required by the regulations is captured in this documentation and the documentation can be maintained for a minimum of 10 years and produced to CMS upon request.

Comment: Some commenters supported updating the model consent form, stating this would provide clarity to agents, brokers, and web-brokers, and help ensure consumers' enrollment applications have correct information.

Response: We agree with commenters that these updates will provide more clarity and assurance to agents, brokers, web-brokers, and agencies on how to meet the applicable regulatory requirements and more consumer clarity and assurance that the agent, broker, or web-broker they are working with is complying with the applicable regulatory requirements.

9. Requirement for Notification of Tax Filers and Consumers Who Have Failed To File and Reconcile APTC for 2 Consecutive Tax Years (§ 155.305)

We anticipate a small financial impact related to our finalized updates to § 155.305(f)(4)(i)(A)(1)–(2). Prior to pausing the FTR process during the COVID–19 PHE, Exchanges provided notice to enrollees or their tax filers (or both) who were identified as at risk of losing their APTC due to their failure to file their Federal income taxes and reconcile their APTC using Form 8962 prior to the FTR Recheck process. The 2025 Payment Notice (89 FR 26299) codified the requirement to send notices in the first tax year a tax filer was identified as having FTR status. The policy finalized in this rule will require sending either direct or indirect notices to tax filers or their enrollees when the tax filer is identified as having an FTR status for a second consecutive tax year, which we estimated in the 2024 Payment Notice (88 FR 25902) to represent 20 percent of the total FTR population. We sought comments on these impacts and assumptions, including regarding additional costs, burdens, and benefits to issuers, consumers, and Exchanges.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates with the following modifications to our initial cost estimates for these new FTR notice requirements.

Since the publication of the proposed rule, HHS has sent out FTR notices regarding APTC eligibility for the 2025 coverage year to enrollees or their tax filers, and we wish to update our initial cost projections for this policy change. Due to increases in enrollment in Exchanges on the Federal platform, the volume of FTR notices sent to enrollees or their tax filers was higher than we originally estimated, which increased the cost of providing FTR direct notices to tax filers. The revised cost for Exchanges on the Federal platform to provide FTR direct notices that protect FTI to tax filers will be approximately $292,000 annually for fiscal years 2025 through 2029, revised from $134,000 as proposed. These cost estimates may fluctuate in future years due to unknown factors, such as increases in the cost of postage and inflation in future years. We expect that the cost of providing notices would decrease in 2026 and the subsequent years if the enhanced PTC subsidies provided by the Inflation Reduction Act are not extended past 2025 because consumers may terminate their Exchange coverage if they become ineligible for financial assistance. However, because it is currently unknown whether the enhanced PTC subsidies will expire or be extended, we have not factored this into our cost estimate. While HHS did not receive any comments related to our estimates regarding the cost of print notices for FTR, we would like to provide more context on why we are not providing more details regarding the contract pricing. We did not publish the cost per print notice because this is proprietary information. Furthermore, HHS will not publish specific future contract estimates in this final rule because the data underlying those estimates could undermine future contract procurements. For example, if HHS were to publish the projected future cost of the contracts used to provide print notifications, the Federal Government would be meaningfully disadvantaged in future contract negotiations related to Federal notice printing activities, as bidders would know how much HHS anticipates such a future contract is worth. Although current contract awards are published and publicly available,[272] these award amounts do not necessarily reflect the future value of the contract, as there may be future changes in policy and operations and the scope of the work.

Our finalized regulations give flexibility to Exchanges to choose to send the required notices to enrollees or tax filers, or both. While most State Exchanges have noted a preference to provide indirect notices to their consumers, there is uncertainty about how State Exchanges would choose to provide notices to their enrollees (for example, mail or electronic) as well as the proportion of enrollees on State Exchanges who fail to file their Federal income taxes and reconcile their APTC for 2 consecutive tax years, and therefore we are unable to provide exact estimates of the cost of providing these notices. We believe that if State Exchanges chose to provide direct mailing notices, the approximate cost could be $0.84 per notice for FY 2025 based on the cost for the Exchanges on the Federal platform to send an average notice and would likely grow with

[272] Available at *https://sam.gov.*

postage and inflation costs in future years. We anticipate approximately 110,000 total notices across State Exchanges based on updated FTR data from the Exchanges on the Federal platform, and so in total, the updated estimated cost to State Exchanges to send these notices will be approximately $92,400 yearly for fiscal years 2025 through 2029. However, we still believe this is likely an overestimate based on conversations with interested parties because many State Exchanges may prefer to provide indirect notices that can be emailed, which would substantially reduce costs to the State Exchanges. There could be some cost related to creation of the notice, but State Exchanges could also choose to use either the language that Exchanges on the Federal platform already use or the language previously used in FTR notices.

10. Timeliness Standard for State Exchanges To Review and Resolve Enrollment Data Inaccuracies (§ 155.400(d)(1))

We are finalizing the addition of § 155.400(d)(1) to codify HHS' guidance document titled, *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs),*[273] which provides that, within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in an State Exchange (hereinafter referred to as ''State Exchange issuer'') that includes a description of an inaccuracy that meets the requirements at § 156.1210(a)–(c) and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuers' enrollment data inaccuracies and submit to HHS a description of the resolution of any inaccuracies described by the State Exchange issuer that the State Exchange confirms to be inaccuracies in a format and manner specified by HHS.[274] This finalized policy aligns with existing guidance [275] and builds on the existing requirement at § 155.400(d) that a State Exchange must reconcile enrollment information with issuers and HHS no less than on a monthly basis. It also provides certainty for State Exchange issuers by providing a timeline for State Exchanges to act upon an enrollment data inaccuracy submitted to the State Exchange by a State Exchange issuer that meets the requirements at § 156.1210(a)–(c).

We do not believe that the finalized amendment will impose substantial additional costs to HHS, State Exchanges, or State Exchanges issuers beyond the costs that are already accounted for as part of the existing issuers' enrollment data inaccuracies description process and existing State Exchange enrollment data reconciliation requirements. The existing process already requires State Exchange issuers to submit enrollment inaccuracies and the State Exchanges to resolve those inaccuracies and reconcile enrollment information with both State Exchange issuers and HHS on no less than a monthly basis. We have no reason to believe that codifying a timeliness standard will materially increase burden.

Furthermore, this finalized policy to codify a timeliness standard for resolution of enrollment data inaccuracies will clarify to issuers in State Exchanges the process for timely reviewing and resolving enrollment data inaccuracies and will ensure the accurate and timely payment of APTCs as this enrollment data is the basis of APTC payments to State Exchange issuers in the automated PBP system.

Therefore, we anticipate that this finalized policy will streamline the existing issuers' enrollment data inaccuracies process and benefit consumers by ensuring accurate payment of APTCs.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

11. Establishment of Optional Fixed-Dollar Premium Payment Threshold and Total Premium Threshold (§ 155.400(g))

We anticipate that the finalized policy to allow issuers to implement a fixed-dollar premium payment threshold, adjusted for inflation by annual agency guidance, will benefit enrollees who may otherwise have been unable to maintain enrollment due to owing *de minimis* amounts of premium. The finalized modification will likely be especially beneficial to enrollees who have low incomes, who might be disproportionately impacted by disruptions in coverage. In addition, we believe that issuers that choose to implement a fixed-dollar premium payment threshold will benefit by being able to continue enrollment for enrollees who owe small amounts of premium. We anticipate that there will be some costs associated with implementing a fixed-dollar threshold for those issuers that choose to do so, as well as State Exchanges that choose to allow issuers to do so.

Since the finalized policy will be optional for issuers to adopt, and some may choose not to adopt a payment threshold at all, it is challenging to quantify the impact on APTC payments. In the proposed rule, assuming a fixed-dollar threshold of $5 or less, based on PY 2023 counts of 79,612 QHP policies terminated for non-payment where the enrollee had a member responsibility amount of $0.01–$5.00, with an average monthly APTC of $604.78 per enrollee (for PY 2023), we estimated that this at most would result in $481,477,453.60 in APTC payments for 10 months that excludes the binder payment and first month of the grace period (for which the issuer already received APTC and would not have to return) that issuers would retain, rather than being returned to the Federal Government.[276]

We sought comment on these impacts and assumptions, including quantifying a lower limit, and whether there are additional costs for other interested parties that have not been considered here.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates with the following modifications: since we are finalizing a fixed-dollar threshold of $10 or less, based on PY2023 counts of 135,185 QHP policies terminated for non-payment where the enrollee had a member responsibility amount of $0.01–$10.00, with an average monthly APTC of $604.78 per enrollee (for PY 2023), we estimate that this at most will result in $817,571,843.00 in APTC payments for 10 months that excludes the binder payment and first month of the grace period (for which the issuer already received APTC and would not have to return) that issuers would retain, rather than being returned to the Federal

[273] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[274] OMB Control No.: 0938–1312 and 0938–1341.

[275] CMS. (2024, Aug. 14). *Reporting and Reviewing Data Inaccuracy Reports in State-based Exchanges (SBE) Frequently Asked Questions (FAQs). https://www.cms.gov/cciio/programs-and-initiatives/health-insurance-marketplaces/downloads/faqs-SBE-reporting-enrollment-data-inaccuracies.pdf.*

[276] See CMS (2024) *Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average. https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.*

Government. This would allow such consumers to remain in coverage, rather than having their policy terminated and health care coverage terminated for owing *de minimis* amounts of premium.

12. General Eligibility Appeals Requirements (§ 155.505)

This finalized modification will allow application filers to file appeals through the HHS appeals entity or a State Exchange appeals entity on behalf of applicants and enrollees on their Exchange application, streamlining the appeals process and ensuring operational consistency between the Exchanges on the Federal platform and appeals entities. We do not anticipate any material financial impact related to our proposed change at § 155.505(b).

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

13. Amendments to Certification Standards for QHPs, Request for the Reconsideration of Denial of Certification, and Non-Certification and Decertification of QHPs (§§ 155.1000 and 155.1090)

We are finalizing an amendment to § 155.1000 by codifying that an Exchange may deny certification to any plan that does not meet the general certification criteria at § 155.1000 and amending § 155.1090 with refinements to the standards for the request for the reconsideration of a denial of certification specific to the FFEs. We anticipate no appreciable changes in impact because of these modifications. We expect that the FFEs will deny certification to one or fewer certification applications on average each year, so we expect the number of affected entities to be small. In addition, the finalized revisions to §§ 155.1000 and 155.1090 do not substantively alter the responsibilities of affected issuers or the content of reconsideration requests. As a result, there is no material impact on regulated entities because of these finalized policies.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

14. General Program Integrity and Oversight Requirements (§ 155.1200)

As part of § 155.1200, we proposed to increase transparency in Exchanges by publishing annual State Exchange and SBE-FP SMARTs, programmatic and financial audits, Blueprint applications, and additional data points in the Open Enrollment data reports. We are finalizing this proposal with a modification to not publish the SMARTs. We anticipate no appreciable change in impact with this finalized policy since this data is already collected through the Blueprint application (OMB Control Number: 0938–1172), SMART (OMB Control Number: 0938–1244), and Enrollment Metrics PRA packages (OMB Control Number: 0938–1119). We expect that this policy will increase the public's understanding of State Exchanges, promote program improvements, and better evaluate Exchange quality.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these assumptions as proposed.

15. FFE and SBE-FP User Fee Rates for the 2026 Benefit Year (§ 156.50)

We are finalizing an updated FFE user fee rate of 2.5 percent of monthly premiums for the 2026 benefit year, which is greater than the FFE user fee rate finalized in the 2025 Payment Notice (89 FR 26336 through 26338) of 1.5 percent of total monthly premiums. We are also finalizing an SBE-FP user fee rate of 2.0 percent for the 2026 benefit year, which is greater than the SBE-FP user fee rate finalized in the 2025 Payment Notice of 1.2 percent of total monthly premiums. We are also finalizing an alternative FFE user fee rate of 2.2 percent of total monthly premiums and an alternative SBE-FP user fee rate of 1.8 percent of total monthly premiums, which would take effect if enhanced PTC subsidies were extended at their current level, or higher, by July 31, 2025. We recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain that the amount collected under these user fee rates will adequately fund all user fee-eligible Exchange and Federal platform functions based on the latest budget estimates.

We provided estimates of FFE and SBE-FP user fee transfers from issuers to the Federal Government in the proposed rule based on the proposed FFE and SBE-FP user fee rates of 2.5 and 2.0 percent of total monthly premiums, respectively, and alternative FFE and SBE-FP user fee rate range between 1.8 and 2.2 percent and between 1.4 and 1.8 percent of total monthly premiums, respectively, and our projections of enrollment and premium growth at the time. We are finalizing the FFE and SBE-FP user fee rates of 2.5 and 2.0 percent of total monthly premiums, respectively, as proposed and finalizing modified alternative FFE and SBE-FP user fee rates of 2.2 percent and 1.8 percent of total monthly premiums, respectively. Therefore, we are updating our estimates of transfers from issuers to the Federal Government in this final rule as follows.

We estimate an increase in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $732 million for benefit year 2026 compared to if the user fee rates from the prior benefit year were maintained in 2026. We estimate additional increases in FFE and SBE-FP user fee transfers from issuers to the Federal Government of $937 million in 2027, $958 million in 2028, and $997 million in 2029 if the finalized 2026 benefit year user fee rates were maintained in subsequent years. Under the alternate FFE and SBE-FP user fee rates, which reflect different enrollment assumptions, we estimate increases in FFE and SBE-FP user fee transfers compared to if the 2025 benefit year user fee rates were maintained for 2026 and beyond from issuers to the Federal Government of $620 million in 2026, $854 million in 2027, $885 million in 2028, and $918 million in 2029 if the alternate user fee rates were maintained in subsequent years.

We anticipate that these finalized user fee rates, along with the impact of the expiration of the enhanced PTCs on enrollment in ACA markets, will exert upward pressure on premiums compared to the 2025 benefit year. However, we believe these user fee rate increases from the 2025 user fee rates are necessary to provide financial stability to the Exchanges on the Federal platform, ensure continuity of special benefits to issuers, and maintain access to QHPs for enrollees. We sought comment on the impacts and assumptions included in the proposed rule, and we responded to all comments received on the FFE and SBE-FP user fees in the preamble section titled FFE and SBE-FP User Fee Rates for the 2026 Benefit Year (§ 156.50). After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our

responses to comments, we are finalizing the impact estimates for this policy as discussed in the preceding paragraphs.

16. CSR Loading (§ 156.80)

While we anticipate that codifying the permissibility of CSR loading will provide greater clarity and generally promote market stability, we do not expect that it will have a substantive economic impact, as it will continue to allow States' existing actuarially justified practices of determining whether and how CSR loading occurs.

17. Amendments to AV Calculator Update Methodology (§ 156.135)

This approach to revise the method for updating the AV Calculator, starting with the 2026 AV Calculator, resulting in an earlier release of the final AV Calculator for a given plan year, will benefit both issuers and States. Issuers have previously provided feedback that HHS should strive to release the final version of the AV Calculator sooner, and this approach addresses such requests. An earlier release of the final AV Calculator benefits issuers by providing additional time to develop plan designs ahead of State filing deadlines. In addition, States could benefit from an earlier release of the final version of the AV Calculator to ensure their EHB-benchmark plans comply with EHB requirements, and States that design their own standardized plan options could benefit from an earlier release to ensure they satisfy the AV de minimis ranges. This approach will have no impact on consumers.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

18. Standardized Plan Options (§ 156.201)

We are finalizing updates to the standardized plan options for PY 2026 to ensure these plans continue to have AVs within the permissible *de minimis* range for each metal level, and we are revising both sets of plan designs at the expanded bronze metal level to conform more closely to the corresponding plan designs for PY 2025. These modifications are discussed in detail in the § 156.201 of the preamble to this rule. We believe maintaining a high degree of continuity in the approach to standardized plan options year over year minimizes the risk of disruption for interested parties, including issuers, agents, brokers, States, and enrollees.

We continue to believe that making major departures from the approach to standardized plan options set forth in the 2023, 2024, and 2025 Payment Notices could result in changes that may cause undue burden for interested parties. For example, if the standardized plan options vary significantly from year to year, those enrolled in these plans could experience unexpected financial harm if the cost sharing for services they rely upon differs substantially from the previous year. Ultimately, we believe consistency in standardized plan options is important to allow both issuers and enrollees to become accustomed to these plan designs.

Thus, similar to the approach taken in the 2023, 2024, and 2025 Payment Notices, we are finalizing standardized plan options that continue to resemble the most popular QHP offerings that millions of consumers are already enrolled in. As such, these finalized standardized plan options are based on updated cost sharing and enrollment data to ensure that these plans continue to reflect the most popular offerings in the Exchanges. By finalizing an approach to standardized plan options similar to that taken in the 2023, 2024, and 2025 Payment Notices, issuers will continue to be able to utilize many existing benefit packages, networks, and formularies, including those paired with standardized plan options for PY 2025. Further, issuers will continue to not be required to extend plan offerings beyond their existing service areas.

We do not anticipate that the modification we are finalizing at § 156.201(c) that will require an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area to meaningfully differentiate these plans from one another in terms of included benefits, networks, included prescription drugs, or a combination of some or all these factors, will have a significant impact on issuers. This is because most issuers have not offered multiple standardized plan options within the same product network type, metal level, and service area since these requirements were introduced in PY 2023. In fact, current QHP certification submission data indicates that only three issuers offered multiple standardized plan options within the same product network type, metal level, and service area in PY 2025.

However, we acknowledge that those issuers that do offer multiple standardized plan options in the same product network type, metal level, and service area will either have to modify certain offerings (such as by modifying included benefits, provider networks, included prescription drugs, or a combination of some or all these factors) or choose to discontinue certain plans to the extent they are not meaningfully different. That said, given that issuers will retain the discretion to choose between modifying or discontinuing plans, and given that making these modifications to plans are a routine part of the annual plan design process, we do not anticipate significant burden for affected issuers related to this proposed requirement.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

19. Non-Standardized Plan Option Limits (§ 156.202)

We are finalizing an amendment to § 156.202(b) and (d) to properly reflect the flexibility that issuers have been operationally permitted since the introduction of these requirements to vary the inclusion of the distinct adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage categories under the non-standardized plan option limit at § 156.202(b) in accordance with § 156.202(c)(1) through (3).

In particular, we are finalizing an amendment to § 156.202(b) to properly distinguish between adult dental benefit coverage at § 156.202(c)(1) and pediatric dental benefit coverage at § 156.202(c)(2), such that an issuer offering QHPs in an FFE or SBE-FP, for PY 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), in any service area.

We are finalizing a similar conforming amendment to § 156.202(d), such that for PY 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of § 156.202), and service area if it demonstrates that these additional plans' cost sharing for

benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area.

We are finalizing these modifications to align the regulation text with the existing flexibility that issuers have been operationally permitted since the non-standardized plan option limit was introduced in the 2024 Payment Notice.[277] Given that issuers have had this flexibility since the non-standardized plan option limit was first introduced PY 2024, we do not anticipate any impact on relevant interested parties.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

20. Essential Community Provider Certification Review for States Performing Plan Management Functions (§ 156.235)

This finalized policy to conduct ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions beginning in PY 2026 will not have a significant financial impact on the Federal Government. HHS continues to perform ECP certification reviews for plans in the FFEs, so the financial burden to conduct the certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions using the existing data infrastructure is a marginal increase within the annual programming for QHP certifications. For PY 2025, HHS will use MPMS for ECP reviews for plans seeking QHP certification in FFEs, and HHS has all the necessary data infrastructure and operational processes to conduct reviews for States performing plan management functions for PY 2026 as finalized. While the Federal Government will undertake additional administrative work to review the ECP data from QHP certification applications submitted by issuers seeking certification of their plans as QHPs in FFEs in States performing plan management functions, the transfer of administrative impact from the State that had been performing these reviews to the Federal Government is marginal, as the Federal Government already has in place processes and procedures to conduct the ECP certification reviews. HHS will continue ECP QHP certification reviews in all other FFE States.

This finalized policy will reduce the administrative burden for these States as they will no longer be responsible for ECP data review. We estimate a cost savings of $148,212.12 per State annually for each of the 12 FFE States performing plan management functions in PY 2026.[278] This is calculated by taking the median hourly wage for a compliance officer of $36.38, according to the Occupational Employment and Wage Statistics,[279] and adding 100 percent fringe benefits to total $72.76. We estimate the operations and maintenance costs for the ECP QHP data collection and the QHP data collection support to equal 485 hours for 4.2 full-time equivalents,[280] totaling $148,212.12. The total cost across the 12 FFE States performing plan management functions will be $1,778,545.44. This cost associated with ECP enforcement/compliance reviews will be transferred from the States performing plan management functions to the Federal Government. We further estimate an annual cost of $8,155 associated with ECP compliance reviews that will be transferred from the States performing plan management functions to the Federal Government based on current contract costs.

Further, this finalized policy should not lead to increased burden for issuers in the FFE in States performing plan management functions as they will still have to submit ECP data to HHS regardless of whether it is the State or HHS conducting the QHP certification review. In previous years, these issuers were required to submit ECP data to HHS via the SERFF binders, whereas these issuers are now required to submit their ECP data to HHS in MPMS beginning with the PY 2025 QHP application submission season, making it now possible for HHS to begin reviewing these ECP data going forward.

In addition, this finalized policy will not financially impact providers on the HHS ECP list.[281] There is no fee to be included in the HHS ECP list, and the administrative burden to complete the petition continues to be the same. The finalized policy will support consumer access to vitally important medical and dental services, enhancing health equity for low-income and medically underserved consumers.

We sought comment on these impacts and assumptions.

We did not receive any comments in response to the proposed impact estimates for this policy. For the reasons outlined in the proposed rule and this final rule, we are finalizing these estimates as proposed.

21. HHS-RADV Materiality Threshold for Rerunning HHS-RADV Results (§ 156.1220(a)(2))

We are finalizing an amendment to § 156.1220(a)(2) to codify a materiality threshold for when HHS will rerun HHS-RADV results in response to a successful HHS-RADV appeal. We believe that this amendment supports providing stability for issuers that participate in risk adjustment because it limits the potential for issuers to reopen their books for small changes to their State transfers because of a successful HHS-RADV appeal. This finalized policy will avoid situations where HHS is required to rerun HHS-RADV results and all issuers are required to reopen their books, when the impact for the filer of a successful HHS-RADV appeal is less than $10,000. Because this approach is limited to small dollar amounts, we do not believe that the finalized policy will materially impact issuers or their premiums and it will provide stability to issuers by limiting the situations where their books will need to be reopened. We believe that this finalized amendment, when applicable, will reduce Federal costs by an estimated $75,000 due to the estimated 575 hours of contractor work.

[277] CMS. (2024, April 10). *2025 Final Letter to Issuers in the Federally-facilitated Exchanges. https://www.cms.gov/files/document/2025-letter-issuers.pdf.*

[278] Twelve FFEs operate in States performing plan management functions for PY 2026: Delaware, Hawaii, Iowa, Kansas, Michigan, Montana, Nebraska, New Hampshire, Ohio, South Dakota, Utah, and West Virginia.

[279] Occupational Employment and Wage Statistics from the US Bureau of Labor Statistics for job code 13–1041 Compliance Officer from *https://www.bls.gov/oes/current/oes131041.htm.*

[280] We estimated 485 hours for 4.2 full time equivalents similar to the administrative burden cost for the Federal Government as indicated in cost estimate of the Supporting Statement for Continuation of Data Collection to Support QHP Certification and other Financial Management and Exchange Operations OMB control number: 0938–1187.

[281] A non-exhaustive list of available ECPs that primarily serve low-income and medically underserved populations which can be counted toward an issuer's satisfaction of the ECP standard as part of the issuer's QHP application.

We also believe that this amendment, when applicable, will reduce Federal costs through a decrease in HHS staff work hours. These HHS staff are funded by the risk adjustment user fee, therefore there is no cost impact. Rerunning HHS-RADV results requires HHS to recalculate all national metrics, reissue all issuers' error rate results, and then apply all of those revised error rates to State transfers for the applicable benefit year before going through the process to net, invoice, collect, and redistribute the changes to the HHS-RADV adjustments to State transfers.

We sought comment on these impacts and assumptions.

After consideration of comments and for the reasons outlined in the proposed rule and this final rule, including our responses to comments, we are finalizing the impact estimates for this policy as proposed. We summarize and respond to public comments received on the proposed estimates below.

Comment: One commenter noted that this policy would reduce the burden on smaller issuers, who are disproportionately impacted when HHS-RADV is rerun.

Response: We agree with this commenter. This policy should provide stability to the HHS-operated risk adjustment markets by limiting the potential for HHS-RADV results to be rerun for a particular benefit year when the financial impact on the filer falls below the materiality threshold and thereby reduce burden on all issuers of risk adjustment covered plans, including smaller issuers, by reducing the situations where there are additional adjustments to the HHS-RADV adjustments to State transfers for any given benefit year.

22. Medical Loss Ratio (§§ 158.103, 158.140, 158.240)

We are finalizing (1) the addition of a definition of ''qualifying issuer'' to § 158.103 with a modification to clarify that the new definition of ''qualifying issuer'' is based on an issuer's 3-year aggregate ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums as defined in § 158.130, but prior to and excluding the adjustments in § 158.130(b)(5) that account for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs, in a relevant State and market, and (2) amending § 158.140(b)(4)(ii) to allow qualifying issuers, at their option, to not adjust incurred claims by the net payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year. This rule also amends § 158.240(c) to add an illustrative example of how qualifying issuers that opt to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii) would determine the amount of rebate owed to each enrollee, and makes a conforming amendment to § 158.240(c) to clarify that the current illustrative example in paragraph (c)(2) would apply to issuers that are not qualifying issuers and to qualifying issuers that do not choose to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii). These finalized policies, which will extend only to qualifying issuers (that is, issuers whose aggregate ratio of net payments related to the risk adjustment program under section 1343 of the ACA to earned premiums as defined in § 158.130, but prior to and excluding the adjustments in § 158.130(b)(5) that account for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs, based on 3 consecutive years of data in a relevant State and market, is greater than or equal to 50 percent), will result in transfers to such issuers from their enrollees in the form of lower rebates or higher premiums. Based on MLR data for 2023, these finalized policies will reduce rebates paid by issuers to consumers or increase premiums collected by issuers from consumers by a total of approximately $35 million per year.

We sought comment on these impacts and assumptions.

After consideration of comments and updated estimates based on the more recent 2023 MLR data, and for the reasons outlined in the proposed rule and this final rule, including our response to comments, we are finalizing these impact estimates. We summarize and respond to public comments received on the proposed estimates below.

Comment: One commenter requested that we provide information regarding the number of issuers that will be impacted by the proposal to enable interested parties to evaluate whether it would in fact be a ''small subset,'' and the magnitude of the impact on MLR calculations.

Response: Since the proposal as finalized is not mandatory for qualifying issuers, CMS cannot, at this time, provide the exact number of impacted issuers. However, based on 2023 MLR data, we estimate that fewer than half a dozen issuers would meet the new definition of ''qualifying issuer'' and, if all of them choose to apply risk adjustment transfer amounts as described and finalized in this rule, would experience a reduction in rebates in a combined total amount of approximately $35 million, out of approximately 180 issuers that owed approximately $946 million in combined total rebates.

23. 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 a range of between the total number of unique commenters on the 2026 Payment Notice proposed rule (266) and the total number of page views on the 2026 Payment Notice proposed rule (about 13,000) will include the actual number of reviewers of this final rule. We therefore use an average number of approximately 6,600 reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some page viewers will not actually read the final rule. For these reasons, we believe that the approximate average of the number of commenters and number of page viewers on the proposed rule will be a fair estimate of the number of reviewers of this final rule. We sought comments on the approach in estimating the number of entities which will review the proposed rule and did not receive any such comments.

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 55 percent of the rule (an average of the range from 10 percent to 100 percent of the rule). We sought comments on this assumption and did not receive any such comments.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $106.42 per hour, including overhead and fringe benefits.[282] Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 4.75 hours for the staff to review 55 percent of this final rule. For each entity that reviews the rule, the

[282] U.S. Bureau of Labor Statistics. (2024, April 9). *Occupational Employment and Wage Statistics. https://www.bls.gov/oes/current/oes_nat.htm.*

estimated cost is $505.50 (4.75 hours × $106.42 per hour). Therefore, we estimate that the total cost of reviewing this regulation is approximately $3,336,300 ($505.50 per reviewer × 6,600 reviewers).

D. Regulatory Alternatives Considered

We are finalizing under § 153.630(b) excluding enrollees without HCCs, removing the FPC, and changing the source of the Neyman allocation data used to calculate the standard deviation of risk score error from MA-RADV data to HHS-RADV data beginning with the 2025 benefit year of HHS-RADV.

The finalized IVA sampling methodology will use the most recent 3 consecutive years of HHS-RADV data with results that have been released before that benefit year's HHS-RADV activities begin to calculate a national variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula, whereas the current IVA sampling methodology relies on MA-RADV data to calculate this national variance of net risk score error.[283] When investigating the impact of switching the Neyman allocation data source to the most recent 3 consecutive years of HHS-RADV data with results that have been released before that benefit year's HHS-RADV activities begin, we considered creating an issuer-specific variance of net risk score error to calculate each issuer's standard deviation of risk score error used in the Neyman allocation formula. However, it would not be possible to calculate an issuer-specific variance of net risk score error for all issuers participating in a given benefit year of HHS-RADV as some issuers would not have 3 consecutive years of HHS-RADV data. As explained in the proposed rule (89 FR 82308, 82353), these issuers would have to rely on fewer years of HHS-RADV data under an issuer-specific calculation, meaning significantly fewer data points compared to other issuers that participated in all years, which could result in large variations in IVA sample stratum size and increased uncertainty in HHS-RADV. Therefore, for this reason and the reasons noted in section III.B.6.a.3 of this final rule, we are finalizing continuing to calculate each issuer's standard deviation of risk score error using a national variance of net risk score error, but to use a three-year rolling window of HHS-RADV data rather than the MA-RADV data as the source data for the Neyman allocation.

We considered proposing to replace the source of the Neyman allocation data while continuing to include enrollees without HCCs in IVA sampling and retaining the FPC.[284] However, this would result in sampling a greater proportion of enrollees without HCCs, who do not have risk scores to adjust when calculating issuers' error rates during HHS-RADV. In addition, keeping the FPC while excluding enrollees without HCCs from IVA sampling and replacing the source data for the Neyman allocation with available HHS-RADV data would lead to a dramatic increase in the number of issuers subject to the FPC and therefore decrease the total count of Super HCCs in issuers' IVA samples. For example, we estimate that the average Super HCC count for issuers currently subject to the FPC would decrease by 26 percent by retaining the FPC, which would increase the proportion of issuers that fail to meet the 30 Super HCC constraint in HHS-RADV.[285] In contrast, removing the FPC would increase the average Super HCC count for these same issuers by 30 percent, which would improve issuers' probability of meeting the 30 Super HCC constraint. Overall, our analyses found that making these modifications in combination will lead to the greater improvements in sampling precision and will allow more than 95 percent of issuers to pass the 10 percent sampling precision target at a two-sided 95 percent confidence level.

We also considered only excluding stratum 10 enrollees from the IVA sampling methodology and retaining RXC-only enrollees in strata 1 through 3. However, we believe removing all enrollees without HCCs (both stratum 10 enrollees and RXC-only enrollees) is the preferred approach so issuers and IVA Entities are not spending resources on enrollees who do not have risk scores to adjust when calculating issuers' error rates during HHS-RADV. In addition, our analysis revealed the greatest improvements in precision and greatest decreases in the average medical records reviewed per enrollee, and therefore the greatest decreases in issuer and IVA Entity burden, when excluding RXC-only enrollees and stratum 10 enrollees from the IVA sampling methodology.

As an alternative respect to the SVA pairwise means test proposal, we considered only changing the pairwise means testing procedure from the 95 percent confidence interval paired t-test to the 90 percent confidence interval bootstrapped test without increasing the initial SVA subsample size to 24. However, our analysis found that maintaining an initial SVA subsample size of 12 under the bootstrapping methodology did not achieve an optimal target false negative rate of approximately 20 percent at various effect sizes. Therefore, we are finalizing a modification to the pairwise means test to use a 90 percent confidence interval bootstrapping methodology and to increase the initial SVA subsample size from 12 enrollees to 24 enrollees beginning with 2024 benefit year HHS-RADV.[286]

We considered taking no action regarding the changes at § 155.305(f)(4)(ii) and instead relying on the guidance released by CMS to inform Exchanges of noticing best practices as was previously done, but instead decided to codify this as a requirement to ensure that tax filers or their enrollees receive multiple educational notices regarding the requirement to file their Federal income taxes and reconcile their APTC.

We considered taking no action regarding modifications to § 155.400(g) to allow issuers to adopt a fixed-dollar premium payment threshold or a gross

[283] As noted in the preamble of this final rule, a new benefit year of HHS-RADV activities generally begins in the spring when issuers can start selecting their IVA entity and IVA entities can start electing to participate in HHS-RADV for that benefit year. We would use data from the 3 most recent consecutive years of HHS-RADV where results have been released. For the most recently published annual HHS-RADV timeline, see the *2023 Benefit Year HHS-RADV Activities Timeline. https://regtap.cms.gov/uploads/library/2023_RADV_Timeline_5CR_072424.pdf.* Note that there were delays in the 2023 Benefit Year HHS-RADV Activities Timeline in recognition of the challenges some issuers were facing related to EDGE server operations after the Change Healthcare Cybersecurity Incident.

[284] As noted in the preamble of this final rule, enrollees without HCCs include stratum 10 enrollees that do not have HCCs nor RXCs and RXC-only enrollees in strata 1 through 3.

[285] As noted earlier in this preamble, this estimate is based on the combined impact of all finalized changes to the IVA sampling methodology.

[286] A standard IVA sample size is 200 enrollees, and it applies to the majority of issuers of risk adjustment covered plans. CMS calculates a smaller IVA sample sizes for issuers for smaller populations by using a Finite Population Correction (FPC) factor. All issuers are subject to the same SVA subsample sizes, but the maximum SVA subsample for pairwise testing is one half of the issuer's IVA sample size. As discussed in section II.B.5.a., we are finalizing changes to the IVA sampling methodology that will exclude enrollees without HCCs from IVA sampling and remove the FPC factor such that all IVA samples will consist of 200 enrollees with HCCs or the issuer's total EDGE population of enrollees with HCCs if they have less than 200 enrollees with HCCs beginning with the 2025 benefit year of HHS-RADV. Under this policy, the SVA subsample size expansion for issuers with less than 200 enrollees with HCCs will continue to follow the standard SVA subsample sizes with a maximum SVA subsample for pairwise testing equal to one half of the issuer's IVA sample size. If the issuer fails at the maximum SVA subsample size for pairwise testing, a precision analysis if performed to determine whether the SVA audit results from that maximum SVA subsample size can be used in error estimation or if the SVA sample needs to expand to the full IVA sample.

premium-based percentage payment threshold. However, the finalized policy will provide important flexibility to issuers that wish to allow enrollees who owe de minimis amounts of premium to maintain their enrollment. This flexibility is limited under current regulation, and as a result enrollees who owe small amounts of premium are sometimes unable to remain enrolled. We solicited feedback from interested parties on whether a fixed-dollar threshold, or a percentage threshold based on gross premium, would better meet our goal of providing flexibility to issuers to allow enrollees to avoid triggering a grace period and termination of enrollment through the Exchange for owing small amounts of premium. For the fixed-dollar premium payment threshold, we also considered whether to implement a $5 or $10 cap on the fixed-dollar threshold because while we believe the $5 cap is sufficient to help many enrollees avoid termination, CMS data on non-payment terminations also indicate that there are a considerable number of policies that were terminated in PY2023 with a member responsibility amount of $10 or less. We solicited feedback from interested parties to determine what the appropriate cap should be on the fixed-dollar threshold and received comments supporting a $10 threshold, which we are finalizing in this rule. We also considered keeping the existing net premium-based threshold at a ''reasonable'' limit, which we recommended to be 95 percent or higher, but we are finalizing specifically defining the threshold at 95 percent or higher, to provide clarity for issuers and Exchanges. We also considered whether it would be administratively feasible to allow issuers to adopt both a fixed-dollar and percentage-based threshold but restricted issuers to choosing one threshold method. We solicited feedback from interested parties on whether we should allow this flexibility and received comments supporting this flexibility, which we are finalizing in this rule.

For the 2026 benefit year FFE and SBE–FP user fees, we considered only proposing one FFE user fee rate and one SBE–FP user fee rate as we have done in previous years. However, we recognize that the expiration of the enhanced PTC subsidies at the end of the 2025 benefit year creates a significant amount of uncertainty in the ACA markets and despite this uncertainty, we maintain our interest in ensuring that we collect user fees at a rate that will allow us to sustain the operations of the FFEs. Therefore, we are finalizing two sets of user fee rates to account for both the expiration and extension of enhanced PTC subsidies.

We are finalizing an updated FFE user fee rate of 2.5 percent of total monthly premiums and an SBE–FP user fee rate of 2.0 percent of total monthly premiums for the 2026 benefit year, which account for the expiration of enhanced PTC subsidies at the end of the 2025 benefit year. The 2026 benefit year FFE and SBE–FP user fee rates are greater than the FFE and SBE–FP user fee rates of 1.5 and 1.2 percent of total monthly premiums, respectively, that were finalized in the 2025 Payment Notice (89 FR 26336 through 26338). We are also finalizing an alternative FFE user fee rate of 2.2 percent of total monthly premiums and an alternative SBE–FP user fee rate of 1.8 percent of total monthly premiums for the 2026 benefit year, which would take effect if enhanced PTC subsidies are extended at their current level, or at a higher level, by July 31, 2025.

We considered taking no action on conducting ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs in States performing plan management functions under § 156.235. Not conducting reviews as finalized would maintain current certification operations for issuers in FFE States that perform plan management functions and continue to provide States with the ability to use a similar approach to Federal ECP certification reviews of plans for which issuers submit QHP certification applications in FFEs. However, due to the implementation of the MPMS and enhancement of the ECP user interface, issuers seeking QHP certification in FFEs, including States performing plan management functions, can now submit ECP data to HHS for data integrity of the Federal platform regardless of whether it is the State or HHS conducting the review.

We are finalizing an amendment § 156.1220(a)(2) to codify when HHS will take action in response to a successful HHS–RADV appeal. We considered several ways to design the new materiality threshold to rerun HHS–RADV results. For example, we considered setting the second materiality threshold to rerun HHS–RADV results to include a percentage of HHS–RADV adjustments and applying a 1 percent test to align with the EDGE materiality threshold in § 153.710(e). However, considering that the HHS–RADV adjustments to State risk adjustment transfer charges and State risk adjustment transfer payments are orders of magnitude smaller than those of the initial State risk adjustment transfer amounts, we were concerned that we would see situations where 1 percent of the applicable payment or charge could be as little as $10 based on our experience running HHS–RADV for the past few years. Specifically, we believe that structuring the threshold, as finalized, to the financial impact of the filer and applying a threshold of equal to or greater than $10,000 amount will balance the need for ensuring that HHS–RADV results are accurate with the desire for ensuring that changes in HHS–RADV results actually have a meaningful financial impact. This finalized new materiality threshold to rerun HHS–RADV results takes into consideration the existing materiality threshold for filing a request for reconsideration, which applies to a number of different program appeals. To remain consistent with this existing threshold and recognizing that HHS–RADV adjustments are significantly smaller in magnitude than risk adjustment transfers, we believe that $10,000 is a reasonable threshold, but we solicited comment on this dollar amount and whether it should be higher or lower or whether we should consider including an inflation adjustment rate to this amount. This new finalized materiality threshold to rerun HHS–RADV results also considers the fact that it costs HHS approximately $75,000 to rerun HHS–RADV and re-release results. Reducing the number of times HHS–RADV needs to be rerun and HHS–RADV adjustments need to be re-released also helps maintain the stability of the market, as there are fewer instances of adjustments after the initial release of HHS–RADV adjustments.

E. 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 small businesses, nonprofit organizations, and small governmental jurisdictions are small entities as that term is used in the RFA. 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 (having revenues of less than $8.0 million to $41.5 million in any 1 year). We do not anticipate that providers will be directly impacted by the provisions in this final rule. Individuals and States are not included in the definition of a small entity. The provisions in this final rule will affect Exchanges and QHP issuers.

For purposes of the RFA, we believe that health insurance issuers will be classified under the NAICS code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $47 million or less would be considered small entities for these NAICS codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard will be $44.5 million or less.[287] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report submissions for the 2023 MLR reporting year, approximately 82 out of 475 issuers of health insurance coverage nationwide had total premium revenue of $47 million or less.[288] This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 80 percent of these small issuers belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $47 million. Therefore, although it is likely that fewer than 82 issuers are considered small entities, for the purposes of this analysis, we assume 82 small issuers will be impacted by this final rule.

The finalized policies that will result in an increased burden to small entities are described below.

We are finalizing an update to the IVA sampling methodology, including the removal of enrollees without HCCs (including RXC-only enrollees), removing the FPC, and replacing the source of the Neyman allocation data with the most recent 3 years of consecutive HHS–RADV data with results that have been released before that benefit year's HHS–RADV activities begin, beginning with benefit year 2025 HHS–RADV. The total cost savings associated with this finalized policy will be approximately $79,121.92 per issuer audited per year. For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this final rule.

We are finalizing in this final rule amendments to add a definition of ''qualifying issuer'' and to give such issuers an option to modify the treatment of payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes beginning with the 2026 MLR reporting year. If every qualifying issuer chooses to take advantage of the option to modify the treatment of the payments or receipts related to the risk adjustment program for MLR reporting and rebate calculation purposes, then this finalized policy will reduce rebates paid by these issuers to consumers or increase premiums collected by these issuers from consumers by approximately $35 million annually. The cost savings per issuer will therefore be approximately $73,684.21.[289] For more details, please refer to the Regulatory Impact Analysis section associated with this policy in this final rule.

Thus, the per-entity estimated annual cost savings for small issuers is $152,806.13, and the total estimated annual cost savings for small issuers is $13,294,133.31. See Tables 8 and 9.

TABLE 8: Detailed Annual Costs for Small Entities

Description of Cost	Annual Cost per Small Entity
HHS-RADV IVA changes	-$79,121.92
MLR changes	-$73,684.21
Total	-$152,806.13

TABLE 9: Aggregate Annual Costs for Small Entities

Affected Entity	Affected Small Entities	Annual Cost per Entity	Aggregate Annual Cost for Small Entities
Issuer	87	-$152,806.13	-$13,294,133.31

We sought comment on this analysis and sought information on the number of small issuers that may be affected by the provisions in these final rules. We did not receive any comments on this analysis and are therefore finalizing the estimates as proposed.

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 do not believe that this threshold will be reached by the requirements in this final rule, given that the annual per-entity cost savings of $152,806.13 per small issuer represents approximately 0.07 percent of the average annual receipts for a small issuer.[290] 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 the 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. While this final rule is not subject to section 1102 of the Act, we have determined that this final rule will not affect small rural hospitals. Therefore, the Secretary has certified that this final

[287] SBA. (n.d.). *Table of size standards. https://www.sba.gov/document/support--table-size-standards.*

[288] CMS. (n.d.). *Medical Loss Ratio Data and System Resources. https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[289] $35 million/475 issuers subject to the MLR requirements = approximately $73,684.21.

[290] United States Census Bureau (2020, March). *2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size. https://www.census.gov/data/tables/2020/econ/susb/2020-susb-annual.html.*

rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. 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 threshold is approximately $183 million. Although we have not been able to quantify all costs, we expect that the combined impact on State, local, or Tribal governments and the private sector does not meet the UMRA definition of an unfunded mandate.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, we have engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC, and consulting with State insurance officials on an individual basis.

While developing this final rule, we attempted to balance the States' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For States that elected previously to operate an Exchange, those States had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to potential direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, the finalized policy to conduct ECP certification reviews of plans for issuers in FFEs in States performing plan management functions effective beginning in PY 2026 may have Federalism implications, given that HHS has not conducted Federal ECP certification reviews of plans in FFEs in States performing plan management functions since PY 2015. However, these Federalism implications may be balanced by enabling HHS to align standards in these States with Federal review standards, and thereby increasing consumer access in these States and improving efficiency of the QHP certification process. Additionally, we do not believe that the finalized amendment to codify the timeliness guidance for State Exchanges to review and resolve the State Exchange issuers enrollment data inaccuracies within 60 calendar days will have significant Federalism implications because this finalized policy is merely codifying a timeline for an existing data submission requirement. Likewise, we do not believe that codifying the permissibility of CSR loading has significant Federalism implications because it continues to allow States to determine whether to allow and how to implement actuarially justified CSR loading in their State, as discussed in section III.D.3 of this preamble.

H. Congressional Review Act

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.*), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, this rule shall be submitted to each House of the Congress and to the Comptroller General as part of a report containing a copy of the rule along with other information specified in 5 U.S.C. 801(a)(1). Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 20, 2024.

List of Subjects

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 1. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 2. Section 155.220 is amended by revising paragraph (k)(3) to read as follows:

§ 155.220 Ability of States to permit agents, brokers, web-brokers, and agencies to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(k) * * *

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, applicants, or enrollees, or Exchange information technology systems, including but not limited to risk related to noncompliance with the standards of conduct under paragraph (j)(2)(i), (ii), or (iii) of this section and the privacy and security standards under § 155.260, until the circumstances of the incident, breach, or noncompliance are remedied or sufficiently mitigated to HHS' satisfaction.

* * * * *

■ 3. Section 155.305 is amended by adding paragraph (f)(4)(ii) to read as follows:

§ 155.305 Eligibility Standards.

* * * * *

(f) * * *

(4) * * *

(ii) If HHS notifies the Exchange as part of the process described in § 155.320(c)(3) that APTC payments were made on behalf of either the tax filer or their spouse, if the tax filer is a married couple, for 2 consecutive tax years for which tax data would be utilized for verification of household income and family size in accordance with § 155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for both years as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period (''file and reconcile''), the Exchange must:

(A) Send a direct notification to the tax filer, consistent with the standards applicable to the protection of Federal Tax Information, that explicitly informs the tax filer that the Exchange has determined that the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file their Federal income taxes and reconcile APTC, and educate the tax filer of the need to file and reconcile or risk being determined ineligible for APTC after 2 consecutive years of failing to file and reconcile; or

(B) Send an indirect notification to either the tax filer or their enrollee, that informs the tax filer or enrollee that they may be at risk of being determined ineligible for APTC after 2 years of failing to file and reconcile. These notices must educate tax filers or their enrollees on the requirement to file and reconcile, while not directly stating that the Internal Revenue Service indicates the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile.

* * * * *

■ 4. Section 155.400 is amended by adding paragraphs (d)(1) and (2) and revising paragraph (g) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(d) * * *

(1) *Timeliness standard for State Exchanges to review, resolve, and report data inaccuracies submitted by a State Exchange issuer.* Within 60 calendar days after a State Exchange receives a data inaccuracy from an issuer operating in the State Exchange that includes a description of a data inaccuracy in accordance with § 156.1210 and all the information that the State Exchange requires or requests to properly assess the inaccuracy, the State Exchange must review and resolve the State Exchange issuer's data inaccuracies and submit to HHS a description of the resolution of the inaccuracies in a format and manner specified by HHS.

(2) [Reserved]

* * * * *

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal platform will, allow issuers to implement a percentage-based premium payment threshold policy (which can be based on either the net premium after application of advance payments of the premium tax credit or gross premium) and/or a fixed-dollar premium payment threshold policy, provided that the threshold and policy is applied in a uniform manner to all applicants and enrollees.

(1) Under a net premium percentage-based premium payment threshold policy, issuers can consider applicants or enrollees to have paid all amounts due for the following purposes, if the applicants or enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than 95 percent of the net monthly premium amount owed by the enrollees. If an applicant or enrollee satisfies the percentage-based premium payment threshold policy, the issuer may:

(i) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(ii) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(iii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(2) Under a gross premium percentage-based premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount sufficient to maintain a percentage of the gross premium of the policy before the application of advance payments of the premium tax credit that is equal to or greater than 98 percent of the gross monthly premium owed by the enrollees. If an enrollee satisfies the gross premium percentage-based premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(3) Under a fixed-dollar premium payment threshold policy, issuers can consider enrollees to have paid all amounts due for the following purposes, if the enrollees pay an amount that is less than the total premium owed, the unpaid remainder of which is equal to or less than a fixed-dollar amount of $10 or less, adjusted for inflation, as prescribed by the issuer. If an enrollee satisfies the fixed-dollar premium payment threshold policy, the issuer may:

(i) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(ii) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

* * * * *

■ 5. Section 155.505 is amended by revising paragraph (b) introductory text to read as follows:

§ 155.505 General Eligibility Appeals Requirements.

* * * * *

(b) *Right to appeal.* An applicant, enrollee, or application filer must have the right to appeal:

* * * * *

■ 6. Section 155.1000 is amended by adding paragraph (e) to read as follows:

§ 155.1000 Certification standards for QHPs.

* * * * *

(e) *Denial of certification.* The Exchange may deny certification to any plan that does not meet the general certification criteria under § 155.1000(c).

■ 7. Section 155.1090 is amended by revising the section heading, the paragraph (a) heading, and paragraphs (a)(2) and (3) to read as follows:

§ 155.1090 Request for the reconsideration of a denial of certification.

(a) *Request for the reconsideration of a denial of certification specific to a Federally-facilitated Exchange*—

* * * * *

(2) *Form and manner of request.* An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to provide in support of its request with its request for reconsideration. The request for reconsideration must provide clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error.

(3) *HHS reconsideration decision.* HHS will review the reconsideration request to determine whether the issuer's reconsideration request provided clear and convincing evidence that HHS' determination that the plan does not meet the general certification criteria at § 155.1000(c) was in error. HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS' final determination.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 8. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

■ 9. Section 156.80 is amended by revising paragraph (d)(2)(i) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(2) * * *

(i) The actuarial value and cost-sharing design of the plan, including, if permitted by the applicable State authority (as defined in § 144.103 of this subchapter), accounting for cost-sharing reduction amounts provided to eligible enrollees under § 156.410, provided the issuer does not otherwise receive reimbursement for such amounts.

* * * * *

■ 10. Section 156.201 is amended by adding paragraph (c) to read as follows:

§ 156.201 Standardized plan options.

* * * * *

(c) For plan year 2026 and subsequent plan years, an issuer that offers multiple standardized plan options within the same product network type, metal level, and service area must meaningfully differentiate these plans from one another in terms of included benefits, provider networks, included prescription drugs, or a combination of some or all these factors. For the purposes of this standard, a standardized plan option with a different product ID, provider network ID, drug list ID, or a combination of some or all these factors, would be considered meaningfully different.

■ 11. Section 156.202 is amended by revising paragraph (b) and paragraph (d) introductory text to read as follows:

§ 156.202 Non-standardized plan option limits.

* * * * *

(b) For plan year 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at § 144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of this section), in any service area.

* * * * *

(d) For plan year 2025 and subsequent plan years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage (as defined in paragraphs (c)(1) through (3) of this section), and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in the issuer's other non-standardized plan option offerings in the same product network type, metal level, inclusion of adult dental benefit coverage, pediatric dental benefit coverage, and adult vision benefit coverage, and service area.

* * * * *

■ 12. Section 156.1220 is amended by adding paragraphs (a)(2)(i) and (ii) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(2) * * *

(i) Notwithstanding paragraphs (a)(1) and (2) of this section, for appeals related to HHS–RADV under paragraphs (a)(1)(vii) and (viii) of this section, HHS will only take action to adjust risk adjustment State payments and charges for an issuer in response to an appeal decision when the impact of the decision to the filer's HHS–RADV adjustments to risk adjustment State transfers is greater than or equal to $10,000.

(ii) [Reserved]

* * * * *

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 13. The authority citation for part 158 continues to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 14. Section 158.103 is amended by adding a definition for ''Qualifying issuer'' in alphabetical order to read as follows:

§ 158.103 Definitions.

* * * * *

Qualifying issuer means an issuer whose aggregate ratio of net payments related to the risk adjustment program under section 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18063, to earned premiums as defined in § 158.130, but prior to and excluding the adjustments in § 158.130(b)(5) that account for the net payments or receipts related to the risk adjustment, risk corridors, and reinsurance programs, based on three consecutive years of data in a relevant State and market, is greater than or equal to 50 percent.

* * * * *

■ 15. Section 158.140 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(4) * * *

(ii) Beginning with the 2026 MLR reporting year, for qualifying issuers (as defined in § 158.103), at such issuers' option, receipts related to the transitional reinsurance program and net payments or receipts related to the risk corridors program (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341 and 1342 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062. For all other issuers, receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

* * * * *

■ 16. Section 158.240 is amended by revising paragraph (c)(2) and adding paragraph (c)(3) to read as follows:

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

* * * * *

(c) * * *

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer is not a qualifying issuer (defined in § 158.103), or is a qualifying issuer that does not opt to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii), the issuer's total earned premium for the MLR reporting year in the individual market in the State is $200,000, incurred claims are $121,250, the issuer received transitional reinsurance payments of $2,500, and made net payments related to risk adjustment and risk corridors of $20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), then the issuer's gross earned premium in the individual market in the State would be $200,000 plus $2,500 minus $20,000, for a total of $182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are $17,500 ($20,000 reduced by $2,500), then the issuer would subtract $15,000 and add $17,500 to gross premium revenue of $182,500, for a base of $185,000 in adjusted premium. The issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid $2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

(3) As another example, if an issuer is a qualifying issuer (defined in § 158.103) that opts to apply risk adjustment transfer amounts as described in § 158.140(b)(4)(ii), the issuer's total earned premium for the MLR reporting year in the individual market in the State is $90,000, incurred claims are $151,250, and the issuer received transitional reinsurance payments of $12,500 and net receipts related to risk adjustment of $110,000, then the issuer's gross earned premium in the individual market in the State would be $90,000 plus $12,500, for a total of $102,500. If the qualifying issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1), and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the reinsurance payments that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240 are $12,500, then the qualifying issuer would subtract $15,000 and $12,500 from gross premium revenue of $102,500, for a subtotal of $75,000. The qualifying issuer would then add $110,000 in net receipts related to risk adjustment, for a base of $185,000 in adjusted premium. The qualifying issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid $900 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

* * * * *

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