DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 460

[CMS–4208–P]

RIN 0938–AV40

Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicaid, Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, drug coverage, dual eligible special needs plans (D–SNPs), utilization management, network adequacy, and other programmatic areas, including the Medicare Drug Price Negotiation Program. This proposed rule also includes proposals to codify existing subregulatory guidance in the Part C and Part D programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Time on January 27, 2025.

ADDRESSES: In commenting, please refer to file code CMS–4208–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4208–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4208–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Matthania Volmy, (667) 290–8662—General Questions.

Naseem Tarmohamed, (410) 786–0814—Part C and Cost Plan Issues.

Matthania Volmy, (667) 290–8662—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeal Issues.

Alissa Stoneking, (410) 786–1120—Parts C and D Payment Issues.

Hunter Coohill, (720) 853–2804—Enforcement Issues.

Lauren Brandow, (410) 786–9765—PACE Issues.

Sara Klotz, (410) 786–1984—D–SNP Issues.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at *https://www.regulations.gov/.*

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare cost plan program, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs for contract year 2026 as well as codify existing Part C and Part D subregulatory guidance.

We note that, as with previous rules, the new marketing and communications policies in this rule are proposed to be applicable for all contract year 2026 marketing and communications, beginning October 1, 2025. However, to operationalize the proposed Format Provider Directories for Medicare Plan Finder provision at § 422.111(m), we anticipate that 2025 plan year directory data will need to be made available online for testing purposes in the summer of 2025, and 2026 plan year data would need to be available online on October 1, 2026. Therefore, we propose an applicability date of July 1, 2025, for this provision.

B. Summary of the Key Provisions

1. Vaccine Cost Sharing Changes

This proposal would implement section 11401 of the Inflation Reduction Act of 2022 (IRA), which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost-sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.

2. Insulin Cost Sharing Changes

This proposal would implement section 11406 of the IRA, which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a one-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. The applicable copayment amount for 2023, 2024, and 2025 is $35. For 2026 and each subsequent year, in accordance with the statute, we are proposing that, with respect to a covered insulin product covered under a prescription drug plan (PDP) or a Medicare Advantage prescription drug

(MA–PD) plan prior to an enrollee reaching the annual out-of-pocket threshold, the ''covered insulin product applicable cost-sharing amount'' is the lesser of—

- $35;
- An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of subchapter XI; or
- An amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the PDP or MA–PD plan.

3. Medicare Prescription Payment Plan

We propose regulatory changes to codify agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan to provide to any enrollee of such plan, including an enrollee who is subsidy eligible, the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped. Specifically, we propose to add new § 423.137, add several new Part D required materials and content at § 423.2267, add Medicare Prescription Payment Plan information to the list of required content for Part D sponsor websites at § 423.2265, and add the Medicare Prescription Payment Plan to the list of Part D requirements waived for the Limited Income Newly Eligible Transition (LI NET) program at § 423.2536.

4. Part D Coverage of Anti-Obesity Medications (§ 423.100) and Application to the Medicaid Program

The statutory definition of a covered Part D drug at section 1860D–2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act. This includes, at section 1927(d)(2)(A) of the Act, ''agents when used for anorexia, weight loss, or weight gain.'' Historically, drugs used for weight loss have been excluded from the definition of covered Part D drug, regardless of their use for treatment of individuals with obesity, and have been an optional drug benefit for Medicaid programs. Increases in the prevalence of obesity in the United States and changes in the prevailing medical consensus towards recognizing obesity as a disease since the beginning of the Part D program in 2006 have compelled CMS to re-evaluate Part D coverage of anti-obesity medications (AOMs) for Medicare Part D enrollees with obesity where the drug's prescribed use is not for a medically accepted indication (MAI) that is currently covered under Part D. We are proposing to reinterpret the statutory exclusion of agents when used for weight loss to allow Part D coverage of AOMs when used to treat obesity by reducing excess body weight or maintaining weight reduction long-term for individuals with obesity who do not have another condition for which the prescribed use is an MAI that is covered under the current Part D policy. The proposed reinterpretation would also apply to the Medicaid program. Thus, AOMs could not be excluded from Medicaid coverage under this interpretation when used for weight loss or chronic weight management for the treatment of obesity. Coverage of AOMs and drugs that contain the same active ingredient as AOMs that meet the definition of a covered outpatient drug are already subject to section 1927 requirements when used for an indication, other than weight loss, that is an MAI, and Medicaid must cover those products when they are medically necessary. Under our proposed reinterpretation, AOMs approved for weight loss and chronic weight management that are used for weight loss in individuals who do not have obesity or another condition that is an MAI for the AOM would remain excluded from the definition of covered Part D drug and would remain optional benefit for Medicaid programs.

5. Promoting Informed Choice—Format Provider Directories for Medicare Plan Finder

We are proposing to require MA provider directory data, as required under § 422.111(b)(3)(i) be submitted for use to populate Medicare Plan Finder (MPF). In addition, we are proposing to require MA organizations to attest that this information is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements at § 422.116(a)(1)(i) when it is submitted to CMS for the purpose of incorporating into MPF. The proposed regulatory changes would further promote informed beneficiary choice and transparency found in online resources, empowering people with Medicare to make informed choices about their coverage. In addition, the proposal will help ensure that provider directory information, including the provider's cultural and linguistic capabilities, which are currently required for MA provider directories, and are especially important to underserved communities, will be more readily available when considering an MA plan.

6. Promoting Informed Choice—Expand Agent and Broker Requirements Regarding Medicare Savings Programs, Extra Help, and Medigap

To ensure beneficiaries are well informed about and have an accurate picture of their MA and Part D enrollment options, we are also proposing to add the following topics to the existing list of requirements that agents and brokers must discuss with their customers: the availability of low-income supports including the Part D Low-Income Subsidy (also known as ''Extra Help'') and Medicare Savings Programs; for beneficiaries enrolling into MA when first eligible for Medicare or dropping a Medigap plan to enroll in an MA plan for the first time, general information on Medigap Federal guaranteed issue (GI) rights, the practical implications of switching from Medicare Advantage to Traditional Medicare, and, when applicable, provide information on state laws regarding Medigap GI rights for those states where the agent or broker is licensed and appointed to sell; and requiring that agents pause to address remaining questions the beneficiary may have related to enrollment in a plan prior to moving forward with an enrollment. As Medicare enrollees consider their coverage options, it is essential that agents and brokers provide adequate information to ensure beneficiaries can make fully informed choices, both to support enrollees and promote a functioning, competitive marketplace.

7. Promoting Informed Choice—Enhancing Review of Marketing and Communications

We are proposing to broaden the marketing definition in §§ 422.2260 and 423.2260, in order to expand CMS oversight of Medicare Advantage and Part D communications materials and activities and strengthen beneficiary protections against misleading and confusing advertising tactics. Currently, communications materials and activities only fall within the regulatory definition of marketing if they meet certain content and intent standards. To satisfy the content portion of the current regulatory definition of marketing, communications materials and activities must include or address content regarding: (1) the plan's benefits, benefits structure, premiums or cost sharing; (2) measuring or ranking standards (for example, Star Ratings or plan comparisons); or (3), for MA plans only, rewards and incentives as defined

under § 422.134(a). In order to broaden the definition of marketing, CMS is proposing to eliminate this content standard and rely solely on an intent standard to determine whether communications material and activities are considered marketing. Broadening the definition of marketing would expand the scope of materials that must be prospectively submitted to CMS for review, which would allow CMS to better ensure that MA organizations, Part D sponsors, and their downstream entities are not providing misleading, inaccurate, or confusing information to current or potential enrollees, or engaging in activities that could misrepresent the MA organization or Part D sponsor, in accordance with §§ 422.2262 and 423.2262. We are also proposing conforming edits to the definition of ''Advertisement (Ad)'' in §§ 422.2260 and 423.2260 to align with the proposed updates to the definition of marketing.

8. Promoting Transparency for Pharmacies and Protecting Beneficiaries From Disruptions

We are proposing to require Part D sponsors (or first tier, downstream, or related entities (FDRs), such as pharmacy benefit managers (PBMs), on the sponsors' behalf) to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year and to require sponsors to provide pharmacies a list of these plans to network pharmacies on request after October 1. We are also proposing to require contracts with pharmacies for participation in Part D networks that allow the Part D sponsor or FDR to terminate the contract without cause to also allow pharmacies to terminate the contracts without cause after providing the same notice that the contract requires the sponsor or FDR to provide the pharmacy. We believe these policies will address concerns raised by pharmacies about their ability to provide accurate information to beneficiaries and will help protect beneficiaries from disruptions in care that occur when network pharmacies stop providing services before formally terminating their contracts.

9. Administration of Supplemental Benefits Coverage Through Debit Cards

This provision would codify existing requirements and new protections for supplemental benefits that are administered using debit cards by MA organizations. Specifically, we are proposing to: (1) describe when, how, and in what manner debit cards can be used by an MA organization and enrollee; (2) introduce additional disclosure requirements to increase transparency, including additional disclosure rules around supplemental benefits and plan debit cards (3) further protect access to plan-covered services for MA enrollees by requiring MA organizations to allow an enrollee to receive covered benefits through an alternative process if there is an issue with a plan debit card, (4) ensure debit cards are electronically linked to plan covered items and services through a real-time identification mechanism, and 5) clarify what types of over the counter (OTC) products are acceptable. Finally, we are proposing to prohibit MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, such as use of a debit card by the enrollee to provide the plan's payment to the provider for the covered item or service.

10. Improving Access—Enhancing Rules on Internal Coverage Criteria

In the final rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the April 12, 2023, **Federal Register** (88 FR 22120) (hereinafter referred to as the ''April 2023 final rule''), we codified regulations that clarified the obligations and responsibilities for MA organizations in covering basic benefits and established guardrails for MA organizations to develop and use coverage criteria in a way that aligns with Traditional Medicare. These rules were applicable to coverage for MA organizations beginning January 1, 2024. Through CMS account manager engagement with MA organizations, incoming inquiries from industry stakeholders, and our ongoing 2024 program audits, we have learned a great deal about common misunderstandings related to these new rules. In order to further clarify these rules, we are proposing to build upon and enhance the regulations from the April 2023 final rule, specifically those related to the use of internal coverage criteria, by defining the meaning of ''internal coverage criteria,'' establishing policy guardrails to ensure access to benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

11. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

Addressing the nation's behavioral health crisis and ensuring equitable access to behavioral health services are key priorities for CMS.[1] Beneficiaries with severe mental illness experienced substantial disruptions in care during the COVID–19 pandemic and these disruptions were greater among disadvantaged populations (including historically underserved racial and ethnic groups and low-income populations).[2] As a result, CMS is pursuing policies to address barriers individuals may face in accessing mental health and substance use disorder care. This includes using the authority under sections 1852(a)(1)(B)(iv), 1856(b)(1), 1857(e)(1), 1876(c)(2)(A), and 1876(i)(3)(D) of the Act to add to the list of Part A and Part B benefits (items and services) for which Medicare Advantage (MA) and Section 1876 Cost Plans' (Cost Plans) in-network cost sharing may not exceed the cost-sharing levels in Traditional Medicare.

We propose to require MA and Cost Plans' in-network cost sharing for categories of mental health and substance use disorder services (collectively called ''behavioral health services'') be no greater than that in Traditional Medicare beginning January 1, 2026.

We are proposing behavioral health cost-sharing standards for MA and Cost Plans that strike a balance between: (1) improving the affordability of these services for enrollees in a timely manner; and (2) minimizing disruption to enrollees' access to care and coverage options. We also propose several changes to the cost-sharing regulations for MA and Cost Plans at §§ 417.454 and 422.100. Additionally, we solicit comment on: (1) whether CMS should apply these proposed changes to the behavioral health cost-sharing standards beginning in contract year 2026 or 2027; (2) whether there should be a transition period from the existing contract year 2025 behavioral health cost-sharing standards in current regulations for select service categories (such as, the standards at § 422.100(f)(6)(i), (iii), or

[1] CMS's behavioral health strategy is available at: *https://www.cms.gov/cms-behavioral-health-strategy*.

[2] Busch AB, Huskamp HA, Raja P, Rose S, Mehrotra A. Disruptions in Care for Medicare Beneficiaries with Severe Mental Illness During the COVID–19 Pandemic. JAMA Netw Open. 2022 Jan 4;5(1):e2145677. doi: 10.1001/jamanetworkopen.2021.45677. PMID: 35089352; PMCID: PMC8800078. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8800078/*.

(iv) for MA plans), to the proposed cost-sharing standard; and (3) how long any transition should be. We also solicit comment regarding this behavioral health cost-sharing proposal's potential impact on how MA plans would satisfy existing requirements that cost sharing be actuarially equivalent to Traditional Medicare cost sharing at § 422.100(j)(1) and (2).

12. Improving Experiences for Dually Eligible Enrollees

Dually eligible individuals face fragmentation in many parts of the health care system, including their experiences as enrollees of Medicare and Medicaid managed care plans. One way in which we seek to address such fragmentation is though policies that integrate care for dually eligible individuals. ''Integrated care'' refers to delivery system and financing approaches that (1) maximize person-centered coordination of Medicare and Medicaid services; (2) mitigate cost-shifting incentives between the two programs; and (3) create a seamless experience for dually eligible individuals. We are proposing to establish new Federal requirements for D–SNPs that are applicable integrated plans to: (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated health risk assessment (HRA) for Medicare and Medicaid, rather than separate HRAs for each program. We are also proposing to codify timeframes for special needs plans to conduct HRAs and individualized care plans (ICPs) and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.

13. Medical Loss Ratio (MLR)

To improve medical loss ratio (MLR) reporting and oversight and to better align MA and Part D MLR requirements with commercial MLR and Medicaid MLR requirements, we are proposing to make certain changes to the regulations that govern MLR requirements for MA and Part D. Specifically, we are proposing to establish clinical and quality improvement standards for provider incentives and bonus arrangements included in the MA MLR numerator in order to help align such bonus payments with care outcomes and avoid excess premium transfer to providers. We also propose to prohibit administrative costs from being included in quality improvement activities in both the MA and Part D MLR numerator. Additionally, we propose to adopt additional requirements for the allocation of expenses in the MLR. We also propose to establish new audit and appeals processes for MLR compliance. In addition, we propose to amend the Medicare MLR regulations authorizing the release of Part C and Part D MLR data. We propose to codify the rules we established in the CY 2025 Part D Redesign Program Instructions for the treatment for MLR purposes of Medicare Prescription Payment Plan unsettled balances for 2026 and subsequent years. We also propose to explicitly provide that the Medicare MLR reporting include detailed information regarding provider payment arrangements. In addition to the proposed changes, we are issuing a request for information on potential policies that CMS could adopt regarding how the MA and Part D MLRs are calculated in order to enable policymakers to address concerns surrounding vertical integration in MA and Part D.

14. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

We propose to amend § 423.505 by adding paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's (''Negotiation Program'') Medicare Transaction Facilitator Data Module (''MTF DM''). We believe the requirement among Part D sponsors' network pharmacies to be enrolled in the MTF DM that would be added to Part D sponsors' network contracts with pharmacies, if finalized, would facilitate continued beneficiary access to selected drugs that are covered Part D drugs, promote access to negotiated maximum fair prices under the Negotiation Program for both beneficiaries and dispensing entities, and help ensure accurate Part D claims information and payment.

15. Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

We propose at § 422.137(d)(6)(iii)(A) through (H) to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services.

In the April 2024 final rule, CMS added health equity related requirements to § 422.137, including a requirement at § 422.137(d)(6) that the Utilization Management committee must conduct an annual health equity analysis of the use of prior authorization. The analysis must examine the impact of prior authorization at the plan level, on enrollees with one or more of the specified social risk factors (SRF). The analysis must use the outlined metrics, aggregated for all items and services, calculated for enrollees with the specified SRFS, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis.

During the public comment period, CMS received a significant number of comments on the requirement that the metrics for the health equity analysis be aggregated for all items and services (89 FR 30569). Commenters recommended that CMS require a further level of granularity to ensure that potential disparities could be identified. Specifically, commenters suggested that CMS require disaggregation by item and service to ensure that CMS can identify specific services that may be disproportionately denied. We are proposing to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services.

16. Ensuring Equitable Access to Medicare Advantage Services—Guardrails for Artificial Intelligence (AI)

On October 30, 2023, the Biden-Harris Administration released an Executive Order, ''Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,'' directing agencies to ensure that artificial intelligence tools do not impede the advancement of equity and civil rights, and that the use of AI within health care organizations does not deny equal opportunity and justice for the American people.[3] Given the growing use of AI within the healthcare sector, such as, but not limited to, AI-based patient care decision support tools, vision transformer-based AI methods for lung cancer imaging applications, and AI and machine learning based decision support systems in mental health care settings, we believe it is necessary to ensure that the use of AI does not result in inequitable treatment, bias, or both, within the healthcare system, and instead is used to promote equitable access to care and culturally competent care for all enrollees. As such, we propose to revise

[3] *https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence.*

§ 422.112(a)(8) to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. We also clarify that in the event that an MA plan uses AI or automated systems, it must comply with section 1852(b) of the Act and § 422.110(a) and other applicable regulations and requirements and provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status.

17. Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors

CMS has become aware that some entities that provide covered benefits may not be included in an MA organization's provider directory. These concerns relate to safety and a lack of transparency regarding supplemental benefit service providers and their access to an enrollee's home, as well as ensuring individuals know which providers are deeply rooted within the communities they serve. This is particularly of concern when the enrollee may not have information about who may have access to their home, personally identifiable information (PII), or protected health information (PHI). As such, to strengthen beneficiary protections and transparency, we propose to: (1) codify definitions of community-based organizations (CBOs), in-home or at-home supplemental benefit providers and direct furnishing entities; (2) require plans to identify, within the provider directory, which providers and direct furnishing entities meet the proposed definition of a CBO; (3) require plans to identify in-home or at-home supplemental benefit providers and direct furnishing entities, including those that provide a hybrid of services (both in-home or at-home, and in-office services), either through a subset list within the provider directory or through a separate list comprising in-home or at-home supplemental benefit providers and direct furnishing entities; and (4) clarify existing policy by stating that all direct furnishing entities must be included within the provider directory.

C. Conclusion

Finally, we are clarifying and emphasizing our intent that if any provision of this rule, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we propose provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

D. Summary of Costs and Benefits

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TABLE 1: SUMMARY OF COSTS AND BENEFITS

Provision	Description	Financial Impact
1. Vaccine Cost Sharing Changes	We are proposing to codify section 11401 of the IRA and require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost-sharing for an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
2. Insulin Cost Sharing Changes	We are proposing to codify section 11406 of the IRA and require that the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a one-month supply of each covered insulin product must not exceed the proposed "covered insulin product applicable cost-sharing amount."	We estimate that this proposal will increase Federal costs by approximately $1.2 billion from 2026-2035.
3. Medicare Prescription Plan Payment Program	We are proposing to codify, with limited modifications, agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires Part D sponsors to provide all Part D enrollees the option to pay their out-of-pocket (OOP) prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs at the point of sale.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
4. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program	We are proposing to reinterpret the statutory exclusion of agents when used for weight loss, as described at section 1927(d)(2)(A) of the Act, such that it would not apply to drugs when used for weight loss or chronic weight management for the treatment of obesity. This would expand coverage of AOMs to Part D enrollees and Medicaid enrollees (in states that do not already provide coverage of AOMs for weight loss) with obesity who do not already have another condition for which the AOM's prescribed use is a medically accepted indication that is coverable under current policy.	We estimate that, over a ten-year period, this proposal would increase Federal costs by $24.8 billion due to expanded Part D coverage and $14.8 billion due to expanded Medicaid coverage, if implemented.
5. Promoting Informed Choice - Format Provider Directories for Medicare Plan Finder	We are proposing to require MA provider directory data, as required under § 422.111(b)(3)(i) be submitted for use to populate Medicare Plan Finder (MPF) in a format, manner, and timeframe determined by CMS/HHS. In addition, we are proposing to require MA organization to attest that this information is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements at § 422.116(a)(1)(i) when it is submitted to CMS for the purpose of incorporating into MPF.	The proposed changes will not affect the Medicare Trust fund. The paperwork burden is half a million dollars annually.
6. Promoting Informed Choice – Expand Agent and Broker Requirements	We are proposing to add requirements under §§ 422.2274(c)(12) and 423.2274(c)(12) for agents and brokers to discuss the availability	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.

Provision	Description	Financial Impact
regarding Medicare Savings Programs, Extra Help, and Medigap	of low-income supports including the Part D Low-Income Subsidy and Medicare Savings Programs, as well as Federal Medigap guaranteed issue rights and the practical implications of switching from Medicare Advantage to Traditional Medicare. In addition, we are proposing to require agents pause to address remaining questions the beneficiary may have related to enrollment in a plan prior to moving forward with an enrollment.	
7. Promoting Informed Choice – Enhancing Review of Marketing & Communications	We are proposing to broaden the marketing definition in §§ 422.2260 and 423.2260 (paragraph 2) in order to expand CMS oversight of MA and Part D communications materials and activities and strengthen beneficiary protections against misleading and confusing advertising tactics. Broadening the definition of marketing would expand the scope of the materials that must be prospectively submitted to CMS for review, which would allow CMS to better ensure that MA organizations, Part D sponsors, and their downstream entities are not providing misleading, inaccurate, or confusing information to current or potential enrollees, or engaging in activities that could misrepresent the MA organization or Part D sponsor, in accordance with §§ 422.2262 and 423.2262.	The proposed revisions will have a negligible effect on the Medicare Trust Fund. We estimate this proposal will create an additional annual paperwork burden of $3.87 million for Medicare Advantage organizations, Part D sponsors and third party marketing organizations.
8. Promoting Transparency for Pharmacies and Protecting Beneficiaries from Disruptions	We are proposing to require Part D sponsors to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year and to require contracts with pharmacies for participation in Part D networks to allow pharmacies to terminate the contracts without cause after providing the same notice that the contract requires the sponsor or FDR to provide the pharmacy.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
9. Administration of Supplemental Benefits Coverage through Debit Cards	We are proposing to codify existing guidance and new protections regarding the administration of supplemental benefits, including the proper administration of plan debit cards. We are also proposing additional guardrails to increase transparency and access around covered benefits that are administered through plan debit cards, as well as a marketing prohibition.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
10. Improving Access – Enhancing Rules on Internal Coverage Criteria	We are proposing to build upon and enhance the regulations from the April 2023 final rule, specifically those related to the use of internal coverage criteria, by defining the meaning of "internal coverage criteria," establishing policy guardrails to ensure access to benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund

Provision	Description	Financial Impact
11. Ensuring Equitable Access to Behavioral Health Benefits through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)	CMS proposes to require MA and Cost Plans' in-network cost sharing for certain categories of mental health and substance use disorder services (collectively called "behavioral health services") be no greater than cost sharing for those services under Traditional Medicare, beginning in contract year 2026. The service categories include mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient services, inpatient hospital psychiatric services (all length of stay scenarios), outpatient substance use disorder services, and opioid treatment program services. We also propose to apply our longstanding determination that payment of less than 50 percent of total plan financial liability discriminates against enrollees who need those services as a requirement for Cost Plans (unless otherwise specified in regulation). This 50% coinsurance (or actuarially equivalent copayment) limit on in-network basic benefits is necessary and appropriate to apply to Cost Plans because: (1) these plans must, pursuant to section 1876(c)(2) of the Act, furnish Part A and Part B services to their enrollees and (2) plan payment less than 50 percent of total plan financial liability for a basic benefit would not protect Cost Plan enrollees from discrimination in accessing benefits.	While complete data is not available to give this proposal a quantitative figure, this proposal may result in some organizations potentially adjusting aspects of their bid design and allocation of rebate dollars (such as changes to behavioral health and non-behavioral health service category cost sharing amounts, premiums, deductibles, or supplemental benefits). The extent to which MA organizations may adjust their plan benefit design as a direct response to this proposal is primarily based on whether that MA plan has behavioral health cost sharing amounts less than, greater than, or equal to cost sharing in Traditional Medicare for these services. Specifically, continuing plans that previously established cost sharing for behavioral health services at amounts that are equal to or less than Traditional Medicare may not have any cost impacts as a direct result of this proposal. In contrast, for MA organizations that do reduce plan cost sharing for one or more behavioral health service categories in response to this proposal, CMS expects they may have to adjust elements of their plan benefit design as previously discussed (premium as one example). However, from an aggregate perspective, CMS is certain this proposal will not result in: (1) additional out of pocket costs for MA enrollees compared to beneficiaries in traditional Medicare or (2) significant losses for MA organizations. This is because there is a statutory requirement for MA organizations to submit bids that are at least actuarially equivalent to coverage in traditional Medicare. In addition, we also expect MA organizations may become better aware of the cost impact of this proposal as potential cost savings from improved enrollee behavioral health outcomes become more apparent in contract year 2027 and future years. As a result, as part of normal business operations, MA organizations may make additional adjustments based on their initial experience of actual changes to their cost of providing behavioral health benefits and profit margins.

Provision	Description	Financial Impact
		Cost Plans are not required to submit a bid that is at least actuarially equivalent to coverage in traditional Medicare. Cost Plan enrollees may continue to receive basic benefits at cost sharing levels found in Traditional Medicare by going out-of-network. As such, beneficiary choice will continue to act as an incentive for Cost Plan organizations to offer favorable benefit designs.
12. Improving Experiences for Dually Eligible Enrollees	We are proposing to establish new Federal requirements for D-SNPs that are applicable integrated plans (AIPs) to 1) have integrated member ID cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled, and 2) conduct an integrated HRA for Medicare and Medicaid, rather than separate HRAs for each program. We are also proposing to codify timeframes for special needs plans to conduct HRAs and ICPs and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.	The integrated HRA proposal may cause AIPs to incur some upfront costs to make administrative updates. We do not expect the provisions regarding integrated member ID cards and ICPs to have any financial impact.
13. Medical Loss Ratio (MLR)	We are proposing to establish clinical and quality improvement standards for provider incentives and bonus arrangements included in the MA MLR numerator, prohibit administrative costs from being included in quality improvement activities in both the MA and Part D MLR numerator, codify additional requirements for the allocation of expenses in the MLR, and establish new audit and appeals processes for MLR compliance. In addition, we are proposing to amend the regulations authorizing the release of MLR data, codify the treatment for MLR purposes of Medicare Prescription Payment Plan unsettled balances, and amend the reporting requirements for provider payment arrangements. Finally, we are issuing a request for information on MLR and vertical integration. These proposed changes would provide greater oversight for MA and Part D MLR reporting and further align the Medicare MLR program with the commercial and Medicaid MLR programs.	We estimate the proposal to prohibit administrative costs from being included in quality improving activities could result in annual remittances paid by MA organizations to the government of an average of approximately $101 million. In addition, we estimate the audit process could result in annual remittances paid back to the government by MA organizations and Part D sponsors of an average of approximately $32 million.
14. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements	We propose at § 423.505(q) to require plan sponsors (or first tier, downstream, or related entities, such as PBMs, on the sponsors' behalf) to include in their network pharmacy agreements a provision that requires such pharmacies to be enrolled in the MTF DM (or any successor to the MTF DM) and to certify to CMS that the enrollment information provided by such pharmacies in the MTF DM is accurate, complete, and up to date.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.

Provision	Description	Financial Impact
15. Enhancing the Health Equity Analysis	We propose at § 422.137(d)(6)(iii)(A) through (H) to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
16. Ensuring Equitable Access to Medicare Advantage Services – Guardrails for Artificial Intelligence (AI)	We clarify current regulations and propose to amend language at § 422.112(a)(8).	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund
17. Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors	We propose to: (1) codify definitions of community-based organizations (CBOs), in-home or at-home supplemental benefit providers and direct furnishing entities; (2) require plans to identify, within the provider directory, which providers and direct furnishing entities meet the proposed definition of a CBO; (3) require plans to identify in-home or at-home supplemental benefit providers and direct furnishing entities, including those that provide a hybrid of services (both in-home or at-home, and in-office services), either through a subset list within the provider directory or through a separate list comprising in-home or at-home supplemental benefit providers and direct furnishing entities; and (4) clarify existing policy by stating that all direct furnishing entities must be included within the provider directory.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.

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II. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program

A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D (§§ 423.100 and 423.120)

1. Background

Section 11401 of the Inflation Reduction Act (IRA) amended section 1860D–2 of the Act by adding new paragraph (8) to subsection (b) and new paragraph (5) to subsection (c) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost-sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.

Section 11401(e) of the IRA directed the Secretary to implement section 11401 of the IRA for 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS issued memoranda via the Health Plan Management System (HPMS) that outlined requirements for Part D sponsors regarding the implementation of section 11401.

On September 26, 2022, CMS released an HPMS memorandum titled ''Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin.'' [4] In this memorandum, we provided guidance that for any new ACIP-recommended adult vaccine that becomes available during a plan year, Part D sponsors must apply the $0 cost-sharing requirements in section 1860D–2(b)(8) of the Act to applicable claims with dates of service after ACIP's issued recommendation.

On April 4, 2023, CMS issued an HPMS memorandum titled ''Final Contract Year (CY) 2024 Part D Bidding Instructions'' in which we explained that, in order for a vaccine to be considered ACIP-recommended for adult use, it must be both adopted by the Director of the Centers for Disease Control and Prevention (CDC) and published in the CDC's Morbidity and Mortality Weekly Report (MMWR).[5]

On July 24, 2023, CMS issued a revision to the April 4, 2023 memorandum in which we clarified that the effective date of the $0 cost-sharing requirement for an ACIP-recommended adult vaccine must be aligned with the date on which the CDC Director adopts the respective ACIP vaccine recommendation, as posted on the CDC's website at *https://www.cdc.gov/vaccines/acip/recommendations.html,* not the date on which the recommendation is published in the MMWR.[6]

In this rule, we propose to codify the requirements related to $0 cost-sharing for adult vaccines recommended by ACIP under Part D for 2026 and each subsequent plan year.

[4] *https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf.*

[5] *https://www.cms.gov/files/document/final-cy-2024-part-d-bidding-instructions.pdf.*

[6] *https://www.cms.gov/files/document/acip-recommended-vaccines-july-2023.pdf.*

2. Definition of ACIP-Recommended Adult Vaccine

Section 1860D–2(b)(8)(B) of the Act specifies that for purposes of section 1860D–2(b)(8) of the Act, the term ''adult vaccine recommended by the Advisory Committee on Immunization Practices'' means a covered Part D drug that is a vaccine licensed by the U.S. Food and Drug Administration (FDA) under section 351 of the Public Health Service Act (PHSA) for use by adult populations and administered in accordance with recommendations of the CDC's ACIP as adopted by the CDC Director. We propose to refer to these vaccines as ''ACIP-recommended adult vaccines'' and to codify this definition at § 423.100. CMS is not proposing to specify a particular age for a vaccine to be considered ''adult'' for the purposes of determining if a Part D vaccine is subject to $0 cost sharing under section 11401 of the IRA. We defer to how the CDC and ACIP categorize such a recommendation. Part D sponsors must use the information provided by the CDC and ACIP to determine if the vaccine is recommended for, and being administered to, an adult.

Consistent with the September 26, 2022 HPMS memorandum, we propose to define an ''ACIP-recommended adult vaccine'' as a vaccine licensed by the FDA for use in adults and administered in accordance with ACIP recommendations. In some cases, the vaccine may be included on the ACIP ''Adult Immunization Schedule'' [7] and, in other cases, the vaccine may be recommended under a separate ACIP recommendation that is not part of the Adult Immunization Schedule. In alignment with the September 26, 2022 HPMS memorandum, we interpret the term ''recommendation'' to refer to a recommendation under any one of ACIP's categories of recommendations, including routine, catch-up, risk-based, and shared clinical decision-making immunization recommendations. As described by ACIP, the different categories of recommendations can be distinguished based on the default decision to vaccinate. Routine, catch-up, and risk-based immunization recommendations include a default decision to vaccinate an individual based on their age or other indication, unless contraindicated. For shared clinical decision-making recommendations, the decision of whether or not to vaccinate is determined based on the ''best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered.'' [8]

Some vaccines that are not on the ACIP Adult Immunization Schedule for routine immunization are included on the ACIP Vaccine Recommendations and Guidelines web page.[9] This web page describes ACIP recommendations for vaccines that are used in limited populations and under limited circumstances. For example, ACIP recommends certain vaccinations for travelers prior to travelling to certain countries. Therefore, consistent with the September 26, 2022 HPMS memorandum, as long as the vaccine is an FDA-licensed vaccine for use by adults that is recommended by ACIP for use by adults, such vaccine would meet our proposed definition of an ACIP-recommended adult vaccine, when provided in accordance with ACIP recommendations.

As described in the September 26, 2022 HPMS memorandum, a Part D vaccine would not meet our proposed definition of an ACIP-recommended adult vaccine and, therefore, would not be subject to the requirements implemented in this proposed rule, if the vaccine is: (1) not licensed by the FDA under section 351 of the PHSA for use by adults; (2) not recommended by ACIP for use by adults; (3) administered to an individual who is not an adult, even if such use in the non-adult is supported by ACIP recommendations (for example, recommendations in the ACIP child and adolescent immunization schedule); or (4) not administered in accordance with ACIP recommendations.

In summary, we propose to add at § 423.100 a definition of ''ACIP-recommended adult vaccine'' that means a covered Part D drug, as defined at § 423.100, that is a vaccine licensed by the FDA under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of ACIP of the CDC as adopted by the CDC Director.

3. No Deductible or Cost-Sharing for ACIP-Recommended Adult Vaccines

Section 1860D–2(b)(8)(A) of the Act specifies that the deductible shall not apply and there shall be no coinsurance or other cost-sharing with respect to ACIP-recommended adult vaccines. Generally, Part D vaccines that have ACIP-recommended uses in the adult population and are administered to an adult must be provided with no enrollee cost-sharing. As described in the September 26, 2022 HPMS memorandum, this means that enrollees must not be subject to cost sharing on the ingredient cost of the vaccine submitted on the prescription drug event (PDE) record, or any associated sales tax, dispensing fee, or vaccine administration fee, regardless of the vaccine's formulary tier placement or the benefit phase that the enrollee is in.

We are also proposing at § 423.120(g)(3) that enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, that a Part D sponsor determines are coverable under their benefit must not be subject to cost sharing. While Part D sponsors generally may charge the enrollee for the difference between the cash price and plan allowance for DMRs for covered Part D drugs accessed from both out-of-network and in-network pharmacies, neither § 423.124(b) nor Chapter 14 of the Prescription Drug Benefit Manual directly addresses covered Part D drugs that have statutorily limited cost sharing.[10] Because there can be no cost sharing for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, that a Part D sponsor determines are coverable under their benefit, the Part D sponsor must reimburse the enrollee for the full cash price paid to the pharmacy or provider for an ACIP-recommended adult vaccine.

The total gross covered drug cost (TGCDC) is usually reported differently on PDEs depending on whether the drug was accessed at an out-of-network or in-

[7] *https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html.*

[8] *https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html.*

[9] *https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.*

[10] Section 423.124(b) currently states that a Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs at out-of-network pharmacies to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance. Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual (*https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-14-coordination-of-benefits-v09-17-2018.pdf*) provides detailed guidance on how Part D sponsors must process DMR requests that are submitted by enrollees who paid cash at an out-of-network (or an in-network) pharmacy (or provider) and where the pharmacy (or provider) did not submit the claim to the Part D plan.

network pharmacy or provider. Specifically, Part D sponsors report the cash price that the enrollee paid to the pharmacy or provider as the TGCDC for out-of-network DMRs but only report the negotiated price as the TGCDC for in-network DMRs. However, we are clarifying here that with respect to ACIP-recommended adult vaccines, as an exception to the Chapter 14 guidance, the sponsor should report the cash price paid to the pharmacy or provider as the TGCDC on the PDE for both out-of-network and in-network DMRs. Regardless, there is no true out-of-pocket (TrOOP) cost accumulation for these claims because the beneficiary has no cost sharing for ACIP-recommended adult vaccines under the basic Part D benefit.

Under our proposed policy at § 423.120(g), and as described in the September 26, 2022 HPMS memorandum, new Part D vaccines that become available during the plan year and meet the definition of an ACIP-recommended adult vaccine are subject to the cost-sharing requirements of section 1860D–2(b)(8)(A) of the Act. Consistent with the definition of a covered Part D drug at § 423.100, the statutory cost-sharing requirements apply regardless of whether a Part D sponsor adds the vaccine to the formulary midyear, or the enrollee obtains the vaccine via a formulary exception. In addition, we propose at § 423.120(g)(2) that if ACIP issues a new or revised recommendation for a vaccine, related to its use in adults during the plan year, Part D sponsors must apply the cost-sharing requirements of this proposed rule, as applicable, to any ACIP-recommended adult vaccine claims with dates of service after the proposed ''Effective date of the ACIP recommendation'' discussed later in this proposed rule.

Consistent with the April 4, 2023, HPMS memorandum, Part D sponsors may place ACIP-recommended adult vaccines on any tier, including a vaccine tier, and apply utilization management strategies (for example, prior authorization), insofar as such tier placement or utilization management strategy is consistent with the requirements of CMS's formulary review and approval process under § 423.120(b).

As described in section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may only use utilization management strategies to assess the necessity of vaccines that are less commonly administered in the Medicare population, facilitate the use of vaccines in line with ACIP recommendations, and evaluate potential reimbursement of vaccines that could be covered under Part B.[11] For example, utilization management strategies may be used to ensure an enrollee meets the age or clinical requirements recommended by ACIP for a particular vaccine, such as the respiratory syncytial virus (RSV) vaccine which is currently recommended by ACIP for adults aged 75 years of age and older and adults aged 60–74 who are at increased risk for severe RSV disease. However, regardless of an ACIP-recommended adult vaccine's tier placement or applicable utilization management strategies, the statutory zero cost-sharing limits required under this proposed rule would still apply.

In summary, we propose to codify at § 423.120(g)(1) the requirement that Part D sponsors must not apply the deductible or charge cost sharing on ACIP-recommended adult vaccines. We also propose to codify at § 423.120(g)(2) that once a new or revised recommendation is posted on the CDC website, Part D sponsors must provide coverage consistent with § 423.120(g)(1) for dates of service on or after the ''Effective date of the ACIP recommendation'' as discussed later in this proposed rule. Finally, we propose to codify at § 423.120(g)(3) that these cost-sharing requirements apply for ACIP-recommended adult vaccines obtained from either in-network or out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)).

4. Effective Date of ACIP Recommendations

In the July 24, 2023, HPMS memorandum, we stated that Part D sponsors must provide $0 cost sharing for an ACIP-recommended adult vaccine as of the date the CDC Director adopts the ACIP's recommendation, and it is posted on the CDC's website. Accordingly, we propose to add at § 423.100 a definition of ''Effective date of the ACIP recommendation'' that means the date specified on the CDC website noting the date the CDC Director adopted the ACIP recommendation.

In the July 24, 2023 HPMS memorandum, we also stated that in the event that the CDC Director's adoption of an ACIP recommendation for an adult vaccine is posted on the CDC's website but an adoption date is not specified, the effective date of the ACIP recommendation is the day after the last day of the ACIP meeting at which the recommendation was approved. However, we are not including this requirement in our proposed definition of ''Effective date of the ACIP recommendation'' at § 423.100 as it is highly unlikely that an ACIP recommendation will be posted without the date on which it was adopted by the CDC Director. In the event that a recommendation is posted without an effective date, CMS will consult with the CDC to obtain the date the recommendation was adopted by the CDC Director and provide guidance.

The ACIP holds three regular meetings annually, generally in February, June, and October, in addition to emergency sessions, for the purpose of reviewing scientific data and voting on vaccine recommendations. We note that the proposed ''Effective date of the ACIP recommendation'' and the date on which it is published on the CDC's website may not always be the same date (if, for example, the website posting occurs after the date specified as the date the CDC Director adopted the recommendation). Nevertheless, the proposed ''Effective date of the ACIP recommendation'' determines when the cost-sharing requirements apply. Consequently, if an enrollee paid cost sharing for an ACIP-recommended adult vaccine after the ''Effective date of the ACIP recommendation'' (for example, the enrollee received the vaccine after the ''Effective date of the ACIP recommendation,'' but prior to the recommendation being posted on the CDC website), once the recommendation has been posted to the CDC website, the Part D sponsor will need to reimburse the enrollee for any cost sharing they paid for the vaccine.

In instances where ACIP expands a previous recommendation, narrows a previous recommendation, or removes a previous recommendation, the ''Effective date of the ACIP recommendation'' is the date the CDC Director adopted the changed recommendation once the recommendation is posted on the CDC's website. We note that a change to an ACIP recommendation alone does not affect a vaccine's status as a Part D drug. Specifically, a Part D drug is defined at § 423.100, in relevant part, as including a vaccine, if used for a medically accepted indication, as defined in section 1860D–2(e)(4) of the Act. Since an ACIP recommendation does not affect what is considered a medically accepted indication, as defined under section 1860D–2(e)(4) of the Act, for a particular vaccine, an ACIP recommendation alone does not affect a vaccine's status as a Part D drug. However, if the FDA labeling changes to

[11] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf*

align with a narrowed ACIP recommendation, this may change what is considered a medically accepted indication and may change what indications are coverable under Part D for a particular vaccine. In other words, if an ACIP recommendation is narrowed or removed, the vaccine may still be coverable under Part D, but an enrollee may be subject to cost-sharing for the vaccine if it is not administered in accordance with the revised ACIP recommendation.

When an ACIP recommendation for a particular vaccine is narrowed (for example, additional restrictions are added or the vaccine is recommended for a more limited patient population), Part D sponsors may implement prior authorization (PA) to determine whether the vaccine is being administered in accordance with ACIP recommendations and whether the enrollee should be subject to cost-sharing. For example, if an ACIP recommendation is amended to raise the age for which a vaccine is recommended to be administered, Part D sponsors may implement PA to ensure a beneficiary meets this new age requirement. However, Part D sponsors are not required to implement PA for vaccines to determine if a vaccine is being used for an ACIP-recommended use and is therefore subject to $0 cost-sharing.

When an ACIP recommendation is narrowed and a Part D sponsor does not currently have a PA in place for that vaccine, the plan must submit a negative formulary change request to add a PA requirement for that vaccine that aligns with the newly narrowed recommendation, consistent with § 423.120(e)(1). As specified in § 423.120(e)(3)(i), negative change requests for maintenance changes are considered to be approved after 30 days unless the Part D sponsor is notified otherwise. Once the request is approved, Part D sponsors may implement the PA requirement and, if the plan determines that the vaccine is not being used for an ACIP—recommended use, may charge the enrollee the applicable cost-sharing. Part D sponsors are permitted, but not required, to make retroactive determinations for claims that were processed with $0 cost-sharing after the ''Effective date of the ACIP recommendation'' and before the date on which the PA requirement went into effect.

If ACIP withdraws a recommendation for a previously recommended vaccine such that the vaccine no longer meets the definition of an ACIP-recommended adult vaccine, Part D sponsors are not required to submit a negative change request and may immediately apply cost sharing for the vaccine for dates of service after the ''Effective date of the ACIP recommendation.''

Because the cost-sharing limits for vaccines outlined in this proposal have been in place since 2023 through program instruction authority and we have annually reviewed cost sharing in plan benefit package submissions, we believe the impacts of our proposed codification of these requirements should have minimal impact on Part D sponsors and beneficiaries.

B. Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D (§§ 423.100 and 423.120)

1. Background

Section 11406 of the Inflation Reduction Act (IRA) amended section 1860D–2 of the the Act by adding new paragraph (9) to subsection (b) and new paragraph (6) to subsection (c) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a 1-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. For 2023, 2024, and 2025, the applicable copayment amount is $35. For 2026 and each subsequent year, the applicable copayment amount is the lesser of: (1) $35, (2) an amount equal to 25 percent of the maximum fair price (MFP) established for the covered insulin product in accordance with part E of subchapter XI of the Act, or (3) an amount equal to 25 percent of the negotiated price of the covered insulin product under the PDP or MA–PD plan.

Section 11406(d) of the IRA directed the Secretary to implement section 11406 of the IRA for 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS issued several memoranda related to cost-sharing for covered insulin products via the Health Plan Management System (HPMS) that outlined expectations for Part D sponsors regarding the implementation of section 11406. On September 26, 2022, CMS released an HPMS memorandum titled ''Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin,'' in which we provided program instructions for the implementation of the requirements in section 11406.[12] On April 4, 2023, we released additional guidance in the ''Final Contract Year (CY) 2024 Part D Bidding Instructions'' in which we provided instructions for Part D sponsors as they prepared to submit bids for CY 2024.[13] Lastly, on April 1, 2024, we released ''Final CY 2025 Part D Redesign Program Instructions.'' [14]

In this rule, we propose to codify the requirements related to appropriate cost-sharing for covered insulin products under Part D for 2026 and each subsequent plan year.

2. Definition of Covered Insulin Product

Section 1860D–2(b)(9)(C) of the Act defines a covered insulin product as ''an insulin product that is a covered Part D drug covered under a PDP or MA–PD plan and that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) or licensed under section 351 of the Public Health Service Act (PHSA) and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the PHSA pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.''

We are proposing to codify the statutory definition of ''covered insulin product'' at § 423.100 and, in alignment with the guidance in CMS's September 26, 2022 HPMS memorandum, we clarify that a covered insulin product includes drug products that are a combination of more than one type of insulin. We are also proposing, consistent with the September 26, 2022 HPMS memorandum, that the definition of a covered insulin product include drug products that are a combination of both insulin and a non-insulin drug or biological product. Our proposed definition of covered insulin product would not, however, include medical supplies associated with the injection of an insulin product, unless such medical supplies are a device constituent part of a combination product (as defined in 21 CFR 3.2(e)) containing insulin and such combination product is licensed under section 351 of the PHSA.

While our proposed definition of ''covered insulin product'' includes drug products that are a combination of more than one type of insulin or both insulin and non-insulin drug or biological products, the definition would be limited to those drug products

[12] *https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf.*

[13] *https://www.cms.gov/files/document/final-cy-2024-part-d-bidding-instructions.pdf.*

[14] *https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.*

that are FDA-licensed products. Consequently, because a compounded drug product, as described in § 423.120(d), is not FDA-licensed, it would not meet the definition of ''covered insulin product''. As such, a compounded drug product would not be subject to the requirements for a ''covered insulin product'' under our proposed definition at § 423.100.

Section 1860D–2(b)(9)(C) of the Act specifies that a ''covered insulin product'' is an insulin product that is a covered Part D drug covered under a PDP or MA–PD plan. Section 423.100 defines a covered Part D drug to be a Part D drug that is included on a Part D sponsor's formulary, treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124(a) and (c). Accordingly, we specify in our proposed definition at § 423.100 that a ''covered insulin product'' is a covered Part D drug as defined in § 423.100.

Additionally, we propose at § 423.100 that a ''covered insulin product'' is licensed under section 351 of the Public Health Service Act and marketed pursuant to such licensure. We clarify that this proposed definition, in accordance with the statute, includes any covered insulin product that had an approved marketing application that was deemed to be a license for the insulin product (that is, an approved biologics license application) under section 351 of the PHSA pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such license. We also note that outside of these situations where the insulin had an approved marketing application under section 505 of the Federal Food, Drug, and Cosmetic Act, that was deemed to be a license for the insulin product (that is, an approved biologics license application) under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, there is no need to reference section 505 of the Federal Food, Drug, and Cosmetic Act since a biological product can no longer be approved under section 505 and must be licensed in a biologics license application under section 351 of the Public Health Service Act. As such, a reference to section 505 is not included in our proposed definition of a ''covered insulin product''.

3. Definition of Applicable Cost-Sharing Amount for Covered Insulin Products

Section 1860D–2(b)(9)(D) of the Act defines ''applicable copayment amount'' with respect to a covered insulin product under a PDP or an MA–PD plan dispensed during plan year 2026, and each subsequent plan year, as the lesser of—

- $35;
- An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of subchapter XI, or;
- An amount equal to 25 percent of the negotiated price of the covered insulin product under the PDP or MA–PD plan.

We interpret the section 1860D–2(b)(9)(D) reference to ''applicable copayment amount'' as an amount that could be either a fixed copayment or a coinsurance percentage. Therefore, we propose to define this ''applicable copayment amount'' as an ''applicable cost-sharing amount'' at § 423.100. In addition, to ensure that the reference to ''applicable cost-sharing amount'' is specific to the cost-sharing for covered insulin products described under proposed § 423.120(h), and discussed later in this proposed rule, we propose to define the term ''covered insulin product applicable cost-sharing amount.''

Specifically, we propose to add at § 423.100 a definition of ''covered insulin product applicable cost-sharing amount'' that means, with respect to a covered insulin product covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold during plan year 2026 and each subsequent plan year, the lesser of—

- $35;
- An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of subchapter XI, or;
- An amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the PDP or MA–PD plan.

For example, the August 15, 2024 publication ''Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026'' establishes the maximum fair price for the covered insulin product Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill as $119 for a 30-day supply in CY 2026.[15] An amount equal to 25 percent of the maximum fair price for this product is $29.75, which is lower than the cost-sharing amount of $35. Therefore, the covered insulin product applicable cost-sharing amount for Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill would be the lesser of: (1) $29.75; or (2) an amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the PDP or MA–PD plan.

4. Cost Sharing for Covered Insulin Products

Section 1860D–2(b)(9)(A) of the Act specifies that for plan year 2023 and subsequent plan years, the deductible, as described in section 1860D–2(b)(1) of the Act, shall not apply with respect to any covered insulin product. Section 1860D–2(b)(9)(B)(ii) of the Act further specifies that for 2025 and subsequent plan years, the coverage provides benefits for any covered insulin product, prior to an individual reaching the out-of-pocket threshold, with cost-sharing for a month's supply that does not exceed the applicable copayment amount. We are proposing to codify these requirements at § 423.120(h)(1) and (2).

In alignment with the guidance in our September 26, 2022 HPMS memorandum, we propose to interpret the section 1860D–2(b)(9) cost-sharing requirements to apply separately to each prescription fill that is dispensed. For a prescription fill dispensed in an amount up to a 1-month supply, $35 (or a lower amount specified by the sponsor) is considered a copayment for purposes of determining the ''covered insulin product applicable cost-sharing amount.'' Under our proposal, and consistent with our current policy in the September 26, 2022 HPMS memorandum, Part D sponsors would not be required to prorate the $35 copayment if less than a 1-month supply is dispensed. We believe this proposed policy is supported by section 1860D–2(b)(9)(D) of the Act, which does not explicitly require prorating the applicable copayment amount for less than a 1-month supply. It also aligns with current regulations because insulin is not a solid oral dosage form subject to daily cost-sharing requirements at § 423.153(b)(4). Under our proposal, if the ''covered insulin product applicable cost-sharing amount'' is a coinsurance, the coinsurance percentage would be

[15] *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.*

applied to the negotiated price regardless of the days' supply dispensed.

With respect to extended-day supplies (that is, greater than a 1-month supply) of covered insulin products, we are proposing that cost sharing must not exceed the cumulative ''covered insulin product applicable cost-sharing amount'' that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary. For example, if a covered insulin product is dispensed for greater than a 1-month supply, but less than a two-month supply, the lesser of $70 or 25 percent of MFP or negotiated price, whichever applies, would remain the maximum cost-sharing amount. Similarly, the lesser of $105 or 25 percent of the MFP or negotiated price, whichever applies, would apply for a covered insulin product that is dispensed for greater than a two-month supply up to a three-month supply. If the ''covered insulin product applicable cost-sharing amount'' is a coinsurance, the coinsurance percentage would be applied to the negotiated price regardless of the days' supply dispensed.

While Part D sponsors must not charge cost-sharing that exceeds the ''covered insulin product applicable cost-sharing amount,'' Part D sponsors may charge cost-sharing that is equal to or less than the ''covered insulin product applicable cost-sharing amount.'' This means that Part D sponsors have the flexibility to specify cost-sharing that is equal to or lower than the lesser of: a $35 copayment, or 25 percent coinsurance based on the MFP (if established for such product under the Medicare Drug Price Negotiation Program for that year), or 25 percent coinsurance based on the negotiated price. Part D sponsors could meet this cost-sharing requirement by establishing a copayment amount that is equal to or lower than $35 for a 1-month supply, establishing a coinsurance percentage that is equal to or lower than 25 percent of the product's MFP or negotiated price, or establishing both a copayment amount equal to or lower than $35 and a coinsurance percentage equal to or lower than 25 percent of the product's MFP or negotiated price.

In the September 26, 2022 HPMS memorandum, we provided guidance on managing out-of-network claims. We are now proposing that enrollees who submit direct member reimbursement (DMR) requests for covered insulin products accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, must not pay more than the ''covered insulin product applicable cost-sharing amount.'' While Part D sponsors generally may charge the enrollee for the difference between the cash price and plan allowance for DMRs for covered Part D drugs accessed from both out-of-network and in-network pharmacies, neither § 423.124(b) nor Chapter 14 of the Prescription Drug Benefit Manual directly addresses covered Part D drugs that have statutorily limited cost sharing.[16] Therefore, for covered insulin products accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, we propose at § 423.120(h)(4) that the Part D sponsor must reimburse the enrollee for the full cash price paid to the pharmacy or provider for a covered insulin product minus the ''covered insulin product applicable cost-sharing amount.''

The total gross covered drug cost (TGCDC) usually is reported differently on prescription drug events (PDEs) depending on whether the drug was accessed at an out-of-network or in-network pharmacy or provider. Specifically, Part D sponsors report the cash price that the enrollee paid to the pharmacy or provider as the TGCDC for out-of-network DMRs but only report the negotiated price as the TGCDC for in-network DMRs. However, we are clarifying here that with respect to covered insulin products, as an exception to the Chapter 14 guidance, the sponsor should report the cash price paid to the pharmacy or provider as the TGCDC on the PDE for both out-of-network and in-network DMRs. Additionally, true out-of-pocket (TrOOP) cost accumulation for covered insulin products would be limited to the beneficiary's cost-sharing amount, which cannot exceed the ''covered insulin product applicable cost-sharing amount.''

[16] Section 423.124(b) currently states that a Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs at out-of-network pharmacies to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance. Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual (*https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-14-coordination-of-benefits-v09-17-2018.pdf*) provides detailed guidance on how Part D sponsors must process DMR requests that are submitted by enrollees who paid cash at an out-of-network (or an in-network) pharmacy (or provider) and where the pharmacy (or provider) did not submit claim to Part D plan.

As described in the April 4, 2023 HPMS memorandum, Part D sponsors may place covered insulin products on any tier, and apply utilization management strategies (for example, prior authorization and step therapy), insofar as such tier placement or utilization management strategy is consistent with the requirements of CMS's formulary review and approval process under § 423.120(b). However, regardless of a covered insulin product's tier placement or applicable utilization management strategy, the statutory cost-sharing limits under this proposed rule still apply.

We propose to codify at § 423.120(h)(1) and (2) that with respect to coverage of a covered insulin product, as we propose to define such term at § 423.100, prior to an enrollee reaching the annual out-of-pocket threshold, a Part D sponsor must not apply a deductible and must ensure any enrollee cost-sharing for each prescription fill up to a 1-month supply does not exceed the ''covered insulin product applicable cost-sharing amount'' as defined at § 423.100. We also propose to codify at § 423.120(h)(3) that Part D sponsors must ensure that any enrollee cost sharing for each prescription fill greater than a 1-month supply does not exceed the cumulative ''covered insulin product applicable cost-sharing amount,'' that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary. Finally, we propose to codify at § 423.120(h)(4) that these cost-sharing requirements apply for covered insulin products obtained from either in-network and out-of-network pharmacies and providers.

C. Medicare Prescription Payment Plan (§§ 423.137, 423.2265, 423.2267, and 423.2536)

1. Background

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) made several additions and amendments to the Social Security Act (the Act) that affect the structure of the defined standard Part D drug benefit. Section 11202 of the IRA (Maximum Monthly Cap on Cost-Sharing Payments under Prescription Drug Plans and MA–PD Plans) added a new section 1860D–2(b)(2)(E) to the Act requiring all Medicare prescription drug plans to offer their Part D enrollees the option to pay out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year instead of at the pharmacy point of sale (POS) beginning January 1, 2025.

CMS undertook consumer focus group testing to select a name for the program

established at section 1860D–2(b)(2)(E) of the Act that would resonate with Medicare Part D enrollees. After multiple rounds of consumer testing fieldwork and evaluation of the results, CMS announced the official name of the program as the ''Medicare Prescription Payment Plan.'' We refer to the program herein using this name.

Section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS released guidance establishing critical operational, technical, and communication requirements for the Medicare Prescription Payment Plan for 2025. To provide Part D sponsors with sufficient time to implement the program, CMS released the guidance in two parts: the first addressed critical operational and technical requirements and the second addressed communications-related requirements.[17] In order to solicit the feedback of interested parties, CMS initially published both parts as draft guidance and voluntarily solicited comment. After consideration of the comments, we then released final versions of each part.

CMS released the draft part one guidance in August 2023, which covered topics such as how incurred OOP pharmacy costs should be re-calculated into monthly billed amounts (''program calculations''); participant billing requirements; pharmacy payment obligations and claims processing; requirements related to Part D enrollee outreach; requirements related to Part D enrollee election; procedures for termination of election; reinstatement and preclusion; participant disputes; and data submission requirements. CMS also provided examples of the program calculations to help Part D sponsors program their claims and billing systems correctly for 2025. After consideration of comments received on the draft part one guidance, CMS released the final part one guidance (hereinafter referred to as ''final part one guidance'') in February 2024.

CMS released the draft part two guidance in February 2024, which covered topics such as outreach, education, and communications requirements for Part D sponsors; CMS Part D enrollee education and outreach; pharmacy processes; and Part D sponsor operational requirements. After consideration of comments received on the draft part two guidance, CMS released the final part two guidance (hereinafter referred to as ''final part two guidance'') in July 2024.

In addition to the final part one and final part two guidance, CMS released a technical memorandum in July 2023 providing examples to demonstrate the calculations of the maximum monthly cap on cost sharing payments under the program in different scenarios, a second technical memorandum in April 2024 providing additional examples of calculations that reflect IRA-related changes to the incurred costs that count toward true out-of-pocket costs (TrOOP), and a set of frequently asked questions in October 2024 providing clarifications on the final part one and final part two guidance.

CMS also developed model and standardized materials to be used by Part D sponsors in meeting the statutory requirement for Part D sponsors to communicate with enrollees about the program. The materials developed by CMS include a model election request form, a model notice of election approval, a standardized likely to benefit notice, a model notice of voluntary termination, a model notice of failure to pay, and a model notice of involuntary termination. Where possible, CMS based development of the Medicare Prescription Payment Plan model materials on Part D plan enrollment and disenrollment notices to promote consistency across the Part D program. CMS issued the model materials through the Office of Management and Budget's Information Collection Request (ICR) process and released final model materials in July 2024 after consideration of public comments received on the ICR package.

CMS does not have authority to implement the Medicare Prescription Payment Plan through program instruction authority beyond 2025. As such, we are pursuing rulemaking to codify the requirements of the program for 2026 and subsequent years.

With only a few exceptions, we are proposing to codify, without modification, the requirements established in the final part one and final part two guidance at § 423.137 for 2026 and subsequent years. Because we are codifying existing guidance, these provisions are not expected to impact the baseline.

Instances where we are making modifications to the requirements previously finalized for 2025 include—

- Proposing to modify the requirements for how Part D sponsors handle adjustments for Part D claims under the Medicare Prescription Payment Plan; and
- Proposing to modify the timing requirements for the grace period and initial notice of failure to pay.

We are also proposing new requirements for three additional topics:

- Requirements related to year-over-year participation for existing participants in the Medicare Prescription Payment Plan and addition of a renewal notice to the required notices related to election into the program;
- Requirements for the effective date of voluntary terminations from the program;
- Requirements for Part D plans to provide pharmacies with easily accessible information on a Part D enrollee's costs incurred under the program.

We are also proposing to modify § 423.2267(e), which lists CMS-required materials and content for Part D sponsors, to include model and standardized materials for the Medicare Prescription Payment Plan, and to modify the list of required content for Part D sponsor websites at § 423.2265 to include Medicare Prescription Payment Plan information. Finally, we are proposing to modify § 423.2536 to waive requirements related to the Medicare Prescription Payment Plan for the Limited Income Newly Eligible Transition (LI NET) program.

2. Provisions of the Proposed Regulation

(a) Basis, Scope, and General Rule

Section 1860D–2(b)(2)(E)(i) of the Act requires that each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan must provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1860D–14(a) of the Act), the option to elect, with respect to a plan year, to pay cost sharing under the plan in monthly amounts that are capped in accordance with section 1860D–2(b)(2)(E) of the Act.

In the final part one guidance, CMS stated that, for calendar year 2025, the provision applies to all Part D sponsors, including both stand-alone PDPs and MA–PDs, as well as Employer Group Waiver Plans (EGWPs), cost plans, and demonstration plans.

In the final part two guidance, CMS stated that while the Medicare Prescription Payment Plan is applicable to all Part D plans, it has no practical

[17] See: Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D–2 of the Social Security Act for 2025, and Response to Relevant Comments; Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D–2 of the Social Security Act for 2025, and Response to Relevant Comments.

application for PACE participants or enrollees in plans that exclusively charge $0 cost sharing for Part D covered drugs. As such, CMS does not expect Part D plans that exclusively charge $0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the final part one guidance or the final part two guidance for calendar year 2025. CMS further stated that, if a Part D plan has any enrollees that could pay any cost sharing, even a nominal amount, under the Part D plan at any point during the year, then this clarification would not be applicable to such a plan.

For the reasons articulated in the final part two guidance, we intend to continue to not expect such plans to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in this proposed rule and in the proposed new regulation at § 423.137.

In this proposed rule, we propose to codify at § 423.137(a) the rules we established in the 2025 guidance to apply to plan year 2026 and subsequent years and, in the case of a plan operating on a non-calendar year basis, for the portion of the plan year starting on January 1, 2026. CMS recognizes that implementing the proposed modifications to the requirements established in the final part one and final part two guidance and the new requirements in this proposed rule could be operationally challenging for plans operating on a non-calendar year basis to implement midway through a plan year. As such, we intend to not expect plans operating on a non-calendar year basis to comply with the Medicare Prescription Payment Plan requirements set forth in this proposed rule and in the proposed new regulation at § 423.137 to the extent that those requirements differ from those established in the final part one and final part two guidance during any portion of the non-calendar plan year that starts in 2025 and continues into 2026.[18] However, such plans would be expected to comply with all requirements set forth in this proposed rule and in the proposed new regulation at § 423.137 for non-calendar plan years beginning in 2026 and subsequent non-calendar plan years.

In our final part one guidance, we also established definitions of key terms related to the Medicare Prescription Payment Plan for plan year 2025. We now propose to codify our existing definitions at § 423.137(b) for plan year 2026 and subsequent years with certain clarifications. Specifically, at § 423.137(b)(1), we propose to define ''OOP costs for the Medicare Prescription Payment Plan'' as the cost sharing amount the Part D enrollee is directly responsible for paying. In the final part one and final part two guidance, we referred to these costs simply as ''OOP costs.'' We propose to codify the more specific definition of ''OOP costs for the Medicare Prescription Payment Plan'' to avoid confusion with other uses of the term OOP costs, which may be inconsistent with the use of that term in the final part one and final part two guidance.

As described in section (b) of this proposed rule, the formula for calculating the maximum monthly cap differs for the first month of participation in the program versus the remaining months of the year. The cap for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan incorporates an enrollee's TrOOP prior to election into the program. However, the subsequent month calculation is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs for the Medicare Prescription Payment Plan in the subsequent month. As such, for the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, the term ''OOP costs for the Medicare Prescription Payment Plan'' includes those Part D cost sharing amounts that the enrollee is responsible for paying after accounting for amounts paid by third-party payers. Specifically, the OOP costs for the Medicare Prescription Payment Plan do not include the covered plan pay amount or other TrOOP-eligible amount(s), such as any amount paid by potential third-party payers, such as State Pharmaceutical Assistance Programs or charities. Additionally, within the definition of OOP costs for the Medicare Prescription Payment Plan, we propose to define ''remaining OOP costs owed by the participant'' to be the sum of OOP costs for the Medicare Prescription Payment Plan that have not yet been billed to the program participant. For example, if a Medicare Prescription Payment Plan participant incurs $2,000 in January and is billed $166.67, the remaining OOP costs owed by the participant are $2,000 − $166.67 = $1,833.33.

Finally, in the final part two guidance, CMS stated that it does not expect the LI NET program to offer enrollees the option to pay their OOP costs through monthly payment over the course of the plan year or to comply with the final part one guidance or final part two guidance for calendar year 2025. CMS clarified that, consistent with the agency's longstanding interpretation and implementation of the LI NET program, participants in the LI NET program are considered to be enrolled in a PDP. However, because the LI NET program is limited to offering Part D-eligible individuals with temporary coverage during a limited, transitional period, CMS stated it does not expect the LI NET program to comply with the requirements of the final part one guidance or the final part two guidance for calendar year 2025 in connection with the offering of such transitional coverage. Pursuant to our authority under section 1860D–14(e)(5)(B) of the Act to waive such requirements of title XI and title XVIII of the Act as may be necessary to carry out the purposes of the LI NET program, we propose to codify in this rule a waiver for the LI NET program with respect to the requirements of the Medicare Prescription Payment Plan for plan year 2026 and subsequent years. The LI NET program is limited to temporary coverage during a limited, transitional period and applying the Medicare Prescription Payment Plan to the LI NET program would be inconsistent with the purposes of such transitional coverage and would raise various operational challenges for the program. Accordingly, we are proposing to revise § 423.2536 to redesignate paragraphs (c) through (k) as paragraphs (d) through (l) and add new paragraph (c) to include the proposed Medicare Prescription Payment Plan requirements at § 423.137 discussed in this section to the list of Part D requirements waived for the LI NET program. In addition, we

[18] Specifically, during any portion of the non-calendar plan year that starts in 2025 and continues into 2026, we intend to not expect plans operating on a non-calendar year basis to comply with the proposed modifications to the requirements for how Part D sponsors handle adjustments for Part D claims under the Medicare Prescription Payment Plan and the timing requirements for the grace period and initial notice of failure to pay. During any portion of the non-calendar plan year that starts in 2025 and continues into 2026, we also intend to not expect plans operating on a non-calendar year basis to comply with proposed new requirements related to year-over-year participation for existing participants in the Medicare Prescription Payment Plan and addition of a renewal notice to the required notices related to election into the program; for the effective date of voluntary terminations from the program; and for Part D plans to provide pharmacies with easily accessible information on a Part D enrollee's costs incurred under the program.

are proposing to revise newly redesignated paragraphs § 423.2536(i)(1) and (i)(4) to add the materials proposed at §§ 423.2265(b)(16) and 423.2267(e)(45) through (51) (discussed previously) to the list of communication requirements waived for the LI NET program.

(b) Calculation of the Maximum Monthly Cap on Cost-Sharing Payments

Section 1860D–2(b)(2)(E)(iv) of the Act specifies how the monthly caps on OOP cost sharing payments are to be calculated. The formula for calculating the cap differs for the first month of participation in the program, versus the remaining months of the year. The maximum monthly cap calculations include specifics of a participant's Part D drug costs (previously incurred costs and new OOP costs), as well as the number of months remaining in the plan year; as such, the amount can vary from person-to-person and month-to-month. Assuming a program participant remains in the Medicare Prescription Payment Plan through the end of the plan year, the total amounts billed monthly through the December payment (which would be billed and paid in the following year) will equal the total OOP costs for the Medicare Prescription Payment Plan during the year.

Under section 1860D–2(b)(2)(E)(iv)(I) of the Act, for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan, the term ''maximum monthly cap'' means an amount calculated by taking the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting into the program, divided by the number of months remaining in the plan year. The number of months remaining in the plan year includes the current reference month (for example, for a calendar year plan, the months remaining in the calculation for the January maximum cap would be 12).

Additionally, incurred costs for the Medicare Prescription Payment Plan (as used in the statutory definition of the first month's maximum cap calculation) means the incurred costs, with the meaning set forth at section 1860D–2(b)(4)(C) of the Act and described in section 30 of the Final CY 2025 Part D Redesign Program Instructions (Final 2025 Program Instructions), that were incurred prior to effectuation of an election into the Medicare Prescription Payment Plan, including all TrOOP-eligible costs.[19] If election into the program occurs mid-month, this would include Part D costs incurred within the calendar month of election but prior to election.

Under section 1860D–2(b)(2)(E)(iv)(II) of the Act, for each subsequent month for which the Part D enrollee has opted into the program, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs for the Medicare Prescription Payment Plan in the subsequent month, divided by the number of months remaining in the plan year. The number of months remaining includes the month for which the cap is being calculated. This calculation repeats for each month in which the participant remains in the Medicare Prescription Payment Plan. The resulting maximum monthly cap will change if additional OOP costs for the Medicare Prescription Payment Plan are incurred.

Under section 1860D–2(b)(4)(B)(i)(VII) of the Act, the annual OOP cost threshold for 2025 is $2,000. Under section 1860D–2(b)(4)(B)(i)(VII) of the Act, for 2026 and subsequent years, the annual OOP cost threshold is equal to the amount specified for the previous year, increased by the annual percentage increase described in section 1860D–2(b)(6). ''Incurred costs'' means any costs incurred or treated as incurred under section 1860D–2(b)(4)(C) of the Act.

In the final part one guidance, we established standards for calculating the maximum monthly cap for the Medicare Prescription Payment Plan. The participant will not have any monthly bills to pay under this program until opting into the program and incurring OOP costs for covered Part D drugs. Once a participant incurs an OOP Part D drug cost, all their OOP costs for all covered Part D drugs will be billed on a monthly basis as long as the participant remains in the program. Program calculations apply to all OOP costs for the Medicare Prescription Payment Plan, including those in the deductible phase. Part D sponsors must include all covered Part D drugs in the program. However, non-covered drugs are excluded. Part D sponsors are responsible for correctly calculating the monthly caps based on the statutory formulas, determining the amount to be billed (not to exceed the cap), and sending monthly bills to program participants.

In the final part one guidance, we also established that opting into the program will not impact how a program participant moves through the Part D benefit or what counts towards their TrOOP costs. Under section 1860D–2(b)(4)(F) of the Act, a participant's TrOOP-eligible costs under the Medicare Prescription Payment Plan will still be treated as incurred based on the date each Part D claim is adjudicated. Opting into the program only provides participants with the ability to spread OOP costs over the year—the total incurred costs and the timing of TrOOP accumulation do not change.

In the final part one guidance, we also established standards for how to incorporate extended day supplies of medications in the calculations. For participants who fill prescriptions for an extended day supply, their OOP costs for those prescriptions will be attributed to the month the prescription was filled and will not be pro-rated over the months covered by the prescription. For example, if a participant in the program has $300 in OOP costs for the Medicare Prescription Payment Plan for a 90-day supply dispensed in January, the full $300 will be counted as incurred in January.

In addition, we stated that when an individual opts into the Medicare Prescription Payment Plan during the plan year, the individual's incurred costs used to calculate the first month maximum cap are equal to the individual's accumulated TrOOP before opting into the program. If election into the program occurs mid-month, this would include Part D costs incurred within the calendar month of election but prior to election (refer to example B4 in Appendix B of the final part one guidance for an illustration of a mid-month election). The number of months remaining in the plan year includes the month when an individual opts into the program. When an individual opts into the Medicare Prescription Payment Plan prior to the start of the plan year (such as during open enrollment), the first month maximum monthly cap calculation applies to their first month of active coverage within the plan year.

The final part one guidance also stated that in scenarios where the OOP costs for the Medicare Prescription Payment Plan in the first month of participation in the program are less than the maximum monthly cap, a Part D sponsor cannot bill the participant more than their actual incurred OOP costs. Specifically, a Part D sponsor must bill the participant the lesser of the participant's OOP costs for the Medicare Prescription Payment Plan or the first month's maximum monthly cap. Section 1860D–2(b)(2)(E)(iv)(I) of the Act clearly states that the first month maximum cap calculation applies to the

[19] Final CY 2025 Part D Redesign Program Instructions: *https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements.*

first month an enrollee has elected to participate in the Medicare Prescription Payment Plan; in scenarios in which a participant incurs $0 in OOP costs for the Medicare Prescription Payment Plan in the first month, the Part D sponsor must not bill the participant for the first month and would use the subsequent month maximum monthly cap calculation for all succeeding months in the year in which the participant remains in the program.

Finally, the final part one guidance established that ''OOP costs'' (defined as ''OOP costs for the Medicare Prescription Payment Plan'' for the purposes of this rule) refers only to the patient pay portion for covered Part D drugs that a program participant would have paid at the POS if they had not opted into the Medicare Prescription Payment Plan, not to all incurred costs as defined under section 1860D–2(b)(4)(C) of the Act. For these calculations, the OOP costs for the Medicare Prescription Payment Plan do not include the covered plan paid amount or amounts paid by third parties, such as qualified State Pharmaceutical Assistance Programs (SPAPs) or charities. OOP costs for the Medicare Prescription Payment Plan also do not include any amounts paid by enrollees for monthly premiums.

In this proposed rule, we propose to codify the standards we established in the final part one guidance for plan year 2026 and subsequent years at § 423.137(c).

(c) Eligibility and Election

Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are eligible for the Low-Income Subsidy (LIS). For 2026 and subsequent years, we propose to codify the statutory requirement that Part D sponsors must offer the program to all Part D enrollees, including those who are LIS eligible, at § 423.137(d).

In the final part one guidance, we explained that while the statute requires that an LIS enrollee must have the option to become a Medicare Prescription Payment Plan participant, individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the program. Further, LIS enrollment, for those who qualify, is more advantageous than participation in the Medicare Prescription Payment Plan. We are aware that there may be limited circumstances in which an LIS enrollee would benefit from participation in the Medicare Prescription Payment Plan, but, in general, participation in the Medicare Prescription Payment Plan is unlikely to benefit LIS enrollees. It is important that Part D sponsors inform any individual interested in the Medicare Prescription Payment Plan of potential eligibility for the LIS program. In this rule, for 2026 and subsequent years, we propose to require Part D sponsors to include information on the availability of the LIS program and other financial assistance programs in the election-related materials described at proposed § 423.137(d)(10) with the goal of alerting Part D enrollees to the availability of these programs that can lower costs.

In addition, under section 1860D–2(b)(2)(E)(v)(III)(aa) of the Act, Part D sponsors may not restrict the application of the Medicare Prescription Payment Plan benefit to specific covered Part D drugs. To minimize potential confusion and operational challenges, in the final part one guidance, we stated that for 2025, once an individual has opted into the program, OOP cost sharing for all covered Part D drugs must be included in program bills until the participant reaches the OOP threshold, opts out of the Medicare Prescription Payment Plan, or is terminated from the Medicare Prescription Payment Plan due to failure to pay. The program must apply to all of a program participant's prescriptions for covered Part D drugs. We propose to codify this requirement for 2026 and subsequent years at § 423.137(d)(5).

Section 1860D–2(b)(2)(E)(v)(II) of the Act states that a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. In the final part one guidance, we established requirements for a process for enrollees to opt into the Medicare Prescription Payment Plan in 2025, consistent with the statutory requirement cited previously. The final part one guidance set forth the following requirements for 2025:

- Part D sponsors must allow Part D enrollees to opt into the Medicare Prescription Payment Plan prior to the plan year (including the Annual Election Period for the subsequent plan year, the Part D initial enrollment period, and Part D special election periods) or at any point during the plan year.
- Part D sponsors must allow Part D enrollees to opt into the Medicare Prescription Payment Plan after the conclusion of an enrollment period and before the new plan enrollment effective date (for example, an enrollee could opt into the program for the upcoming plan year after the conclusion of the Annual Election Period and in advance of the January 1 new plan enrollment effective date).

In this proposed rule, for 2026 and subsequent years, we propose to codify these requirements at § 423.137(d)(4)(1).

In the final part one guidance, we also established requirements for election into the program in 2025, which were designed to reduce administrative burden by aligning with existing requirements and procedures for Part D plan enrollment and to provide a uniform experience for Part D enrollees by reducing potential variation in program administration across Part D plans. We required the Part D enrollee, or their authorized legal representative, to complete an election request, provide the required information to the Part D sponsor, and be approved by the Part D sponsor to opt into the Medicare Prescription Payment Plan. Part D sponsors must have the following mechanisms available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan:

- A paper election request form that can be mailed.
- A toll-free telephone number that must provide the individual with evidence the election request was received (for example, a confirmation number).
- A website application that must provide the individual with evidence the election request was received (for example, a confirmation number).

Part D sponsors must consider Medicare Prescription Payment Plan election requests regardless of the election mechanism or format (for example, a handwritten letter). For an election request to be considered complete, the Part D sponsor must receive the name of the Part D enrollee, their Medicare ID number, and the signature (or verbal attestation, in the case of telephonic requests)

of the Part D enrollee or their authorized legal representative validating that the requestor understands and accepts the Part D sponsor's terms and conditions for the program. In this proposed rule, for 2026 and subsequent years, we propose to codify these requirements at §§ 423.137(d)(2) and 423.137(d)(3).

We are committed to ensuring that Part D enrollees, once they request to participate, are able to access the benefits of the program as timely as possible and recognize the importance of timely access to prevent enrollees from not filling prescriptions due to affordability challenges. To that end, we requested comment in the draft part one guidance on real-time or POS election approaches that would require Part D sponsors to effectuate election into the

Medicare Prescription Payment Plan without any delay or with only a nominal delay between the election request and effectuation. As we clarified in the final part one guidance, real-time election refers to a process that would enable a Part D enrollee to request election and be effectuated into the program in one instance from any setting (and so is not limited to only the pharmacy POS setting). POS election, rather, is limited to the pharmacy POS setting and would require updates to pharmacies' claims processing systems.

In response to the request for comment in the draft part one guidance, many commenters expressed support for real-time election, noting that it would prevent dispensing delays and prescription abandonment. However, due to a number of policy and operational barriers and the restricted lead-up time to the statutory implementation date of January 1, 2025, we did not require real-time or POS election for 2025. In the final part one guidance for 2025, we required a 24-hour effectuation timeframe for election requests made during the plan year, to reduce the likelihood of dispensing delays and prescription abandonment while reducing operational burden for plans and pharmacies. Specifically, we stated that when a Part D sponsor receives a program election request for the next, upcoming plan year (or in advance of a new plan enrollment effective date during a plan year) through either an election request form or through other means, the Part D sponsor must process the request within 10 calendar days of receipt, or the number of calendar days before the plan enrollment starts, whichever is shorter. When a current Part D enrollee requests to opt into the Medicare Prescription Payment Plan during the plan year, Part D sponsors must process the election request within 24 hours.

Since publication of the final part one guidance, we have conducted extensive outreach with a variety of stakeholders and conducted in-depth research to assess the feasibility of real-time or POS election options for 2026 or future years. Our research indicates that there is no mechanism for program election information to be passed through the current National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard and easily integrated into Part D sponsor and/or pharmacy benefit manager (PBM) systems; updates to current standards would also be needed to support POS election. These updates would require significant lead time and coordination with industry standards committees that have existing processes and timelines outside of CMS's purview. However, real-time election (facilitated by Part D sponsors outside of the POS) is operationally feasible and need not involve changes to the current Telecommunication Standard; in fact, some Part D sponsors have indicated to CMS that they plan to offer real-time election to their enrollees in 2025. We also note that real-time election facilitated by Part D sponsors could still *take place* at the POS; for example, an individual who receives the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' while picking up a high-cost prescription could step away from the pharmacy counter to call their Part D plan or submit an online election request, and then return to the counter, request that the pharmacist re-process the claim, and pay $0 at POS for the prescription.

In this rule, for 2026 and subsequent years, we propose to codify the 24-hour effectuation requirement at § 423.137(d)(4), but request comment on a potential requirement for Part D sponsors to effectuate election requests received via phone or web in real-time for 2026 or future years. In particular, we are interested in the operational feasibility of implementing a real-time election requirement for 2026, what technology and processes would be required to enable a real-time election requirement for 2026, implications for Part D enrollees, and potential burden on interested parties. We are also interested in opportunities for pharmacists to support enrollees in using any future Part D sponsor-adjudicated real-time election mechanisms at the POS.

In the final part two guidance, we stated that for 2025, paper election requests are considered received on the date and time—

- The Part D sponsor initially stamps a document received by regular mail (that is, U.S. Postal Service); or
- A delivery service that has the ability to track when a shipment is delivered (for example, U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

A telephonic election request is considered received on the date and time:

- The verbal request is made by telephone with a customer service representative; or
- A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

An electronic election request is considered received on the date and time a request is received through the Part D sponsor's website and/or portal. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request. In this rule, for 2026 and subsequent years, we propose to codify these processing time requirements at § 423.137(d)(2).

In the final part one guidance, we stated that in 2025, if a Part D sponsor receives an election request that does not have all necessary elements required to consider it complete, the sponsor must not immediately deny the request. For requests received prior to the plan year, the Part D sponsor must contact the individual to request the additional documentation necessary to process the request within 10 calendar days of receipt of the incomplete election request. For requests received during the plan year, the Part D sponsor must contact the individual to request the additional documentation necessary to process the request within 24 hours of receipt of the incomplete election request. Additional documentation to make the program election request complete must be received by the Part D sponsor within 21 calendar days of the request for additional information. The Part D sponsor may deny the election request if the requisite information is not received from the individual in that timeframe. If a Part D enrollee has fulfilled all program election requirements, but the Part D sponsor is unable to process the election into the program in the required amount of time due to no fault of the individual, the Part D sponsor must process a retroactive election back to the original date when the individual should have been admitted into the Medicare Prescription Payment Plan (that is, within 24 hours of the individual providing the requisite information for election into the program). In addition, the Part D sponsor must reimburse the participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the program within 45 calendar days. In this rule, for 2026 and subsequent years, we propose to codify these requirements for how Part D sponsors must process program election requests, including timing and notice requirements, procedures for collecting missing information on election requests, and requirements for retroactive election in the event the Part D sponsor fails to process an election within 24 hours at § 423.137(d)(4). Section 423.137(d)(4)(i) includes proposed requirements for processing election requests made prior to the plan year, and § 423.137(d)(4)(ii) includes proposed requirements for processing

election requests made during the plan year.

In the final part one guidance, we also included requirements for Part D sponsors to process retroactive election requests in cases where an enrollee cannot have immediate election into the program and believes that any delay in filling a prescription due to the 24-hour timeframe required to process a program election request may seriously jeopardize their life, health, or ability to regain maximum function and so must pay out-of-pocket to the pharmacy. In the final part one guidance, we state that in this situation in 2025, the enrollee must request retroactive election within 72 hours of the date and time when the claim was adjudicated. In this rule, for 2026 and subsequent years, we propose to codify these requirements at § 423.137(d)(6). These requirements ensure that enrollees can participate in the program in cases where they believe that a delay in filling a prescription would seriously jeopardize their life, health, or ability to regain maximum function and can be reimbursed for costs they paid for the prescription before being effectuated in the program.

At § 423.137(d)(7), for 2026 and subsequent years, we propose to codify requirements for Part D sponsors to develop standardized procedures for determining and processing reimbursements for excess program payments made by participants who become LIS eligible, consistent with the final part one guidance for 2025. CMS regulations at 42 CFR 423.800(c) apply to all subsidy eligible individuals and require Part D sponsors to reimburse subsidy-eligible individuals, and any organizations paying cost sharing on behalf of such individuals, any excess premium or OOP cost sharing paid by the individual or organization after the effective date of the individual's eligibility for a subsidy. This requirement applies to any OOP cost sharing paid under the Part D benefit, including cost sharing paid by or on behalf of an enrollee who has participated in the Medicare Prescription Payment Plan. Under the timeframes specified at 42 CFR 423.800(e) and 423.466(a), Part D sponsors must process retroactive claims and premium adjustments for LIS-eligible individuals and make any resulting refunds and recoveries within 45 calendar days of the Part D sponsor's receipt of complete information regarding these adjustments.[20] These same requirements apply to enrollees who have elected into the Medicare Prescription Payment Plan and later become LIS-eligible.

Section 1860D–2(b)(2)(E)(v)(II) of the Act requires Part D sponsors to offer the Medicare Prescription Payment Plan to all Part D enrollees in any month during the year. At § 423.137(d)(8), for 2026 and subsequent years, we propose to codify requirements for mid-year plan switches, consistent with the requirements included in the final part one guidance for 2025. If a Part D enrollee who opted into the Medicare Prescription Payment Plan switches plans (Plan Benefit Package (PBP)) during the plan year or is reassigned by CMS, regardless of whether the new plan is offered by the same or a different Part D sponsor, the Part D sponsor of the prior Part D plan must offer the participant the option to repay the full outstanding amount in a lump sum. If the individual chooses to continue paying monthly, the Part D sponsor must continue to bill the participant monthly based on the participant's accrued OOP costs while in the program under that sponsor's Part D plan. The Part D sponsor cannot require full immediate repayment.

The Part D sponsor is not permitted to automatically sign up the individual for the Medicare Prescription Payment Plan under the new plan. However, an individual must be able to opt into the program regardless of whether they had participated in the program under the prior plan. If an individual opts into the Medicare Prescription Payment Plan under their new plan after switching plans mid-year, the new Part D sponsor must calculate the individual's monthly cap for the first month of participation under the new plan using the formula for the calculation of the maximum monthly cap in the first month. This is the case even when the first plan and the second plan are administered by the same Part D sponsor.

As outlined in section (e) of this proposed rule, preclusion is only permitted in plans that are offered by the same Part D sponsor and may extend beyond the immediately subsequent plan year if a Part D enrollee remains in a plan offered by the same Part D sponsor and continues to owe an overdue balance. If an individual pays off the outstanding balance during a subsequent year, the enrollee is eligible to request to participate in the Medicare Prescription Payment Plan program again.

At § 423.137(d)(9), for 2026 and subsequent years, we propose to codify requirements related to participation renewal year-over-year, a topic CMS did not address in the final part one or final part two guidance because the IRA limited CMS program instruction for a single year of the program (CY 2025). To streamline the process for Part D enrollees and Part D sponsors, we propose an automatic election renewal process, wherein program participation continues into the next upcoming year automatically, provided the participant remains in the same PBP in the upcoming year, unless the program participant indicates otherwise. If an enrollee is switching Part D plans, including switching between two PBPs offered by the same Part D sponsor, the automatic election renewal process would not apply. We propose requiring Part D sponsors to send a notice alerting the Part D enrollee that their participation in the program will continue into the next year unless they indicate that they would like to opt out for the upcoming year. This notice would be required to be sent out to program participants by the end of the Annual Election Period (no later than December 7) and must include the Part D sponsor's program terms and conditions for the upcoming year. This proposed automatic renewal process reduces burden for Part D enrollees who would like to remain in the program, as they would not need to complete additional paperwork to renew their election, and it is consistent with automatic renewal of Part D plan enrollment, which provides a seamless experience for Part D enrollees. Automatic renewal also entails less administrative burden for Part D sponsors, as they are not required to process full election request forms again for program participants and would not be required to perform ''likely to benefit'' analyses (see section (d) of this proposed rule) for the upcoming plan year on program participants. CMS also considered requiring Part D enrollees to actively re-elect into the program each year. Under this approach, Part D sponsors would be required to terminate an enrollee's participation at the end of the contract year and the enrollee would be required to opt back into the program (with the standard election request form or a streamlined renewal form) in order to participate in the following year. CMS opted to propose the automatic election renewal, because the alternative active re-election process places additional burden on both Part D enrollees and Part D sponsors. In addition, this approach is consistent with the existing Part D enrollment process, which automatically renews each year. We request comment on the proposal for automatic election renewal, including the process for enabling

[20] Refer to Medicare Prescription Drug Benefit Manual; Chapter 13—Premium and Cost-Sharing Subsidies for Low-Income Individuals.

automatic election and associated notification requirements.

In the final part two guidance, we addressed program election communications and notice requirements for Part D sponsors, including timing, content, and supplemental information requirements for each required notice in 2025. We required Part D sponsors to make an election request form available throughout the plan year and during the Part D plan enrollment periods.

Part D sponsors must send a paper election request form within the same timeframe as the membership ID card mailing specified at 42 CFR 423.2267(e)(32)(i).

The election request form may be sent in the membership ID card mailing, or in a separate mailing in the same timeframe. The election request form must include all of the following:

- Fields for the Part D enrollees' first and last name, Medicare Number, birth date, phone number, permanent residence street address, and mailing address, if different from permanent residence street address.
- A signature field, allowing the enrollee to attest that they understand—

++ That the form is a request to participate in the Medicare Prescription Payment Plan, and the Part D sponsor will contact them if more information is needed to complete the request;

++ That by signing the form, they have read and understood the form and the Part D sponsor's terms and conditions; and

++ That the Part D sponsor will inform the individual when their participation in the program is active, and, until the individual receives that notification, that they are not a participant in the program.

- Instructions for how to submit the form to the Part D sponsor.
- Instructions for how the Part D enrollee can contact the Part D sponsor for questions or assistance.

A Part D sponsor may include the program terms and conditions on the election request form or may include them on a separate attachment. In this rule, we propose to codify these requirements for 2026 and subsequent years at § 423.137(d)(10)(i).

Once a program election request is accepted by the Part D sponsor, the Part D sponsor must communicate to the Part D enrollee that the request to participate in the Medicare Prescription Payment Plan has been accepted and effectuated via written notice of election approval, within the timeframes described at § 423.137(d)(10)(ii)(A). For requests received prior to the plan year, Part D sponsors are required to send the written notice of election approval within the timeframe described at § 423.137(d)(10)(ii)(A)(1). For requests received during the plan year, regardless of how the Part D enrollee submitted the election request (paper, telephone, or electronic), the Part D sponsor must deliver the notice of election approval within the timeframe described at § 423.137(d)(10)(ii)(A)(2) first telephonically and then via a written notice. The call must include the required elements for the notice of election approval described at § 423.137(d)(10)(ii)(B). The Part D sponsor must then deliver the written notice of election approval to the program participant either via mail or electronically, depending on the participant's preferred and authorized communication method, within 3 calendar days of delivering the initial telephone notice.

If a Part D sponsor is processing an election request over the phone and is able to confirm in that phone call that the election request is approved and the Part D enrollee's participation is active, that same phone call can serve to meet the acceptance of election telephone notification requirement. Similarly, if an electronic election request is approved and effectuated in real time and the Part D sponsor is able to provide a digital confirmation of program participation, the Part D sponsor is not required to also deliver the notice of election approval via phone call. In either case, the Part D sponsor must still deliver the written notice within 3 calendar days.

In the final part two guidance, we set forth requirements for Part D plan sponsors related to the contents of the notice of election approval in 2025. The notice of election approval must include—

- The effective date of the individual's participation;
- A description of how payments for covered Part D drugs under the program will work, including that the individual will pay $0 to the pharmacy for covered Part D drugs and the Part D plan will bill the individual each month;
- An overview of how the monthly bill is calculated, including a statement on how monthly bills may change each month, and a statement outlining that under the program, the individual will not pay more for covered Part D drugs than they would have paid without the program or more than the Medicare Part D annual out-of-pocket maximum;
- Information about procedures for involuntary termination due to failure to pay and how to submit an inquiry or file a grievance, as well as a statement informing the individual that they can voluntarily leave the program at any time;
- A statement describing that leaving the Medicare Prescription Payment Plan, either involuntarily or voluntarily, will not affect the individual's Medicare Part D coverage with the Part D plan;
- A description of how if an individual leaves the program, they may still owe a program balance, they can pay the balance all at once or be billed monthly, and they will resume paying the pharmacy directly for their Part D prescriptions after leaving the program; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs.

In this rule, we propose to codify these requirements for 2026 and subsequent years at § 423.137(d)(10)(ii).

Part D sponsors are required to send a notice of denial upon denial of an election request. In the final part one guidance, we set forth the following requirements for 2025. For requests received prior to the plan year, the notice of denial must be sent within 10 calendar days of receipt of the election request. For requests received during the plan year, the notice of denial must be sent within 24 hours of receipt of the election request. For incomplete election requests, the notice of denial must be sent within 10 calendar days of the expiration of the timeframe for submission of additional information.

Finally, the notice of denial must explain the reason for denial and provide a description of the grievance process available to the individual. In this rule, for 2026 and subsequent years, we propose to codify these requirements at § 423.137(d)(10)(iii).

For 2026, we also propose to require Part D sponsors to send a renewal notice alerting the program participant that their participation in the program will continue into the next year unless they indicate that they would like to opt out for the upcoming year. This notice would be required to be sent out to program participants by the end of the AEP (no later than December 7) and must include the Part D sponsor's program terms and conditions for the upcoming year and a reminder that the participant may opt out of the program at any time, including for the upcoming plan year.

In this rule, for 2026 and subsequent years, we propose to codify these requirements at § 423.137(d)(10)(iv) and to add the election request form, notice

of election approval, and renewal notice as required materials and content for Part D sponsors at § 423.2267(e)(45), (e)(46) and (e)(51).

CMS issued model materials that Part D enrollees can use to fulfill the election request and election approval requirements through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS–10882; OMB 0938–1475) ICR package. As established in § 423.2267(c), model materials and content are required materials and content created by CMS as an example of how to convey beneficiary information. If Part D sponsors choose to not use a CMS-developed model version of a particular required material or content, they must still accurately convey the vital information in the required material or content to the beneficiary.

For the required program election request form that CMS proposes to codify at § 423.2267(e)(45), this means that a Part D sponsor who chooses to develop their own form must include or provide all of the elements outlined at § 423.137(d)(10)(i)(B). For the notice of election approval that CMS proposes to codify at (e)(46), a Part D sponsor who chooses to develop their own notice must include all of the elements outlined at § 423.137(d)(10)(ii)(B). Finally, for the renewal notice that CMS proposes to codify at (e)(51), a Part D sponsor who chooses to develop their own notice must include all of the elements outlined at § 423.137(d)(10)(iv)(B). These notification and content requirements are consistent with the requirements outlined in the final part two guidance for 2025, with the exception of the renewal notice, which was not included in the program instructions.

Additionally, Part D sponsors are required to furnish additional educational information on the Medicare Prescription Payment Plan with the election request form and the notice of acceptance. Part D sponsors are encouraged to use the CMS-developed program fact sheet available on *Medicare.gov* to satisfy these requirements. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy these requirements, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V. In this rule, for 2026 and subsequent years, we propose to codify this requirement at § 423.137(d)(10)(i)(C) and 423.137(d)(10)(ii)(C).

(d) Part D Enrollee Targeted Outreach

The statute establishes that some Part D enrollees will incur OOP costs that make them likely to benefit from election into the Medicare Prescription Payment Plan. As stated in the final part one guidance for 2025, by ''likely to benefit,'' we generally mean that a participant's monthly costs would be lower under the program compared to any single monthly amount they would have had to pay at the pharmacy without the program. We acknowledge, however, that individuals may consider a number of other factors in determining whether they, personally, would benefit from the program.

While this program is open to all Part D enrollees, Part D enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit. Section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act requires that Part D sponsors have a mechanism in place to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program.

CMS recognizes, however, that notification of Part D enrollees likely to benefit from the Medicare Prescription Payment Plan prior to reaching the pharmacy POS will be a critical component to program success. Early notification will streamline the election process and prevent potential drug dispensing delays. As such, in addition to the statutory requirement for pharmacy POS notification (as outlined in section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act), in the final part two guidance, CMS also established requirements for 2025 for Part D sponsors to undertake targeted outreach, both prior to and during the plan year, directly to Part D enrollees likely to benefit from the program.

While the statute requires a likely to benefit notification, it does not outline the specific criteria or define the profile of someone who is likely to benefit under the program. In the final part one guidance, CMS developed a standardized, quantitative framework for assessing ''likely to benefit,'' which was used to inform targeted outreach requirements both prior to and during the plan year. However as noted previously, CMS recognizes that an individual Part D enrollee may find that they would personally benefit from the program even if they would not be identified as likely to benefit under this particular standardized framework. Those individuals are certainly permitted to opt into the program, as are all Part D enrollees. The definition and framework for ''likely to benefit'' described in the final part one guidance is specifically for identifying Part D enrollees for targeted outreach and communication in the absence of any information regarding an individual's specific financial circumstances.

As described in the final part one guidance, in retrospective modeling of prescription drug event (PDE) data, CMS found that to be ''likely to benefit'' from the program, the Part D enrollee would have to incur some level of substantial OOP costs; further, the Part D enrollee's highest monthly OOP cost incurred would have to be more than the highest monthly paid amount under the Medicare Prescription Payment Plan (if the program had applied). CMS used this approach to identify ''likely to benefit'' because it focuses on addressing Part D enrollees' potential cash-flow concerns by lowering their maximum OOP costs in a month (and limiting the potential for participants to be faced with Medicare Prescription Payment Plan monthly payments that may initially provide substantial financial relief but later, due to timing constraints, result in monthly beneficiary payments that are higher than they would have been absent the program). This approach strictly compares the monthly OOP amounts with and without the Medicare Prescription Payment Plan, without any subjective assessments of what amount might be beneficial to an individual Part D enrollee. CMS used the approach described previously to set thresholds for targeted outreach criteria in the first year of the program (2025). In the final part one guidance, we established a 2025 POS notification threshold of $600 for a single prescription. Additional details regarding the POS notification process are described in section (h) of this proposed rule.

In the final part two guidance, we established a requirement for Part D sponsors to notify enrollees who were likely to benefit prior to the 2025 plan year. In setting criteria to identify Part D enrollees likely to benefit prior to the plan year, CMS seeks to identify individuals who have persistently high costs for covered Part D prescription drugs. That is balanced, however, by a desire to limit notifications to Part D enrollees who are not likely to benefit from participation in the program (such as Part D enrollees for whom the program would initially provide substantial financial relief but later, due to timing constraints, would result in monthly payments that are higher than they would have been absent the

program). With the goal of assessing the persistence of high OOP costs, and thus, the likelihood of a prior year's OOP costs predicting future OOP burden, CMS analyzed PDE records. CMS first identified Part D enrollees who had incurred total OOP costs of at least $2,000 in the first three quarters of 2021, then examined their total OOP costs in the subsequent year, 2022. CMS's analysis was based on the patient payment amount for covered Part D claims only, reflecting the actual OOP financial burden for Part D enrollees.

In the final part two guidance, we established that to fulfill the requirements for prior to the plan year notification, during the fourth quarter of the year, Part D sponsors must review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. For CY 2025, Part D sponsors are required to conduct outreach to Part D enrollees who incurred at least $2,000 in OOP costs for covered drugs through September of 2024. Based on this analysis and any additional analysis Part D sponsors conduct to identify enrollees who may be likely to benefit from this program, the Part D sponsor must send the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to identified enrollees no later than the end of the Annual Election Period (open enrollment), which is December 7 of each year. For example, for CY 2025, Part D sponsors assessed claims for covered Part D drugs with dates of services from January through September 2024 and sent the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' in October, November, or early December 2024 (no later than December 7, 2024). If Part D sponsors develop supplemental strategies for identification of Part D enrollees likely to benefit prior to the plan year, these notifications must be provided during the same timeframe.

In the final part two guidance, we established that prior to the plan year, when a Part D sponsor identifies current Part D enrollees as likely to benefit using the methods noted previously, it is then required to notify each such Part D enrollee in writing that they are likely to benefit from the Medicare Prescription Payment Plan, using the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice.'' This outreach may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods) and must include a Medicare Prescription Payment Plan election request form. The outreach must also include additional information about the Medicare Prescription Payment Plan; this additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V and in the Medicare Communications and Marketing Guidelines (MCMG) Additionally, the initial notice may be provided via telephone, so long as the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' and additional information are sent within 3 calendar days of the telephone notification.

In the final part two guidance, we established that while Part D sponsors are required to notify all Part D enrollees who meet the criteria outlined previously, Part D sponsors should be aware that potential changes to a Part D enrollee's clinical condition, medication status, or cost sharing (for example, discontinuation of therapy or addition of supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the Medicare Prescription Payment Plan. Part D sponsors should be aware of potential status changes when contacted by an enrollee to discuss participation in the program and should counsel enrollees accordingly.

In addition to the criteria for identification of Part D enrollees likely to benefit from the program *in advance of* an upcoming plan year, in the final part two guidance, CMS established a requirement for 2025 for Part D sponsors to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. For example, Part D sponsors may undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription for a Part D enrollee that would trigger the pharmacy POS notification process. If Part D sponsors have prior authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold, then the Part D sponsor could initiate outreach to the Part D enrollee based on approved prior authorization requests, informing them of the Medicare Prescription Payment Plan and of the opportunity to opt into the program.

A Part D enrollee is less likely to benefit from opting in during the last quarter of a year (for example, in December, the last month of the plan year, because OOP costs for the Medicare Prescription Payment Plan in that month cannot be spread over more than 1 month). As such, in the final part one and final part two guidance, we established that a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year for that plan year; however, Part D sponsors may choose to provide them with information on how to opt into the program for the upcoming year. Participants who have already opted into the Medicare Prescription Payment Plan should not be notified about opting into the program while their participation is in effect. Additionally, enrollees who are precluded from opting into the program due to failed monthly payment after conclusion of the required grace period should not be notified that they are likely to benefit from the program during the plan years in which they are precluded from participating in the program. Finally, PDPs that are non-renewing their contracts or individual plan benefit packages are not required to comply with the requirements at § 423.137(e)(3)(i) related to prior to plan year targeted outreach. Non-renewing PDPs must still comply with the requirements at § 423.137(e)(3)(ii) related to during the plan year targeted outreach through the end of the plan year but are not required to identify and outreach to Part D enrollees likely to benefit from the program in the upcoming plan year.

In the final part two guidance, we established that Part D sponsors may develop strategies other than the approach outlined previously for identification of additional Part D enrollees likely to benefit during the plan year. However, Part D sponsors must develop standardized processes for implementing their criteria for identification of enrollees likely to benefit from the program during the plan year, including outreach timeframe and mode of communication, and must apply any identification criteria to every Part D enrollee uniformly.

In the final part two guidance, we established that during the plan year, when a Part D sponsor identifies current Part D enrollees as likely to benefit from the program, it is required to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the identified Part D enrollee along with a Medicare Prescription Payment Plan election request form and additional information about the Medicare Prescription Payment Plan. This additional information requirement may be fulfilled by including with the notice

the CMS-developed fact sheet about the program. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V and in the MCMG. This outreach may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods). Additionally, the initial notice may be provided via telephone, so long as the written ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' election request form, and additional information are sent within 3 calendar days of the telephone notification. Part D sponsors are encouraged to inform the Part D enrollee that they are likely to benefit when contacting the Part D enrollee for other reasons, such as while communicating a prior authorization coverage determination.

For the initial years of the program, we propose to maintain the criteria for Part D sponsor outreach prior to the plan year, during the plan year, and at the point of sale that were established in the final part one and final part two guidance for 2025. More specifically, we propose that Part D sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed the POS threshold of $600. To identify Part D enrollees likely to benefit in advance of the plan year, we propose that Part D sponsors be required to assess their current Part D enrollees' prescription drug costs from the current year and conduct outreach to Part D enrollees who incurred $2,000 in OOP costs for covered Part D drugs through September of that year. We also propose that Part D sponsors will be required to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. As described in this section, an example of a reasonable guideline for ongoing identification during the plan year would be a standardized approach in which a Part D sponsor undertakes targeted outreach to Part D enrollees when they become aware in advance (such as through the prior authorization process) of a new high-cost prescription that would trigger the pharmacy POS notification process. We remind Part D sponsors that they must develop standardized processes for implementing their criteria for identification of enrollees likely to benefit from the program during the plan year, including outreach timeframe and mode of communication, and must apply any identification criteria to every Part D enrollee uniformly.

We plan to revisit these requirements in future rulemaking, as CMS gains program experience and can evaluate program data and operations. In general, we expect to maintain the same overall framework for targeted outreach, which will include a POS notification threshold based on incurred OOP costs, prior to plan year criteria based on incurred OOP costs in the current year, and requirements for Part D sponsors to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year. We would assess the targeted outreach requirements for the POS notification threshold and prior to plan year criteria on an annual basis and make modifications, if needed, based on review and analysis of Medicare Prescription Payment Plan data and other Medicare data, including: (1) analysis of program participation levels; (2) analysis of the proportion of participants who met our definition of ''likely to benefit,'' as established in the final part one guidance and described in this section, based on actual OOP costs incurred and program payments; (3) analysis of the proportion of Part D enrollees who would have met our definition of ''likely to benefit'' if they had elected into the Medicare Prescription Payment Plan but were not identified based on current targeted outreach criteria; (4) program operations; and (5) level of burden on pharmacies and Part D sponsors. After the assessment and review of the aforementioned factors, CMS would then publish the specific targeted outreach parameters for the upcoming plan year. In this proposed rule, CMS is not codifying an approach to modifying targeted outreach criteria for future years of the program; however, we seek comment on the approach described here and will use feedback from interested parties to support future policy development.

In addition to the agency's authorities with respect to the Medicare Prescription Payment Plan under section 11202 of the IRA, CMS also has authority under section 1860D–12(b)(3)(D) of the Act to impose additional contractual terms and conditions on Part D plan sponsors that are necessary and appropriate. Consistent with our authority under section 11202 of the IRA and under section 1860D–12(b)(3)(D) of the Act, in this proposed rule, we propose to codify the targeted outreach framework and thresholds established in the final part one and final part two guidance at § 423.137(e).

Specifically, we propose to codify the likely to benefit criteria at paragraph (e)(1), the requirements for the pharmacy POS notification at paragraph (e)(2), and the requirements for Part D sponsor direct outreach to identified likely to benefit enrollees prior to and during the plan year at paragraph (e)(3). Additionally, we propose to codify the targeted outreach notification and education requirements at paragraph (e)(4) and to codify targeted outreach exclusions at paragraph (e)(5). Finally, we propose to add the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' as a required standardized communication material for Part D sponsors at § 423.2267(e)(47).

As stated in the final part two guidance for 2025, the thresholds published by CMS are a minimum requirement. Part D sponsors may develop supplemental strategies for identification of additional Part D enrollees likely to benefit prior to and during the plan year. If supplemental strategies are implemented, then Part D sponsors must apply any additional identification criteria to every enrollee of each plan equally, which we propose to codify at paragraph (e)(1)(ii).

We are not scoring any aspects of this provision related to the development and distribution of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' in the Collection of Information section of this rule since we believe all information impacts of those provisions have already been accounted for under OMB control number 0938–1475.

(e) Termination of Election, Reinstatement, and Preclusion

Section 1860D–2(b)(2)(E)(v)(IV)(aa) of the Act requires a Part D sponsor to terminate an individual's Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount. In addition, under section 1860D–2(b)(2)(E)(v)(IV)(bb) of the Act, Part D sponsors may preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual fails to pay the amount billed for a month as required under the program.

In the final part one guidance, we established standards for termination of election, reinstatement, and preclusion in 2025 consistent with the statutory requirements. CMS established procedures for voluntary termination of election, under which Part D sponsors are required to have a process to allow a participant who has opted into the

Medicare Prescription Payment Plan to opt out during the plan year. In the final part two guidance, we stated that the Part D sponsor must process the participant's voluntary termination request and send the individual a notification confirming the termination within 10 calendar days of receipt of the request but did not specify the effective date of termination. For 2026 and subsequent years, we propose to maintain the requirement for Part D sponsors to send the notice of voluntary termination within 10 calendar days of receipt but require that the effective date of termination must be within 24 hours of receipt of the voluntary termination request. We believe this aligns with the required timeframe for processing election requests during the plan year and ensures timely response to opt out requests during the plan year. We seek comment on this proposal.

When a participant opts out of the Medicare Prescription Payment Plan, a Part D sponsor must provide the individual with a notice of termination after the individual notifies the Part D sponsor that they intend to opt out under the Part D sponsor's established process. The notice of voluntary termination must include—

- Pertinent dates, including the date on which the individual's participation in the program ends;
- An explanation that the individual is receiving the notice either because they requested a voluntary termination or because they changed Part D plans;
- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted;
- A statement clarifying that the individual will continue to be billed monthly or can choose to pay the amount owed all at once, and that the individual will not pay interest or fees on the amount owed;
- A statement clarifying that the individual can join the Medicare Prescription Payment Plan again and instructions for how to do so, which may differ depending on whether the voluntary termination was requested by the individual or if it was because the individual changed Part D plans; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs.

The Part D sponsor must also offer the participant the option to repay the full outstanding amount in a lump sum. However, the Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan. If the participant opts not to repay the full outstanding amount in a lump sum, the sponsor must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated. In this rule, for 2026 and subsequent years, we propose to codify these requirements at § 423.137(f)(2)(i) and to add the voluntary termination notice as a required material and content for Part D sponsors at § 423.2267(e)(50).

CMS issued model material that Part D enrollees can use to fulfill the voluntary termination notice requirement through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS–10882; OMB 0938–1475) ICR package. As established in § 423.2267(c), model materials and content are required materials and content created by CMS as an example of how to convey beneficiary information. If Part D sponsors choose to not use the CMS-developed model notice and develop their own voluntary termination notice, they must include all of the required elements outlined at § 423.137(f)(2)(i)(A)(2)(ii). These notification and content requirements are consistent with the requirements outlined in the final part two guidance for 2025.

We also established standards for involuntary termination in 2025, including requirements for the provision of a grace period of at least two months when an individual has failed to pay the billed amount by the payment due date. If an individual fails to pay the billed amount within 15 calendar days of the payment due date, the Part D sponsor must send the individual an initial notice of failure to pay. The notice of failure to pay must include—

- Pertinent dates and key pieces of information, including the date the missed monthly payment was due, the amount the individual must pay to remain in the program, and the date by when payment must be received, which is the date of the end of the grace period;
- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted;
- Instructions for how to submit payment;
- Information about procedures for involuntary termination due to failure to pay, including the date on which the participant would be removed if payment is not received, and how to submit an inquiry or file a grievance;
- A statement on how individuals should pay their Part D plan premium first if they cannot afford both their premium and their program balance; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs.

If the individual fails to pay the amount due by the end of the grace period, the Part D sponsor must send the individual an involuntary termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan. The involuntary termination notice must be sent within 3 business days following the last day of the end of the grace period, and must include the following:

- Pertinent dates, including the date the individual was originally notified of the missed monthly payment and the due date for that payment, as well as the date on which the individual's participation in the program ends, which should be the same date as the notice;
- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted;
- Instructions for how to submit payment and the amount owed;
- How to submit an inquiry or file a grievance;
- A statement clarifying that the individual can join the Medicare Prescription Payment Plan again if they pay the amount owed; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs.

If either the notice of failure to pay or notice of involuntary termination is returned to the Part D sponsor as undeliverable, the Part D sponsor must immediately implement its existing procedure for researching a potential change of address. In this rule, for 2026

and subsequent years, we propose to codify these notice requirement standards at § 423.137(f)(2)(ii) and to add the notice of failure to pay and notice of involuntary termination as required model materials and content for Part D sponsors at § 423.2267(e)(48) and (e)(49).

CMS issued model materials that Part D enrollees can use to fulfill the failure to pay and involuntary termination notice requirements through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS–10882; OMB 0938–1475) ICR package. As established in § 423.2267(c), model materials and content are required materials and content created by CMS as an example of how to convey beneficiary information. If Part D sponsors choose to not use the CMS-developed models and develop their own notice of failure to pay or involuntary termination notice, they must include all of the required elements for each notice outlined at § 423.137(f)(2)(ii)(C)(*2*) and (D)(*2*), respectively. These notification and content requirements are consistent with the requirements outlined in the final part two guidance for 2025.

We also set forth requirements for 2025 related to the grace period and reinstatement. When a program participant fails to pay a program bill, the Part D sponsor must provide individuals with a grace period of at least two months upon notifying the individual of the initial missed payment.

We propose to make certain modifications to the timing requirements for the grace period and initial notice of nonpayment established in the final part one guidance. Specifically, in the final part one guidance, we stated that the grace period must begin on the first day of the month for which the balance is unpaid or the first day of the month following the date on which the payment is requested, whichever is later. In this proposed rule, we propose to change the date on which the grace period must begin to the first day of the month following the date on which the initial notice is sent. We believe this would simplify the timing requirements for the notice of nonpayment and the required grace period. We seek comment on whether to adopt this change or continue with the approach described in the final part one guidance.

In the final part one guidance for 2025, we also stated that if a participant fails to pay their monthly billed amount with fewer than two full calendar months remaining in the calendar year, the grace period must carry over into the next calendar year. If the program participant is within their grace period from the prior year, the Part D sponsor must allow the participant to opt into the program for the next year, but if the participant fails to pay the amount due from the prior year during the required grace period, the Part D sponsor may terminate the individual's participation in the program in the new year.

A participant must be allowed to pay the overdue balance in full during the grace period to remain in the program. Additionally, Part D sponsors must reinstate an individual who has been terminated from the Medicare Prescription Payment Plan within a reasonable timeframe if the individual demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed. In response to public comments received on the final part one guidance, we clarified that CMS was adopting the same meaning of ''good cause'' outlined in section 60.2.4 of the Medicare Prescription Drug Benefit Manual, Chapter 3—Eligibility, Enrollment and Disenrollment that applies to reinstatements when an enrollee fails to pay their Part D premiums. CMS also described specific circumstances that constitute good cause, including—

- A serious illness, institutionalization and/or hospitalization of the program participant or their authorized representative (that is, the individual responsible for the participant's financial affairs), that lasted for a significant portion of the grace period for Medicare Prescription Payment Plan payment;
- Prolonged illness that is not chronic in nature, a serious (unexpected) complication to a chronic condition or rapid deterioration of the health of the participant, a spouse, another person living in the same household, a person providing caregiver services to the participant, or the participant's authorized representative (that is, the individual responsible for the participant's financial affairs) that occurs during the grace period for the Medicare Prescription Payment Plan payment;
- Recent death of a spouse, immediate family member, person living in the same household, or person providing caregiver services to the participant, or the participant's authorized representative (that is, the individual responsible for the participant's financial affairs);
- Home was severely damaged by a fire, natural disaster or other unexpected event, such that the participant or the participant's authorized representative was prevented from making arrangement for payment during the grace period for the Medicare Prescription Payment Plan;
- An extreme weather-related, public safety or other unforeseen event declared as a Federal or state level of emergency prevented premium payment at any point during the Medicare Prescription Payment Plan grace period. For example, the participant's bank or U.S. Post Office closes for a significant portion of the grace period; or
- For Part D plan disenrollments effectuated by CMS for failure to pay Part D Income Related Monthly Adjustment Amount (IRMAA), Federal government error (that is, CMS, SSA or the Railroad Retirement Board (RRB)) caused the Medicare Prescription Payment Plan payment to be incorrect or late, and the participant was unaware of the error or unable to take action prior to the disenrollment effective date.

In addition, we stated that there may be circumstances other than those listed which meet the definition of good cause, provided these circumstances meet the standard of being outside of the participant's control or are unexpected such that the participant could not have reasonably foreseen their occurrence, and these circumstances are the cause for the non-payment of past due program balances. Finally, we stated that a Part D sponsor may reinstate an individual who has been terminated from the Medicare Prescription Payment Plan and pays all overdue amounts billed in full, at the sponsor's discretion and within a reasonable timeframe, even if the individual does not demonstrate good cause. In this rule, for 2026 and subsequent years, we propose to codify these grace period and reinstatement requirements at § 423.137(f)(3).

We also established standards for 2025 for preclusion of election in a subsequent plan year. We clarified that, consistent with the statute, a Part D sponsor may only preclude an individual from participating in the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that plan sponsor. If an individual enrolls in a Part D plan offered by a different Part D sponsor than the Part D sponsor to which the individual owes an overdue balance, that individual cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by that different Part D sponsor. We also stated that preclusion may extend beyond the immediate subsequent plan year if a Part D enrollee

remains in a plan offered by the same Part D sponsor and continues to owe an overdue balance. While a Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plans, the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan. In this rule, for 2026 and subsequent years, we propose to codify requirements related to preclusion of election in a subsequent plan year at § 423.137(f)(4).

For 2025, we established a prohibition on Part D enrollment penalties for failure to pay a Medicare Prescription Payment Plan amount billed. We stated that a Part D plan sponsor is prohibited from disenrolling a Part D enrollee from a Part D plan or declining future enrollment into a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan. In this rule, for 2026 and subsequent years, we propose to codify this requirement at § 423.137(f)(5).

Finally, we clarified that, if a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions at 42 CFR 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan. In this rule, for 2026 and subsequent years, we propose to codify this requirement at § 423.137(f)(6). We note that nothing in proposed section § 423.137(f) prohibits a Part D sponsor from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed.

We are not scoring any aspects of this provision related to the development and distribution of the notice of voluntary termination, the notice of failure to pay, and the notice of involuntary termination in the Collection of Information section of this rule since we believe all information impacts of those provisions have already been accounted for under OMB control number 0938–1475.

(f) Participant Billing Rights

Section 1860D–2(b)(2)(E)(iii) of the Act requires Part D sponsors, on a monthly basis, to bill participants who are in the Medicare Prescription Payment Plan and incur OOP costs for the Medicare Prescription Payment Plan an amount that cannot exceed the applicable maximum monthly cap.

In the final part one guidance, we established standards for participant billing rights for 2025 consistent with the statute. Specifically, we established that for each billing period after an individual has opted into the program, a Part D sponsor must not bill a participant who is in the program but has not yet incurred any OOP costs for the Medicare Prescription Payment Plan during the plan year. The Part D sponsor will calculate a monthly amount that takes into account the OOP costs for the Medicare Prescription Payment Plan in that month that were incurred on or after the date on which the individual opted into the program, and that each billing period will be a calendar month. In the final part one guidance, we further explained that the billing period begins either on the effective date of a Part D enrollee's participation in the Medicare Prescription Payment Plan (for the first month a participant elects into the program during the plan year) or the first day of the month (for each subsequent month or for the first month of a participant who elects into the program prior to the start of the plan year). The billing period ends on the last date of that month. Additionally, in the final part one guidance, we established that Part D sponsors must send a bill for the Medicare Prescription Payment Plan that is separate from the bill for the collection of premiums, if applicable, and continue to follow existing regulations and guidance for the collection of premiums as described at 42 CFR 423.293.

We clarified that past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap. However, the amount billed for the month for which the maximum monthly cap is being calculated cannot be higher than the cap for that month as established in the statute.

We also encouraged Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by check and to offer participants flexibility around requesting a specific day of the month for program charges and withdrawals from a bank account. We reiterate that encouragement here.

In addition, we stated that, because under section 1860D–2(b)(2)(E)(iii) of the Act, Part D sponsors may not bill a participant more than the maximum monthly cap, late fees, interest payments, or other fees, such as for different payment mechanisms, are not permitted under the Medicare Prescription Payment Plan. We also stated that plan sponsors are responsible for ensuring that any third parties they contract with also comply with such requirements.

We also reminded Part D sponsors (and any third parties Part D sponsors contract with) that actions to collect unpaid balances related to the Medicare Prescription Payment Plan may be subject to other applicable Federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection. These requirements also apply in the event of a death of a program participant.

We also stated that, while Part D sponsors may create their own billing and payment procedures for the Medicare Prescription Payment Plan, Part D sponsors are required to prioritize payments towards Part D plan premiums to avoid a Part D enrollee losing their Part D coverage when it is unclear whether a payment received from a participant is intended by the participant to cover their outstanding Part D plan premium or Medicare Prescription Payment Plan balance. Specifically, if a Part D enrollee has opted into the program and makes payments directly to the Part D sponsor, and it is unclear whether a payment should go towards the participant's outstanding Part D plan premium or Medicare Prescription Payment Plan balance, the Part D sponsor may contact the enrollee to clarify the purpose of the payment. If the Part D sponsor does not contact the enrollee or is not able to ascertain the purpose of the payment, then the payment must be applied to the Part D premium.

Under section 1860D–2(b)(2)(E)(v)(VI) of the Act, Part D sponsors must treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses. In addition, the statute requires that the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids. In the final part two guidance, we stated that if a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, it cannot treat the amount as a loss and cannot include it in its bid. Only uncompensated unsettled balances can be included in the bid. We also stated that the Part D bid pricing tool (BPT) has been modified to reflect projected losses associated with the Medicare Prescription Payment Plan. Specifically, these losses must be reflected as administrative costs in the Part D BPT.

Under section 1860D–2(b)(2)(E)(v)(III)(gg) of the Act, Part D sponsors must have a financial reconciliation process in place to correct

inaccuracies in billing and/or payments. In the final part one guidance, we established standards for Part D sponsors related to financial reconciliation for Medicare Prescription Payment Plan payments. We stated that while a Part D sponsor may not bill a program participant an amount for a month that is more than the maximum monthly cap, a participant may pay more than the maximum monthly cap, up to the annual OOP threshold. However, the participant cannot pay more than their total OOP costs for the Medicare Prescription Payment Plan. If a participant does pay more than their total OOP costs for the Medicare Prescription Payment Plan, the Part D sponsor must reimburse the participant the amount that is paid above the balance owed.

In addition, in the final part one guidance, we stated that, for 2025, CMS expects that Part D sponsors will develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants and that Part D sponsors bear the responsibility for timely financial reconciliation with Part D enrollees. Federal regulations at 42 CFR 423.466(a) require sponsors to process the adjustment and issue refunds or recovery notices within 45 calendar days of receipt of LIS changes, Financial Information Reporting (FIR), or Information Reporting (Nx) transactions necessitating the claims adjustment. As such, Part D sponsors must make the retroactive adjustments and promptly issue refunds or initiate recovery once complete information regarding a claim's adjustment is received. In the final part one guidance, we also stated that the plan must work with the participant to determine if they should either refund the difference directly to the Part D enrollee or apply the overpayment to the remaining OOP costs owed. In addition, Part D sponsors are responsible for appropriately updating TrOOP accumulators and restacking claims.

We also stated that when reconciliation results in an increased amount owed by the participant, plans should recalculate the maximum monthly cap for the month(s) in question. As stated in the final part one guidance, under section 1860D–2(b)(2)(E)(iv)(II) of the Act, for each subsequent month for which the Part D enrollee has opted into the program, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs for the Medicare Prescription Payment Plan in the subsequent month, divided by the number of months remaining in the plan year. When Part D claims adjustments result in increased amounts owed by the participant, and these amounts have not yet been billed to the participant, they should be included in the revised remaining OOP costs owed by the participant and, thus, in the subsequent month maximum cap for the next billing period. Finally, when a covered Part D drug claim adjustment occurs after the end of a plan year, the Part D sponsor should use the general guidance provided earlier in this section to appropriately recalculate the amount owed to or by the participant and issue a final bill or refund, as necessary.

In this proposed rule, we propose to codify the requirements established for calendar year 2025 in the final part one guidance discussed in this section for 2026 and subsequent years at § 423.137(g) with an exception. In the final part one guidance, we stated that the plan must work with the participant to determine if they should either refund the difference directly to the Part D enrollee or apply the overpayment to the remaining OOP costs owed by the participant. In this proposed rule, we are proposing to modify that requirement and instead require a plan follow its normal processes for adjustments and issuing refunds. We believe this modification will simplify operational processes on the part of Part D sponsors without negatively impacting Medicare Prescription Payment Plan participants. In addition, in this proposed rule, we are proposing to modify the approach when Part D claims adjustments result in increased amounts owed by the participant; instead of stating that Part D sponsors ''should'' include the additional costs in the revised remaining OOP costs owed by the participant, we now propose that Part D sponsors ''must'' include the increased amount in this manner. This is consistent with the requirement established in the final part one guidance and included in section (b) of this proposed rule, which states that once a participant incurs an OOP Part D drug cost, all their OOP costs for all covered Part D drugs will be billed on a monthly basis as long as the participant remains in the program as well as the uniform benefits requirements at § 423.104(b)(2). We seek comment on whether we should finalize these proposed changes or adopt the processes as established in the 2025 final part one guidance for 2026 and subsequent years.

We propose to codify the requirement that the Part D sponsor will calculate a monthly amount that takes into account the OOP costs for the Medicare Prescription Payment Plan in that month that were incurred on or after the date on which the individual opted into the program at paragraph (g)(1). We propose to define each billing period as a calendar month at paragraph (g)(2). We propose to establish requirements for the contents of a billing statement at paragraph (g)(3). We propose to establish that unsettled balances with respect to amounts owed under the program will be treated as plan losses at paragraph (g)(4). We propose to establish requirements for prioritization of premium payments at paragraph (g)(5). Finally, we propose to establish general standards for Medicare Prescription Payment Plan financial reconciliation at paragraph (g)(6).

(g) Participant Disputes

In the final part one guidance, we stated that Part D sponsors must apply their established Part D coverage determination and appeals procedures, as required under section 1860D–4(g) and (h) of the Act and § 423.566(a), to any dispute made by a Medicare Prescription Payment Plan participant about the amount of Part D cost sharing owed by that participant for a covered Part D drug. We also stated that Part D sponsors must apply their established Part D grievance procedures, which Part D sponsors are required to have in place under section 1860D–4(f) of the Act and § 423.562, to any dispute made by a Medicare Prescription Payment Plan participant related to any aspect of the Medicare Prescription Payment Plan. This includes election requests, billing requirements, and termination-related issues other than disputes related to the amount of Part D cost sharing owed by a participant for a drug. We also clarified that a decision on the amount of cost sharing for a drug is a coverage determination and directed readers to § 423.566(b)(5) and to the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for requirements related to grievances, coverage determinations, and redeterminations. We stipulated that Part D sponsors must use their existing coverage determination, appeals, and grievance procedures for the Medicare Prescription Payment Plan to ensure that Part D enrollees have the ability to contest copay amounts and any adverse decisions related to participation in the Medicare Prescription Payment Plan. Applying existing procedures required under Part D also reduces the need for Part D sponsors to develop new processes and allows Part D enrollees to use

procedures to which they are accustomed.

Consistent with the requirements established in the final part one guidance, at § 423.137(h), we propose to codify requirements for Part D sponsors to apply their existing Part D coverage determination, appeal, and grievance procedures to the Medicare Prescription Payment Plan.

We are not scoring this provision in the Collection of Information section of this rule because it codifies existing guidance, and because the filing of an appeal is an information collection associated with an administrative action pertaining to specific individuals or entities and thus is exempt from Paperwork Reduction Act requirements under 5 CFR 1320.4(a)(2) and (c). We seek comment on this assumption.

(h) Pharmacy POS Notification Process

Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act and discussed in section (d) of this proposed rule, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. The final part one and final part two guidance established standards for 2025 related to pharmacy POS notification processes.

In the final part two guidance, we established that all Part D sponsors must use the standard codes developed by NCPDP for communication with network pharmacies about enrollees' Medicare Prescription Payment Plan status, as appropriate. This includes the mechanism to notify the pharmacy that a Part D enrollee has been identified as likely to benefit based on OOP costs at the POS.

As established in the final part two guidance, in pharmacy settings in which there is direct contact with enrollees (for example, community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. This includes pharmacies with a drive-through or curbside pick-up option. Pharmacies should make available the CMS-developed Spanish-language version of the notice, in lieu of the English-language version, to their patients upon request. Identified enrollees who receive the notice from the pharmacy and need the notice in another format or language are instructed to call their Part D sponsor for assistance. The Part D sponsor should ensure compliance with the language access and accessibility requirements at § 423.2267 in the delivery of the ''Medicare Prescription Payment Plan Likely to Benefit Notice.'' CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed fact sheet, which could also be distributed to Part D enrollees along with the notice.

The final part two guidance established that the requirement to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. Pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan at the time they provide an enrollee with the notice.

In the final part two guidance, CMS established that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription purchase, the Part D sponsor must ensure that the pharmacy provides the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee. For example, if a Part D enrollee visits a retail pharmacy to pick up their prescription but then declines to complete the transaction because of the cost, the Part D sponsor must still ensure that the pharmacy provides the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to that Part D enrollee.

In the final part two guidance, we also established that when a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' from the pharmacy, in addition to providing the notice of election approval, as described in section (c) of this proposed rule, the Part D sponsor is responsible for clearly communicating additional necessary next steps to the Part D enrollee. Next steps may include, but are not limited to, how to proceed with filling any outstanding prescriptions.

In the final part one and final part two guidance, we established that, in general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including mail order, home infusion, specialty, and long-term care pharmacies. However, CMS is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing the physical standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' directly to the Part D enrollee. Therefore, in the final part one and final part two guidance, we established standards for unique pharmacy scenarios and different pharmacy types.

In the final part two guidance, we noted that long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). In these cases, the pharmacy may deliver medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (that is, billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the Part D sponsor should not require that the long-term care pharmacy provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' prior to dispensing the medication. Instead, the Part D sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process. Given our understanding of the variation in how long-term care pharmacies dispense and bill covered Part D drugs, we are not proposing specific timing requirements for provision of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' via long-term care pharmacies. We encourage Part D sponsors to assess the particular circumstances of their network long-term care pharmacies when establishing timing requirements for pharmacy distribution of the notice.

The final part two guidance also described special approaches to the POS notification requirements for Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies. I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan's benefit structure, is not collected at the

POS. As such, if a high-cost prescription drug claim for a Part D enrollee is submitted to a Part D sponsor from an I/T/U pharmacy, the Part D sponsor is not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program. Part D sponsors should also ensure that their customer service representatives are aware of this situation regarding I/T/U pharmacies when receiving inquiries from Part D enrollees regarding program election. In discussing a Part D enrollee's prescription drug costs, customer service representatives may need to review the primary pharmacy type used by the Part D enrollee. Part D enrollees who solely use I/T/U pharmacies, and thus have $0 in OOP costs for covered Part D drugs, may not benefit from participation in the Medicare Prescription Payment Plan.

In the final part two guidance, we established that for other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' prior to processing payment for the prescription that triggered the notice. As with retail pharmacies, CMS encourages other pharmacy types to consider providing the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' via additional modes of communication beyond the requirements in this section, such as through a patient portal or secure email. CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees.

In addition to the notification mechanisms described in the final part two guidance, we also stated that pharmacies may also choose to develop additional strategies to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to enrollees identified as likely to benefit.

In the final part two guidance, we established that, given the statutory requirement for notification of enrollees likely to benefit at the pharmacy point of sale, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees. This provision is sufficient to meet the proposed requirements for Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Additional tracking or documentation by the pharmacy or on behalf of the pharmacy by the Part D sponsor that the notice has been delivered to the identified enrollee is not required.

In the final part two guidance, CMS acknowledged that a small portion of Part D enrollees will have supplemental coverage, such as through an SPAP, charity, or other health insurance (OHI), that will modify the final OOP amount the enrollee would otherwise owe at the point of sale. The ''Medicare Prescription Payment Plan Likely to Benefit Notice'' contains language directing enrollees with supplemental coverage to seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan. Part D sponsors should ensure that their customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election. When discussing a Part D enrollee's prescription drug costs, customer service representatives may need to review records for Information Reporting (Nx) transactions, indicating supplemental coverage or OHI.

As specified by section 1860D–2(b)(2)(E)(iv) of the Act, the number of months remaining in the plan year is an important component of the maximum monthly cap calculation. As described in the final part one guidance, the maximum monthly cap in the first month of program participation is determined by calculating the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year. Given that the pharmacy POS threshold is a static amount, this may result in scenarios late in the plan year in which Part D enrollees who receive the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' at the pharmacy based on their OOP costs, but whose costs are below the maximum monthly cap, are then required to pay the full amount as part of their first month's bill. For example, if a Part D enrollee has not yet opted into the Medicare Prescription Payment Plan and fills a new prescription with an OOP cost of $650 in October 2025, their maximum monthly cap in the first month could be as high as $666.67 (assuming $0 in prior TrOOP accumulation). In this scenario, a Part D enrollee could receive the POS notification based on their OOP costs exceeding the threshold of $600 for 2025, but if they opted into the Medicare Prescription Payment Plan, because their OOP costs are below the maximum monthly cap, the Part D sponsor would bill them for the entire $650 as part of their first month's bill. Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election.

In this proposed rule, we propose to codify the requirements noted previously that were established in the final part one and final part two guidance for 2026 and subsequent years at § 423.137(i). Specifically, we propose to codify the requirement that the Part D sponsor must use standard NCPDP codes for notifying the pharmacy that an enrollee has been identified as likely to benefit at (i)(1). We propose to codify point of sale requirements for the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' at paragraph (i)(2). Finally, we propose to codify requirements for Part D sponsors to include a provision in their pharmacy network contracts requiring pharmacies to provide the likely to benefit notification to Part D enrollees at (i)(3).

(i) Pharmacy Claims Processing

In accordance with section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, Part D sponsors must ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments. In the final part one guidance, we established that Medicare Prescription Payment Plan participants will pay $0 at the POS instead of the OOP cost sharing they would normally pay at the POS when filling a prescription. Consequently, Part D sponsors must pay the pharmacy the enrollee's cost-sharing amount in addition to the Part D sponsor's portion of the payment. The final part one and final part two guidance established standards for 2025 related to pharmacy claims processing. Additional details related to pharmacy payment obligations are discussed in section (j) of this proposed rule.

To ensure a uniform, consistent claims adjudication process and to leverage existing Part D processes to minimize operational burdens, the final part one guidance established that Part D sponsors and pharmacies must use a Bank Identification Number (BIN) and/

or Processor Control Number (PCN) electronic claims processing methodology for applicable Medicare Prescription Payment Plan transactions. CMS believes that this standardized approach to processing claims under the Medicare Prescription Payment Plan satisfies the statutory provisions of the Medicare Prescription Payment Plan (such as enabling $0 OOP cost sharing at the POS for all covered Part D drugs) while also having minimal effect on other existing Part D processes (such as COB claims processing with supplemental payers, PDE cost/payment field reporting, or TrOOP accumulation).

In addition to the agency's authorities with respect to the Medicare Prescription Payment Plan under section 11202 of the IRA, CMS has authority under section 1860D–12(b)(3)(D) of the Act to impose additional contractual terms and conditions on Part D plan sponsors that are necessary and appropriate. Consistent with our authority under section 11202 of the IRA and under section 1860D–12(b)(3)(D) of the Act, in this proposed rule, we propose to codify the requirement that Part D sponsors use, and ensure that pharmacies use, the Medicare Prescription Payment Plan claims processing methodology outlined herein. Except for certain scenarios discussed in the final part two guidance and in detail in this section, Part D sponsors must utilize, and must ensure that pharmacies utilize, an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants. Part D sponsors must provide the unique Medicare Prescription Payment Plan BIN/PCN and any other pertinent billing information to the pharmacy on paid claim responses when the enrollee is also a Medicare Prescription Payment Plan participant.

CMS regulations at 42 CFR 423.120(c)(4) require the Part D sponsor to assign and exclusively use unique routing and beneficiary identifiers for the Medicare Part D program. The intent of the requirement is to ensure that: (1) pharmacies can routinely identify situations in which they are billing a Part D claim, and (2) payers secondary to Part D can properly coordinate benefits on Part D claims. During the bidding process, plans are required to submit BIN/PCN information; CMS periodically extracts and posts the information on the CMS website to assist those involved in the processing of pharmacy claims for beneficiaries enrolled in Part D. The posting of BIN/PCN information would also be of assistance to pharmacies as part of Medicare Prescription Payment Plan transaction processing as it provides the information necessary for a pharmacy to route the claim to the correct processor. We required in final part one guidance that Part D sponsors assign a program-specific PCN that starts with ''MPPP.'' In addition, Part D sponsors must report the new BIN/PCN to CMS.

The method established in the final part one guidance results in two transactions being submitted by the pharmacy to the same Part D sponsor (or their PBM), using two different BIN/PCN combinations. The Part D sponsor's primary unique BIN/PCN (as required by 42 CFR 423.120(c)(4)) is used for the initial Part D claim adjudication; the Part D sponsor then returns the appropriate OOP cost sharing amount in the NCPDP Telecommunication Standard response pricing segment field ''Patient Pay Amount'' (505–F5). Then, a second Medicare Prescription Payment Plan BIN/PCN is used to process only the final OOP participant liability amount; this process accounts for any other payments made by supplemental coverage to which the participant may be entitled that may reduce the participant's OOP cost. The transaction processed through the Medicare Prescription Payment Plan BIN/PCN must be submitted after processing any applicable other payer transactions in order to capture the final patient responsibility amount after all other payers have paid. This allows the Part D sponsor to pay the pharmacy for the amount the participant would otherwise have paid at the POS to obtain their prescription. This process also allows the ''Patient Pay Amount'' to be used by Part D sponsors for other downstream reporting requirements, such as PDE records and explanation of benefits (EOB) reporting, which reflect the actual participant liability amounts as incurred.

To clarify, Medicare Prescription Payment Plan payments are not considered to be OHI, as the participant's Part D sponsor is the source of both primary and Medicare Prescription Payment Plan payments to the pharmacy. Information Reporting (Nx) transactions will not be generated for Medicare Prescription Payment Plan COB transactions, as the Part D plan is the entity processing both the primary and Medicare Prescription Payment Plan claims and will already be aware of necessary transaction data.

The process established in the final part one guidance also allows Part D sponsors to continue to adhere to Medicare Secondary Payer (MSP) laws and any other Federal and state laws establishing payers of last resort (for example, AIDS Drug Assistance Programs (ADAPs)), as discussed in the Medicare Prescription Drug Benefit Manual Chapter 14, Section 30.3.13. As noted earlier in this section, transactions submitted through the Medicare Prescription Payment Plan BIN/PCNs are to be processed after all other payers, including SPAPs, ADAPs, or charities. CMS is aware of concerns that the return of a $0 claim response at the POS may inhibit pharmacies from offering suggestions for their patients to explore other mechanisms to reduce OOP costs, like charitable organizations. CMS recognizes the importance of charitable organizations and other supplemental payers in reducing OOP costs for eligible Part D enrollees; nothing in the final part one or part two guidance prohibits pharmacies from continuing their current practices with regard to recommending charitable support to patients.

The final part two guidance also noted that final patient pay amount returned to the pharmacy by a supplemental payer for a covered Part D drug may occasionally be higher than the original Part D patient pay amount. In these cases, for the program participant's portion of the claim (what they would have paid directly to the pharmacy), the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant's original Part D cost sharing, as determined by their plan-specific benefit structure.

The final part one guidance stated that Part D sponsors must ensure that there is no impact to PDE cost/payment field reporting as a result of this claims processing methodology. PDE submissions must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply. Additionally, this approach should have no impact to prescriber or participant real-time benefit tools, meaning participant liability amounts must be represented as if the Medicare Prescription Payment Plan did not apply. If the individual has opted into the program, Part D sponsors can consider providing patient costs that reflect the program in their participant real-time benefit tool, as long as the total expected cost-sharing is clearly communicated to the individual. If the individual has not opted into the program, the participant real-time benefit tool could be used to alert the individual about the program (either generally or conditionally when the participant real-time benefit tool returns a liability amount over a particular dollar amount).

Except as proposed in paragraph § 423.137(d)(6) of this proposed rule, Part D sponsors are not required to include under this program paper claims submitted to the Part D sponsor by a Medicare Prescription Payment Plan participant. ''Paper claims'' refer to any claims for which the participant requests retroactive reimbursement by the Part D sponsor (whether the request is made via a paper form, telephonically, or electronically), including requests for direct member reimbursement for OON claims.

In the final part two guidance, we established requirements for the readjudication of eligible prescription drug claims for new Medicare Prescription Payment Plan participants. When a Part D enrollee receives the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription that triggered the notification. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription after successfully opting into the program, the prescription claim that triggered the notification must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. Should a Part D enrollee have other unpaid claims at the same pharmacy for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification, they may also request that those claims be readjudicated, so as to be included in the Medicare Prescription Payment Plan. CMS encourages Part D sponsors to provide their enrollees with education and information on how to proceed with readjudication of other unpaid claims for covered Part D drugs.

For example, a Part D enrollee is prescribed a new medication with an OOP cost that is above the POS notification threshold. The Part D sponsor would notify the pharmacy that the enrollee is likely to benefit from the Medicare Prescription Payment Plan. The pharmacy would then provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee. The enrollee decides to leave the pharmacy without paying for their high-cost prescription, so they can contact their plan and opt into the program. However, the pharmacy also has two other covered Part D prescriptions filled for the Part D enrollee from prior dates of service, for which the Part D enrollee also decided to leave the pharmacy without picking up and paying. When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the Part D sponsor must require the pharmacy to reverse and reprocess the high-cost claim that triggered the likely to benefit notification. The program participant would then pay $0 at the pharmacy for the high-cost claim and pay their typical plan-defined cost sharing for the other claims with prior dates of service. Alternatively, the Part D enrollee could request that the pharmacy reverse and reprocess all three claims, so the program participant pays $0 at the pharmacy for all three drugs.

In the case of same-day program effectuation (when the Part D claim date of service is the same as the date of program effectuation), the pharmacy is not required to reverse and resubmit the Part D claim, provided that the pharmacy otherwise obtains the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

CMS noted that Part D sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. As noted in the final part one guidance and proposed here at § 423.137(d)(6), Part D sponsors must have processes in place to reimburse enrollee cost sharing when an enrollee has met the conditions for a retroactive election into the Medicare Prescription Payment Plan.

As noted in section (h) of this proposed rule, in the final part one and final part two guidance, we established that, in general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including mail order, home infusion, specialty, and long-term care pharmacies. However, CMS is aware that different pharmacy types may have slightly different approaches to processing covered Part D claims for Medicare Prescription Payment Plan participants. Therefore, in the final part one and final part two guidance, we established standards for unique pharmacy scenarios and different pharmacy types.

The final part two guidance described the processing of covered Part D claims for Medicare Prescription Payment Plan participants in special pharmacy settings. As discussed in that guidance, CMS is aware that there are multiple types of payment arrangements between long-term care pharmacies and long-term care facilities and/or Part D enrollees. In some situations, long-term care pharmacies do not collect Part D cost sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the Medicare Prescription Payment Plan, billing the participant's Part D plan's Medicare Prescription Payment Plan BIN/PCN for the participant's OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. Given our understanding of the variation in how long-term care pharmacies dispense and bill covered Part D drugs, we are not proposing specific requirements for Part D sponsors related to the use of the Medicare Prescription Payment Plan BIN/PCN with long-term care pharmacies. CMS encourages Part D sponsors to take the participant's particular circumstances into account when considering Medicare Prescription Payment Plan billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant.

Additionally, as noted in section (h) of this proposed rule, I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan's benefit structure, is not collected at the POS. Given that, if an IHS-eligible Part D enrollee is also participating in the Medicare Prescription Payment Plan, the Part D plan sponsor must ensure that the I/T/U pharmacy does not bill the Part D plan's Medicare Prescription Payment Plan BIN/PCN. Instead, the Part D plan sponsor must ensure that the I/T/U pharmacy processes the claim as if the IHS-eligible enrollee were not participating in the Medicare Prescription Payment Plan. If a Part D sponsor receives a claim from an I/T/U pharmacy that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim. To help prevent this situation from occurring, Part D sponsors must also put in place processes to prevent Medicare Prescription Payment Plan BIN/PCNs from being returned on paid claim responses to I/T/U pharmacies. These requirements apply only with respect to I/T/U pharmacies that dispense prescriptions at no cost to the IHS enrollee. The Part D sponsor must

ensure other network pharmacies providing services to Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements, as established in the final part one guidance and final part two guidance.

At § 423.137(j)(7), we propose requirements related to transparency around OOP costs for the Medicare Prescription Payment Plan at the pharmacy POS, a topic CMS did not address through program instruction for CY 2025. Once an enrollee is a participant in the Medicare Prescription Payment Plan, they will pay $0 at the pharmacy POS. Part D sponsors then correctly calculate the monthly caps based on the statutory formulas, determine the amount to be billed, and send monthly bills to program participants. CMS has heard concerns about the potential lack of participant visibility into their OOP costs for the Medicare Prescription Payment Plan at the POS, given the $0 final claim response from the Part D sponsor to the pharmacy. As noted in the final part two guidance, CMS strongly encourages Part D sponsors to educate program participants on the options for assessing OOP costs for the Medicare Prescription Payment Plan prior to the pharmacy POS (such as utilizing interactive prescription drug cost tools available on the Part D sponsor's website or calling the plan's customer service line). However, to provide additional support for OOP cost transparency for Medicare Prescription Payment Plan participants, we are proposing requirements for Part D sponsors to ensure that pharmacies can easily access information on a Part D enrollee's OOP costs for the Medicare Prescription Payment Plan for prescriptions processed under the program at the POS. These costs should be provided in the paid claim billing response on the Medicare Prescription Payment Plan COB transaction. In addition, Part D sponsors must ensure that pharmacies are prepared to provide this information to a participant at the POS. We seek comment on the proposal, including suggested processes for how Part D sponsors can provide this information to pharmacies in a manner that conforms with existing standards.

In this proposed rule, we propose to codify the requirements established in the final part one and final part two guidance for 2026 and subsequent years and noted previously at § 423.137(j). We propose to codify that Part D sponsors and pharmacies must use a BIN/PCN electronic claims processing methodology for Medicare Prescription Payment Plan transactions at paragraph (j)(1). We propose to codify the requirement for handling of higher final patient pay amounts from supplemental payers at paragraph (j)(2). We propose to codify that the claims processing methodology have no impact on PDE reporting at paragraph (j)(3). We propose to codify that program participation and the associated claims processing methodology have no impact on the cost-sharing information displayed in real-time benefit tools at paragraph (j)(4). We propose to establish standards for exclusion of retroactive or ''paper'' claims at paragraph (j)(5). We propose to codify requirements for the readjudication of certain covered Part D claims for program participants at (j)(6). Finally, we propose to codify new requirements for Part D sponsors to enhance OOP cost transparency at the POS at (j)(7).

(j) Pharmacy Payment Obligations

Consistent with 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, Part D sponsors must pay the pharmacy the enrollee's cost-sharing amount in addition to the Part D sponsor's portion of the payment. The final part one and final part two guidance established standards for 2025 related to pharmacy payment obligations.

Consistent with section 1860D–12(b)(4) of the Act and 42 CFR 423.520, and as stated in the final part one guidance, Part D sponsors must reimburse a network pharmacy the total of a participant's OOP costs for the Medicare Prescription Payment Plan and the Part D sponsor portion of the payment for a covered Part D drug no later than 14 calendar days after the date on which the claim is received for an electronic claim or no later than 30 calendar days after the date on which the claim is received for any other claim. The timing of payment of the total of a participant's OOP costs for the Medicare Prescription Payment Plan and the Part D sponsor portion of the payment for long-term care and home infusion pharmacies should follow current practices for payment of the Part D sponsor portion to be consistent with this requirement.

Consistent with section 1860D–11(i) of the Act, CMS may not interfere with the negotiations between Part D sponsors and pharmacies and generally may not institute a price structure for the reimbursement of covered Part D drugs. Further, as stated in the final part one guidance, CMS does not have the statutory authority to directly reimburse Part D sponsors' contracted pharmacies for costs associated with administering the program. That said, CMS recognizes the important role that pharmacies will play in the implementation of this program and strongly encourages Part D sponsors to ensure that pharmacies receive adequate reimbursement for services provided to Part D enrollees related to participation in the Medicare Prescription Payment Plan.

As established in the final part one and final part two guidance, any additional transaction fees or other costs pharmacies incur from processing claims under the Medicare Prescription Payment Plan or otherwise related to the program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees. Consistent with 42 CFR 423.100 and sections 20.6 and 20.7 of Chapter 5 of the Medicare Prescription Drug Benefit Manual, a drug's negotiated price must include any dispensing fees, and uniform negotiated prices must be available to plan enrollees for a particular covered Part D drug when purchased from the same pharmacy. Should Part D sponsors and pharmacies come to contractual arrangements that reimburse pharmacies for program operations through a non-dispensing fee mechanism (for example, remuneration for administrative services), these arrangements must be reported appropriately via the bid pricing tool and direct and indirect remuneration (DIR) reporting, as necessary.

As established in the final part one guidance and section (f) of this proposed rule, it is not permissible for Part D sponsors to charge program participants fees related to the Medicare Prescription Payment Plan. Additionally, section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act requires Part D sponsors to ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments. As a result, Part D sponsors cannot impose any fees or costs related to program implementation on pharmacies, as such fees or costs would affect the amount paid to pharmacies in violation of the statute. As established in the final part one guidance, participation in the Medicare Prescription Payment Plan is an arrangement between the Part D sponsor and the Part D enrollee; pharmacies cannot be held responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

In this proposed rule, we propose to codify the requirements established in the final part one and final part two guidance for 2026 and subsequent years as noted previously at § 423.137(k).

Specifically, we propose to codify the requirement that the Medicare Prescription Payment Plan does not affect the amount or timing of payment to pharmacies at paragraph (k)(1), including that Part D sponsors cannot impose any fees or costs related to program implementation on pharmacies and that pharmacies cannot be held responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

(k) Monitoring, Compliance and Data Submission Requirements

In the final part one guidance, we clarified that existing requirements in 42 CFR 423.514(a) governing data collection for Part D sponsors apply to the Medicare Prescription Payment Plan. Accordingly, in the final part one guidance, we stated that Part D sponsors must report information related to the Medicare Prescription Payment Plan on PDE records and through new reporting requirements at the beneficiary level and contract-PBP levels. Part D sponsors must report data at the beneficiary-level on election status in the program through the MARx System and contract-level data about the program through HPMS. These data elements were formally issued for public comment in the **Federal Register** through the Office of Management and Budget (OMB) Information Collection Request (ICR) process. We are not scoring this provision in the Collection of Information section of this rule since we believe all information impacts of this provision have already been accounted for under OMB control numbers 0938–1468, 0938–0982, and 0938–0992.

In the final part two guidance, we stated that CMS will use this data, along with data about plan grievances and beneficiary complaints entered in the Medicare Complaints Tracking Module (CTM), to assess compliance with all Medicare Prescription Payment Plan requirements and ensure program integrity. We stated our expectation that Part D sponsors incorporate the Medicare Prescription Payment Plan into their compliance programs in accordance with 42 CFR 423.504(b)(4)(vi) to ensure they are meeting program requirements. We also noted that, as stated in 42 CFR 422.504(e) and 423.505(e), CMS and/or its contractors may conduct specific audits of Part D sponsors' implementation of the Medicare Prescription Payment Plan and may initiate audit activity that requires additional data collection or site visits.

(l) General Part D Sponsor Outreach and Education Requirements

Under section 1860D–2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D–2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also provide information on such option in educational materials to Part D enrollees.

To ensure all prospective and current Part D enrollees are aware of the program, we propose to codify requirements that are consistent with those included in the final part two guidance for Part D sponsors to provide general education on the program via a mailing and through their websites for 2026 and subsequent years at §§ 423.137(m)(1) and 423.137(m)(2), respectively. We propose requiring Part D sponsors to send a program election request form and additional educational information on the program either in the membership ID card mailing, described at § 423.2267(e)(32), or in a separate mailing sent out within the same timeframe. Under § 423.2267(e)(32), membership ID cards must be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the plan effective date, whichever is later. Part D sponsors may send the Medicare Prescription Payment Plan mailing described at § 423.137(m)(1) to only new plan enrollees who typically receive the membership ID card mailing or to all of their Part D enrollees. Further, for 2026 and subsequent years, we propose to codify requirements at § 423.137(m)(2) for plans to include certain information, as described in more detail later in this section, on their publicly available websites, described at § 423.128(d)(2). As we stated in the final part two guidance, Part D sponsors are encouraged to use the CMS-developed educational fact sheet to satisfy requirements to provide supplemental information on the program.

In the final part two guidance, we explained that CMS has updated existing Part D resources that are required to be furnished to Part D enrollees under § 423.2267(e) to include information about the program. These include the Annual Notice of Change (ANOC, described at § 423.2267(e)(3)), the Evidence of Coverage (EOC, described at § 423.2267(e)(1)), and the Explanation of Benefits (EOB, described at § 423.128(e)(7)). Each has been updated to include program information through the OMB ICR process (for the EOB) or through the general annual issuance of Part D model materials (for the ANOC and EOC). In addition to meeting these requirements, we propose to codify at § 423.137(m)(2) for 2026 and subsequent years the following requirements for a Part D sponsor to include on its website:

- An election request mechanism, as described at § 423.137(d)(2).
- An overview of the Medicare Prescription Payment Plan.
- Examples of program calculations and explanations.
- A description of Part D enrollees who may be likely to benefit.
- The financial implications of program participation.
- The implications of missing monthly payments.
- Instructions for opting into and out of the program.
- A description of the standards for retroactive election when an enrollee believes that a delay in filling a prescription due to the 24-hour effectuation timeframe may seriously jeopardize their life, health, or ability to regain maximum function.
- A description of the dispute and grievance procedure, as required under § 423.137(h).
- Contact information for Part D enrollees to obtain further information.
- General information about the LIS program, including how LIS enrollment for eligible individuals is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.

We also propose to amend § 423.2265(b) to add paragraph (b)(16) to include information on the Medicare Prescription Payment Plan as required content for Part D sponsor websites.

Additionally, as described in the final part two guidance, Part D sponsors may also include information on the Medicare Prescription Payment Plan in their marketing materials. In developing their materials, Part D sponsors must ensure that the materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of those marketing materials using HPMS, and use of marketing materials.

CMS is aware that health care providers and pharmacists play a key role in cost-of-care conversations with their patients that can include

discussions about potential prescription drug costs. As noted in the final part two guidance, CMS encourages Part D sponsors to include information about the Medicare Prescription Payment Plan in their communications with contracted providers and network pharmacies. More specifically for contracted providers, CMS encourages Part D sponsors to target these communications to subgroups of providers based on provider specialty and likelihood of prescribing high cost covered Part D drugs.

With regard to network pharmacies, CMS encourages Part D sponsors to provide pharmacies with education and resources related to the Medicare Prescription Payment Plan. While some pharmacies, such as specialty pharmacies, may be more likely to dispense high-cost drugs that trigger the POS notification, all pharmacy types would benefit from program resources and a thorough understanding of how the Medicare Prescription Payment Plan works and how it can benefit participants.

The CMS-developed fact sheet may serve as a useful tool for Part D sponsors to communicate information on the Medicare Prescription Payment Plan with both contracted providers and pharmacies.

We are not scoring any aspects of this provision related to the inclusion of Medicare Prescription Payment Plan information in the ANOC, EOC, or EOB in the Collection of Information section of this rule since we believe all information impacts of those provisions have already been accounted for under OMB control numbers 0938–1051 and 0938–1228. We are also not scoring the requirement to provide the election request form, as we believe the information impact of that provision has already been accounted for under OMB control number 0938–1475.

(m) Severability

The Medicare Prescription Payment Plan provisions proposed herein are separate and severable from one another. If any of these provisions, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it is our intention that such provision shall be severable from this rule and not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

III. Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies

A. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program

1. Background

The statutory definition of a covered Part D drug at section 1860D–2(e)(2) of the Social Security Act (the Act) excludes certain drugs and uses—specifically, those that may be excluded by Medicaid under section 1927(d)(2) of the Act. This includes ''[a]gents when used for anorexia, weight loss, or weight gain.'' Since the drugs, classes of drugs, and medical uses listed in section 1927(d)(2) of the Act ''*may* be excluded from coverage'' (emphasis added) under Medicaid, state Medicaid programs have discretion over whether to provide such coverage, whereas Medicare does not. Since the beginning of the Part D program in 2006, CMS has interpreted the statutory exclusion of ''[a]gents when used for . . . weight loss . . . '' at section 1927(d)(2)(A) of the Act to mean that a drug when used for weight loss, even when not used for cosmetic purposes, is excluded from the definition of covered Part D drug.[21] All drugs used for weight loss have been excluded historically from the definition of covered Part D drug and considered to be an optional benefit under the Medicaid program, at the discretion of the state Medicaid program, regardless of their use to treat the disease of obesity. Drugs used for weight loss or chronic weight management can be covered by Part D plans only as a supplemental benefit.

Multiple medical and scientific organizations consider obesity to be a chronic disease.[22] [23] [24] [25] In its 2013 resolution to recognize obesity as a disease, the American Medical Association (AMA) noted that although obesity is characterized by increased adiposity (body fat), obesity is a hormonal disease state with impaired functioning of multiple metabolic processes.[26] Similarly, the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) recognizes obesity as a chronic disease state with adiposity-based complications and pathophysiologic processes resulting from the dysregulated secretion of inflammatory and hormonal factors from fat cells.[27] Obesity increases the risk of, or exacerbates, hypertension, dyslipidemia, type 2 diabetes, cardiovascular disease, obstructive sleep apnea, nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH), and some cancers, among other conditions.[28] Obesity also is associated with increased risk of all-cause mortality and death due to cardiovascular disease.[29]

The prevalence of obesity in both the United States (U.S.) population, and in the Medicare population more specifically, has increased since the beginning of the Part D program. According to the Centers for Disease Control and Prevention (CDC), the prevalence of obesity (defined by CDC as body mass index [BMI] of 30 kg/m^2 or greater) in the U.S. population increased from 30.5 percent in 1999 to 2000 to 41.9 percent from 2017 to March 2020.[30] The prevalence of obesity from 2017 to March 2020 was 49.9 percent of non-Hispanic Black adults, 45.6 percent

[21] 73 FR 20489–20490 in ''Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit'' published April 15, 2008 (73 FR 20486). However, CMS's longstanding interpretation of the phrase ''[a]gents when used for . . . weight *gain* . . . '' (emphasis added) in the same section of the Act has not included drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia (73 FR 20490).

[22] Recognition of Obesity as a Disease H–440.842. Accessed June 28, 2024 from *https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml.*

[23] CDC. Adult Obesity Facts. May 14, 2024. Accessed June 28, 2024 from *https://www.cdc.gov/obesity/php/data-research/adult-obesity-facts.html.*

[24] Mechanick J.I., Garber A.J., Handelsman Y, Garvey W.T. American Association of Clinical Endocrinologists' position statement on obesity and obesity medicine. Endocr Pract. 2012 Sep–Oct;18(5):642–8. doi: 10.4158/EP12160.PS.

[25] World Health Organization. Obesity and Overweight. March 1, 2024. Accessed August 21, 2024 from *https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight.*

[26] American Medical Association House of Delegates. Resolution 420 (A–13). Recognition of Obesity as a Disease. May 15, 2013. Available from: *https://media.npr.org/documents2013/jun/ama-resolution-obesity.pdf.*

[27] Mechanick J.I., Hurley D.L., Garvey W.T. Adiposity-Based Chronic Disease As a New Diagnostic Term: The American Association of Clinical Endocrinologists and American College Of Endocrinology Position Statement. Endocr Pract. 2017 Mar;23(3):372–378. doi: 10.4158/EP161688.PS.

[28] American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity, Endocrine Practice, Volume 22, Supplement 3, 2016, Pages 1–203, *https://doi.org/10.4158/EP161365.GL.*

[29] Jensen M.D., Ryan D.H., Apovian C.M., et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society [published correction appears in Circulation. 2014 Jun 24;129(25 Suppl 2):S139–40]. *Circulation.* 2014;129(25 Suppl 2):S102–S138. doi:10.1161/01.cir.0000437739.71477.ee.

[30] CDC. Adult Obesity Facts. May 14, 2024. Available from *https://www.cdc.gov/obesity/adult-obesity-facts/index.html.*

of Hispanic adults, 41.4 percent of non-Hispanic white adults, and 16.1 percent of non-Hispanic Asian adults.[31] With respect to the Medicare population, CMS data indicate that approximately 22 percent of all Medicare beneficiaries had a diagnosis of obesity in 2022 [32] compared to 8.7 percent in 2012.[33] As of 2020, the proportion of Medicare fee-for-service beneficiaries with obesity was 24 percent of the Black/African American population, 19 percent of the White population, 18 percent of the Hispanic population, 17 percent of the American Indian/Alaska Native population, and 7 percent of the Asian/Pacific Islander population.[34] However, obesity prevalence based on Medicare claims data likely underestimates actual obesity prevalence in the Medicare population since data are dependent on the degree to which obesity was recorded as a diagnosis code on medical claims. This assumption is supported by the fact that available National Health and Nutrition Examination Survey (NHANES) data from 2017 to March 2020 indicate that the prevalence of obesity in the U.S. population age 60 and older was 41.5 percent, which parallels the trend in the general U.S. population described in the CDC statistics and is much higher than the obesity prevalence calculated based on Medicare claims data.[35]

Data on obesity prevalence across the entire Medicaid population are limited. For example, available state-level data indicate that 43.7 percent of adult Medicaid enrollees in Rhode Island had obesity in 2017 to 2018, which was similar to the rate of obesity in the U.S. adult population at the same time (42.4 percent), but higher than the prevalence of obesity among adults in the state with commercial insurance (36.0 percent).[36] [37] The prevalence of obesity varies by state; [38] therefore, the prevalence of obesity among each state's Medicaid enrollees may be proportional.

Given the prevalence and the impact of obesity in the U.S., the Biden-Harris Administration released the National Strategy on Hunger, Nutrition, and Health focused on ending hunger and reducing diet-related diseases such as obesity.[39] One of the Strategy's pillars is integrating nutrition and health, which recognizes the opportunities within Medicare and Medicaid to support beneficiaries' access to nutritious foods, obesity counseling, and other nutrition-related services. Reinterpreting the statute to provide for coverage for AOMs for individuals who have obesity would build on that National Strategy by offering another tool that can support Medicare and Medicaid beneficiaries in addressing obesity and living healthier lives. Further, CMS believes that excluding AOMs from Part D coverage has created a scenario where Medicare Part D enrollees with obesity have been unable to access drug therapy to treat what is recognized as a chronic disease, potentially exacerbating health disparities in groups disproportionately affected by obesity.

Available AOMs in the glucagon-like peptide-1 (GLP–1) and glucose-dependent insulinotropic polypeptide (GIP)/GLP–1 receptor agonist classes contain the same active ingredients initially approved by the U.S. Food and Drug Administration (FDA) to improve glycemic control in patients with type 2 diabetes, and later approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. One AOM in the GLP–1 receptor agonist class has received FDA approval for the reduction of the risk of major adverse cardiovascular events in non-diabetic adults with established cardiovascular disease and either obesity or overweight.[40] The scientific evidence on AOMs continues to evolve—novel AOMs are in development or new indications for existing AOMs may be approved in the future. A medically accepted indication (MAI), as defined in section 1860D–2(e)(4) of the Act, refers, in part, to the definition of MAI in section 1927(k)(6) of the Act. CMS issued guidance on March 20, 2024 via a Health Plan Management System (HPMS) email clarifying that AOMs that receive FDA approval for an additional indication other than chronic weight management can be considered a Part D drug for that specific use since the use is an MAI that is not a use that is excluded from the definition of a Part D drug.[41] Therefore, under current policy, AOMs are coverable under Part D for individuals with obesity or overweight only if the drug is being prescribed for another condition (other than weight loss or chronic weight management) for which the drug has an FDA-approved indication or its use is supported by CMS-approved compendia.[42] Currently, this means that AOMs (or drugs with the same active ingredients) are coverable under Part D for individuals with obesity or overweight for the FDA-approved uses of glycemic control in patients with type 2 diabetes, reduced risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease, reduced risk of major adverse cardiovascular events in non-diabetic adults with established cardiovascular disease. Should our proposed reinterpretation be finalized, Part D enrollees with obesity could receive coverage for AOMs even in cases where the AOM is prescribed for treatment of obesity, and not prescribed for another condition that is an FDA-approved indication or that is supported by CMS-approved compendia.

While we refer to AOMs generally throughout the discussion of this proposed reinterpretation and have referred to specific classes of AOMs, this proposal is not limited to particular drugs or drug classes. Currently

[31] Stierman, B., et al. National Health and Nutrition Examination Survey 2017–March 2020 Prepandemic Data Files—Development of Files and Prevalence Estimates for Selected Health Outcomes. 2021. Available from *https://stacks.cdc.gov/view/cdc/106273*. Note that race and ethnicity categories reflect the 1997 Standards for the Classification of Federal Data on Race and Ethnicity (62 FR 58782) which have since been updated in 2024 (89 FR 22182).

[32] Internal analysis of 2022 Chronic Conditions Data.

[33] Chronic Conditions Data Warehouse. Other Chronic or Disabling Conditions Trends, 2012–2021. April 2023. Available from: *https://www2.ccwdata.org/web/guest/medicare-charts/medicare-other-chronic-and-disabling-condtions/#b2bother trend*. See also: *https://www2.ccwdata.org/documents/10280/19099072/b2b-other-trend.jpg*.

[34] Obesity Disparities in Medicare Fee-For-Service Beneficiaries Data Snapshot. January 2022. Available from: *https://www.cms.gov/files/document/omh-datasnapshot-obesity.pdf*.

[35] Stierman, B., et al. National Health and Nutrition Examination Survey 2017–March 2020 Prepandemic Data Files—Development of Files and Prevalence Estimates for Selected Health Outcomes. 2021. Available from *https://stacks.cdc.gov/view/cdc/106273*.

[36] *https://www.niddk.nih.gov/health-information/health-statistics/oversight-obesity*.

[37] Mylona E.K., Benitez G., Shehadeh F., Fleury E., Mylonakis S.C., Kalligeros M., Mylonakis E. The association of obesity with health insurance coverage and demongraphic characteristics: a statewide cross-sectional study. Medicince (Baltimore). 2020 Jul 2;99(27):e21016. doi: 10.1097/MD.0000000000021016.

[38] *https://www.cdc.gov/obesity/php/data-research/adult-obesity-prevalence-maps.html#cdc_data_surveillance_section_4-across-states-and-territories*.

[39] White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf.

[40] Table: GLP–1 and GIP/GLP–1 receptor agonists for chronic weight management. Med Lett Drugs Ther. 2024 Aug 5;66(1708):e1-e2. doi: 10.58347/tml.2024.1708d.

[41] HPMS email. Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications. March 20, 2024. Available from: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-march-18-22*.

[42] CMS-approved compendia are described in section 1927(g)(1)(B)(i) of the Act. The recognized compendia are American Hospital Formulary Service Drug Information and DRUGDEX® Information System. See section 10.6 in chapter 6 of the Prescription Drug Benefit Manual. Available from *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf*.

available AOMs achieve therapeutic action through a variety of mechanisms including slowed gastric emptying, inhibiting dietary fat absorption, and targeting receptor pathways in the brain that are involved in hunger, cravings, and feelings of fullness. We also acknowledge that ''AOM'' is a term used pervasively throughout the medical literature but is not a term used by the FDA in reference to drug development. For purposes of this proposal, we use the term ''AOM'' to refer to products (drugs and biologicals) for the indication of weight management that are intended to be used for medical weight loss, as described in FDA draft guidance [43], consistent with clinical practice guidelines.[44] We also acknowledge that AOMs, when used for medical weight loss, are generally indicated to reduce excess body weight and maintain weight reduction long-term, and not overtly for ''treatment of obesity.''

2. Proposed Reinterpretation

Given the changes in how the medical community has come to regard obesity as a disease since the start of the Part D program, CMS believes that its longstanding interpretation of the reference in section 1927(d)(2) of the Act to ''[a]gents when used for . . . weight loss'' as including AOMs when used for weight loss or chronic weight management regardless of whether the AOMs were used to treat obesity reflects an outdated medical understanding, and that it would be more consistent with current medical views to propose to reinterpret the phrase ''[a]gents when used for . . . weight loss'' to exclude AOMs when used for the treatment of obesity. As a result of this proposed reinterpretation, AOMs— when used for weight loss or chronic weight management for the treatment of obesity—would no longer be excluded from Part D coverage based on section 1860D–2(e)(2) of the Act, which prohibits Part D coverage of ''drugs or classes of drugs. . .which may be excluded from coverage or otherwise restricted under section 1927(d)(2).'' In addition, CMS would no longer consider AOMs when used for weight loss or chronic weight management for the treatment of obesity to be excluded from the definition of Part D drug at § 423.100, which at paragraph (2)(ii) excludes drugs that may be excluded from Medicaid coverage under section 1927(d)(2). Our proposal is not contingent on the underlying etiology of obesity (for example, due to unspecified causes or specified causes such as drug-induced obesity or obesity due to specific genetic variants or syndromes) and would encompass any drugs that are indicated for weight loss or chronic weight management for the treatment of obesity. In table 2., we provide examples to illustrate the effect of our proposal on AOM coverage in Medicare Part D.

This proposed reinterpretation would align with our longstanding policy interpreting the phrase ''[a]gents when used for. . .weight gain'' in section 1927(d)(2)(A) to not include drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia (73 FR 20490).[45] CMS believes that its longstanding interpretation of the phrase ''[a]gents when used for . . . weight gain'' in section 1927(d)(2)(A) is correct, and by adjusting its interpretation of ''[a]gents when used for . . . weight loss,'' we would be bringing the interpretation of these two phrases into alignment.

We are not proposing to reinterpret the statutory exclusion of ''[a]gents when used for . . . weight loss'' in section 1927(d)(2) of the Act to permit Part D coverage of AOMs when used for weight loss or chronic weight management in individuals with overweight, even if such individuals have weight-related comorbid conditions. We are not proposing such a change in interpretation because, unlike obesity, overweight is not recognized as a disease. The FDA-approved indications for most AOMs used for weight loss or chronic weight management specify that individuals with overweight must also have weight-related conditions, but there is no such requirement for the presence of comorbid conditions in individuals with obesity. We believe this supports recognizing obesity as a distinct disease. Our proposal to limit the reinterpretation to AOMs used for weight loss or weight management for the treatment of obesity is based on the distinction between obesity as a disease and overweight, which is not recognized as a disease, but may occur in combination with other conditions that are weight related. As we have discussed, some AOMs are FDA-approved to improve glycemic control in patients with type 2 diabetes and reduce major cardiovascular events in adults with established cardiovascular disease (in adults with type 2 diabetes, obesity, or overweight), independent of the indication for weight loss or chronic weight management. AOMs that have received FDA approval for these uses have demonstrated effectiveness in these conditions (which are common weight-related conditions) independent of weight loss. Therefore, we believe that for individuals with overweight, the current policy for coverage under Part D should be maintained to permit coverage of an AOM when the AOM is used for a weight-related condition for which the AOM has demonstrated effectiveness independent of weight loss and is an MAI. By contrast, in obesity, we consider weight loss to be the mechanism for reducing excess adiposity and mitigating its accompanying hormonal and metabolic dysregulation. We acknowledge, however, that by limiting our proposed reinterpretation, we could create a perverse incentive for some individuals with overweight to gain additional weight in order to meet criteria for obesity. We solicit comment on our proposed reinterpretation, including our underlying assumptions and the decision not to extend our reinterpretation of the statutory exclusion to provide that individuals with overweight and at least one weight-related comorbidity could receive coverage of AOMs for weight loss or chronic weight management under Part D.

We are not proposing a definition of obesity for the purpose of determining eligibility for Part D coverage of AOMs. Obesity is most commonly defined as a BMI of 30 kg/m^2 or greater, but AACE/ACE has described the limitations of relying on BMI alone to adequately characterize obesity as a chronic disease of excess adiposity.[46] [47] For purposes of

[43] FDA. Draft Guidance for Industry Developing Products for Weight Management. February 2007. Available from *https://www.fda.gov/media/71252/download*.

[44] American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity, Endocrine Practice, Volume 22, Supplement 3, 2016, Pages 1–203, *https://doi.org/10.4158/EP161365.GL.*

[45] Since the inception of the Part D program, CMS has aligned Part D with the Medicaid policy that prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain, and therefore such products are not excluded under in section 1927(d)(2)(A) of the Act. The Medicaid policy was effective April 5, 1999. See Medicaid Drug Rebate Program Release #88. March 5, 1999. Available from *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-088.pdf.*

[46] American Association of Clinical Endocrinologists and American College of Endorinology Comprehensive Clinical Practice Guidlines for Medical Care of Patients with Obesity, Endocrine Pratice, Volume 22, Supplement 3, 2016, Pages 1–203, *https://doi.org/10.4158/EP161365.GL.*

[47] Mechanick J.I., Hurley D.L., Gavery W.T. Adiposity-Based Chronic Disease As a New Diagnostic Term: The American Association of

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defining ''individuals at risk for diabetes'' who may receive diabetes screening tests, section 1861(yy)(2)(C) of the Act defines obesity as a BMI greater than or equal to 30 kg/m ^{2}. Some available AOMs specify obesity as a BMI greater than or equal to 30 kg/m ^{2} in the FDA-approved indication. The FDA-approved indications for other AOMs initially specified obesity as a BMI greater than or equal to 30 kg/m ^{2}, but the indications have since been revised and reference to a specific BMI has been removed. We would permit Part D sponsors to define obesity for the purposes of their prior authorization (PA) criteria as long as the Part D sponsor's PA criteria are not more restrictive than the FDA labeling for the particular AOM. This approach is consistent with other disease states for which CMS does not specify diagnostic criteria, but reviews Part D plan-submitted PA criteria for clinical appropriateness.

As required under § 423.120(b)(1)(vi), Part D sponsors' Pharmacy and Therapeutics (P&T) committees are required to consider the therapeutic advantages in terms of safety and efficacy of Part D drugs that are included in the plan formulary. This process includes drug-specific safety considerations for the elderly or individuals with disabilities. Further, as required under § 423.120(b)(1)(x), Part D sponsors' P&T committees must review utilization management (UM) criteria for clinical appropriateness. CMS maintains a robust, clinical formulary review process to ensure that all Part D plan formularies comply with statutory and regulatory requirements, including the requirement under section 1860D–11(e)(2)(D)(i) of the Act that CMS may only approve a Part D plan if it ''does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.'' As part of the formulary content review, CMS reviews submitted UM criteria, which include PA criteria and step therapy (ST) requirements, to ensure these criteria are consistent with the FDA labeling and widely used treatment guidelines, as appropriate. Recognizing that obesity is a chronic disease and weight gain is common if drug therapy for obesity is discontinued, we would review Part D sponsors' PA criteria for AOMs in the same manner that we would review the PA criteria for drugs used to treat other chronic conditions that require ongoing drug therapy to maintain successful treatment. PA criteria for AOMs that are overly restrictive may be deemed to be inconsistent with CMS' formulary review requirements if the criteria appear to be likely to substantially discourage enrollment of individuals with obesity in the Part D plan. Similarly, CMS would not approve ST requirements for AOMs that are inconsistent with clinical guidelines.

In general, Part D sponsors must cover formulary drugs for all FDA-approved indications that are not excluded from Part D coverage.[48] Most available AOMs are also indicated for use in individuals with overweight with weight-related comorbid conditions. A weight-related comorbid condition might include, for example, hypertension, type 2 diabetes, dyslipidemia, sleep apnea, or cardiovascular disease. As stated previously, some available AOMs contain the same active ingredients approved by the FDA to improve glycemic control in patients with type 2 diabetes and reduce major cardiovascular events in adults with established cardiovascular disease and type 2 diabetes, and one AOM has received FDA approval to reduce the risk of major adverse cardiovascular events in non-diabetic adults with established cardiovascular disease and either obesity or overweight. Therefore, individuals with type 2 diabetes or established cardiovascular disease (with type 2 diabetes, obesity, or overweight) are already eligible for AOM coverage under current policy because these FDA-approved indications are distinct from the indication of weight loss or chronic weight management. Should our reinterpretation be finalized as proposed, individuals with obesity would be eligible for AOM coverage covered regardless of weight-related comorbid conditions. In comparison, AOMs used for weight loss or chronic weight management in individuals with overweight, who do not have another condition that is an MAI for the AOM, would continue to be excluded from the definition of a Part D drug and would not be coverable under Part D. In other words, Part D sponsors would continue to exclude drugs with FDA-approved indications of weight loss or chronic weight management in individuals with overweight with weight-related comorbidities from Part D coverage, unless the individual has another condition that is an MAI for the AOM. See examples in table 2 illustrating the effect of our proposal as it relates to AOM coverage for individuals with overweight. Consistent with current guidance, CMS expects Part D sponsors to consistently utilize PA for drugs with the highest likelihood of non-Part D covered uses, including when there is a high likelihood that a drug's medical use is excluded from Part D coverage.[49]

3. Impact on Medicaid Coverage

Our proposal to reinterpret the reference to ''[a]gents when used for . . . weight loss'' in section 1927(d)(2)(A) of the Act to allow for Medicare Part D coverage of drugs used for the treatment of obesity would also apply to the Medicaid program. Since both Medicaid and Medicare reference the Medicaid definition of covered outpatient drugs in section 1927(k)(2) of the Act and rely on section 1927(d)(2)(A) of the Act for what may constitute ''[a]gents when used for . . . weight loss,'' it follows that CMS should apply the same interpretation of these provisions for Medicare and Medicaid. Thus, if finalized, our proposed reinterpretation would mean that AOMs, when used for weight loss or chronic weight management for the treatment of obesity, could not be excluded from Medicaid drug coverage. States would continue to have the discretion to utilize preferred drug lists and PA to establish certain limitations on the coverage of these drugs as long as such practices are consistent with the requirements of section 1927(d) of the Act to ensure appropriate utilization. In the case of an individual without obesity seeking coverage for an AOM for weight loss or chronic weight management, a state's coverage determinations and State Plan requirements related to ''[a]gents when used for . . . weight loss,'' under section 1927(d)(2)(A) of the Act would govern. AOMs and drugs that contain the same active ingredient as AOMs that meet the definition of a covered outpatient drug are already subject to section 1927 requirements, and

Clinical Endocrinologists and American College of Endocrinology Position Statement. Endor Pract. 2017 Mar;23(3):372–378. doi: 10.4158/EP161688.PS.

[48] HPMS memorandum. Issuance of the 2010 Call Letter. March 30, 2009. Available from *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/2010callletter.pdf.* Note, Part D sponsors may limit PA criteria to cover only certain FDA-approved indications if they are implementing indication-based formulary design, consistent with the August 29, 2018 HPMS memorandum, ''Indication-Based Formulary Design Beginning in Contract Year (CY) 2020.'' Available from: *https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2018-aug-29th.*

[49] See section 30.2.2.3 in chapter 6 of the Prescription Drug Benefit Manual. Available from *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

Medicaid must cover those products when the prescribed use is an MAI other than weight loss or chronic weight management when they are medically necessary. In table 2, we provide examples to illustrate the effect of our proposal on AOM coverage in Medicaid.

We believe that our proposed interpretation for the Medicaid program is consistent with the relevant statutory provisions and with our reinterpretation for the Medicare program and would result in the same benefits and achieve the same goals for the Medicaid program as those articulated for the Medicare program. This proposed policy is intended to facilitate access to these medications for individuals who meet the criteria for obesity whether they are enrolled in Medicaid, Medicare, or both.

We seek comments on how this interpretation can best be implemented for state Medicaid programs and Medicaid enrollees. Among other areas, we seek comment on potential interactions with rate setting and coverage standards for Medicaid managed care plans, and ways to ensure adequate notice to beneficiaries and other stakeholders of the changes resulting from this interpretation should this proposal be finalized.

4. Coverage Considerations

CMS is considering what an appropriate applicability date for the reinterpretation in the Part D program would be in light of section 1860D–12(f) of the Act and § 423.516, which provide that CMS may not implement, other than at the beginning of a calendar year, regulations that impose new, significant regulatory requirements on a prescription drug plan (PDP) sponsor or a PDP, and seeks comment on this issue.

We have not identified any similar basis for delaying the applicability date for Medicaid to align with a Part D applicability date at the beginning of a calendar year. Accordingly, any reinterpretation of section 1927(d)(2) of the Act would be applicable under the Medicaid program as of the effective date of the rule in which this provision is finalized. Therefore, should this proposal be finalized, state Medicaid programs that provide drug coverage would generally be required to provide coverage of AOMs for weight loss or chronic weight management for treating obesity in Medicaid-enrolled individuals as of the effective date of the final rule, which is generally 60 days after the final rule is published. Should the proposed reinterpretation be applicable to Medicare at the beginning of a calendar year, consistent with section 1860D–12(f) of the Act and § 423.516, there could be a time period during which AOMs used for weight loss or chronic weight management for treatment of obesity would be required to be covered by state Medicaid programs that cover prescription drugs, but would not be covered by Part D. As a result, Medicaid programs that provide drug coverage would be required to cover AOMs used for weight loss or chronic weight management for certain dually eligible individuals until such time as Part D coverage began.

We invite commenters to share feedback on the impact of this reinterpretation to Part D sponsors and their enrollees. We also solicit comments on the impact of our proposal on state Medicaid programs and Medicaid enrollees, including dually eligible enrollees. Specifically, we seek comment on the implications of aligning or not aligning the applicability dates for coverage under Medicaid and Medicare. We also seek comments on implementation considerations this proposal might raise under Medicaid, including related to any potential coverage changes, state plan changes, coordination of care, or budget implications, and any implications related to state contracts with Medicaid managed care organizations.

5. Summary

In summary, due to changes in the prevailing medical consensus towards recognizing obesity as a disease, we are re-evaluating Part D coverage of AOMs for Medicare beneficiaries with obesity who do not have another condition for which an AOM is indicated and for whom the prescribed use would be otherwise coverable under Part D. As a result of our proposed reinterpretation of the phrase ''[a]gents when used for . . . weight loss'' in section 1927(d)(2) of the Act, AOMs that are used for treating obesity and that otherwise meet the definition of Part D drug at § 423.100 would no longer be excluded from Part D coverage pursuant to the exclusion in paragraph (2)(ii) of that definition for drugs that may be excluded from Medicaid coverage under section 1927(d)(2) of the Act. Our proposed reinterpretation would also apply to Medicaid such that state Medicaid programs would no longer have the discretion to exclude AOMs from Medicaid drug coverage as ''[a]gents when used for . . . weight loss'' when used for weight loss or weight management for the treatment of obesity. If our reinterpretation is finalized as proposed, states that are not already covering AOMs for weight loss or weight management would be required to do so to treat obesity in Medicaid enrollees with obesity. AOMs, when used for weight loss or chronic weight management in individuals who do not have obesity, would continue to be excluded from the definition of Part D drug, and may be excluded at state option from coverage by state Medicaid programs, unless the AOM is being used for a condition other than weight loss or chronic weight management for which such use would be covered as an MAI as defined in section 1927(k)(6) of the Act.

We solicit comment on this proposal.

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TABLE 2. EXAMPLES OF CURRENT AND PROPOSED COVERAGE OF AOMS IN MEDICARE PART D AND MEDICAID

Example Uses for AOMs*	Medicare Definition of a Part D Drug		Medicaid Drug Coverage	
	Current Policy	Proposed Policy	Current Policy	Proposed Policy
To improve glycemic control in patients with type 2 diabetes mellitus	Not excluded†	Not excluded†	May not be excluded‡	May not be excluded‡
To reduce the risk of major adverse cardiovascular events in patients with type 2 diabetes mellitus and established cardiovascular disease	Not excluded†	Not excluded†	May not be excluded‡	May not be excluded‡
To reduce the risk of major adverse cardiovascular events in patients with established cardiovascular disease and obesity	Not excluded†	Not excluded†	May not be excluded‡	May not be excluded‡
To reduce the risk of major adverse cardiovascular events in patients with established cardiovascular disease and overweight	Not excluded†	Not excluded†	May not be excluded‡	May not be excluded‡
To reduce excess body weight and maintain weight reduction long term in patients with obesity	Excluded	Not excluded†	May be excluded (subject to state discretion)	May not be excluded‡
To reduce excess body weight and maintain weight reduction long term in patients with overweight in the presence of at least one weight-related comorbid condition	Excluded	Excluded	May be excluded (subject to state discretion)	May be excluded (subject to state discretion)
Chronic weight management in patients with an initial BMI of 30 kg/m^2 or greater (obesity)	Excluded	Not excluded†	May be excluded (subject to state discretion)	May not be excluded‡
Chronic weight management in patients with an initial BMI of 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition	Excluded	Excluded	May be excluded (subject to state discretion)	May be excluded (subject to state discretion)
Chronic weight management in patients with monogenic or syndromic obesity	Excluded	Not excluded†	May be excluded (subject to state discretion)	May not be excluded‡
Obesity management including weight loss, weight maintenance, and to reduce the risk for weight regain after prior weight loss, for patients with obesity with an initial BMI of 30 kg/m^2 or greater	Excluded	Not excluded†	May be excluded (subject to state discretion)	May not be excluded‡
To reduce excess body weight and maintain weight reduction long term in patients with obesity	Excluded	Not excluded†	May be excluded (subject to state discretion)	May not be excluded‡
To reduce excess body weight and maintain weight reduction long term in patients with overweight in the presence of at least one weight-related comorbid condition	Excluded	Excluded	May be excluded (subject to state discretion)	May be excluded (subject to state discretion)

*Example uses are illustrative and not intended to refer to specific drugs.
†Where the prescribed use meets the definition of an MAI as defined in section 1860D-2(e)(4) of the Act.
‡Where the prescribed use meets the definition of an MAI as defined in section 1927(k)(6) of the Act.
Proposed changes to current policy are highlighted in grey

B. Network Transparency for Pharmacies

At § 423.505(i), we propose to require Part D sponsors to notify network pharmacies which plans the pharmacies will be in-network for in a given plan year by October 1 of the year prior to that plan year. We also propose to require sponsors to provide pharmacies with such a list of in-network plans on request after October 1. We believe this change is necessary to ensure that pharmacies can provide their customers with accurate information about which plans the pharmacy is participating in.

Part D sponsors contract with network pharmacies, either directly or through pharmacy benefit managers (''PBMs''), to provide Part D drugs to their enrollees. Sponsors and PBMs can contract with pharmacies at any time, but they generally perform most of their contracting activities for a plan year in the winter and spring of the prior year (for example, between January and May of 2024 for the 2025 plan year). However, sponsors do not submit bids for their Part D plans until the first Monday in June of the year prior to the plan year (for example, bids for the 2025 plan year were submitted by June 3, 2024) and do not receive final approval of those bids until August. Because sponsors and PBMs typically offer more than one plan in a service area, sometimes under more than one contract and under more than one marketing name, neither they nor the pharmacies they contract with know which plans will be served by the networks the pharmacies agree to join until months after executing network contracts.

Pharmacies often do not have the ability to meaningfully negotiate with or demand clear information from PBMs and plans regarding which networks they will participate in. Congress and the Federal Trade Commission (''FTC'') have initiated inquiries into PBM practices, including pharmacy contracting practices, in recent years. The FTC determined that large PBMs employ ''lopsided and unfair contracting practices'' that prevent pharmacies, particularly smaller pharmacies not affiliated with large chains, from engaging in meaningful negotiations about contracting terms, including monetary and non-monetary terms.[50] The FTC highlighted PBM's practice of unilaterally amending contracts by requiring pharmacies to opt out of new terms, rather than affirmatively opt in, as making it difficult for pharmacies to understand what terms apply at any given time.[51] This ''passive contracting'' often changes the networks pharmacies participate in with little notice or clear communication.[52]

Part D beneficiaries often base their enrollment decisions in part on whether the pharmacies they wish to use are in a plan's network. At the beginning of each plan year, CMS commonly receives complaints from beneficiaries reporting that they enrolled in a plan because they believed their preferred pharmacy was in the network, only to discover that it was not when they attempted to fill a prescription. These beneficiaries often request special enrollment periods (''SEP'') based on this misunderstanding. Beneficiaries may ask their pharmacies which plans the pharmacies are or will be in network for prior to selecting a plan. Pharmacies have reported to CMS that they often do not know which plans they will be in network for in the following plan year unless they check Medicare Plan Finder (''MPF''). While the individuals can use MPF to identify whether a particular pharmacy is in a particular plan for the following plan year during the AEP, MPF does not provide users a comprehensive list of all the plans in a service area that a particular pharmacy is in network for. Rather, a user must select each Part D plan to identify whether the pharmacy is in network. Pharmacies report that this cumbersome process hinders their ability to provide timely and accurate information to their Part D-eligible customers during the AEP in particular.

In order to allow pharmacies to provide accurate information to Part D beneficiaries about their network participation, we propose to require sponsors (or first tier, downstream, or related entities (''FDRs''), such as PBMs, on the sponsors' behalf) to provide each network pharmacy a list of the plans the network pharmacy will be participating in for a plan year by October 1 of the year prior to the plan year. We propose to adopt this requirement pursuant to our authority at section 1857(e) of the Act, made applicable to Part D through section 1860D–12(b)(3)(D) of the Act, which authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate, so long as those terms are not inconsistent with the Part D statute. This will allow pharmacies to efficiently provide customers accurate information about their network participation during the AEP that commences on October 15 of each year. We also propose to require that sponsors provide this information on request to network pharmacies after October 1. The information provided must include the contract number, plan ID, and marketing name for each of the sponsor's plans for which the pharmacy is in network. We propose to allow the sponsor to provide the information in hard copy and/or electronically.

We solicit comments on this proposal.

C. Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d)(2))

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries as described in section 1860D–4(c)(2)(A)(ii) of the Act, Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D eligible individuals who have multiple chronic diseases, are taking multiple covered Part D drugs, and are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. Since January 1, 2022, Part D sponsors are also required by section 1860D–4(c)(2)(A)(ii)(II) of the Act to target all at-risk beneficiaries (ARBs) in their Part D drug management program (DMP) for MTM. CMS codified the MTM targeting criteria at § 423.153(d)(2).

The regulation at § 423.153(d)(2)(i)(A) specifies that to be targeted for MTM, beneficiaries must have multiple chronic diseases, with three chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. CMS established improved targeting criteria for the Part D MTM program to help ensure more consistent, equitable, and expanded access to MTM services, effective January 1, 2025, in the April 2024 final rule (89 FR 30448). Specifically, CMS finalized the provision at § 423.153(d)(2)(iii) that Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). The 10 core chronic diseases are: (1) Alzheimer's disease; (2) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis); (3) Chronic congestive heart failure (CHF); (4) Diabetes; (5) Dyslipidemia; (6)

[50] Federal Trade Commission, ''Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies: Interim Staff Report'', July 2024, available at *https://www.ftc.gov/reports/pharmacy-benefit-managers-report,* pp. 48–49.

[51] *Id,* at p. 50.

[52] Ibid.

End-stage renal disease (ESRD); (7) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (8) Hypertension; (9) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and (10) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders). Sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic diseases.

The Affordable Care Act amended the Act by adding section 1860D–4(c)(2)(C)(i), which requires all Part D sponsors to offer all enrollees targeted for MTM an annual comprehensive medication review (CMR). Part D sponsors must offer each beneficiary enrolled in the MTM program an annual CMR with written summaries in CMS' Standardized Format under § 423.153(d)(1)(vii)(B) and (D). We recognize that some MTM enrollees may suffer cognitive impairments and, therefore, may not be able to participate in the CMR. In the April 2024 final rule, CMS codified at § 423.153(d)(1)(vii)(B)(2) its longstanding policy that the pharmacist or qualified provider may perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual if the beneficiary is offered the CMR and is unable to accept the offer to participate in the CMR due to cognitive impairment. Furthermore, CMS acknowledges that beneficiaries may invite other individuals, such as their caregiver or authorized representative, to join them in the CMR [53] under any circumstance. This situation is outside of the policy established under § 423.153(d)(1)(vii)(B)(2) for when the beneficiary is unable to accept the offer to participate due to cognitive impairment. CMS requires Part D sponsors to comply with all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information per § 423.136. Accordingly, we expect Part D sponsors and MTM providers to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations and maintain documentation of who participated in the CMR in accordance with § 423.153(d)(1)(vii)(B).

In response to the December 2022 proposed rule (87 FR 79452), some commenters suggested expanding the inclusion of Alzheimer's disease on the list of core chronic diseases to include other dementias such as Lewy Body disease or frontotemporal lobar degeneration. In our responses to those comments in the April 2024 final rule, we stated that we would continue to analyze chronic diseases that are highly prevalent in the Part D population, align with common targeting practices across sponsors, and are commonly treated with covered Part D drugs, where MTM services could most impact therapeutic clinical outcomes, including those suggested by the commenters, and that we may consider proposing additional core chronic diseases in future rulemaking.

We agree that beneficiaries with other dementias may benefit from MTM services. Although Alzheimer's disease is the most common cause of dementia at 60 to 80 percent of dementia cases, the 2024 Alzheimer's Disease Facts and Figures Special Report: Mapping a Better Future for Dementia Care Navigation [54] notes that many people with dementia, especially those over the age of 85, have two or more causes of dementia (mixed dementia) including cerebrovascular disease, hippocampal sclerosis, and Parkinson's Disease. The report discusses that it is not possible to definitively distinguish one cause of dementia from another based on symptoms alone. The same report further notes that autopsy and biomarker-based studies have found that 15 to 30 percent of individuals who met the criteria for clinical Alzheimer's dementia based on symptoms did not have the specific brain changes associated with Alzheimer's disease. Since Alzheimer's disease is just one of many possible causes of dementia, changing the core chronic disease from Alzheimer's disease to ''Alzheimer's disease and dementia'' would allow enrollment of more beneficiaries with other causes of dementia who could potentially benefit from MTM services.

MTM services are beneficial for people with dementia. One report notes that complex medication regimens for such individuals may lead to polypharmacy and increased adverse drug reactions (ADRs) and interactions, especially if the beneficiary is taking potentially inappropriate medications (PIMs).[55] The same report states, for instance, that people with dementia are frequently prescribed medications that can impair cognition, such as anticholinergics or sedatives, and that antipsychotics are also often inappropriately prescribed to people with dementia to treat behaviors that can be a symptom of dementia. A CMR with a pharmacist or other trained clinician could help reduce PIM use in this population.[56] We believe that MTM services such as CMRs empower beneficiaries to speak with their prescribers about preventing any ADRs.

There is also evidence that access to MTM services would improve medication adherence for beneficiaries with dementia. Medication nonadherence is a common problem in people with dementia due to memory loss and cognitive impairment; one article estimated that somewhere from 33 to over 40 percent of such individuals are nonadherent to their oral antidementia medications.[57] The article stated that Black, Hispanic, and Asian dementia patients were more likely to be nonadherent to antidementia medications than white patients, and that MTM services significantly reduced nonadherence in Black and Hispanic dementia patients. Having a CMR has also been associated with reduced nonadherence to medications for diabetes, hypertension, and hyperlipidemia in people with Alzheimer's disease.[6]

Therefore, we have concluded that it would be appropriate to update the list of core chronic diseases used to identify Part D enrollees who have multiple chronic diseases for purposes of determining eligibility for MTM enrollment to include not only

[53] May 6, 2024 HPMS memorandum, Contract Year 2025 Part D Medication Therapy Management Program Guidance and Submission Instructions available at: *https://www.cms.gov/files/document/memo-contract-year-2025-medication-therapy-management-mtm-program-submission-v050624.pdf.*

[54] *https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf.*

[55] Maidment I.D., Fox C., Boustani M., Katona C. Medication management—the missing link in dementia interventions. Int J Geriatr Psychiatry. 2012 May;27(5):439–42. doi: 10.1002/gps.2745. Epub 2011 Jun 29. PMID: 21714119.

[56] Rao P., Hung A. Impact of medication therapy management programs on potentially inappropriate medication use in older adults: A systematic review. J Manag Care Spec Pharm. 2024 Jan;30(1):3–14. doi: 10.18553/jmcp.2024.30.1.03. PMID: 38153866; PMCID: PMC10775773.

[57] Dong X., Tsang C., Wan J., Chisolhm-Burns M., et al. Effects of Medicare Part D medication therapy management on racial/ethnic disparities in adherence to antidementia medications among patients with Alzheimer's disease and related dementias: An observational study. Exploratory Research in Clinical and Social Pharmacy. 2024 March; Volume 13, Article 100420:2667–2766. *https://doi.org/10.1016/j.rcsop.2024.100420.*

[6] Dong, X., Tsang, C. C. S., Zhao, S., Browning, J. A., Wan, J. Y., Chisholm-Burns, M. A., . . . Wang, J. (2021). Effects of the Medicare Part D comprehensive medication review on medication adherence among patients with Alzheimer's disease. Current Medical Research and Opinion, 37(9), 1581–1588. *https://doi.org/10.1080/03007995.2021.1935224.*

Alzheimer's disease but also all other causes of dementia to improve medication adherence and to reduce the risk of adverse events. Consistent with this proposal, we propose to modify the regulatory text at § 423.153(d)(2)(iii)(A) identifying ''Alzheimer's disease'' as a core chronic disease to include ''Alzheimer's disease and dementia'' effective January 1, 2026.

D. Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights To Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs

1. Terminate Contracts Without Cause

At § 423.505(i), we propose to require Part D sponsors to allow pharmacies to terminate their network contracts without cause after the same notice period that the sponsor is allowed to terminate network pharmacy contracts without cause. This provision would only apply if the network pharmacy contract allows terminations without cause by the sponsor; if the contract does not allow terminations without cause by the sponsor, it would not be required to allow such terminations by the pharmacy. This change would prohibit the current practice CMS has observed by some sponsors and their FDRs to only allow pharmacies to terminate their network contracts without cause after giving a relatively long period of notice (sometimes exceeding one year), while preserving their right to terminate without cause on much shorter notice. We believe this change to provide greater fairness in contracting terms is necessary to protect beneficiaries from disruptions in receiving Part D benefits that would occur if network pharmacies stop providing services before formally terminating their contracts.

Part D sponsors contract with network pharmacies, either directly or through FDRs, to their enrollees. Under § 423.505(b)(18), Part D sponsors must have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy. This requirement was adopted pursuant to section 1860D–4(b) of the Act, which requires prescription drug plan sponsors to permit the participation of any pharmacy that meets the terms and conditions under the plan. In addition to the standard terms and conditions that sponsors must offer to any willing pharmacy, sponsors may negotiate non-standard terms and conditions with certain pharmacies that would govern those pharmacies' participation in the sponsor's Part D network.

Both the Part D statute and regulations require that all network contracts with pharmacies, including both the standard contract and any non-standard contract a sponsor may use to contract with a network pharmacy, contain certain terms meant to protect beneficiaries and ensure compliance with Part D requirements. For example, section 1860D–4(b)(1)(E) of the Act prohibits sponsors from requiring network pharmacies to accept insurance risk in their network contracts. Section 1860D–4(m) of the Act prohibits sponsors from restricting a pharmacy from informing an enrollee of any differential between the negotiated price of, or copayment or coinsurance for, a drug or biological and a lower price the enrollee would pay for the drug or biological without using health insurance coverage. Finally, § 423.505(i) requires that contracts between sponsors and network pharmacies contain several provisions, including—

- Provisions prohibiting pharmacies from holding an enrollee liable for payment of any fees that are the responsibility of the Part D sponsor (§ 423.505(i)(3)(i));
- A provision requiring prompt payment of clean claims (§ 423.505(i)(3)(v)); and
- A provision requiring disclosure and updating of any drug pricing standards used to determine payment, in accordance with § 423.505(b)(21)(i) (§ 423.505(i)(3)(vii)).

Part D sponsors often use FDRs, such as PBMs, to contract with network pharmacies on their behalf. In accordance with § 423.505(i)(3)(iii) and (iv), contracts between sponsors and PBMs must contain the same provisions required for all FDR contracts, including a provision requiring that the PBM perform activities in a manner that complies with all applicable regulations and with the Part D sponsor's contractual obligations to CMS.

Therefore, any network pharmacy contracts a PBM enters into as part of its services to the Part D sponsor must contain the same terms that would be required for the contracts if they were directly between the sponsor and the network pharmacy.

In recent years, CMS has received an increasing number of complaints from pharmacies about sponsors' and PBMs' Part D network pharmacy contracts. Specifically, pharmacies often report being dissatisfied with reimbursement terms. Many of these pharmacies report that they would like to exit their Part D network contracts, but that they are unable to do so without providing extensive notice. Some of these reports have included copies of the executed contracts in question that include the termination terms. At least one PBM requires 3-years notice for a retail pharmacy in its network to terminate the contract without cause. The notice provisions are often not reciprocal—one PBM network contract requires at least ten months' notice from a pharmacy seeking to exit its network without cause but allows the PBM to terminate the contract without cause on a 90-day notice.

CMS has also received reports of pharmacies that are unable to formally terminate their networks contracts simply refusing to fill prescriptions for Part D beneficiaries covered by the plans using those networks. Such ad hoc refusals to fill prescriptions are very disruptive to beneficiaries. The pharmacies that refuse to fill prescriptions for a particular network continue to appear in Medicare Plan Finder and on sponsor websites as network pharmacies until and unless the plan takes action to terminate the pharmacy, which results in beneficiaries receiving misleading information about where they may obtain Part D drugs under the plans they are enrolled in. Because these refusals occur without official terminations, sponsors and PBMs do not receive advance notice of them and cannot perform the transition activities they ordinarily would when a pharmacy leaves a network. These transition activities often include notifying affected beneficiaries and arranging for transfer of prescriptions.

We do not believe that pharmacies—particularly small pharmacies unaffiliated with larger chains—have the ability to negotiate such reciprocal termination terms on their own. As described in section III.B. of this proposed rule, pharmacies often do not have the ability to meaningfully negotiate with or demand clear information from PBMs and plans regarding contracting terms. Congress and the FTC have initiated inquiries into PBM practices, including pharmacy contracting practices, in recent years. The FTC determined that large PBMs employ ''lopsided and unfair contracting practices'' that prevent pharmacies, particularly smaller pharmacies not affiliated with large chains, from engaging in meaningful negotiations about contracting terms, including monetary and non-monetary terms.[58] The FTC highlighted PBMs'

[58] Federal Trade Commission, ''Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug

Continued

practice of unilaterally amending contracts by requiring pharmacies to opt out of new terms, rather than affirmatively opt in, making it difficult for pharmacies to understand what terms apply at any given time.[59]

To prevent disruptions in care for beneficiaries, CMS proposes to require contracts with pharmacies for participation in Part D networks that allow the sponsor or FDR, such as a PBM, to terminate the contract without cause to allow pharmacies to terminate the contract without cause after providing the same notice that the contract requires the sponsor or FDR to provide the pharmacy. A single network pharmacy contract often governs participation in multiple networks, with some pharmacies participating in all the Part D networks offered by a sponsor or FDR and some only participating in some of the networks. Therefore, we also propose that if the network pharmacy contract allows the sponsor or FDR to terminate the pharmacy's participation in some, but not all, of the networks covered by the contract without cause, that the contract allow the network pharmacy to terminate its participation in some, but not all, networks without cause after providing the same notice the contract requires the sponsor or FDR to provide. We propose to adopt this requirement under our authority at section 1857(e) of the Act, made applicable to Part D through section 1860D–12(b)(3)(D) of the Act, which authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate, so long as those terms are not inconsistent with the Part D statute. This requirement would be consistent with other requirements CMS currently imposes for downstream contracts, including pharmacy contracts, such as the requirement at § 423.505(i)(3)(v) that contracts require sponsors to promptly pay clean claims and at § 423.505(i)(5) that contracts allow Part D sponsors to approve, suspend, or terminate contracts with network pharmacies.

2. Request for Information on Access to Pharmacy Services and Prescription Drugs

As noted in a December 14, 2023 letter from the CMS Office of the Administrator to pPlans and PBMs, pharmacies serve a critical role in Medicare Part D by providing access to medications across the country, including to Part D beneficiaries.[60] CMS is concerned about the sustainability of these businesses, especially small and independent pharmacies, and their potential closures that may leave Part D beneficiaries without convenient access to pharmacy services—especially in rural and underserved areas. We have also heard that pharmacies may decline to fill certain prescriptions that would result in a net loss in reimbursement.

CMS reminds plans that under section 1860D–4(b)(1)(A) of the Act and § 423.505(b)(18), they must offer a standard contract with reasonable and relevant contract terms whereby any willing pharmacy may participate as a network pharmacy. Additionally, under section 1860D–4(b)(1)(C) of the Act and § 423.120(a), plans must have a contracted pharmacy network that is sufficient to ensure that Part D beneficiaries have convenient access to pharmacy services. CMS seeks comment on what additional data or information to consider—such as reimbursement rates, underlying costs, steering, contracting terms, and other elements which may affect pharmacies' ability to continue providing Part D drugs to beneficiaries—to improve our ability to protect beneficiaries' convenient access to Part D drugs consistent with current access standards at § 423.120.

E. Modifying the Definition of ''Service area'' § 422.2

In § 422.2, CMS defines service area to include ''a geographic area that for local MA plans is a county or multiple counties''. We are proposing to modify the definition to align with our proposal to include a definition of county in § 422.116 that includes ''county-equivalents'' as recognized by the United States Census Bureau for economic census purposes. To ensure consistency in the use of the term ''county'' across service area and network adequacy requirements and to codify our longstanding policy of treating county-equivalents the same as counties for these purposes, we are proposing to amend the definition of service area in § 422.2 to refer to ''a geographic area that for local MA plans is one or more counties, as defined in § 422.116(a)(1)''.

F. Administration of Supplemental Benefits Coverage Through Debit Cards §§ 422.2, 422.102, 422.102, 422.111, and 422.2263

1. Background

We have made a concerted effort in the past several years to better understand how supplemental benefits are provided by MA plans, how they are being used by enrollees, and how the provision of these benefits can be improved. These most recent efforts began with a request for information (RFI) published in in the August 1, 2022, **Federal Register** (87 FR 46918) that solicited feedback on ways to strengthen the MA program, including ways to improve the transparency of supplemental benefits. We received thousands of responses to these requests, and we have used this information to inform our efforts to improve how benefits are administrated within the MA program. A few commenters to the RFI suggested that CMS collect information regarding the usage of Special Supplemental Benefits for the Chronically Ill (SSBCI) so that there would be increased transparency around utilization patterns and costs associated with supplemental benefits, including SSBCI. We finalized a reporting requirement regarding the usage of supplemental benefits in the Paperwork Reduction Act package released on March 14, 2023, and expect to receive this data for the first time in 2025 (88 FR 15726). This data should promote greater transparency regarding the overall utility of these benefits while also helping to inform future decision making. Most recently, in the April 2024 final rule, we added evidentiary standards to SSBCI requirements by requiring MA plans to establish a bibliography of relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee (89 FR 30560). CMS has already begun implementing this requirement and will continue to review these bibliographies to ensure that MA plans are offering SSBCI that are supported by evidence and consistent with statutory and regulatory standards. Overall, through these initiatives, we have focused our efforts on ensuring supplemental benefits improve health outcomes and are continuing this theme in this proposed rule.

Section 1852(a)(3)(A) of the Act gives MA organizations the ability to offer supplemental benefits to plan enrollees, subject to the Secretary's approval. CMS has adopted rules—primarily in §§ 422.100(c)(2) and 422.102—to regulate how those supplemental benefits, such as vision, dental, gym membership, and others must be offered. For example, in Medicare Program, Establishment of the Medicare

Costs and Squeezing Main Street Pharmacies: Interim Staff Report'', July 2024, available at *https://www.ftc.gov/reports/pharmacy-benefit-managers-report,* pp. 48–49.

[59] *Id*, at 50, 54.

[60] *https://www.cms.gov/files/document/pharmacy-benefit-manager-insurer-letter.pdf.*

Advantage Program Final Rule,[61] which appeared in the **Federal Register** on January 28, 2005, we established at § 422.102(a)(4) that an MA organization could offer as a mandatory supplemental benefit a reduction in cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act (70 FR 4617). Later, in the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule[62] (January 19, 2021; 86 FR 5913) (hereinafter referred to as the January 2021 final rule), we further clarified the scope of supplemental benefits that reduce cost sharing by adding rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to clarify the different circumstances under which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit and the mechanisms by which an MA plan may make such reductions in cost sharing available to enrollees. Mandatory supplemental benefits are benefits that are included in the plan and are generally available to all enrollees with no additional premiums. As described in § 422.102(b), optional supplemental benefits are benefits that are available to plan enrollees who choose to pay an additional premium in order to receive those services. The majority of supplemental benefits that beneficiaries receive in MA are mandatory supplemental benefits, and we refer to mandatory supplemental benefits in this section unless otherwise specified.

In the January 2021 final rule, we explained that MA plans may choose to structure mandatory supplemental benefits in a few ways (86 FR 5913). For example, an MA plan may offer, as a mandatory supplemental benefit, the use of a debit card to administer reduced cost sharing for plan-covered services or to provide coverage of 100 percent of the cost of plan-covered items or services. This may include reduced cost sharing for dental and vision services (when offered as a mandatory supplemental benefit, not as an optional benefit) where a claim for additional payment is submitted to the plan, and/or coverage by the plan (through use of the card) of all or part of the cost of OTC items, fitness-related benefits, food and produce, transportation, and utilities support. With respect to a mandatory supplemental benefit in the form of reduced cost sharing, a beneficiary may receive a debit card to use to pay for any applicable cost sharing when receiving a basic benefit or mandatory supplemental benefit, including SSBCI. For example, if the plan provides a transportation service as a covered benefit and provides a debit card to be used to reduce cost sharing for those defined transportation services, the beneficiary could use the debit card to pay for those services. We remind readers that reduced cost sharing is not permitted as an optional supplemental benefit (that is a supplemental benefit that a beneficiary would select in exchange for additional premiums) (see 86 FR 5913). Thus, this mechanism of using debit cards is not permitted to administer optional supplemental benefits (that is, an optional dental or vision service package).

We further explained in the January 2021 final rule that MA organizations that choose to use a debit card to administer mandatory supplemental benefits must do so in a manner that ensures the debit card can only be used towards plan-covered items and services. To the extent these items and services are mandatory supplemental benefits, they must also meet all the regulatory supplemental benefit standards at §§ 422.100(c)(2) and 422.102(a) through (f). To summarize, CMS's prior rulemakings provided standards around supplemental benefits, including codifying the definition of a supplemental benefit, identifying the requirements for a benefit to be considered primarily health related, and in regard to Special Supplemental Benefits for the Chronically Ill (SSBCI), requiring plans to establish a bibliography of relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.

The use of debit cards is permitted for administering both mandatory supplemental benefits for all MA enrollees and mandatory supplemental benefits available as Special Supplemental Benefits for the Chronically Ill (SSBCI) as defined at § 422.102(f). We also explained in the January 2021 final rule that debit cards may only be used to administer coverage of items and services that are identified in the MA plan's bid and marketing and communication materials as covered benefits (86 FR 5913). Consistent with guidance in Chapter 4 of the Medicare Managed Care Manual (MCM), § 40.3, we stated that debit cards used for plan-covered benefits must be exclusively linked to only the covered items and drugs specified by the MA organization and that MA organizations are not permitted to offer use of a debit card to enrollees for purchasing items or services that are not plan-covered (86 FR 5913). In addition, the use of the debit card to pay cost sharing or pay for covered items and services must be tied to the period of coverage, that is the specific plan year or part of a plan year during which the enrollee is enrolled with and covered by the MA plan. (MA organizations may include a maximum dollar limit on a per-month basis, per-year basis, or other periodicity within the plan year tied to the benefit maximum.) The debit card itself is not a supplemental benefit; rather, it is a tool used to administer coverage to an enrollee for identified plan-covered items and services at a reduced cost. Plan-covered items and services that are paid for by a debit card must meet the requirements and standards for mandatory supplemental benefits or be basic benefits in the case of reduced cost sharing for a Part A or B covered benefit, as specified in the January 2021 final rule (86 FR 5913).

Since the January 2021 final rule, many MA organizations have disclosed the use of debit cards to administer a benefit in their annual bid notes. In reviewing annual bids, we've observed that MA organizations appear to regularly use debit cards to administer several mandatory supplemental benefits, including reductions in cost sharing for dental and vision services and/or payment for OTC items, fitness-related benefits, food and produce, transportation, and utilities support. In recent years, based on questions from stakeholders, including beneficiaries, we have also become aware that there is some confusion around the use of debit cards. For example, we have received many stakeholder questions requesting CMS clarify what these cards are and how they can be used. We have also received complaints from enrollees who tell us that they are confused when trying to use their debit card. Often these individuals do not receive guidance on which plan covered supplemental benefits can be purchased with their debit card or where and how they can use them. Additionally, stakeholders have raised concerns that there are not enough guardrails on how these cards are used and how purchases are tracked, especially at large box stores that carry non-covered items and services (for example, Costco or Walmart) that would be inappropriate

[61] *https://www.federalregister.gov/documents/2005/12/23/05-24446/medicare-program-establishment-of-the-medicare-advantage-program.*

[62] *https://www.govinfo.gov/content/pkg/FR-2021-01-19/pdf/2021-00538.pdf.*

for the MA plan to cover as supplemental benefits. For example, there are concerns that the enrollee may use the plan debit card to purchase items and services that are not covered or that do not meet the requirements for MA supplemental benefits.

To provide further clarity to both MA organizations and beneficiaries on the parameters around the appropriate use of plan debit cards, we are proposing requirements on the proper administration of supplemental benefits. Based on our authority under section 1856(b)(1) of the Act to establish standards for MA organizations, along with our authority in section 1857(e)(1) of the Act to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program, we propose to codify in regulation text the requirements and limitations discussed in the preamble of the 2022 final rule and later in the May 6, 2024, memo titled ''Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation'' regarding the administration of supplemental benefits, including the use of plan debit cards. We believe codifying these standards will also ensure that MA requirements regarding supplemental benefits are applied uniformly across the MA industry and for all supplemental benefits: both standard (that is, primarily health related) supplemental benefits and non-primarily health related SSBCI. We also propose to expand on these requirements by adopting additional disclosure and access guardrails to increase transparency, protect access to plan-covered services for MA enrollees, and ensure that MA plans cover (that is, provide, furnish, and/or pay for) only those items and services that are permissible MA benefits.

Specifically, we propose to add a new paragraph (g) at § 422.102 to codify existing guidelines for administering supplemental benefits, including the use of debit cards to administer plan-covered benefits, and add new guardrails to ensure that beneficiaries are fully aware of covered supplemental benefits and how to access those benefits.

2. The Administration of Supplemental Benefits

Our regulations at § 422.100(c)(2) define a mandatory or optional supplemental health care benefit (with the exception of Special Supplemental Benefits for the Chronically Ill (SSBCI) as defined at § 422.102(f)) as an item or service: (1) not covered by original Medicare; (2) that is primarily health related; and (3) for which the plan must incur a non-zero direct medical cost. The 2022 Final Rule further clarified at § 422.100(c)(2)(ii)(A) that to be considered primarily health related, a supplemental benefit must be to diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization. Additionally, we have codified numerous requirements that MA organizations must comply with when delivering supplemental benefits at § 422.102(a) through (e). More recently, we codified standards for SSBCI benefits at § 422.102(f), which include the requirements that SSBCI may only be offered to chronically ill enrollees as defined by section 1852(a)(3)(D) of the Act, must incur a non-zero non-administrative cost, and must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. SSBCI may include benefits that are not primarily health related per § 422.100(c)(2)(ii)(A) but must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Additionally, per section 1852(a)(3)(D)(ii)(II) of the Act, CMS has authority to waive the uniformity requirements that usually apply for all MA benefits so that SSBCI can be offered non-uniformly.

We are proposing in this rule that MA organizations must have processes for delivering all MA plan covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to suppliers and providers in accordance with § 422.112(a) as applicable. Per § 422.112(a), MA coordinated care plans may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. The MA organization may therefore contract with providers or vendors to furnish covered services, including supplemental benefits administered via a debit card or otherwise. For example, a plan may contract with a particular vendor to provide their food and produce benefit. In this scenario, that specific vendor is the network provider for furnishing the food and produce benefit. We note that section 1854(a)(6)(B)(iii) of the Act, commonly known as the ''non-interference clause,'' prohibits CMS from requiring any MA organization to contract with a particular provider to furnish covered items and services. Therefore, CMS does not specify which vendors MA organizations contract with to furnish covered items and services. (Note however that § 422.204(b)(3) requires that providers that furnish covered Part A and B benefits must meet the applicable requirements of Title XVIII of the Act and that certain types of institutional providers must have participation agreements with Medicare.)

We also note that all coordinated care plans are required to cover benefits, including supplemental benefits, at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs in accordance with the standards set forth in our rules and regulations.[63] This is required for all benefits, regardless of how they are administered.

If an in-network provider is unavailable or inadequate to administer covered plan benefits, whether Parts A and B or supplemental benefits, the MA organization should have a plan or process in place to ensure that the requirements under § 422.112(a)(1)(iii) are met. However, given inconsistencies in how supplemental benefits are provided, we believe it is necessary to clarify this requirement in regulatory text. Therefore, we propose and seek comment on new § 422.102(g)(1) that would require MA organizations to have processes for delivering all MA organization covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to all covered services in accordance with § 422.112(a).

3. New Guardrails for Plan Debit Cards

As described in section III.H.2 of this proposed rule, we are proposing to include a clarification in § 422.102(g)(1) requiring that MA organizations have processes for delivering all MA organization covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to all covered services per § 422.112(a). Thus, we believe it is necessary to specify that this requirement would apply to all plan covered supplemental benefits, including supplemental benefits administered through debit cards.

[63] § 422.112 (a)(1)(iii); Chapter 4, section 30.2 of the Medicare Managed Care Manual; 88 FR 22200.

Under this proposal, plans must have a process in place to maintain enrollee access to these benefits. When plans offer debit cards to assist with the cost sharing for covered benefits or otherwise administer supplemental benefits, the MA organization must ensure that the access requirements at § 422.112(a) are met. This means regardless of the mode of delivery (*e.g.,* debit card or other means), MA organizations must ensure that all covered services, including supplemental benefits, and SSBCI for eligible enrollees, contracted for by (or on behalf of) enrollees, are available and accessible under the plan.

In addition, we require that plan-covered benefits be disclosed in the plan's evidence of coverage (EOC). Section 422.111 requires that MA organizations disclose all benefits offered under an MA plan, including applicable conditions and limitations, and any other conditions associated with receipt or use of benefits. These requirements are applicable to all benefits, including those administered via debit card. We also note that MA organizations are required to send an Explanation of Benefits (EOB) to an enrollee that captures all claims activity that occurs during a reporting period (monthly or quarterly cycle). The EOB must include claims information for all Part C claims processed during the reporting period, including all claims for Part A and Part B covered items and services, mandatory supplemental benefits, optional supplemental benefits, and SSBCI.[64] The EOB must disclose for each claim a descriptor, billing code and amount billed, total cost approved for reimbursement, share of the total cost paid by the plan, and share of the total cost for which the enrollee is liable. Additionally, the EOB must include certain year-to-date information such as the amount an enrollee has incurred toward the Maximum Out-of-Pocket (MOOP) limit.[65] These EOB requirements include supplemental benefits that MA plans elect to cover through a debit card.

However, given stakeholder and enrollee feedback, we believe additional clarity and more specific guardrails regarding the use of debit cards are necessary to ensure that enrollees are adequately aware of the benefits that are available to them from their plan through a debit card and how to access them.

In the January 2021 final rule, we stated that consistent with current guidance in section 40.3 of Chapter 4 of the Medicare MCM, debit cards may only be used for plan-covered benefits under the condition that the card is exclusively linked to the covered items. We also suggested in the January 2021 final rule (86 FR 5913) that MA organizations may accomplish this by providing a debit card that is linked to an appropriate merchant and item/service codes so that the enrollee may pay the cost sharing at the point of service. We believe such a link is necessary to ensure that the debit card is used for the permissible purpose—to reduce the enrollee's cost sharing for a covered item or service or to pay for an item or service that is covered by the MA plan at up to 100 percent of the cost. Therefore, we propose at § 422.102(g)(2)(i) the following requirements that MA organizations must meet if they choose to administer reductions in cost sharing or provide coverage of 100 percent of the cost of a mandatory supplemental benefit. We are proposing at § 422.102(g)(2)(i) that when administering a mandatory supplemental benefit through plan debit cards, an MA organization must provide debit cards that are electronically linked to plan covered benefits through a real-time identification mechanism to verify eligibility of plan covered benefits at the point of sale. This means that a plan issued debit card must be electronically linked to the covered benefit through a real-time mechanism that ensures the enrollee is only able to receive covered items or services that they are eligible to receive at the point of sale. The debit card must include some sort of mechanism that ensures the enrollee may only use the card to purchase the covered item or service. For example, an MA organization could provide a debit card linked to covered benefits through the use of item/service codes so that the enrollee is only able to pay the cost sharing for those select items at the point of sale. In this scenario, the MA organization would have to ensure that the enrollee is only able to purchase items or services they are specifically eligible to receive. This is necessary to ensure that enrollees only receive benefits they are eligible to receive and to ensure that MA organizations do not inadvertently furnish non-covered benefits. The debit card is intended only to facilitate or administer certain covered benefits and may not be used to pay for non-covered items or services. We are not proposing to prescribe exactly how plans effectuate the proposed requirements at § 422.102(g)(2)(i) because we believe flexibility for plans to innovate around these processes will be beneficial to the industry. However, if an MA organization provides a debit card that is not electronically linked to covered items and services and does not include checks to ensure that the enrollee may only receive covered benefits they are eligible to receive, the MA organization would be in violation of these proposed requirements.

Next, we propose at § 422.102(g)(2)(ii) to require MA organizations that use debit cards to administer a supplemental benefit to provide instructions for debit card use and customer service support to enrollees to answer questions or help with issues related to the administration of the card. For example, if an MA organization provides a food and produce benefit that may be accessed via a debit card, the plan must provide eligible enrollees with instructions on how to use the debit card and provide customer support service to beneficiaries who have questions about how to use the debit card. This support service must include instructions to beneficiaries on the process to access these benefits if not accessible by debit card, in accordance with § 422.112(a). We believe this is necessary to ensure that enrollees are fully aware of their benefits and how to properly access those benefits, particularly those living in rural areas with limited access to broadband/internet for communication. Finally, all benefits must be limited to the specific plan year. Therefore, we propose to state at § 422.102(g)(2)(iv) that MA organizations must ensure the use of a debit card to administer a covered benefit is limited to the specific plan year.

In the January 2021 final rule, we amended § 422.102(a)(6) to state that an MA organization may offer reduced cost sharing as a mandatory supplemental benefit through the use of reimbursement, through a debit card or other means. In order to further support the proposed requirements at § 422.102(g)(1), we also propose to revise § 422.102(a)(6) by removing ''or other means'' and adding ''manual'' before reimbursement to ensure that reductions in cost sharing as a supplemental benefit are clearly limited to either manual reimbursement or to a debit card governed by the proposed rules under § 422.102(g) for covered items and services. We believe this revision ensures that when providing reduced cost sharing through a debit card, that card is governed by the proposed requirements at § 422.102(g)(1)(i). This proposal would

[64] *https://www.ecfr.gov/current/title-42/part-422/section-422.111#p-422.111(k).*

[65] *https://www.ecfr.gov/current/title-42/part-422/section-422.111#p-422.111(k).*

prohibit plans from using other mechanisms not directly described in § 422.102(a)(6)(i).

We further believe this revision is necessary because ''other means'' could be interpreted to allow an unrestricted card or other vague mechanisms, which would conflict with CMS requirements that a debit card be exclusively linked to covered benefits and limited to the plan year or the requirements being proposed at § 422.102(g)(1)(i). Further, MA organizations are required to administer reductions in cost sharing in a manner that ensures the debit card, reimbursement, or allowance can only be used towards plan-covered services and are limited to the specific plan year. The use of an unrestricted card cannot guarantee compliance with these requirements.

While we are proposing to remove ''or other means,'' we solicit comment on what other means, outside of manual reimbursement or a debit card, would be unintentionally removed as options to plans should we finalize this proposed revision. We also solicit comment on how these other means or mechanisms may still guarantee compliance with existing requirements at § 422.102(a)(6) and the requirements proposed at §§ 422.102(g) and 422.111(b)(6) (discussed in section III.H.2 of this proposed rule). For example, it is not our intent that the proposed changes at § 422.102(a)(6) prohibit an organization from using a stored value card,[66] provided the use of these cards by MA plans complies with the requirements at § 422.102(g). Therefore, we also solicit comment on whether the use of stored value cards meets the requirements at § 422.102(g). Specifically, we solicit comment on whether the mechanisms available and used with stored valued cards are sufficient so that the purchases made through such cards can be electronically linked to plan covered items through a real-time identification mechanism that verifies the eligibility of plan covered benefits at the point of sale, and can restrict the time period allowed for the use of the stored value card to the plan year only. We also solicit comment on whether stored value cards should be explicitly added to § 422.102(a)(6) and § 422.102(g) as an acceptable means of administering reductions in cost sharing and the coverage of supplemental benefits.

We solicit comment on all aspects of this proposal and may consider finalizing revisions to our policies based on the comments received.

[66] *https://www.fiscal.treasury.gov/stored-value-card/.*

4. Access

While a MA organization may utilize a debit card to administer a benefit, this does not exempt the plan from ensuring access and network adequacy is preserved for the benefit if there is an issue with the vendor or a technical issue with the debit card. As discussed earlier, the regulations at § 422.112(a)(1)(iii) specify that coordinated care plans must arrange for, and cover any, medically necessary (clinically appropriate for non-primarily health related SSBCI) covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. Additionally, our long-standing guidance under section 40.3.1 of Chapter 4 of the Medicare MCM states, ''Every MA plan, independent of the payment method it chooses, must also allow—under circumstances which it describes (for example, when the debit card network is not operating correctly)—for manual reimbursement for the purchase of OTC items based on submitted receipts.'' We included this language in the Medicare MCM Chapter 4 to ensure enrollee access by requiring plans to have an alternative method (for example, reimbursement based on submitted receipts) for enrollees to receive their OTC benefits if there was an issue with the contracted vendor or an operational issue with the debit card. We believe that it is important to adopt a similar policy here in order to maintain enrollee access for all benefits administered through a debit card, not just OTC benefits.

Therefore, we propose at § 422.102(g)(2)(iii) that a plan must have an alternative process that allows for reimbursement of eligible expenses for plan covered benefits. We believe this proposal would allow enrollees to maintain access to covered benefits that are administered through the offering of a debit card should the real-time identification mechanism fail or otherwise be unavailable. This would allow enrollees to be reimbursed for the purchase of eligible plan covered benefits if they are unable to use their plan debit cards. We believe that requiring plans to allow this alternative will ensure that the enrollee has access to the benefit if there is an issue with the vendor, a technical issue with the debit card, or any other situation in which the use of a debit card is unfeasible for the enrollee. This may include non-technical issues, such as when an enrollee is having trouble understanding how to use the debit card or is otherwise running into non-technical obstacles to its use. This alternative reimbursement process could also apply if there are failures with the electronic processing system used by the provider. This includes situations where a permitted transaction is erroneously declined. In other words, in the case that the debit card is not operating correctly or as intended, there is an issue with the vendor, or any other situation in which the use of a debit card is unfeasible for the enrollee, the MA plan must allow enrollees to be reimbursed for the purchase of the covered benefit based on submitted receipts. This also includes situations in which a contracted vendor is not easily accessible due to an enrollee's transportation constraints. This proposed requirement protects enrollee access to benefits that they are entitled to receive regardless of issues that may arise from a plan's chosen mode of delivery (for example, plan debit card).

This alternative process must be in place for both in-network and out-of-network access to the benefit where necessary (for example, in the event that in-network providers and/or vendors are unavailable or inadequate to meet the enrollee's needs). In this scenario, the plan would still be responsible for ensuring out of network access at in network cost sharing. We expect MA organizations to adequately disclose the process by which reimbursement may be made to enrollees and to ensure that the process is accessible to all enrollees. We also encourage MA organizations to be mindful of enrollees in rural areas, especially those who have limited access to broadband or internet communication, when implementing this requirement and when disclosing information about how to effectuate a reimbursement to plan enrollees. This is consistent with and will further ensure compliance by MA coordinated care plans with § 422.112(a).

We also note that MA plans that are PPOs are required to provide reimbursement for all covered services, regardless of whether the items are provided within the network of providers under § 422.4(a)(1)(v). Regarding reimbursement, § 422.4(a)(1)(v)(B) requires PPOs to provide for ''reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers.'' This applies to all supplemental benefits, including those administered through a debit card (we note that in this scenario, an enrollee may be subject to increased cost sharing). For example, a MA organization may contract with a particular grocery store to furnish their

food and produce benefit. However, in a PPO, enrollees may purchase eligible food and produce at another non-contracted grocer (out of network provider) and be reimbursed for those covered items. We expect MA PPOs to have processes to verify out of network reimbursement is only made for plan-covered services and to indicate to enrollees the process by which reimbursement can be made. As noted above, that process should be mindful of enrollees in rural or remote areas with limited access to providers and internet-based communication methods.

Finally, we remind MA plans that our regulations at § 422.112(b)(3) provide for coordinated care MA plans to include community-based services in their plans for coordination and continuity of care for enrollees. In addition, § 422.112(b)(3) specifically states that MA coordinated care plans are required to ''coordinate MA benefits with community and social services generally available in the area served by the MA plan.'' MA plans may contract with community-based organizations to provide supplemental benefits that are compliant with the statutory and regulatory requirements. We strongly encourage, for example, an MA plan that elects to offer a food and produce supplemental benefit to do so via a community-based organization that is able to process the benefit through a debit card. We understand that in some areas there may be a limited number of community-based providers, including small businesses. However, we strongly encourage plans to partner with community-based providers or other local, smaller businesses when offering supplemental benefits, particularly regarding food and produce benefits that may be offered to chronically ill enrollees under SSBCI regulations at § 422.102(f). We believe that encouraging plans to contract with community-based providers will improve enrollee access to benefits. With covered benefits available in their communities, enrollees will be able to more readily and easily obtain and use covered benefits and thus have the potential to improve their overall health.

5. Additional Disclosure Guardrails

To increase transparency for beneficiaries accessing plan-covered benefits, we also propose to add additional disclosure requirements specific to supplemental benefits under § 422.111. Section 422.111(b) currently requires MA organizations to disclose mandatory and optional supplemental benefits and the premium for those benefits. We propose to amend § 422.111(b)(6) to state that MA organizations must disclose any mandatory supplemental benefits (including reductions in cost sharing) or optional supplemental benefits, the premium for optional supplemental benefits, and any applicable conditions and limitations associated with receipt or use of supplemental benefits. We propose to clarify that this disclosure must include eligible OTC items and, where supplemental benefits are administered through a debit card, must specify which benefits may be accessed using the debit card. We believe that such disclosure is necessary to ensure transparency considering the growth of the scope of supplemental benefits and authorized administrative flexibilities, such as the use of plan-furnished debit cards to administer certain supplemental benefits. This will help ensure that plan enrollees are sufficiently aware of what covered benefits may be accessed through any debit card they receive from their plan.

Lastly, regarding OTC items, longstanding CMS guidance (section 40.1 of Chapter 4 of the Medicare MCM) defines OTC items as health-related items and medications that are available without a prescription, and § 422.102(c)(2) provides that permissible supplemental benefits are items and services that are not covered by Medicare Part A, Part B or Part D. Per § 422.100(c)(2), plans may never offer as a supplemental benefit something that is covered under Part B or that is paid for under Part D for the plan's enrollees, including an OTC item or medication. Additionally, while the 2022 Final Rule did include OTC items as an example of permissible primarily health-related supplemental benefits (86 FR 5971), it did not include a non-exhaustive list of acceptable and non-acceptable items. We have also received feedback that a non-exhaustive list could provide further clarity for MA organizations. Therefore, we include a non-exhaustive list here. Examples of permitted primarily health related OTC items that have been reviewed and approved by CMS during the bid review process include, but are not limited to: amplified phones, analgesics, antacids, anti-bacterial grooming products (when recommended by a provider), antihistamines, anti-inflammatories, antiseptics, blood pressure cuffs, callous/wart remover, custom made compression garments (if furnished under circumstances when it would not be covered by the Part B benefit), contact lens solution and cases, over the counter contraceptives (such as condoms and over the counter, non-prescription birth control pills), cotton swabs, COVID–19 tests (over the counter), decongestants, dressing and eating aids, extension grabbers or reaching aids, facial cleaners (including acne wash), feminine hygiene products (such as douche, lubricants, pads, tampons, wipes), fiber supplements, first aid supplies, energy protein bars and power drinks, nutritional drinks/shakes, hand sanitizer, hearing aid batteries, hearing amplifiers, herbal supplements, hip kits, dietary supplements (such as CoQ10, garlic, gingko biloba, melatonin, and saw palmetto,) incontinence supplies (such as adult diapers and under pads), insulin refrigeration units, and lip soothers/balms (non-medicated), low vision aids, magnifying glasses, medicine dispensers, mouth/oral care products (such as toothbrush/paste, floss, mouthwash, denture adhesives/cleaners), naloxone (if furnished under circumstances when it would not be covered by Medicare Part B or Part D), night lights, nicotine replacement therapy (NRT), pain relief products (such as Epsom salt and ice packs), pill bottle openers, pill/tablet boxes, cutters, and crushers, pulse oximeters, probiotics, nonprescription reading glasses, shoe insoles/inserts/arch supports, skin moisturizers for dry skin, skin protectant (such as diaper rash ointment, moleskin, mosquito repellent, petroleum jelly), witch hazel, sleep aids, soap (doctor recommended antibacterial/antimicrobial), sunscreen, supportive items (such as compression hosiery, rib belts, elastic knee support), toilet lights, vitamins and minerals, nonprescription weight loss items, weight scales, and disposable face masks (to protect against respiratory illnesses). Although this is not considered to be an exhaustive list of OTC items, we solicit comment on whether there are additional items that stakeholders believe should be included on this list.

CMS has also reviewed items that CMS has determined not to be permissible MA supplemental benefits because they do not meet the requirement that the item or service be primarily health related. Such OTC items that cannot be covered as MA supplemental benefits include air conditioners, baby items, bad breath remedies (gum, breath mints), bagging fees, body scrubs, cannabidiol, cleaning products (Clorox, Lysol), clocks, dehumidifiers, deodorant, grooming/shaving supplies, hair care (shampoo, conditioner, dye, bleach, hair removal and hair growth products), humidifiers, jar openers, paper products (tissue,

toilet paper, paper towels), perfume, pest control, skin moisturizers used for anti-aging, teeth whiteners, water bottles, and personal coolers. We note that items such as air conditioners, cleaning products, dehumidifiers, humidifiers, grooming supplies to assist with hygiene, paper products (tissue, toilet paper, paper towels), and pest control may be permissible as a non-primarily health related SSBCI provided the item has a reasonable expectation of improving or maintaining the health or overall function of the enrollee and meets the standards at § 422.102(f). For example, research indicates that air conditioners may improve the breathing of patients with COPD and asthma.[67] We solicit comment on these listed items and may revise the list based on feedback received.

Again, we reiterate that the list of permissible primarily health related OTC items set forth in this proposed rule is non-exhaustive. We've also included a non-exhaustive list of items that are not primarily health related but could be offered as a non-primarily health related SSBCI provided the requirements under § 422.102(f) are met. CMS reviews bids each year to ensure that proposed supplemental benefits meet the applicable regulatory and statutory standards.[68] For example, MA organizations may propose to offer OTC items not on this list and CMS may come across items in the future, not listed here, that we believe do not meet the definition of a supplemental benefit per § 422.100(c)(2) or are not primarily health related per § 422.100(c)(2)(ii). However, we believe including these lists in this preamble discussion will help MA organizations consistently apply the requirements at §§ 422.100(c)(2) and 422.100(c)(2)(ii) and assist MA organizations when planning and preparing their annual bid packages.

6. Marketing Supplemental Benefits

Another important consideration related to debit cards is MA organizations' marketing tactics. We have become aware of certain advertisements that solely mention debit cards, or marketing terms such as ''Medicare flex cards,'' with an alluring value attached to them, potentially giving false impressions that the card itself is the benefit, that it can be used to purchase anything and can be used anywhere, and that an individual can receive it automatically by enrolling in the advertised MA plan.

CMS has concerns with these advertisements. As discussed previously, the debit card itself is not the supplemental benefit, rather, it is the mechanism through which the MA organization administers and pays for the covered supplemental benefit. There is a risk that a beneficiary might view this type of advertisement and make an enrollment decision based on the belief that, by enrolling in the plan, they will automatically receive a card with ''free'' money to spend wherever they choose. In reality, that is not the case because debit cards used by MA plans in administering MA supplemental benefits have various restrictions, including restrictions related to eligibility, the timeframe in which the debit card may be used, the providers with whom the debit card may be used, and the covered items and services for which the debit card may be used.

To prevent such inaccurate or misleading advertising, we are proposing new parameters for MA organizations' marketing of supplemental benefits. Specifically, we propose to add new paragraph (b)(11) to § 422.2263, prohibiting MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, such as use of a debit card by the enrollee to provide the plan's payment to the provider for the covered services. We believe that this proposed requirement is necessary to promote informed choice among prospective and current MA enrollees. By prohibiting the dollar value and administration method in marketing materials, it will provide the beneficiary with enough information to inquire further if the supplemental benefit would be helpful to their care, rather than an overly simplified advertisement that does not include the level of information required for an informed enrollment decision. Our proposal would also reduce the number of misleading MA supplemental benefit advertisements.

We solicit comment on all aspects of this proposal and may consider revisions based on the comments received.

This proposal primarily codifies and clarifies existing guidance and practices and is not expected to have additional impact above current operating expenses. This proposal would not impose any new collection of information requirements.

G. Non-Allowable Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

Section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. The 2024 final rule titled the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' (the ''April 2024 Final Rule'') (89 FR 30448) finalized requirements at § 422.102(f)(3) that, by the date on which it submits its bid to CMS, an MA organization must establish a bibliography of relevant acceptable evidence that an item or service offered as an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. In the 2024 Final Rule, we also codified at § 422.102(f)(5) that CMS may decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. In addition, in the April 2024 final rule (89 FR 30448), we modified and strengthened the current requirements in § 422.2267(e)(34) for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned. Specifically, we required that the SSBCI disclaimer list the relevant chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization. We also finalized specific font and reading pace parameters for the SSBCI disclaimer in print, television, online, social media, radio, other voice-based ads, and outdoor advertising (including billboards). Finally, we required that MA organizations include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. These requirements further help to ensure that the marketing of and communication about these benefits was not misleading or potentially confusing

[67] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291496/.*

[68] We strongly encourage MA organizations that are looking to cover new or novel benefits to raise those to CMS well in advance of bid submission to allow ample time for the MA organization to provide, and CMS to review, information explaining how the applicable statutory and regulatory standards are met for the proposed benefits without the time pressures of the bid review process.

to enrollees who rely on these materials to make enrollment decisions.

Section 1852(a)(3)(A) provides CMS the authority to approve supplemental benefits. Supplemental benefits must meet the regulatory and statutory requirements for approval, including that the benefits may not be approved if the agency finds that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice (now Medicare Advantage) eligible individuals with the organization. Further, per section 1854(a)(5)(C) of the Act, CMS is not obligated to accept any or every bid submitted by an MA organization. Based on our experience reviewing, approving, and denying bid proposals throughout the years, we are relying upon these authorities to propose in regulation a non-exhaustive list of non-primarily health related items or services that do not meet the standard of having a reasonable expectation of improving or maintaining the health or overall function of the enrollee standard as described in section 1852(a)(3)(D)(ii)(I) of the Act and at CMS regulations at § 422.102(f)(1)(ii). Therefore, none of these items and services are permissible SSBCI. We believe that codifying this non-exhaustive list of examples of items or services that do not meet these standards provides transparency and greater certainty for MA organizations and enrollees about the rules that govern these benefits, which is necessary and appropriate to ensure that supplemental benefits coverage is properly furnished by all MA organizations that choose to offer these supplemental benefits.

SSBCI must meet the regulatory requirements set forth under § 422.102(f). They must also meet the requirements to be a supplemental benefit as described at 422.100(c)(2), with the exceptions that the benefits need not be primarily health related, as described at § 422.100(c)(2)(ii)(A), and the MA organization must incur a non-zero direct non-administrative cost (as opposed to a non-zero medical cost) in covering the benefit. Further, while an SSBCI may be non-primarily health related, there must still be a reasonable expectation that the item or service will improve or maintain the health or overall function of the chronically ill enrollee. For example, an air conditioner is not a primarily health related item or service, but there is acceptable evidence that using an air conditioner may improve the health of patients with asthma, chronic obstructive pulmonary disease (COPD),[69] or other breathing problems for whom an air conditioner might keep them from being hospitalized during times of excessive heat or wildfires.[70] A health plan's care coordination team might be able to identify these individuals in advance to provide them access to an air conditioner.

We propose to codify a non-exhaustive list of non-primarily health related items or services that do not have a reasonable expectation of improving or maintaining the health of a chronically ill enrollee and therefore cannot be offered as SSBCI. Those items include—

- Procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage (for example, cosmetic surgery such as facelifts or cosmetic treatment for facial lines, atrophy of collagen and fat, and bone loss due to aging);
- Alcohol, tobacco, and cannabis products;
- Funeral planning and expenses;
- Life insurance;
- Hospital indemnity insurance; and
- Broad membership-type programs inclusive of multiple unrelated services and discounts.

These items and services cannot be offered as SSBCI for the following reasons:

Regarding cosmetic services, CMS explained in previous guidance (see HPMS memorandum, ''Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation,'' dated May 6, 2024, pp. 30–31) that coverage for procedures that are cosmetic in nature are not permitted to be offered as SSBCI because these benefits do not meet the statutory requirement of a ''reasonable expectation of improving or maintaining the health or overall function of the enrollee.'' CMS may decline an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. Some plans have proposed to offer cosmetic services for aesthetic purposes only, such as botulinum toxin injections for lines and wrinkles, in their bids. CMS disapproved these proposals during bid review. While MA organizations are permitted to offer non-primarily health related benefits to chronically ill enrollees, these benefits must still have a direct impact on the enrollee's health. Purely cosmetic procedures are not health related and thus cannot be permitted as a supplemental benefit. For these reasons, procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage cannot be offered as SSBCI.

We do note however that some cosmetic procedures may be acceptable to be offered as an SSBCI benefit if used to treat medical conditions that affect health or overall function and would not be considered purely cosmetic in nature. For example, the use of botulinum toxin injections is acceptable when treating medical conditions such as an overactive bladder, bladder leakage issues due to neurologic disease, headache prevention in adults with chronic migraine, increased muscle stiffness in adults with limb spasticity, cervical dystonia (CD), strabismus, eyelid spasms or blepharospasm, and hyperhidrosis. There are some circumstances in which Traditional Medicare (*i.e.,* Medicare Parts A and B) provides coverage for these items. These would be acceptable as a supplemental benefit in situations in which the MA organization is extending upon or providing coverage, beyond that which is provided under Traditional Medicare, related to these procedures. Additionally, coverage for reconstructive medical procedures that extend upon or wrap around Traditional Medicare coverage and are not solely cosmetic in nature (for example, reconstructive surgery for blepharoplasty, subperichondrial hematoma, sebaceous cysts, cleft palate, or trauma related injuries) would also be permitted as a supplemental benefit.

In the 2019 HPMS memo titled ''Implementing Supplemental Benefits for Chronically Ill Enrollees,'' we stated that MA organizations may offer food and produce to assist chronically ill enrollees in meeting nutritional needs assuming all requirements for SSBCI under § 422.102(f) are met, and that such items may include items such as (but not limited to) produce, frozen foods, and canned goods. We noted that tobacco and alcohol are expressly prohibited however, as neither are considered food or nutritional. In addition, CMS has received inquiries from MA organizations about whether they are permitted to offer cannabis-based products as a supplemental benefit. In response to these inquiries, CMS has stated that medical marijuana or derivatives, such as cannabis oil, cannot be covered by MA organizations

[69] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291496/.*

[70] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2900329/.*

as they are illegal substances under Federal law.

In the 2019 HPMS memo titled ''Implementing Supplemental Benefits for Chronically Ill Enrollees,'' we also stated that while MA organizations may provide services to assist in the establishment of decision-making authority for health care needs (for example, power of attorney for health services) and/or may provide education such as financial literacy classes, technology education, and language classes, assuming all requirements for SSBCI under § 422.102(f) are met, but coverage of funeral expenses is not permitted. Funeral services are provided after the death of the beneficiary and, as such, cannot be tied to improving or maintaining that individual's health or overall function. Similarly, life insurance would not be permissible as SSBCI.

We also do not consider hospital indemnity insurance to meet the definition of a supplemental benefit. MA organizations offering supplemental benefits must incur a non-zero direct medical cost, except that in the case of an SSBCI that is not primarily health related the MA organization may instead incur a non-zero, direct non-administrative cost (§ 422.100(c)(2)(ii)(B)). Reductions in cost sharing fit into the definition of a supplemental benefit as they are increases in the MA organization's share of the overall payment for the covered health care item or service. However, payment for hospital indemnity insurance premiums would not fit this definition because an MA organization paying for separate, third-party insurance for the enrollee does not incur a direct cost on behalf of the enrollee. Rather, it shifts payment for medical costs to another payer.

Additionally, MA organizations are already permitted to reduce cost sharing for inpatient and other covered benefits as part of an SSBCI reduction in cost sharing package. Therefore, MA organizations already have a mechanism to reduce cost sharing under existing rules that do not require offering separate, third-party insurance coverage. Finally, 42 CFR part 422 subpart M appeal and grievance requirements require all covered benefits to be subject to the MA appeal rights. The purchase of a hospital indemnity insurance policy would mean that the actual benefits from the policy to enrollees (that is, payment toward or reimbursement of the costs of health care items and services) would not be covered by subpart M. Having only the payment of premium subject to appeal is inconsistent with how other benefits available through the MA organizations are subject to appeal and potentially creates enrollee confusion or misleads enrollees as to what the MA organization is responsible for furnishing and paying and thus is inappropriate as a supplemental benefit.

Finally, CMS has received and declined proposals from MA organizations to offer broad membership programs, inclusive of multiple unrelated services discounts, such as Amazon Prime, Costco, and others, as SSBCI. A generic membership is not permissible as SSBCI because it is not limited to items or services that have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. That is not to say that an MA organization cannot contract with any of these retailers to offer covered benefits in some capacity (for example, benefits administered via a restricted debit card). However, a generic membership that would include items or services that do not have a reasonable expectation of improving or maintaining the health or overall function of the enrollee and no mechanism to ensure that enrollees receive only covered benefits is not compliant with CMS rules regarding supplemental benefits and thus not allowable as a supplemental benefit.

Lastly, we reiterate the statutory prohibition against MA organizations offering cash or monetary rebates (section 1851(h)(4)(A) of the Act), and we further reiterate that items or services that are not intended to improve the enrollee's health, such as gambling items (*e.g.,* online casino games, lottery tickets), firearms and ammunition, would not meet our requirements for supplemental benefits.

We propose to codify examples discussed here as items and services that cannot be offered as SSBCI at § 422.102(f)(1)(iii). We solicit comment on all aspects of this proposal and may consider revisions to our proposal based on the comments received. These revisions may include, but are not limited to, a revision to the non-exhaustive list of non-primarily health related items and services that do not have a reasonable expectation of improving or maintaining the health of a chronically ill enrollee and may not be offered as SSBCI.

CMS also solicits comment on other items and services not listed here that would be appropriate to include in the list of items that may not be offered as SSBCI.

We ask that commenters include in their comments explanations and why they believe suggested items do not meet the statutory requirement of having a reasonable expectation of improving or maintaining the health or overall function of the enrollee and include any relevant information and research for CMS to consider. Based on the comments received, we may consider finalizing revisions to this proposed policy.

Finally, we note that just because we are proposing to codify a non-exhaustive list of benefits and services that may not be offered as an SSBCI, this does not mean that all items not included on this list are allowable. All benefits must be proposed in a plan's annual bid and are subject to review by CMS. Further, all SSBCI must meet the requirements under § 422.102(f), including the requirement of a written bibliography of relevant acceptable evidence that demonstrates the impact of a service on the health or overall function of its recipient (§ 422.102(f)(3)), and the requirement that any enrollees targeted with an SSBCI service or benefit must meet all the eligibility requirements under § 422.102(f).

This proposal primarily codifies and clarifies existing guidance and practices and is not expected to have additional impact above current operating expenses for MA organizations. This proposal would not impose any new collection of information requirements.

We seek comment on all aspects of this proposal and may consider revisions to the final policy based on the comments received.

H. Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) and Technical Changes to the Definition of Chronically Ill Enrollee (§ 422.102)

1. Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI)

The Balanced Budget Act (BBA) of 2018 (Pub. L. 115–123) provided new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans. We addressed these new supplemental benefits extensively in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (hereafter referred to as ''June 2020 final rule'') (85 FR 33800 through 33805), where we referred to them as Special Supplemental Benefits for the Chronically Ill (SSBCI).

Supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars. The MA rebate dollars may be used for mandatory, but not optional, supplemental benefits

offered by the plan (§ 422.266(b)(1)).[71] When submitting an annual bid to participate in the MA program, an MA organization includes in its bid a Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) for each of its plans, where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. Since the statutory amendment authorizing SSBCI and our subsequent guidance in a Health Plan Management System (HPMS) memorandum dated April 24, 2019 (''2019 HPMS memo'' hereafter),[72] the number of MA plans that offer SSBCI—and the number and scope of SSBCI offered by an individual plan—has significantly increased. We have observed these trends in reviewing PBPs from MA plans submitted over the last 5 years.

As we described in Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (hereafter referred to as the ''April 2024 final rule'') (89 FR 30551), to offer an item or service as an SSBCI to an enrollee, an MA plan must make at least two separate determinations with respect to that enrollee in order to satisfy the statutory and regulatory requirements for these benefits. First, the MA plan must determine that an enrollee is eligible for the SSBCI by meeting the statutory definition of ''chronically ill enrollee.'' Section 1852(a)(3)(D)(iii) of the Act defines ''chronically ill enrollee'' as an individual enrolled in the MA plan who meets all of the following: (I) has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (II) has a high risk of hospitalization or other adverse health outcomes; and (III) requires intensive care coordination. Per § 422.102(f)(1)(i)(B), CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life-threatening or significantly limit the overall health or function of an individual. This list of chronic conditions is the same as the list for which MA organizations may offer chronic condition special needs plans (C–SNPs), which can be found in the definition of ''severe or disabling chronic condition'' within § 422.2.

Section 422.102(f)(4)(i) and (ii) requires that the MA plans have written policies for making SSBCI enrollment determinations, document that each enrollee eligible for SSBCI is a chronically ill enrollee and provide this documentation to CMS upon request.[73]

Second, the MA plan must determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee.

Section 422.102(f)(4)(iii)(A) requires MA plans must have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI. Section 422.102(f)(4)(v) further requires that MA plans maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

In the June 2020 final rule, we stated that it is our expectation that plans communicate to enrollees information in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits (85 FR 33803). We made further changes to our regulations in our April 2024 final rule, where we modified the disclaimer requirements at § 422.2267(e)(34) to require plans to include clear information about SSBCI eligibility criteria in marketing and communications materials that mention SSBCI, including by listing the chronic conditions an enrollee must have in order to be eligible for the SSBCI. Taken together, these previous actions and the proposed changes to the regulation here demonstrate our broader concern about the importance of transparency as it applies to SSBCI eligibility.

Currently, as permitted by § 422.504(f)(2), CMS may review SSBCI eligibility criteria by requesting it from plans. This is currently done on a case-by-case basis. Since there is no public posting of a plan's criteria for determining how an enrollee may or may not qualify for an SSBCI, enrollees are left to speculate whether a particular benefit, which may be attractive to an enrollee and spur them to enroll in a plan, is even available to them. This lack of transparency limits a potential enrollee's ability to review and determine whether they may be eligible for SSBCI based on the plan's eligibility criteria. Additionally, we received several comments in response to the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (herein after referred to as the ''November 2023 proposed rule'') requesting that plans post their objective eligibility criteria for SSBCI on a public-facing website to increase transparency for potential enrollees. In response to these comments, we noted that CMS would consider taking this action in future rulemaking (89 FR 30558).[74]

Further, when reviewing SSBCI eligibility criteria, we have discovered that several plans offering SSBCI benefits do not determine eligibility in an objective manner, as required at § 422.102(f)(4)(iii)(A).[75] For example, an enrollee may self-attest that they are eligible for SSBCI without additional criteria or any verification from the plan of this eligibility status. This would not meet our requirements. Additionally, we have noted in our reviews that some plans determine what SSBCI to cover and pay for without consultation with a doctor or other medical professional to determine the clinical appropriateness of the items and services offered under the SSBCI benefit. CMS has also identified instances where plans, when determining eligibility, are not properly evaluating enrollees using all three components of the definition for ''chronically ill enrollee'' as defined in section 1852(a)(3)(D)(iii) of the Act. One of the three requirements in the statutory definition of ''chronically ill enrollee'' is that the individual requires intensive care coordination. As we noted in the June 2020 Final Rule, we did not define ''intensive care coordination'' or establish standards for when an MA enrollee requires such services.[76] We wished to allow plans flexibility in determining what the phrase meant to best serve their enrollees. However, we noted some examples of methods through which

[71] Rebates can also be used to buy down Part B and D premiums under § 422.266(b)(2) and (b)(3).

[72] *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/supplemental_benefits_chronically_ill_hpms_042419.pdf.*

[73] 89 FR 30551.

[74] *https://www.federalregister.gov/d/2024-07105/p-1069.*

[75] Prior to the effective date the April 2024 final rule, this requirement was codified at 42 CFR. 422.102(f)(3)(iii). The April 2024 final rule slightly reorganized § 422.102(f) as part of amendments to adopt new requirements.

[76] *https://www.federalregister.gov/d/2020-11342/p-59.*

plans may determine an enrollee required intensive care coordination, such as conducting a health risk assessment, performing a retrospective claims review for an enrollee, or by other means the plan deems necessary. CMS reaffirms its position stated in the June 2020 final rule, that objective criteria which utilize the above mechanisms for meeting the three-pronged definition are present in the medical community and may be readily accessible to the plan.

We have identified that the current regulation text (§ 422.102(f)(1)(i)(A)) may need further clarification for plans. It was never our intention to imply that the presence of a chronic illness or chronic condition alone is sufficient to satisfy all three of the statutory criteria to qualify as a chronically ill enrollee. Therefore, we are clarifying that having a medically complex chronic condition or comorbidity by itself is insufficient to satisfy the requirements in § 422.102(f)(1)(i)(A)(1), (f)(1)(i)(A)(2), and (f)(1)(i)(A)(3), and are proposing a technical edit to clarify this requirement. We propose to amend § 422.102(f)(1)(i)(A) and (f)(1)(i)(A)(1) through (3) to specify that '' a chronically ill enrollee is an individual enrolled in the MA plan who meets all of the following:

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.
- Has a high risk of hospitalization or other adverse health outcomes. (3) Requires intensive care coordination. This is consistent with the statute, which defines a ''chronically ill enrollee'' at section 1852(a)(3)(D)(iii) of the Act as an enrollee who: (1) has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee; (2) has a high risk of hospitalization or other adverse health outcomes; and (3) requires intensive care coordination. This clarification would allow the definition of a chronically ill enrollee at § 422.102(f)(1)(i)(A)(1) through (3) to mirror the statutory language at section 1852(a)(3)(D)(iii) of the Act as intended in the 2020 final rule.

Additionally, we propose that plans must demonstrate that an enrollee has met all three of the criteria set forth in § 422.102(f)(1)(i)(A) through the use an objective process (for example, either a health risk assessment, a claims review, or other similar means). We wish to continue to allow plans flexibility in the methods they use to determine that enrollees have met all three criteria.

By way of example, a plan could establish that in order to be eligible for certain SSBCI, an enrollee must have a confirmed diagnosis of diabetes by their primary care physician, and must also have been admitted to the hospital in the last 90 days. Under this example, the diagnosis of a chronic illness is sufficient to satisfy the first criterion (as proposed), that the enrollee, ''has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee[77].'' However, the plan must also determine that the enrollee has met the second and third criteria: (2) has a high risk of hospitalization or other adverse health outcomes; and (3) requires intensive care coordination. The plan may determine that an enrollee meets the second requirement by being hospitalized in the last 90 days. The plan may reason that enrollees who have been hospitalized in the last 90 days are at high risk of readmission and so meet the second statutory requirement of having a high risk of hospitalization. The plan may further decide that the enrollee would require intensive care coordination to prevent further hospitalization, and thus would satisfy the third regulatory requirement. In this hypothetical scenario, the plan has determined through an objective process that the chronically ill enrollee meets all three requirements at § 422.102(f)(1)(i)(A). Given the variability, inconsistency and subjective eligibility determinations by plans that we have observed or been notified about as part of our routine monitoring, we are proposing three additional amendments to the regulation text. First, we propose to codify at a new paragraph at § 422.102(f)(1)(i)(C) a provision prohibiting MA plans from using the presence of a chronic illness as the sole basis for determining eligibility for SSBCI, in accordance with statute and the minimum requirements for an MA plan to determine that an individual meets the statutory definition of ''chronically ill enrollee.'' As described previously, it has become evident through our routine monitoring that some plans are not abiding by the statutory requirements to determine eligibility for SSBCI. CMS has proceeded with compliance actions in these cases, and while we noted in the June 2020 final rule that we wished to allow flexibility for plans to identify needs within their unique plan population, some plans have inappropriately determined eligibility for SSBCI when the enrollee does not meet the three-pronged criteria set forth at section 1852(a)(3)(D)(iii) of the Act to receive SSBCI. As we make the technical edit to clarify our regulation, we also propose to add regulation text to § 422.102(f)(1)(i)(C) which provides that having one or more comorbidities and medically complex chronic conditions alone is not sufficient to demonstrate that an enrollee meets all three criteria set forth in paragraph (f)(1)(i)(A) and that MA plans must, through health risk assessments, review of claims data, or other similar means, demonstrate that enrollees meet all three criteria set forth in paragraph (f)(1)(i)(A). Our proposal to make a technical correction would clarify our policy as it regards SSBCI eligibility and would not impose any new collection of information requirements.

We further propose that plans must publish on their public-facing website the objective criteria developed and used by the MA plan as required in § 422.102(f)(4)(i) and (iii)(A) to determine whether an enrollee is eligible to receive any, and which particular, SSBCI benefits the plan offers. These objective criteria must set forth how the plan evaluates each enrollee and determines whether the enrollee meets the three-pronged definition of a chronically ill enrollee as set forth in the statute. Specifically, we are proposing that plans must post on their public-facing website their objective criteria for determining that an enrollee is a chronically ill enrollee within the statutory and regulatory definition and is eligible to receive SSBCI offered by the plan. Plans must make this information available to all persons on their public-facing website. We remind MA plans of their digital accessibility obligations as recipients of Federal assistance under section 504 of the Rehabilitation Act.[78] We propose this requirement be codified in the regulation text at § 422.102(f)(4)(iii)(C). In addition, we propose minor reorganization of paragraph (f)(4)(iii) by adding the words, ''Have objective criteria for SSBCI. Specifically, the plan must'' and then listing the requirements in paragraphs (f)(4)(iii)(A) through (C).

We believe this proposal would provide greater transparency and

[77] As previously noted, the list of chronic conditions that qualify as comorbid and medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an enrollee for purposes of SSBCI eligibility can be found within the definition of ''severe or disabling chronic condition'' in CMS's regulations at § 422.2.

[78] 29 U.S.C. 794; 45 CFR pt. 84.

consistency to the eligibility determination process for potential enrollees and will enhance the enrollees' ability to make informed decisions about their enrollment and the benefits. We remind plans that § 422.102(f)(4)(v) requires that plans maintain their evidentiary standards or objective criteria for enrollee eligibility for the entire coverage year.

In addition, we remind plans that under § 422.2262, general communications materials and activities requirements, MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees. Consistent with these existing requirements, we expect that MA organizations, as well as the agents and brokers that are operating on behalf of such organizations, will provide appropriate information on how the plan evaluates each enrollee and determines whether the enrollee meets the three-pronged definition of a chronically ill enrollee when discussing SSBCI benefits with a current or potential enrollee, to ensure that information about SSBCI provided in such discussions is accurate and not misleading.

Additionally, while there is not currently a consistent manner by which plans publicly report this information or submit the information directly to CMS, we believe these proposals will provide an increased level of compliance oversight, increase good governance and oversight of the Medicare Trust Fund, and improve patient participation in their care and awareness of their eligibility for benefits, by making this information publicly available rather than only available upon request by CMS.

We seek public comment on both proposals and may, based on the comments received, consider finalizing revisions to this final policy.

I. Risk Adjustment Data Updates

1. Update Hierarchical Condition Categories (HCC) Definition (§ 422.2)

The current definition of Hierarchical Condition Categories (HCC) at 42 CFR 422.2 references the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM),* which was the standard medical data code set HHS adopted for health conditions from October 16, 2002, to September 30, 2015 (45 CFR 162.1002(a)(1) and 45 CFR 162.1002(b)(1)). For the period starting on October 1, 2015, HHS adopted an updated version of the ICD, *ICD–10–CM,* as the standard medical data code set for health conditions (45 CFR 162.1002(c)(2)). The ICD diagnosis codes—referred to as disease codes in the current HCC definition—that are grouped in an HCC for risk score calculation are only those valid codes that are from the ICD version that is in place during a respective year. For example, for dates of service starting on October 1, 2015, only valid *ICD–10–CM* codes would have been included in HCCs, since *ICD–9–CM* codes were no longer in use.

We are proposing to remove the reference to a specific version of the ICD from the definition of HCC in § 422.2, while maintaining a reference to the ICD in general. The ICD is updated as advances are made in healthcare, and as new editions are issued, the code set standard adopted by HHS may change to use the most current edition. See section 1173(c) of the Act for the Secretary's authority to adopt code sets, as well as 45 CFR part 162 (specifically, §§ 162.1000 through 162.1011) for the diagnosis code sets adopted for HIPAA transactions. The current HCC definition in § 422.2 states that disease groupings consist of ''disease codes (currently *ICD–9–CM* codes) that predict average healthcare spending.'' Amending the HCC definition to remove reference to a specific version of the ICD would keep the definition in § 422.2 current as updates are made to the HCCs in model calibrations and newer versions of the ICD are created and adopted by the Secretary. We are also proposing to substitute the terms ''disease codes'' with ''diagnosis codes'' and ''disease groupings'' with ''diagnosis groupings'' to be consistent with ICD terminology.

The proposed update at § 422.2 is a technical change to the longstanding definition of HCC. The proposal to remove the reference to a specific version of the ICD from the HCC definition does not change the meaning of HCC or how it is used in § 422.311, which has been defined and used in MA regulations since 2010 (75 FR 19803) as part of describing risk adjustment data validation audit reports and the voluntary dispute resolution process available for MA organizations to dispute errors identified during those audits. For this reason, we do not expect the proposed change to result in additional costs or savings and are not scoring this provision in the Regulatory Impact Analysis section. Further, as we are not imposing any new reporting requirements, we do not believe that our proposal will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

2. Clarifying the Obligation of PACE Regulations To Submit Data (§ 460.180(b))

CMS is authorized under section 1894(d)(1) of the Act to make payments to PACE organizations in the same manner as MA organizations. Consistent with that, PACE organizations must submit data in accordance with the risk adjustment data requirements for MA organizations at § 422.310. Codified at 42 CFR 460.200, PACE organizations are required to collect data, maintain records, and submit reports as required by CMS to establish payments rates. We are proposing to codify our longstanding practice of requiring the collection and mandatory submission of risk adjustment data by PACE organizations by adding a new paragraph at 42 CFR 460.180(b)(3) that requires the data they submit is in accordance with risk adjustment data submission requirements in § 422.310. By codifying this longstanding requirement of PACE organizations, the proposed provision does not create any new requirements or make changes to payment for PACE organizations. See, for example, 64 FR 66234, 66266 (Nov. 24, 1999) (''We will subsequently require PACE organizations to submit additional encounter data consistent with the encounter data requirements for [MAOs] set forth in 42 CFR 422.257 [the precursor to § 422.310] . . . .''); see also the system of record notice (SORN) for the CMS Encounter Data System (EDS), System No. 09–70–0506, at 79 FR 34539 (July 17, 2014) and the CMS Risk Adjustment Suite of Systems (RASS), System No. 09–70–0508, at 80 FR 49237 (August 17, 2015).

We are proposing to add a new paragraph at § 460.180(b)(3) to codify existing longstanding practice for the collection and mandatory submission of risk adjustment data, as specified in § 422.310, for PACE organizations. The proposed provision does not create any new requirements or make any changes to payment for PACE organizations. The proposed regulatory changes will not result in additional costs, nor do we expect the impact of these changes to result in savings. For this reason, we do not expect the proposed change to result in additional costs or savings and are not scoring this provision in the Regulatory Impact Analysis section. Further, as we are not imposing any new reporting requirements, we do not believe that our proposal will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

3. Clarifying the Obligation of Cost Plans To Submit Certain Data (§ 417.486(a))

Currently, we require the submission of risk adjustment data from organizations that operate cost plans under section 1876 of the Act in the same manner as MA organizations. Codified at 42 CFR 417.486(a), the contract of Section 1876 Cost plans must provide that the plan agrees to submit to CMS: (1) all financial information required under subpart O of this part and for final settlement; and (2) any other information necessary for the administration or evaluation of the Medicare program.

In this proposed rule, we propose to amend § 417.486(a) to add a new § 417.486(a)(3) to codify existing longstanding practice of requiring the collection and mandatory submission of risk adjustment data as specified in 42 CFR 422.310 by 1876 Cost plans. As stated in the 2012 Advance Notice, we have required the submission of encounter data for Cost plans under our authority in sections 1876(h)(3), 1833(a)(1)(A), and 1861(v) to determine ''reasonable costs.'' Also see 42 CFR 417.568 (requiring Cost plans to ''provide adequate cost and statistical data . . . that can be verified by qualified auditors'') and § 417.576(b)(2)(iii) (requiring Cost plans to submit ''[a]ny other information required by CMS''). These proposed regulatory changes will not result in additional costs, nor do we expect the impact of these changes to result in savings. For this reason, we do not expect the proposed change to result in additional costs or savings and are not scoring this provision in the Regulatory Impact Analysis section. Further, as we are not imposing any new reporting requirements, we do not believe that our proposal will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

J. Ensuring Equitable Access to Medicare Advantage (MA) Services—Guardrails for Artificial Intelligence (§ 422.112)

1. Background

On January 25, 2021, the Biden-Harris Administration released an Executive Order, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' (*E.O. 13985*), directing agencies to embed equity principles, policies, and approaches across Federal Government programs. In October 2022, the White House Office of Science and Technology Policy (OSTP) released the Blueprint for an AI Bill of Rights,[79] identifying five principles to protect the public from the misuse of artificial intelligence, including eliminating discriminatory practices by algorithms and systems. On October 30, 2023, the Biden-Harris Administration also released an Executive Order, ''Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,'' directing agencies to ensure that artificial intelligence tools do not impede the advancement of equity and civil rights, and that the use of AI within health care organizations does not deny equal opportunity and justice for the American people.[80] On January 30, 2024, CMS published ''Medicare Program; Request for Information on Medicare Advantage Data'' which received several comments related to the use and regulation of AI and requests for CMS ensure that MA plans' use of AI complies with existing CMS rules without negatively impacting health disparities.[81]

15 U.S.C. 9401(3) defines ''artificial intelligence'' or ''AI'' as ''a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to—(A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action.''

The health care industry has seen the adoption of AI in multiple capacities, such as, but not limited to, AI-based patient care decision support tools, vision transformer-based AI methods for lung cancer imaging applications, and AI and machine learning based decision support systems in mental health care settings.[82] In some instances, automation has created efficiencies, cost savings, and time management improvements for health providers and support staff.

However, there have been many instances of algorithmic discrimination, where the use of AI has resulted in deepening bias and discrimination, exacerbating existing inequities within the health care system.[83] Often, these individual patients are members of historically underserved and marginalized groups, which, increases the risk of automated bias and discrimination for these populations when AI tools are used within their health care.[84] A study in the Journal of Biomedical Informatics determined that people of color or individuals with lower socioeconomic status typically have less complete electronic health records (EHRs). The study demonstrates that as advances in AI are incorporated into the clinic, patients of lower socioeconomic status and patients of color, can receive differential treatment in early disease detection and risk prediction.''[85] Also, AI and related tools rely on large data sets which can have missing or incorrect information. The massive volume of data needed to train an AI model amplifies bias and may result in low quality AI recommendations without complete and substantial data. It is not uncommon for individual patients to have incorrect or missing data in their medical records, which produces flawed AI recommendations.[86] In addition, CMS has received concerns from external stakeholders through various formats about beneficiary harm potentially resulting from MA organizations' use of AI.

One example of algorithmic discrimination involves the use of AI to predict which patients are most likely to miss their medical appointments. The AI often uses data, such as prior no-show history, to advise providers to double-book certain patients. In this instance, lower-income patients were more likely to miss their medical appointments due to challenges around transportation, childcare, and work schedules. As a result of using this data

[79] *https://www.whitehouse.gov/ostp/ai-bill-of-rights/.*

[80] *https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence.*

[81] *https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.*

[82] Khosravi M., Zare Z., Mojtabaeian S.M., Izadi R., Artificial Intelligence and Decision-Making in Healthcare: A Thematic Analysis of a Systematic Review of Reviews. Health Serv Res Manag Epidemiol. 2024 Mar 5;11:23333928241234863. doi: 10.1177/23333928241234863. PMID: 38449840; PMCID: PMC10916499.

[83] Executive Office of the President, May 2016, ''Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights.'' *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2016_0504_data_discrimination.pdf.*

[84] Hoffman and Podgurski, ''Artificial Intelligence and Discrimination in Health Care, Yale Journal of Health Policy, Law, and Ethics,'' Vol. 19 [2020], Iss. 3, Art. 1. *https://yaleconnect.yale.edu/get_file?pid=bbaf6b35fe2b49fd1f4c39fbb91951db5b92a42618d4fd2a6724813f4cf64872.*

[85] Getzen, Emily et al. ''Mining for equitable health: Assessing the impact of missing data in electronic health records.'' *Journal of biomedical informatics* vol. 139 (2023): 104269. doi:10.1016/j.jbi.2022.104269.

[86] Hoffman and Podgurski, ''Artificial Intelligence and Discrimination in Health Care, Yale Journal of Health Policy, Law, and Ethics,'' Vol. 19 [2020], Iss. 3, Art. 1.

within the AI tool, providers double-booked lower-income patients, causing longer wait times for lower-income patients and perpetuating the cycle of additional missed appointments for vulnerable patients.[87]

Our proposed policy intends to make clear that MA organizations must provide all enrollees, without exception, equitable access to services, including when MA organizations use AI or other automated systems to aid their decision-making.

2. Proposed Policy

On June 29, 2000 (65 FR 40170), we issued a final rule titled, Medicare Program; Medicare+Choice Program (the June 2000 final rule), which described the requirement that MA plans must provide services in a culturally competent manner that addresses unique racial and ethnically related health care concerns. We stated that these services should accommodate the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their caregivers to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups (65 FR 40217). Furthermore, we required that MA organizations ensure that all covered benefits are ''available and accessible to all enrollees.'' As such, § 422.112(a)(8) requires MA organizations that offer coordinated care plans to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

In the April 2023 final rule (88 FR 22120), CMS revised the paragraph heading at § 422.112(a)(8), from ''*Cultural considerations*'' to ''*Ensuring Equitable Access to Medicare Advantage (MA) Services.*'' Additionally, in the April 2023 final rule (88 FR 22120), at § 422.112(a)(8), CMS replaced the phrase, ''those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds'' after the word ''including'' and added in its place paragraphs (i) through (vii), listing more examples of underserved populations to whom an MA organization must ensure that services are provided in a culturally competent manner and promote equitable access to services in order to satisfy the existing requirement. CMS noted specifically in the April 2023 final rule that, ''MA organizations must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance.'' [88]

Given the growing use of AI within the health care sector, we believe it is necessary to ensure that the use of AI does not result in inequitable treatment, bias, or both, within the health care system, and instead is used to promote equitable access to care and culturally competent care for all enrollees. As such, we propose to revise § 422.112(a)(8), *Ensuring equitable access to Medicare Advantage (MA) Services,* by moving the examples listed in paragraphs (i) through (vii) under a new paragraph (i)(A) through (G), and creating a new paragraph (ii) that requires MA organizations to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. We specify that artificial intelligence or automated systems, if utilized, must be used in a manner that preserves equitable access to MA services.

In the same way that MA organizations, ''must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance,'' [89] MA organizations must provide enrollees with equitable access to services under the MA plan design or benefits or both regardless of the tools or methods utilized to make care decisions or to provide that care. Section 1852(b) of the Act and § 422.110(a) prohibit an MA organization from denying, limiting, or conditioning the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status. Additionally, § 422.100(f)(2) provides that plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. We are not proposing any regulatory modifications to these requirements, as these existing requirements already apply to MA plans if they use AI or automated systems. Instead, we reiterate that in the event that an MA plan uses AI or automated systems, they must comply with section 1852(b) of the Act, § 422.110(a) and other applicable regulations and requirements, provide equitable access to services, and not discriminate on the basis of any factor that is related to the enrollee's health status. Regarding enforcement and oversight of MA organizations, CMS has a well-established, robust, and successful process for ensuring organizations that offer MA plans are complying with our regulations and program guidance. As a result of CMS's authority under 42 CFR part 422, subparts K and O, CMS may conduct program audits and compliance activities as well as issue compliance and enforcement actions to MA organizations who fail to comply with our regulations.

As the health care system evolves and utilizes new and emerging AI tools, we feel the need to clarify that these tools, including but not limited to, machine learning, patient care decision support tools, and/or other algorithmic tools, must not violate CMS rules. If MA organizations use these AI tools or automated systems in any manner, it is their responsibility to ensure that the usage of such tools complies with all existing Medicare policies, including, but not limited to, providing culturally competent care to all enrollees in a non-discriminatory manner. In the event that an MA organization licenses an AI or automated system, or contracts with a third party for services that are furnished using one of these tools, the MA organization will be held responsible in accordance with §§ 422.110(a) and 422.504(i)(1), which provides that an MA organization is ultimately responsible even if it uses an First Tier, Downstream, and Related Entity (FDR) to fulfill obligations and responsibilities under the MA regulations and MA contract with CMS. We also note that MA organizations are responsible for ensuring that usage of AI tools complies with internal coverage criteria rules. This provision addresses the equitable coverage of Medicare-covered benefits and therefore applies equally to Cost plans. Because this is a clarification of existing policy, we do not anticipate any new burden associated with this proposal. Further, at this time, this proposal is specific to MA plans. We note that CMS's formulary review process of Medicare Part D plans includes a comprehensive check to ensure enrollees are not facing discrimination or bias or both.

We recognize that technology in this space is quickly evolving. As such, we want to ensure that these proposed

[87] Hoffman and Podgurski, ''Artificial Intelligence and Discrimination in Health Care, Yale Journal of Health Policy, Law, and Ethics,'' Vol. 19 [2020], Iss. 3, Art. 1. *https://yaleconnect.yale.edu/get_file?pid=bbaf6b35fe2b49fd1f4c39fbb91951db5b92a42618d4fd2a6724813f4cf64872.*

[88] *https://www.federalregister.gov/d/2023-07115/p-361.*

[89] *https://www.federalregister.gov/d/2023-07115/p-361.*

revisions and clarifications take into consideration the fast-paced nature of this industry and the evolving application of these tools within the health care industry. As such, we have provided examples for how MA organizations could ensure they remain in compliance with this proposal. MA organizations could maintain compliance by: (1) ensuring that they understand, recognize, and limit the impact of biased data inputs within any AI and/or automated system they utilize; (2) that they create and follow a process to regularly review any automated system they utilize to ensure that the use of the automated system is non-discriminatory; and (3) that outputs with a known discriminatory bias (such as expected utilization or predictability of payment or both) are not used within a MA organization's automated system in a manner that discriminates in the delivery of services in violation of section 1852(b) of the Act or § 422.110(a).

3. Definitions

For purposes of this policy, we propose to adopt the following definition of ''automated system'' in § 422.2 based on the Blueprint for an AI Bill of Rights. We propose to define ''automated system'' as ''any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques, and exclude passive computing infrastructure. 'Passive computing infrastructure' is any intermediary technology that does not influence or determine the outcome of decision, make or aid in decisions, inform policy implementation, or collect data or observations, including web hosting, domain registration, networking, caching, data storage, or cybersecurity. As used in this part, automated systems that are within the scope of this definition are only those that have the potential to meaningfully impact individuals' or communities' rights, opportunities, or access.'' [90]

We also propose to define ''Patient care decision support tool,'' consistent with the definition at 45 CFR 92.4, as any automated or non-automated tool, mechanism, method, technology, or combination thereof used by an MA organization to support clinical decision-making in its health programs or activities. We recognize that this industry is fast-evolving and ever-changing, and therefore the following uses are examples, but not an exhaustive list. Patient care decision support tools are tools used to guide health care decision-making and can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models. MA organizations may use these systems to assist with decision-making for various purposes. Patient care decision support tools are used for screening, risk prediction, diagnosis, prognosis, clinical decision-making, treatment planning, health care operations, and allocation of resources, all of which affect the care that individuals receive. Patient care decision support tools may create or contribute to discrimination and their use may lead to poorer health outcomes among members of historically marginalized communities.

We reiterate that ''artificial intelligence'' or ''AI'' is defined in 15 U.S.C. 9401(3) as ''a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to—(A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action.''

We seek comment on this proposal and may consider finalizing revisions based on the comments received.

K. Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors (§ 422.2, 422.111)

Section 1852(c)(1) of the Act requires an MA organization to disclose, among other things, the number, mix, and distribution of plan providers in a clear, accurate, and standardized form to each enrollee in an MA plan offered by the MA organization at the time of enrollment and at least annually thereafter. CMS implemented this requirement in a regulation at § 422.111(a) and (b)(3)(i), requiring that an MA organization must disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services, in the manner specified by CMS, to each enrollee electing an MA plan it offers; in a clear, accurate, and standardized form; and at the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period. In addition, under § 417.427, the MA disclosure requirements at § 422.111 also apply to section 1876 cost plans. The regulatory proposals herein apply to all organizations offering network-based plans as defined at § 422.2, including MA plans and section 1876 cost plans. We refer to these entities generally as ''plans'' throughout this proposal.

CMS has historically interpreted the disclosure requirement at § 422.111(b)(3)(i)—''the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services''—as referring to the provider directory. CMS developed the MA and Section 1876 Cost Plan Provider Directory Model and Instructions document,[91] a model material created as an example of how to convey the required information to enrollees. In accordance with § 422.2267(c), when drafting their provider directories based on CMS's model, plans must accurately convey the vital information in the required material and follow the order of content when specified by CMS.

The current provider directory model contains an array of specific required information based on § 422.111(b)(3)(i) but also provides some flexibility to plans. For example, plans that offer supplemental benefits must furnish a provider directory for those benefits, but plans may choose to include these network providers that offer supplemental benefits in a directory combined with health care providers or in an entirely separate provider directory. The provider directory model also requires that plans include in the directory any providers or entities providing covered benefits or services, which may be reasonably contacted by an enrollee for the purposes of making an appointment (for example, dentist appointment). However, this means that some entities which provide covered benefits to enrollees may be currently excluded from the directory as they do not have a phone number for appointments, or because they take appointments by booking through a third party. Due to these and other possible scenarios, CMS has become aware that some entities that provide covered benefits, especially those that provide covered supplemental benefits,

[90] *https://www.whitehouse.gov/ostp/ai-bill-of-rights/.*

[91] The current MA and Section 1876 Cost Plan Provider Directory Model and Instructions document is located at: *https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials.*

including non-primarily health related benefits, may not be included in the provider directory (such as, but not limited to, adult day care entities, transportation services, pest control services, contractors or other building services which construct ramps for homes, etc.). While our intent was to require plans to include all entities that furnish covered benefits to enrollees, CMS has become aware that some plans do not include all such entities (while still complying with regulations and acting consistent with current guidance).

We therefore propose to add at § 422.2 a definition for a ''direct furnishing entity'' which means any individual or entity that delivers or furnishes covered benefits to the enrollee. This includes Medicare Part A and B covered benefits, as well as all types of supplemental benefits. A direct furnishing entity may include entities like transportation services or adult day care facilities. We also note that direct furnishing entities may include first tier, downstream, or related entities (FDRs), but we wish to define a new term to clarify that with this definition, we mean entities from whom enrollees may expect to receive directly furnished services, regardless of their status as an FDR. We further note the distinction between services administered to enrollees and plan-covered services. Agents and brokers, for example, fall under the definition of an FDR, but would not meet the proposed definitions of a direct furnishing entity as they do not cover, furnish or directly provide Medicare Part A or B benefits or services, nor any supplemental benefits.

We solicit feedback on the proposed definition for a direct furnishing entity. Specifically, we are interested in: (1) whether this definition is sufficient to encompass individuals or entities who may reasonably provide covered supplemental benefits to the enrollee and should therefore be included in the provider directory, or (2) whether the definition should be further refined to include a more tailored subset of individuals or entities. We may consider finalizing changes to this definition based on comments received.

Our intent in requiring a provider directory and further specifying parameters for required provider directory data elements was to include entities that meet the above proposed definition of a direct furnishing entity in the provider directory under § 422.111(b)(3)(i) because enrollees may reasonably be expected to obtain services from them. However, as we noted previously, it is possible that in certain instances, a plan may have contracted with a direct furnishing entity to provide some covered benefits, but reasonably believed that § 422.111(b)(3)(i) did not require that particular direct furnishing entity to be included in the provider directory because there is no phone number the enrollee can call to request an appointment with that entity at a specific address (as required per the current provider directory model).

CMS has also been alerted to concerns related to the possible exclusion of these direct furnishing entities from provider directories. These concerns relate to safety and a lack of transparency regarding supplemental benefit service providers and their access to an enrollee's home. Since many supplemental benefits include interaction with an enrollee at the enrollee's home (for example, in-home support services, meal delivery, home modifications, individuals providing adult day care services), a greater safety risk exists for enrollees who use these services. This is particularly of concern when the enrollee may not have information about who may have access to their home, personally identifiable information (PII), or protected health information (PHI). In 2023, CMS became aware of news reports that an FDR contracted with several MA organizations to provide in-home support services had over 1,200 complaint reports logged against the FDR's employees, including several allegations of sexual harassment and assault that occurred in the enrollees' home that were referred to law enforcement for further investigation.[2] It has been further reported that other FDRs that furnished covered benefits in an enrollee's home may have jeopardized enrollees' safety and caused harm. In these instances, enrollees and their caregivers may have benefited from increased transparency from the MA plan regarding the specific FDRs that the MA organization utilizes to furnish services, including those that may likely enter the enrollee's home to furnish covered items and services.

CMS also strongly encourages plans to do business with organizations deeply rooted within the community they serve and may be best suited to serve. As explained in the Calendar Year 2023 Physician Fee Schedule proposed rule (87 FR 46102), community-based organizations (CBOs) are defined as public or private not-for-profit entities that provide specific services to the community, or targeted populations in the community, to address the health and social needs of those populations. They may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers, or other non-profits that apply for grants to perform social services. While we currently require at § 422.112(b)(3) that coordinated care plans' arrangements with contracted providers include programs for the coordination of plan services with community and social services generally available in the area served by the MA plan, we note that there is currently no way for enrollees to determine through the provider directory, or other means set forth in regulation, which contracted providers are CBOs located in or near the community in which the enrollee lives.

In an effort to allow enrollees more access to information regarding their service providers, and further encourage MA plans' use of community-based providers, CMS is proposing to codify new requirements in the regulation. We propose to add new language to clarify that plans must include in their provider directory all direct furnishing entities. We propose to clarify our policy by amending § 422.111(b)(3) to explicitly state the requirement to include direct furnishing entities. We propose that § 422.111(b)(3)(i)(A) and (B) would be revised to specify the following:

- All direct furnishing entities as defined in § 422.2, from whom enrollees may reasonably be expected to obtain services.
- Each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

Section 422.111(b)(3)(i)(C) and (D) are described later in this section. Section 422.111(b)(3)(i)(E) and (F) would be revised to specify the following:

- Any out-of-network coverage; any point-of-service option, including the supplemental premium for that option.
- How the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

While it has been CMS's expectation that plans include the information at proposed § 422.111(b)(3)(i)(A) already in their provider directories (to the extent that there is a reasonable expectation that enrollees may obtain services from these direct furnishing entities), we believe that adjusting our regulation text to codify this policy explicitly will

[2] *https://www.bloomberg.com/news/features/2023-05-30/papa-eldercare-startup-faces-abuse-claims-by-seniors-caregivers?embedded-checkout=true&leadSource=uverify%20wall.*

prevent any confusion or misunderstanding regarding CMS's MA provider directory requirements.

Further, we propose that plans must clearly identify all direct furnishing entities that provide in-home or at-home supplemental benefits or services, or a hybrid of these benefits or services (both in-home or at-home, and in-office benefits or services) at § 422.111(b)(3)(i)(D). We propose that § 422.111(b)(3)(i)(D) would require easily identifiable notations, filters, or other distinguishing features to indicate in-home or at-home supplemental benefit providers (as defined in § 422.2). For the purposes of this requirement, we are proposing to define an in-home or at-home supplemental benefit provider as any direct furnishing entity in which the direct furnishing entity or an employee of the direct furnishing entity is given an enrollee's physical address in order to provide in-person supplemental benefits or SSBCI items or services to that enrollee. We also propose that this definition state that an in-home or at-home supplemental benefit provider may include direct furnishing entities who offer both in-office as well as in-home or at-home supplemental benefits. We propose that this definition be added to the regulation at § 422.2. We solicit comment on this definition and whether it should be expanded to include any entity that may enter an individual's home for purposes beyond providing supplemental benefits, items, or services to enrollees. We are particularly interested in whether additional transparency and further safety assurances are necessary for individuals who may receive covered benefits including Medicare Parts A and B benefits at their physical address. We may consider finalizing changes to this definition based on the comments received.

We also seek comment on the manner plans would be required to identify these in-home or at-home supplemental benefit providers. We note that currently the provider directory model requires plans to include a notation next to any provider listings where the providers only offer home visits and do not see patients at a physical office location. Because the provider directory model currently requires that supplemental benefit providers only offering in-home or at-home services be easily identified, it excludes providers and suppliers who may provide in-home or at-home services in addition to in-office services. Therefore, any enrollees wishing to find in-home or at-home supplemental benefit providers may refer to this notation in the provider directory but may not be aware of other providers and suppliers that provide a hybrid of services (both in-home or at-home, and in-office services). Additionally, we note that some provider directories may include a large volume of providers, both PCPs as well as supplemental benefit providers, making some lists prohibitively large. We propose that plans would be required to create a subset of the provider directory through which plans identify in-home or at-home supplemental benefit service providers, including those that may provide a hybrid of services (both in-home or at-home, and in-office services). An example of how a plan may identify this subset list is a designated section for these types of providers under section 2 (List of Network Providers) of their provider directory, as shown in the model document, alongside the plan's other listed provider types (for example, PCPs, specialists, hospitals, etc.). Another example specific to a plan's online provider directory is a filter function for this provider type, which would result in a filtered list of the in-home or at-home supplemental benefit providers. Such a subset list of in-home or at-home service providers, including those that may provide a hybrid of services (both in-home or at-home, and in-office supplemental benefit services), would allow the enrollee to clearly identify and differentiate which direct furnishing entities may be entering their home. We propose that, by including such a list, plans must continue to adhere to the current provider directory requirements set forth at §§ 422.111(a)(2), 422.111(b)(3)(i), 422.111(h)(2)(i) and (ii), 422.120, 422.2262, 422.2265(b)(3) and (4), 422.2265(c)(1)(iv), 422.2267(a), 422.2267(c), 422.2267(d), and 422.2267(e)(11) regarding what information must be included, and all other relevant provider directory requirements. We seek comment on this proposed requirement and may consider revisions to a final policy based on the comments received.

As an alternative to this subset list, which would be found within the provider directory, we propose and seek comment on requiring plans to create a list that is entirely separate from the currently required provider directory that identifies the in-home or at-home supplemental benefit providers including those that may provide a hybrid of services (both in-home or at-home, and in-office services) under the plan. This alternative proposal may reduce enrollee burden in identifying such providers and increase transparency for the enrollee, as they would not have to filter a provider directory or scroll through a potentially large directory to locate a specific designation for these types of providers in order to find the relevant information. We similarly propose, as an alternative, that the list required by this alternative would have to be easily available through the plan's public-facing website, and plans must continue to adhere to the current provider directory requirements set forth at §§ 422.111(a)(2), 422.111(b)(3)(i), 422.120, 422.2262, and 422.2267(e)(11) regarding what information must be included, and other relevant provider directory requirements. We seek comment on this alternative and may consider finalizing it or making revisions based on comments received.

We further propose to define community-based organizations (CBOs) in regulation, as there currently exists no definition in MA regulations. We propose to add this definition to § 422.2. This definition would provide clarity to plans when adding the new proposed CBO notation to their provider directories regarding which direct furnishing entities are CBOs. This proposed definition is taken from the Calendar Year 2023 Medicare Physician Fee Schedule proposed rule (87 FR 46102) cited previously. We propose to define CBOs as ''public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health and social needs of those populations.'' We noted in the Calendar Year 2023 Medicare Physician Fee Schedule proposed rule that these CBOs may include community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with health care entities to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), or state-funded grants to provide social services. We solicit comment on this proposed definition, and whether this definition would be sufficiently broad enough to include all locally based organizations with whom an enrollee may wish to engage. We may consider finalizing revisions to this

definition based on the comments received.

We also propose to include new regulation text at § 422.111(b)(3)(i)(C) requiring plans to include in their provider directory easily identifiable notations indicating direct furnishing entities that are CBOs. We propose to codify this requirement in § 422.111(b)(3)(i)(C) that plans must include in their provider directories easily identifiable notations, filters, or other distinguishing features to indicate providers and direct furnishing entities that are community-based organizations (CBOs) (as defined in § 422.2).

We are interested in encouraging more engagement from both plans and enrollees with organizations invested in the community and local economy and wish to provide enrollees the ability to more easily identify and engage with CBOs. We also wish to encourage plans, to the extent possible, to engage with local businesses and vendors when determining which entities to contract with. As we noted in the Calendar Year 2025 Medicare Physician Fee Schedule proposed rule (89 FR 61875), local businesses and CBOs, ''know the populations they serve and their communities and may have the infrastructure or systems in place to help coordinate supportive services that address social determinants of health or serve as a source from which ACOs can receive information regarding community needs.'' While CMS is prohibited from requiring plans to contract with specific providers under section 1854(a)(6)(B)(iii) of the Act and § 422.256(a)(2)(i), we strongly encourage plans to engage with CBOs given evidence indicating that providers who coordinate care with CBOs to address health related social needs (HRSNs) (for example, housing, transportation, care management, etc.) can positively influence health outcomes.[92] Therefore, we wish to strongly encourage collaboration of this kind. We further note that this complies with our regulation at § 422.112(b)(3) requiring coordinated care plans to coordinate MA plan services with community and social services generally available in the area served by the MA plan. Plans may contract with CBOs to provide benefits—including supplemental benefits—that are compliant with the statutory and regulatory requirements. For example, a plan could elect to offer a meal or food and produce supplemental benefit (so long as the benefit meets the requirements of § 422.100(c)(2) and other requirements for supplemental benefits) and pay a CBO for furnishing the covered benefit. We understand that in some areas there may be a limited number of CBO providers, and so we encourage plans to continue engaging with CBOs. Plans including a notation within the provider directory identifying an entity that is a CBO would increase enrollee awareness of these types of entities. This could lead to more enrollees choosing to receive items and services from CBOs that are more familiar with their community, can better coordinate supportive services, and can further address their community needs.

We believe the burden associated with these proposed requirements would be minimal. First, the proposed addition of the CBO notation in the provider directory would likely involve minimal burden given that plans must also include a notation or filter for other types of entities. With our proposed CBO definition, it should take little time for plans to identify their contracted CBOs and websites to add a notation to the listings for these entities in their provider directory. The proposed addition of direct furnishing entity listings should also create minimal burden since this is a clarification of existing policy and plans may already include all direct furnishing entities in their provider directories currently. There should therefore be few plans that need to make adjustments to their current provider directory due to the new proposed regulation text clarifying this requirement. We also expect if commenters believe that a subset list of in-home or at-home supplemental benefit providers is a satisfactory method to identify these providers, then there would be minimal burden associated as plans already must maintain an updated provider list as required by regulation. However, should commenters believe that the creation of a separate list for in-home and at-home supplemental benefit providers be prudent, we would likewise expect a low associated burden. As discussed, this list would be a subgroup of the current provider directory and include only in-home or at-home supplemental benefit providers, and, as previously noted, plans should already have information regarding which organizations fall under the proposed definition for an in-home or at-home supplemental benefit provider.

In summary, we propose to: (1) codify definitions of CBOs and in-home or at-home supplemental benefit providers and direct furnishing entities; (2) require plans to identify, within the provider directory, which providers and direct furnishing entities meet the proposed definition of a CBO; (3) require plans to identify in-home or at-home supplemental benefit providers and direct furnishing entities, including those that provide a hybrid of services (both in-home or at-home, and in-office services), either through a subset list within the provider directory or through a separate list comprising in-home or at-home supplemental benefit providers and direct furnishing entities; and (4) clarify existing policy by stating that all direct furnishing entities must be included within the provider directory.

We solicit comment on these proposals and may consider finalizing revisions based on the comments received.

L. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

Traditional Medicare benefits (that is, Medicare Parts A and B) include a wide range of mental health and substance use disorder services (collectively called ''behavioral health services'').[93] Per section 1876(c)(2)(A) of the Act and §§ 417.416 and 417.440(b)(1) and section 1852(a)(1) of the Act and §§ 422.100 and 422.101, respectively, Section 1876 Cost Plans (Cost Plans) and Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs)) must cover these Medicare Parts A and B services, subject to limited exclusions.[94] As part of CMS's behavioral health strategy, we aim to ensure equitable access to behavioral health services across all of Medicare, including for MA and Cost Plan enrollees, and to effectively expand access to these services in both programs.[95] [96] We believe improving

[92] McCarthy, D., Lewis, C., Horstman, C., Bryan, A., & Shah, T. (2022). ''Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update'' [ROI Calculator for Partnerships to Address the Social Determinants of Health]. The Commonwealth Fund. *https://www.commonwealthfund.org/sites/default/files/202209/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.*

[93] McGinty, Beth. ''Medicare's Mental Health Coverage: What's Included, What's Changed, and What Gaps Remain,'' Commonwealth Fund, Mar. 2, 2023. Retrieved from: *https://www.commonwealthfund.org/publications/explainer/2023/mar/medicare-mental-health-coverage-included-changed-gaps-remain.*

[94] For example, MA plans are not required to provide hospice services—a service covered in Traditional Medicare.

[95] CMS's behavioral health strategy is available at: *https://www.cms.gov/cms-behavioral-health-strategy.*

[96] Fleet, Alexa. Improving Behavioral Health Care For Older Americans: If Not Now, When? June 2022. Retrieved from: *https://www.healthaffairs.org/content/forefront/improving-behavioral-health-care-older-americans-if-not-now.*

equitable access to behavioral health services is especially crucial for MA enrollees because: (1) beneficiaries in Traditional Medicare pay 20 percent coinsurance (with zero cost sharing for opioid treatment program services) while MA enrollees may be charged up to 50 percent coinsurance (or actuarially equivalent copayment) for the same behavioral health services, (2) lower-income beneficiaries are more likely to be diagnosed with mental health conditions and may not receive the behavioral health services they need, suggesting potential affordability concerns,[97] [98] and (3) based on contract year 2024 plan data: [99]

- Between 23 percent and 25 percent of all MA plans charge in-network cost-sharing amounts that are greater than cost sharing in Traditional Medicare for: mental health specialty services, psychiatric services, and partial hospitalization (as shown in table 8).
- Between 42 percent and 71 percent of all MA plans charge in-network cost-sharing amounts that are greater than cost sharing in Traditional Medicare for: outpatient substance use disorder services and opioid treatment program services (as shown in table 8).
- MA enrollees in plans charging cost-sharing amounts greater than cost sharing in Traditional Medicare can expect to pay between $7 and $21 more on average in cost sharing per visit for those services received in-network for: mental health specialty services, psychiatric services, and partial hospitalization in comparison to beneficiaries in Traditional Medicare (as shown in table 10).
- MA enrollees in plans charging cost-sharing amounts greater than cost sharing in Traditional Medicare can expect to pay between $30 and $47 more on average in cost sharing per visit for those services received in-network for: mental health specialty services, psychiatric services, and partial hospitalization in comparison to beneficiaries in Traditional Medicare (as shown in table 10).

Improving equitable access to behavioral health services by providing in-network cost sharing for MA and Cost Plan enrollees that is in line with Traditional Medicare cost sharing for these services would positively impact a significant proportion of Medicare-eligible beneficiaries. We believe this would have this positive impact because: (1) about 25 percent of Medicare beneficiaries live with a mental illness and roughly half of Medicare beneficiaries are enrolled in an MA plan; [100] [101] (2) the number of MA enrollees with a need for behavioral health services will likely continue to grow alongside increasing Medicare enrollment trends; [102] and (3) improved access to and compliance with behavioral health treatment may improve beneficiaries' overall cost of care over time.[103] [104] While enrollment in Cost Plans represents a small proportion of all Medicare-eligible beneficiaries (approximately 169,000 as of July 2024,) [105] we believe extending this proposal to Cost Plan enrollees is appropriate because (1) CMS wants to improve equitable access to behavioral health services across all Medicare program choices; and (2) we expect the positive effects from improved access to behavioral health services for MA enrollees will extend to Cost Plan enrollees as current in-network cost sharing for these services may be as high as 50 percent coinsurance in these plans. Based on contract year 2024 Cost Plan data: [106]

- Between 5 percent and 50 percent of all Cost Plans charge in-network cost sharing amounts that are greater than cost sharing in Traditional Medicare for one or more professional behavioral health service categories (as shown in table 9).
- Cost Plan enrollees in those plans can expect to pay between $5 and $20 more on average in cost sharing per visit for those services received in-network (depending on the service category) in comparison to beneficiaries in Traditional Medicare (as shown in table 11).

We propose, beginning in contract year 2026, to require that in-network [107] cost sharing for behavioral health service categories be no greater than that of Traditional Medicare for MA and Cost Plans (including EGWPs). The authorities for this proposal are discussed in detail in the following section of this proposed rule. Specifically, CMS proposes to amend the existing requirements at §§ 417.454(e) and 422.100(j) (that cost sharing for certain benefits not exceed cost sharing in Original Medicare) to add the behavioral health service categories: mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient services, inpatient hospital psychiatric services (all length of stay scenarios), outpatient substance use disorder services, and opioid treatment program services.[108] To this end, CMS is proposing behavioral health cost-sharing standards in MA and Cost Plans that strike a balance between: (1) improving the affordability of behavioral health services for enrollees in a timely manner and (2) minimizing disruption to MA enrollees access to care and coverage options.

As discussed in sections III.L.X.e.(4). and VII.E.3. of this proposed rule, we solicit comment on: (1) whether CMS should apply these proposed changes beginning in contract year 2026 or 2027, (2) whether there should be a transition period from the existing contract year

[97] American Counseling Association. More Than 30 Years of Mental Health Care Inequity: Restricted Access to Providers for Medicare Beneficiaries. August 2021. Retrieved from: *https://www.counseling.org/docs/default-source/government-affairs/medicare-issue-brief.pdf.*

[98] Carter, Julie; Medicare Rights Center. ''Coverage Gaps Keep Medicare Beneficiaries from Needed Care.'' June 2024. Retrieved from: *https://www.medicarerights.org/medicare-watch/2024/06/13/coverage-gaps-keep-medicare-beneficiaries-from-needed-care.*

[99] This is based on March 1, 2024, contract year 2024 plan data (excludes employer, D–SNPs, and MSAs) of the plan's maximum cost sharing (including no cost sharing) and reflects plans with coinsurance and copayment amounts.

[100] Kaiser Family Foundation: Wyatt Koma et. al. One in Four Older Adults Report Anxiety or Depression Amid the COVID–19 Pandemic. October 2020. Retrieved from: *https://www.kff.org/mental-health/issue-brief/one-in-four-older-adults-report-anxiety-or-depression-amid-the-covid-19-pandemic/.*

[101] McGinty, Beth. ''Medicare's Mental Health Coverage: What's Included, What's Changed, and What Gaps Remain,'' Commonwealth Fund, Mar. 2, 2023. As of February 5, 2024: *https://www.commonwealthfund.org/publications/explainer/2023/mar/medicare-mental-health-coverage-included-changed-gaps-remain.*

[102] Kaiser Family Foundation: Freed, Meredith; Sroczynski, Nolan; and Neuman, Tricia. Mental Health and Substance Use Disorder Coverage in Medicare Advantage Plans. April 2023. Retrieved from: *https://www.kff.org/mental-health/issue-brief/mental-health-and-substance-use-disorder-coverage-in-medicare-advantage-plans/.*

[103] American Counseling Association. More Than 30 Years of Mental Health Care Inequity: Restricted Access to Providers for Medicare Beneficiaries. August 2021. Retrieved from: *https://www.counseling.org/docs/default-source/government-affairs/medicare-issue-brief.pdf.*

[104] Milliman. Potential economic impact of integrated medical-behavioral healthcare: Updated projections for 2017. February 2018. Retrieved from: *https://www.milliman.com/en/insight/potential-economic-impact-of-integrated-medical-behavioral-healthcare-updated-projections.*

[105] CMS. Contract Summary 2024. Data as of July 2024. Retrieved from: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.*

[106] This is based on March 1, 2024, contract year 2024 plan data of the plan's maximum cost sharing (including no cost sharing) and reflects plans with coinsurance and copayment amounts. It does not consider inpatient hospital cost sharing as Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services.

[107] This proposal would also apply to out-of-network cost sharing standards for D–SNP PPOs per § 422.100(o).

[108] In this proposal behavioral health services are generally considered to be any service furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders.

2025 behavioral health cost-sharing standards (in current regulations at § 422.100(f)(6)(i), (f)(6)(iii), and (f)(6)(iv)) to the proposed cost-sharing standard for select behavioral health service categories, and (3) how long any transition should be. We also solicit comment regarding this proposal's potential impact on the ability of MA plans to satisfy the existing actuarial equivalence requirements for the entire Part A and B benefits package (that is, the package of basic benefits) at section 1852(a)(1)(B) of the Act and § 422.100(j)(1) and (2) in section III.L.X.e.(4). of this proposed rule. Under this proposal, the requirements at § 422.100(f)(7)(iii), requiring CMS to communicate and provide a public comment period on how we apply the proposed cost-sharing standards each year prior to bid submission, such as through Health Plan Management System (HPMS) memoranda prior to bid submission, will apply to the proposed new behavioral health cost-sharing limits.

a. Legal Authority

Section 1852 of the Act imposes requirements that apply to the cost sharing and benefit design of MA plans. Section 1852(a)(1)(B)(iv)(VIII) of the Act explicitly authorizes the Secretary to identify services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries) to be subject to a cost-sharing limit that is tied to the cost sharing imposed for those services under original Medicare. Section 1852(b) of the Act also prohibits MA plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs. Sections 1856(b) and 1857(e) of the Act authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C. Under this authority, we propose to revise § 422.100(j)(1)(i) and add new paragraphs (j)(1)(i)(G) and (j)(1)(i)(H) to limit MA plan in-network cost sharing for the following service categories as defined in the plan benefit package: intensive outpatient services, mental health specialty services, outpatient substance use disorder services, partial hospitalization, psychiatric services, and inpatient hospital psychiatric services (all length of stay scenarios currently specified in paragraph (f)(6)(iv)) to that charged under Traditional Medicare. This necessarily includes revising § 422.100(f)(6)(iii), (f)(6)(iv), and (j)(1)(i). First, at § 422.100(f)(6)(iii)(A) we propose to replace the reference to partial hospitalization with rehabilitation services to serve as an example of a category subject to the range of cost-sharing standards in paragraph (f)(6)(iii).

Second, at § 422.100(f)(6)(iv) we propose to: (1) add a reference to § 422.100(j)(1)(i)(H) in paragraph (f)(6)(iv)(A) to reflect the proposed cost-sharing standard for inpatient hospital psychiatric services and (2) revise paragraphs (f)(6)(iv)(B) and (f)(6)(iv)(D) to remove references to inpatient hospital psychiatric services because cost sharing for inpatient hospital psychiatric services will be addressed as specified in proposed new paragraph (j)(1)(i)(H). Third, at § 422.100(j)(1)(i) we propose to clarify that the proposed behavioral health cost-sharing standards would not apply until contract year 2026.

Similarly, we propose to add new paragraphs § 417.454(e)(5) and (e)(6) to limit in-network behavioral health cost sharing of Cost Plans in the same manner as for MA plans. This necessarily includes clarifying at § 417.454(e): (1) when the proposed cost sharing limit (that cost sharing may not be greater than cost sharing in Traditional Medicare (original Medicare) for that benefit) will apply for the additional categories of services and (2) the methods Cost Plan organizations may use for coinsurance or copayment structures to abide by the proposed behavioral health cost-sharing requirements for these basic benefits. We also make a technical change to § 417.454(e) to clarify that the cost sharing limits apply to all Cost Plans by adding references to Competitive Medical Plans (CMPs). These proposals reflect CMS's authority to interpret and implement the requirement, at section 1876(c)(2) of the Act, that Cost Plans cover Part A and B benefits and, at section 1876(i)(3)(D) of the Act, to add new contract terms and conditions for Cost Plans that are not inconsistent with section 1876 as the Secretary may find necessary and appropriate.

In addition, in proposing to apply Traditional Medicare cost-sharing amounts to opioid treatment program services or any other service with zero cost sharing, we rely on our authority in section 1856(b)(1) and 1857(e)(1) of the Act. Section 1856(b)(1) of the Act provides CMS authority to establish MA standards by regulation and section 1857(e)(1) of the Act provides authority to impose additional ''terms and conditions'' found ''necessary and appropriate.'' Under these authorities, we propose to add opioid treatment program services in proposed new §§ 417.454(e)(5) and 422.100(j)(1)(i)(G) to limit MA and Cost Plan cost sharing for these services to that charged under Traditional Medicare, meaning that no cost sharing could be imposed for these services.

We also propose the following revisions to the cost-sharing regulations at §§ 417.454 and 422.100(f) and (j): (1) revise language at § 417.454(e)(1) to match terminology of chemotherapy administration services with language at § 422.100(j)(1)(i)(A), (2) remove language at § 422.100(f)(6)(iv)(D) that the total inpatient benefit cost sharing must not exceed the MA plan's MOOP amount to reflect how CMS has not applied this requirement, (3) remove paragraphs (j)(1)(i)(C)*(1)* and (j)(1)(i)(C)*(2)* to consolidate the skilled nursing facility cost-sharing standard information at § 422.100(j)(1)(i)(C), and (4) clarify that the skilled nursing facility per-day cost sharing for days 21 through 100 must not be greater than one-eighth of the projected (or actual) Part A deductible amount for the year at paragraph (j)(1)(i)(C). As such, this proposal codifies our current practice with some revisions (such as, annually updating the copayment limits for Cost Plans to remain actuarially equivalent to 50 percent coinsurance). Primarily, we propose these changes to increase the level of transparency for these policies and provide more stability and predictability for MA and Cost Plan organizations.

At new § 417.454(f), we propose to codify the policy of a 50 percent coinsurance (or actuarially equivalent copayment) limit on in-network basic benefits as applicable to Cost Plans as we believe payment of less than 50 percent of total Cost Plan financial liability discriminates against enrollees who need those services. For example, setting limits on cost sharing for covered services and ensuring Cost Plan organizations comply with these limits are important ways to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in a Cost Plan by beneficiaries who have high health care needs. In addition, this 50 percent coinsurance (or actuarially equivalent copayment) limit on in-network basic benefits is necessary and appropriate to apply to Cost Plans pursuant to how these plans must, under section 1876(c)(2) of the Act, furnish Part A and Part B services (with limited exceptions such as for the hospice benefit) to their enrollees.

In making these revisions to clarify how the actuarially equivalent copayment limits will be set for basic benefits, we expect Cost Plan

organizations should have: (1) greater knowledge about how cost-sharing limits are set; and (2) a better ability to anticipate where the copayment limits will be in future years. These additional proposals reflect CMS's authority under sections 1856(b), 1857(e), 1876(c)(2), and 1876(i)(3)(D) of the Act.

b. Behavioral Health Crisis

A Kaiser Family Foundation (KFF)/CNN Mental Health in America survey found that 90 percent of Americans believe our nation is experiencing a mental health crisis.[109] This crisis grew more challenging because of the COVID–19 pandemic. For example, beneficiaries with severe mental illness experienced substantial disruptions in care during the COVID–19 pandemic and these disruptions were greater among certain populations, including historically underserved racial and ethnic groups and low-income populations.[110]

Poor behavioral health outcomes are especially detrimental to older adults. Addressing the behavioral health needs of beneficiaries during this crisis is a key priority for CMS as illustrated by study findings that:

- Older adults have higher rates of suicide compared to those under 55 years old and, between 2001 and 2021, suicide rates significantly increased for men ages 55–74 (25 percent increase, from 21.2 to 26.6 per 100,000 population) and women ages 55–84 (44 percent increase, from 3.9 to 5.6 per 100,000 population).[111]
- Lower income Medicare beneficiaries (with household incomes under $25,000) are more likely to have mental health conditions than those with higher household incomes.[112] [113] [114]
- Older adults face significant barriers to access behavioral health services including workforce shortages, issues of affordability, and a shortage of services in the home and community settings.[115] [116]

In addition, studies on behavioral health needs of MA enrollees find:

- About 13 percent to 28 percent of MA enrollees live with mental illness.[117]
- On average, only 3 percent of MA enrollees received treatment from a behavioral health provider in 2023.[118]
- MA enrollees paid about $9 more on average for in-network mental health services than for comparable physical-health services.[119]
- MA enrollees who receive behavioral health services typically see their provider five times a year while beneficiaries in Traditional Medicare saw their behavioral health provider eight times a year.

Other research emphasizes the negative impact high-cost sharing can have on beneficiary utilization of high-value health services, clinical outcomes, and total costs of care.[120] [121] [122] These findings are more striking for beneficiaries with disabilities or those with an income just above the threshold Medicaid uses to determine eligibility for additional coverage.[123]

Considering these findings, HHS and CMS are pursuing policies that can address barriers individuals may face in accessing mental health and substance use disorder care.[124] [125] [126] Some of the policies CMS is pursuing to address these behavioral health access concerns are summarized in the following section.

c. CMS's Behavioral Health Strategy

CMS's vision is that beneficiaries and consumers with behavioral health needs have access to person-centered, timely, affordable care that enables optimal health and wellness.[127] For example, in the Calendar Year 2023 Physician Fee Schedule (87 FR 69404) [128] and the

[109] Kaiser Family Foundation: Lopes, Lunna et al. KFF/CNN Mental Health In America Survey. October 2022. Retrieved from: *https://www.kff.org/report-section/kff-cnn-mental-health-in-america-survey-findings/.*

[110] Busch AB, Huskamp HA, Raja P, Rose S, Mehrotra A. Disruptions in Care for Medicare Beneficiaries With Severe Mental Illness During the COVID–19 Pandemic. JAMA Netw Open. 2022 Jan 4;5(1):e2145677. doi: 10.1001/jamanetworkopen.2021.45677. PMID: 35089352; PMCID: PMC8800078. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8800078/.*

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[112] Friedman C. The mental health of Medicare beneficiaries with disabilities during the COVID–19 pandemic. Rehabil Psychol. 2022 Feb;67(1):20–27. doi: 10.1037/rep0000427. Epub 2021 Nov 8. PMID: 34748364. Retrieved from: *https://psycnet.apa.org/record/2022-02246-001.*

[113] American Counseling Association. More Than 30 Years of Mental Health Care Inequity: Restricted Access to Providers for Medicare Beneficiaries. August 2021. Retrieved from: *https://www.counseling.org/docs/default-source/government-affairs/medicare-issue-brief.pdf.*

[114] Kaiser Family Foundation: Wyatt Koma et. al. One in Four Older Adults Report Anxiety or Depression Amid the COVID–19 Pandemic. October 2020. Retrieved from: *https://www.kff.org/mental-health/issue-brief/one-in-four-older-adults-report-anxiety-or-depression-amid-the-covid-19-pandemic/.*

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[116] HHS Office of Inspector General. ''A Lack of Behavioral Health Providers in Medicare and Medicaid Impedes Enrollees' Access to Care'' April 2024. Retrieved from: *https://oig.hhs.gov/reports-and-publications/all-reports-and-publications/a-lack-of-behavioral-health-providers-in-medicare-and-medicaid-impedes-enrollees-access-to-care/.*

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[118] HHS Office of Inspector General. ''A Lack of Behavioral Health Providers in Medicare and Medicaid Impedes Enrollees' Access to Care'' April 2024. Retrieved from: *https://oig.hhs.gov/reports-and-publications/all-reports-and-publications/a-lack-of-behavioral-health-providers-in-medicare-and-medicaid-impedes-enrollees-access-to-care/.*

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[121] Health Affairs: Shivani, A. et. al. Fine-Tuning Cost Sharing As Part Of Health Reform December 3, 2021. DOI: 10.1377/hblog20211130.358084. Retrieved from: *https://www.healthaffairs.org/content/forefront/fine-tuning-cost-sharing-part-health-reform.*

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[123] Nelson, Hannah. Cost-Sharing Burden Limits Access to Care for Medicare Members. April 2021. Retrieved from: *https://healthpayerintelligence.com/news/cost-sharing-burden-limits-access-to-care-for-medicare-members.*

[124] Office of the Assistant Secretary for Planning and Evaluation (ASPE). Issue Brief: HHS Roadmap for Behavioral Health Integration. September 2022. Retrieved from: *https://aspe.hhs.gov/sites/default/files/documents/4e2fff45d3f5706d35326b320ed842b3/roadmap-behavioral-health-integration.pdf.*

[125] CMS. CMS Action Plan to Enhance Prevention and Treatment for Opioid Use Disorder. June 2021. Retrieved from: *https:/;www.cms.gov/files/document/action-plan-behavioral-health-strategy.pdf.*

[126] Kaiser Family Foundation: Meredith Freed, Juliette Cubanski, and Tricia Neuman. FAQs on Mental Health and Substance Use Disorder Coverage in Medicare. January 2023. Retrieved from: *https://www.kff.org/mental-health/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.*

[127] CMS's behavioral health strategy is available at: *https://www.cms.gov/cms-behavioral-health-strategy.*

[128] ''Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or

Calendar Year 2024 Physician Fee Schedule (88 FR 81540),[129] CMS finalized provisions effectively expanding access to the following behavioral health services in Traditional Medicare:

- Counseling and cognitive behavioral therapy—this was done by codifying new benefit categories for mental health counselors, marriage and family therapists.[130]
- Buprenorphine treatment for beneficiaries with opioid use disorder (OUD)—this was done by permitting the use of audio-only communication technology to initiate treatment in cases where audio-video technology is not available to the beneficiary, and all other applicable requirements are met.[131]
- Behavioral health care—this was done by paying for an ''Intensive Outpatient Program'' (IOP), which can be performed by hospital outpatient departments, community mental health clinics, Federally Qualified Health Centers (FQHCs), Opioid Treatment Providers (OTPs), or Rural Health Clinics (RHCs).[132]

In addition, in the April 2024 final rule,[133] CMS finalized expanding beneficiaries' access to additional behavioral health providers in MA by requiring Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers, Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities to meet MA network adequacy standards under a new facility-specialty type, ''Outpatient Behavioral Health.'' We also recently announced the Innovation in Behavioral Health Model to improve quality of care for Medicare and Medicaid enrollees with mental health and substance use disorders.[134] Through this model, CMS will support innovative approaches to connect people with the physical, behavioral, and social supports needed to manage these conditions.

This proposal continues to advance CMS's behavioral health strategy through changes to our MA and Cost Plan cost-sharing standards that we believe would improve enrollee access to behavioral health services. A brief history of the MA behavioral health cost-sharing standards follows.

d. Regulatory History of Behavioral Health Cost-Sharing Standards

Section 422.100(f)(6) provides that cost sharing for basic benefits offered through a MA plan must not exceed levels annually determined by CMS to be discriminatory for such services, which CMS determines using specific standards adopted through previous rulemakings. (All MA organizations and Cost Plan organizations must also comply with applicable Federal civil rights laws that prohibit discrimination, including those that prohibit discrimination on the basis of race, color, national origin, sex, age, and disability, such as section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.)

CMS imposes cost-sharing limits to ensure that the cost sharing aspect of a plan's design does not discriminate against or discourage enrollment of beneficiaries who have high health care needs and who need specific services. CMS issued cost-sharing limits for covered services and guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter (prior to 2020) and in annual bidding instructions. Prior to contract year 2023, the behavioral health service category cost-sharing limits CMS set for MA plans were based on the following limits:

- Opioid treatment program services, outpatient substance use disorder services, mental health specialty services, psychiatric services, and partial hospitalization: 50 percent coinsurance for all plans.
- Inpatient hospital psychiatric services: 100 percent of Medicare FFS cost sharing for plans with a mandatory MOOP type and 125 percent of Medicare FFS cost sharing for plans with a lower (voluntary) MOOP type.

For contract year 2025 and prior years, CMS typically utilized behavioral health professional and inpatient hospital cost-sharing data validations of 50 percent coinsurance to guard against potentially discriminatory benefit designs for Cost Plans.

CMS also set professional behavioral health service category copayment limits that were in place without change for many years for MA plans until contract year 2022. These copayment limits were originally set to strike a balance between limiting beneficiary out-of-pocket costs and the potential impact to plan design and costs. The overarching goal of these copayment limits was to ensure beneficiary access to affordable and sustainable benefit packages rather than to be precisely tied to actuarially equivalent values to the coinsurance limit each year. For MA plans, CMS began to annually update these behavioral health cost-sharing limits for contract year 2023 through contract year 2025 using the methodology in § 422.100(f)(6) through (f)(8) that was established in the April 2022 final rule. We also solicited comment on potential future rulemaking to further limit MA behavioral health service category cost-sharing standards in that final rule.[135]

Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules.'' Available at: *https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other.*

[129] ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction'' final rule with comment period. Available at: *https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.*

[130] The November 2022 final rule is available at: *https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other.*

[131] The November 2022 final rule is available at: *https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other.*

[132] The November 2023 final rule is available at: *https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.*

[133] ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' final rule. Available at: *https://www.federalregister.gov/public-inspection/2024-07105/medicare-program-medicare-advantage-and-the-medicare-prescription-drug-benefit-program-for-contract.*

[134] Centers for Medicare & Medicaid Services, 2024. ''CMS Announces New Model to Advance Integration in Behavioral Health.'' Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-advance-integration-behavioral-health.*

[135] ''Contract Year (CY) 2023 Medicare Advantage (MA) Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards Final Rule with Comment Period.'' Available at: *https://www.federalregister.gov/documents/2022/04/14/2022-07642/medicare-program-maximum-out-of-pocket-moop-limits-and-service-category-cost-sharing-standards.*

(1) April 2022 Final Rule

The April 2022 final rule amended §§ 422.100 and 422.113 to establish the methodologies CMS uses to set annual cost-sharing limits for MA plans [136] for contract year 2023 and future years. As a general matter, these MA cost sharing limitations do not apply to Cost Plans. In the April 2022 final rule, CMS finalized a four-year transition for professional service category MA cost-sharing limits, beginning in contract year 2023, from 50 percent coinsurance to a range of cost-sharing limits (30 to 50 percent coinsurance and actuarially equivalent copayment amounts) based on MOOP type. This requirement provides lower MOOP types the most cost sharing flexibility to incentivize MA plans to establish lower MOOP amounts. The range of MA cost-sharing limits established by the April 2022 final rule (30 to 50 percent coinsurance and actuarially equivalent copayments for contract year 2026 and future years) apply to the following professional behavioral health service categories: mental health specialty services, psychiatric services, partial hospitalization, and intensive outpatient program services. The April 2022 final rule also codified MA cost-sharing limits for contract year 2023 and future years generally based on the following for the other behavioral health service categories:

- 50 percent coinsurance and actuarially equivalent copayment amounts for the opioid treatment program services and outpatient substance use disorder services categories.
- 100 percent of Medicare FFS cost sharing and actuarially equivalent copayment amounts for plans with a mandatory MOOP type and 125 percent of Medicare FFS cost sharing and actuarially equivalent copayment amounts up to the MOOP limit for plans with a lower (voluntary) MOOP type for inpatient hospital psychiatric services.

In addition, the April 2022 final rule finalized the addition of a third, intermediate MOOP type and MA cost-sharing standards specific to this MOOP type. The MA cost-sharing standards for the intermediate MOOP type are, in most cases, primarily based on the numeric midpoint between the cost-sharing limits CMS sets for the mandatory and lower MOOP types. Specifically, the behavioral health service category contract year 2026 MA cost-sharing limits at § 422.100(f)(6)(i), (iii), and (iv) for the intermediate MOOP type are as follows:

- 40 percent coinsurance or an actuarially equivalent copayment for mental health specialty services, psychiatric services, partial hospitalization, and intensive outpatient program services.
- 50 percent coinsurance or an actuarially equivalent copayment for the opioid treatment program services and outpatient substance use disorder services categories.
- A dollar value that reflects approximately 112.5 percent of estimated Medicare FFS cost sharing for inpatient hospital psychiatric services.[137]

Per § 422.100(f)(6)(ii), CMS also applies specific rounding rules in calculating MA behavioral health service category copayment limits for all MOOP types.

In the April 2022 final rule, we noted that CMS may pursue future rulemaking to alter the methodology for calculating the MA MOOP and cost-sharing limits finalized in that rule if: (1) there are significant unforeseen impacts or negative consequences that need to be addressed; or (2) additional changes outweigh the interests of maintaining a settled methodology and sufficiently protect enrollees from changes in cost sharing and benefits from one year to the next. Related to this, CMS included a comment solicitation in the April 2022 final rule that is discussed in the following section.

(2) Behavioral Health Cost-Sharing Limits Comment Solicitation

CMS included a comment solicitation in the April 2022 final rule to do all of the following:

- Highlight the importance of in-network behavioral health cost sharing.
- Inform stakeholders that CMS may pursue future rulemaking to further limit MA behavioral health service category cost-sharing standards (compared to the standards set through the April 2022 final rule).
- Receive feedback to consider before pursuing potential future rulemaking on this topic.

We shared that CMS was considering whether MA cost-sharing limits for mental health care (such as mental health specialty services, psychiatric services, partial hospitalization, opioid treatment program services, and treatment for substance use disorders) should be subject to additional cost-sharing limits, such as a requirement that cost sharing for those services not exceed cost sharing in Traditional Medicare. In response to the April 2022 final rule comment solicitation on this topic, CMS received a few timely comments.[138]

A couple of commenters were supportive of lowering MA cost-sharing limits for mental health services and treatment for substance use disorders or setting limits that had parity with the cost sharing for medical services. These commenters stated that changing the cost-sharing limits for these services would: (1) prevent MA organizations from discriminating against beneficiaries that use these services; (2) improve health care treatment by making the mental health treatment affordable for beneficiaries; and (3) align with the President's FY 2023 Budget and Unity Agenda that direct more resources to improving access to mental health and substance use disorder treatment.

A commenter stated that CMS should ensure MA beneficiary cost sharing for mental health and substance use disorder treatments are not subject to additional non-quantitative treatment limits (NQTLs) (like prior authorization and step therapy) in comparison to medical services. This commenter also requested CMS:

- Remove or reduce cost sharing for primary care services overall and specifically for behavioral health services that are provided in a primary care physician (PCP) setting to defined patient populations (such as those living in mental health professional shortage areas and underserved Black and Hispanic individuals); and
- Ensure MA plans provide coverage and adequate payment for integrated behavioral health services by PCPs and other licensed behavioral health professionals in PCP settings.

This commenter stated these requests would: (1) provide cost savings to patients and payers; (2) improve access to care and health equity; (3) align with CMS' goal to have 100 percent of Medicare beneficiaries in an accountable relationship by 2030; (4) increase utilization of preventive services; and (5) improve beneficiary health outcomes.

A couple of commenters were opposed to lowering MA cost-sharing

[136] The April 2022 final rule did not change Cost Plan cost-sharing standards.

[137] If the inpatient hospital psychiatric services dollar limit for particular length of stay scenario(s) is set at the MOOP limit for the other MOOP type(s), the percentage of estimated Medicare FFS cost sharing that approximately represents the dollar limit for the intermediate MOOP type in that length of stay scenario may be less than 112.5%. This is because the dollar limit for the intermediate MOOP type reflects the numeric midpoint of the actual cost-sharing limits applied to the other MOOP types (before rounding rules are applied).

[138] Public comments for this solicitation that were received before the close of the comment period are posted at: *https://www.regulations.gov/document/CMS-2020-0010-0667*.

limits generally or specifically for mental health services. A commenter stated that current anti-discriminatory measures (including the non-discriminatory limits set by the April 2022 final rule, CMS's discrimination reviews of each plan's benefit design, and the risk adjustment aspect of the MA program designed to protect against discrimination) are sufficient and mentioned MA plans produce better beneficiary outcomes than Medicare FFS.

CMS considered these comments when developing this proposal and we thank the commenters for their feedback.

e. Proposed Behavioral Health Cost-Sharing Standard: Cost Sharing No Greater Than Original Medicare (§ 422.100(j)(1))

After considering: (1) the comments received on the April 2022 final rule comment solicitation related to behavioral health cost-sharing limits; and (2) behavioral health-related research conducted since the April 2022 final rule publication (discussed in section III.L.b. of this proposed rule), CMS developed and considered changes to in-network cost-sharing standards to propose for behavioral health services (versus the standards for contract year 2026 and future years in existing regulations). Our goal in choosing between these different standards was to strike a balance between: (1) improving the affordability of behavioral health services for enrollees in a timely manner; and (2) minimizing disruption to enrollees' access to care and coverage options. These different behavioral health cost-sharing standards are described and evaluated in detail in section VII.E.3. of this proposed rule. In brief, for MA plans, CMS evaluated each approach through analyses primarily focused on the following:

- Calculating the difference between the proposed and existing MA behavioral health service category cost-sharing standards for contract year 2026 and future years using illustrative actuarially equivalent dollar values based on contract year 2025 Medicare FFS data projections.
- Estimating: (1) the number of MA plans that may reduce their behavioral health service category cost sharing to comply with the standard posed by the alternative; and (2) how much MA plan cost sharing may be lowered for each service category on a weighted average basis based on contract year 2024 MA plans with cost-sharing amounts above the limits posed by each alternative.

Similar analyses were completed for cost plans.

Based on the analyses summarized in section VII.E.3. of this proposed rule, CMS has determined that applying cost sharing no greater than Traditional Medicare to the behavioral health service categories (identified in the introduction of this section) beginning in contract year 2026 would strike an appropriate balance between beneficiary affordability and minimizing disruption to enrollees' access to care and coverage options. As a result, CMS is proposing here to set the professional MA behavioral health service category cost-sharing limits beginning contract year 2026 (as discussed in the April 2022 final rule, contract year 2026 is the last year of the range of cost-sharing limits transition at § 422.100(f)(6)(iii) and (f)(8) for MA) because this proposal's intended outcome aligns with our behavioral health strategy and outweighs the potential benefits of maintaining the current, settled methodology.

We note this proposal would affect D–SNP PPOs because § 422.100(o)(1) requires that, starting in 2026, an MA organization offering a local PPO plan or regional PPO plan that is a D–SNP limit cost sharing for out-of-network services to the cost-sharing limits applicable to specific in-network services for all MA plans, as described in § 422.100(f)(6). Section 422.100(o)(2) also limits D–SNP PPO out-of-network cost sharing to the cost-sharing limits for such services established at § 422.100(j)(1) when such services are delivered in-network. These requirements were finalized in the April 2024 final rule.[139] We propose to revise the last phrase of § 422.100(o)(2) regarding regional PPO D–SNPs to align the cross-references with the language that we have proposed to update in this rulemaking. Specifically, we are proposing to update the cross-reference in § 422.100(o)(2) from ''excluding paragraph (j)(1)(i)(C)(*2*)'' to ''excluding the last sentence of paragraph (j)(1)(i)(C).''

We propose to update the cost sharing standards for several categories of benefits, including behavioral health and non-behavioral health related benefit categories, for Cost Plans to match the standards for MA plans. The following sections describe the: (1) proposed in-network behavioral health service category cost-sharing limits and (2) potential impacts this proposal may have on contract year 2026 plan cost-sharing amounts by service category. If this proposal is finalized, CMS will continue to examine the affordability and availability of behavioral health services for MA enrollees. This may include monitoring the utilization of behavioral health services by MA enrollees through encounter data (as discussed in section III.L.e.(4). of this proposed rule) which may inform CMS's understanding of the utilization of certain categories of services and future rulemaking.

(1) Proposed In-Network Service Category Cost-Sharing Limits

Table 3 (MA plans) and table 4 (Cost Plans) compare existing and proposed behavioral health in-network service category cost-sharing standards for contract year 2026 and future years. In effect, these tables summarize this proposal's impact to behavioral health service category cost-sharing limits if finalized (based on contract year 2025 Medicare FFS data projections, the most recent data available at the time of developing this proposal). Specifically, table 3 reflects this proposal's impact to MA coinsurance limits and its potential impact to the dollar limits (based on actuarially equivalent values to the specified coinsurance limits or percentages of estimated Traditional Medicare FFS cost sharing for inpatient hospital psychiatric services). We note the illustrative dollar limits for the behavioral health service categories in table 3 are similar to cost sharing for these services in qualified health plans (QHPs) in the marketplace. For example, QHPs are required to offer standardized options for 2024 with set copayments for mental health and substance use disorder outpatient office visits that range between $0 and $50 based on the plan level (for example, bronze or silver).[140] In comparison, based on the information in table 3, the partial hospitalization copayment limit for an MA plan with a lower MOOP type in contract year 2026 could decrease from 50 percent coinsurance or $150 copayment to 20 percent coinsurance or $60 copayment if this proposal is finalized (a $90 difference in the

[139] ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' published in the **Federal Register** April 23, 2024; Available at: *https://www.federalregister.gov/documents/2024/08/06/2024-17024/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit.*

[140] See table 9 and 10 on page 25850 and 25851 from, ''Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024'' final rule published April 27, 2023. Retrieved from: *https://www.federalregister.gov/documents/2023/04/27/2023-08368/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2024.*

copayment limit). Similarly, table 4 reflects this proposal's impact to Cost Plan in-network cost-sharing limits.

We note that the dollar limits included in table 4 under the existing cost sharing validations column do not reflect actuarially equivalent values to the coinsurance percentage listed. This is because Cost Plan cost sharing validations have been maintained for many years at these amounts. As part of this proposal, copayment limits [141] for Cost Plans would be updated annually following the rules at § 422.100(f)(7), including the subregulatory process specified at § 422.100(f)(7)(iii) to reflect actuarially equivalent values to the coinsurance limits based on the most recent Medicare FFS data projections available and application of the rounding rules in paragraph (f)(6)(ii). As a result, comparing the difference in copayment limits between the existing and proposed standards in table 4 reflect the impacts from: (1) using updated Medicare FFS data projections to set actuarially equivalent copayment limits and (2) basing copayment limits on revised coinsurance limits specified in Medicare FFS for these benefits. For example, in comparison to the $150 actuarially equivalent copayment value to 50 percent coinsurance in table 3 for partial hospitalization services, table 4 reflects a $55 copayment limit in the existing cost sharing validations column for this service category. This illustrates how this proposal will have different levels of impact for Cost Plans than for MA plans in some cases. Specifically for this example, based on the information in table 4, the partial hospitalization copayment limit for a Cost Plan in contract year 2026 could change from 50 percent coinsurance or $55 copayment to 20 percent coinsurance or $60 copayment if this proposal is finalized (a $5 increase in the copayment limit). We also note that Cost Plan enrollees may continue to receive basic benefits at cost sharing in Traditional Medicare by going out-of-network. Ensuring that Cost Plan cost sharing does not exceed Traditional Medicare cost sharing for these services avoids an incentive for Cost Plan enrollees to go out-of-network, which might mean foregoing any coordination services or efforts by the Cost Plan that come with using the Cost Plan's network providers.

We emphasize that the dollar values in table 3 and the proposed dollar limits in table 4 are illustrative (based on contract year 2025 Medicare FFS data projections). As a result, CMS expects the proposed copayment and dollar limits illustrated in tables 3 and 4 would be different in contract year 2026 and future years based on using updated data to develop the actuarially equivalent values for the coinsurance cost sharing limits that we are proposing. This may also include, as discussed in the April 2022 Final Rule, changes to the approach to calculate actuarially equivalent copayments in future years. For example, CMS may change the calculation to consider a different list of provider specialties, services, or facilities based on generally accepted actuarial principles and practices outlined in § 422.100(f)(7)(i). We would generally describe such changes in the annual guidance described in § 422.100(f)(7)(iii).

[141] As discussed in more detail subsequently in this section of the proposed rule, this annual process to update the copayment limits for Cost Plans would apply to all basic benefits.

TABLE 3: COMPARISON OF EXISTING AND PROPOSED MA BEHAVIORAL HEALTH SERVICE CATEGORY COST-SHARING STANDARDS FOR CONTRACT YEAR 2026 AND FUTURE YEARS (COINSURANCE PERCENTAGES AND ILLUSTRATIVE ACTUARIALLY EQUIVALENT COPAYMENT AND DOLLAR LIMITS[1])

Service Category	Existing Standards (Varies by MOOP Type)	Proposed Standards (All MOOP Types)
Inpatient hospital psychiatric services – 60 days	$3,284 to $4,105 dollar limits[6]	$3,284 dollar limit[9]
Inpatient hospital psychiatric services 15 days	$2,204 to $2,755 dollar limits[6]	$2,204 dollar limit[9]
Inpatient hospital psychiatric services – 8 days	$2,036 to $2,545 dollar limits[7]	$2,036 dollar limit[10]
Mental health specialty services[2]	30% to 50% coinsurance or $50 to $85 copayment[8]	20% coinsurance or $35 copayment
Psychiatric services[3]	30% to 50% coinsurance or $50 to $80 copayment[8]	20% coinsurance or $35 copayment
Partial hospitalization[4,5]	30% to 50% coinsurance or $90 to $150 copayment[8]	20% coinsurance or $60 copayment
Intensive outpatient services[5]	30% to 50% coinsurance	20% coinsurance
Outpatient substance use disorder services[6]	50% coinsurance or $75 copayment	20% coinsurance or $30 copayment
Opioid treatment program services	50% coinsurance or $155[9] copayment	Zero cost sharing

[1]The dollar values in this table are illustrative (based on the most recent data available at the time of developing this proposal: contract year 2025 Medicare FFS data projections). The Office of the Actuary (OACT) employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)). However, if this proposal is finalized and Traditional Medicare changes the cost sharing amount for one of the behavioral health service categories subject to § 422.100(j)(1), the new Traditional Medicare cost sharing amount would apply as the limit for that category. CMS would set actual contract year 2026 and future year dollar and copayment limits annually based on updated Medicare FFS data projections. *See* § 422.100(f)(4)(i) and (f)(7)(ii)(A).

[2]The illustrative copayment limits for the "mental health specialty services" service category reflect actuarially equivalent values to the coinsurance percentages listed in the table. These actuarially equivalent values are based on (1) the OACT's contract year 2025 projected total average Medicare FFS allowed amount per mental health specialty visit (excluding drug costs), weighted by utilization of the following provider specialty types: clinical psychologist, licensed clinical social worker, and psychiatry and (2) application of the rounding rules at § 422.100(f)(6)(ii). Beginning January 1, 2024, Medicare started allowing marriage, family, and mental health counselors to bill independently for their professional services and made changes to payment for certain mental health specialty services, including services involving community health workers and outpatient psychotherapy for crisis services. At the time of developing this proposal, the OACT did not have sufficient utilization data available for these services to incorporate their costs into the projected weighted average allowed amount for this service category. Instead, the OACT developed the contract year 2025 projected total average Medicare FFS allowed amount for this service category by: (1) using 2022 Medicare FFS cost and utilization data of the referenced provider specialties in an office setting and their projections of cost changes between 2022 to 2025 and (2) employing generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)). For the final rule, CMS expects OACT will have sufficient data to inform the calculation of the CY 2026 "mental health specialty services" service category copayment limit to include covered services provided by marriage, family, and mental health counselors and new payment rates for certain mental health specialty services.

[3]The illustrative copayment limits for the "psychiatric services" service category reflect actuarially equivalent values to the coinsurance percentages listed in the table. These actuarially equivalent values are based on (1) the OACT's contract year 2025 projected total average Medicare FFS allowed amount per visit (excluding drug costs) for the provider specialty type: psychiatry and (2) application of the rounding rules at § 422.100(f)(6)(ii). The OACT developed the contract year 2025 projected total average Medicare FFS allowed amount for this service category using 2022 Medicare FFS cost and utilization data of the referenced provider specialty in an office setting and their projections of cost changes between 2022 to 2025.

[4]The illustrative copayment limits for the partial hospitalization service category reflect actuarially equivalent values to the coinsurance percentages listed in the table. These actuarially equivalent values are based on (1) the OACT's contract year 2025 projected total average Medicare FFS allowed amount per day of partial hospitalization (including physician fees and facility fees/APC codes 5863 and 5853), weighted by the type of setting (such as, hospital outpatient departments and community mental health centers) and (2) application of the rounding rules at § 422.100(f)(6)(ii). The OACT developed the contract year 2025 projected total average Medicare FFS allowed amount for this service category using 2022 Medicare FFS data and OACT's cost and utilization projections of partial hospitalization (which requires 20 or more hours of care each week beginning on January 1, 2024) between 2022 to 2025.

[5]Beginning January 1, 2024, Medicare also started covering Intensive Outpatient Program services for individuals with an acute mental illness or substance use disorder. This benefit provides the same services as the partial hospitalization program benefit but requires fewer hours of therapy per week (a minimum of 9 hours versus over 20 hours). At the time of developing this proposal, the OACT did not have sufficient utilization data available for this service type to project a CY 2025 allowed amount for these Intensive Outpatient Program services that is separate from partial hospitalization program services. As a result, the cost sharing limit for partial hospitalization services in this table also considers costs applicable to the Intensive Outpatient Program. For the final rule, CMS expects to have CY 2026 Medicare FFS data projections from the OACT that will allow us to set cost sharing limits specific to Intensive Outpatient Program services that are separate from the cost sharing limits appliable to partial hospitalization program services and establish separate data entry for this benefit in the PBP module.

[6]The illustrative copayment limits for the "outpatient substance use disorder services" service category reflect actuarially equivalent values to the coinsurance percentages listed in the table. These actuarially equivalent values are based on: (1) the OACT's contract year 2025 Medicare FFS average allowed amount per day for these services, weighted by utilization of HCPCS codes (G2086 – G2088), that was developed using 2022-2023 Medicare FFS data and the OACT's projections for 2025 and (2) application of the rounding rules at § 422.100(f)(6)(ii).

[7]These amounts reflect the dollar range between 100% to 125% of estimated Medicare FFS cost sharing for each length of stay scenario established at § 422.100(f)(6)(iv)(B) for each MOOP type and application of the rounding rules in paragraph (f)(6)(ii). Specifically, paragraph (f)(6)(iv)(B) requires the following inpatient hospital psychiatric cost-sharing standards based on MOOP type with: the mandatory MOOP type subject to 100% of estimated Medicare FFS cost sharing, the lower MOOP type subject to 125% of estimated Medicare FFS cost sharing, and the intermediate MOOP type subject to cost-sharing standards that reflect the numeric midpoint of the dollar limits set for the other MOOP types. The estimated Medicare FFS cost sharing is the sum of projected Part A deductible and Part B professional psychiatric day cost sharing (based on the number of days in the length of stay scenario). The OACT developed these projected values based on 2023 Medicare FFS data and the OACT's projections for 2025. CMS used these projected values to calculate the dollar ranges in this table.

[8]The coinsurance percentages and illustrative copayment limits shown reflect the range of cost-sharing standards these professional behavioral health service categories are subject to for contract year 2026 and subsequent years based on the existing regulations at § 422.100(f)(6)(iii)(F).

Specifically, paragraph (f)(6)(iii)(F) requires the following cost-sharing standards based on MOOP type with: the mandatory MOOP type subject to 30% coinsurance or an actuarially equivalent copayment limit, the intermediate MOOP type subject to 40% coinsurance or an actuarially equivalent copayment limit, and the lower MOOP type subject to 50% coinsurance or an actuarially equivalent copayment limit.

[9]The illustrative copayment limit for the "opioid treatment program services" service category reflects an actuarially equivalent value to 50% coinsurance based on: (1) the OACT's contract year 2025 Medicare FFS average allowed amount per visit or per periodic bundled payment for these services received at a non-residential opioid treatment facility (some payments include drug costs), weighted by utilization of HCPCS codes (G2067 – G2080, G2215, G2216, G1028, and G0137), that was developed using 2022-2023 Medicare FFS data and the OACT's projections for 2025 and (2) application of the rounding rules at § 422.100(f)(6)(ii).

[10]These amounts reflect 100% of estimated Medicare FFS cost sharing for each length of stay scenario established at § 422.100(f)(6)(iv)(B) for each MOOP type and application of the rounding rules in paragraph (f)(6)(ii).

TABLE 4: COMPARISON OF EXISTING AND PROPOSED COST PLAN BEHAVIORAL HEALTH SERVICE CATEGORY COST-SHARING STANDARDS FOR CONTRACT YEAR 2026 AND FUTURE YEARS (COINSURANCE PERCENTAGES, DOLLAR LIMITS, AND ILLUSTRATIVE ACTUARIALLY EQUIVALENT COPAYMENTS)

Service Category	Existing Cost Sharing Validations[1]	Proposed Standards[2]
Inpatient hospital psychiatric services – 60 days	50% coinsurance or $9,999.99	$3,284 dollar limit
Inpatient hospital psychiatric services – 15 days	50% coinsurance or $9,999.99	$2,204 dollar limit
Inpatient hospital psychiatric services – 8 days	50% coinsurance or $9,999.99	$2,036 dollar limit
Mental health specialty services	50% coinsurance or $40	20% coinsurance or $35 copayment
Psychiatric services	50% coinsurance or $40	20% coinsurance or $35 copayment
Partial hospitalization	50% coinsurance or $55	20% coinsurance or $60 copayment
Outpatient substance use disorder services	20% coinsurance or $9,999.99	20% coinsurance or $30 copayment
Opioid treatment program services	50% coinsurance or $9,999.99	Zero cost sharing

[1]The limits in this column reflect longstanding cost sharing PBP data validations applied to Cost Plans.

[2]The dollar values in this column are illustrative (based on the most recent data available at the time of developing this proposal: contract year 2025 Medicare FFS data projections). These projections are described in detail in the footnotes of table 3. CMS would set actual contract year 2026 and future year dollar and copayment limits annually based on updated Medicare FFS data projections if finalized. However, if this proposal is finalized and Traditional Medicare changes the cost sharing amount for one of the behavioral health service categories subject to §§ 417.454(e), the new Traditional Medicare cost sharing amount would apply as the limit for that category.

Under this proposal, the requirement that cost-sharing limits applicable for any service category cannot exceed the associated MOOP limit would continue to apply for MA plans, including for the inpatient hospital psychiatric length of stay scenarios at § 422.100(f)(6)(iv). For example, in table 3, the illustrative MA inpatient hospital psychiatric services dollar limits for each length of stay scenario are all less than the contract year 2025 MOOP limits (for example, the contract year 2025 lower MOOP limit is $4,150).[142] However, if 100 percent of estimated Medicare FFS cost sharing for an inpatient hospital psychiatric length of stay scenario resulted in a dollar limit that exceeded the MOOP limit, CMS would set the MA dollar limit for that scenario and MOOP type at the MOOP limit for that contract year under this proposal. In essence, our proposal could result in MA inpatient hospital psychiatric dollar limits that vary by MOOP type if dollar limit calculations result in values that exceed MOOP limit(s).

In conjunction with proposing these behavioral health cost-sharing standards, we propose to: (1) revise § 417.454(e) to apply a limit for cost sharing for certain benefit categories, similar to the MA cost sharing standards, of cost sharing no greater than Traditional Medicare, to Cost Plans; and (2) add new § 417.454(f) to codify and clarify our longstanding policy for Cost Plans that in-network cost sharing be no greater than the 50 percent coinsurance (or actuarially equivalent copayment) standard at § 422.100(f)(6)(i) for which Cost Plans have historically been subject as part of our PBP data validations. We believe that these proposals will protect enrollees of Cost Plans and create consistent flexibility in cost sharing standards between MA and Cost Plans for the following non-behavioral service categories: inpatient hospital acute services, home health, certain categories of DME, and Part B drugs other than chemotherapy drugs. Specifically, at § 417.454(e) we propose to add paragraphs (5) through (9) which reference those service categories and behavioral health service categories. In addition, CMS proposes to add new paragraph § 417.454(f) which references the cost sharing standard at § 422.100(f)(6)(i) (the 50 percent coinsurance or actuarially equivalent copayment cost sharing standard) as applicable as the in-network basic benefit cost sharing standard for Cost Plans, excluding benefits addressed at § 417.454(e). Under these proposals, the Cost Plan must use cost sharing that does not exceed specific coinsurance thresholds. This may be achieved by the Cost Plan using coinsurance that does not exceed the coinsurance limit or copayments that do not exceed dollar values that are actuarially equivalent to the coinsurance limit.

Under these proposals, CMS may annually update the copayment limits for service categories subject to § 417.454(e) or (f) to retain actuarially equivalent values to the applicable coinsurance standard for each service category. In annually setting these copayment limits, we intend to not disincentivize Cost Plans from using copayments in their plan designs. Specifically, CMS proposes to revise § 417.454(e) to specify that when Cost

[142] "Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation" issued May 6, 2024. Available at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly*.

Plans use: (1) coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare; or (2) copayments, the copayment must not exceed the actuarially equivalent value calculated for that benefit using the Medicare Advantage rules at § 422.100(j)(1)(ii) and Medicare FFS data projections as defined in § 422.100(f)(4)(i). Per § 422.100(j)(1)(ii), CMS calculates copayment limits using the rules specified in § 422.100(f)(7) and (f)(8). If CMS does not calculate a specific copayment limit, the plan would have to establish a copayment that does not exceed an actuarially equivalent value to the coinsurance required under original Medicare; such actuarially equivalent value must be established in accordance with § 422.100(f)(7)(i) (which requires compliance with generally accepted actuarial principles and practices) and based on the average Medicare FFS allowed amount in the plan's service area or the estimated total MA plan financial liability for that benefit for that contract year. Under this proposal, the Cost Plan would have to comply with the MA requirements specified in the cross-referenced regulations. Cross-referencing the MA regulations would ensure consistency across the programs for Medicare beneficiaries that elect Part A and B coverage through one of these Medicare health plans and avoid repetitive and lengthy regulation text being added to § 417.454(e). This proposal would therefore result in consistently updated actuarially equivalent copayment limits for the applicable service categories across the MA and Cost Plan programs.

The subregulatory process for how the actuarially equivalent copayment limits are calculated and established is addressed at § 422.100(f)(7) and would utilize the most recent Medicare FFS data projections available (as defined in § 422.100(f)(4)(i)) and application of the rounding rules in paragraph (f)(6)(ii). This includes the subregulatory notice and comment process outlined in § 422.100(f)(7)(iii). Section 422.100(j)(1)(ii) also requires compliance with paragraph (f)(8), the requirements for copayment limits during the actuarially equivalent copayment transition from 2023 through 2025. However, as the actuarially equivalent copayment transition concludes before this proposal would be applicable, paragraph (f)(8) is not relevant for Cost Plans. Table 5 shows the potential impact of these proposals for Cost Plans based on the most recent Medicare FFS data projections available for non-behavioral health related service categories.

TABLE 5: COMPARISON OF COST PLAN EXISTING AND PROPOSED NON-BEHAVIORAL HEALTH COST-SHARING STANDARDS FOR CONTRACT YEAR 2026 AND FUTURE YEARS (COINSURANCE PERCENTAGES, DOLLAR LIMITS, AND ILLUSTRATIVE ACTUARIALLY EQUIVALENT COPAYMENTS)

Service Category	Existing Cost Sharing Validations[1]	Proposed Standards[2]
Inpatient hospital acute services – 60 days	50% coinsurance or $9,999.99	$6,012.00[4]
Inpatient hospital acute services – 10 days	50% coinsurance or $9,999.99	$2,662.00[4]
Inpatient hospital acute services – 6 days	50% coinsurance or $9,999.99	$2,394.00[4]
Inpatient hospital acute services – 3 days	50% coinsurance or $9,999.99	$2,185.00[4]
Skilled Nursing Facility First 20 Days	$0/day[3]	$0/day
Skilled Nursing Facility – Days 21 through 100	$214/day[3]	$214/day
Cardiac Rehabilitation	50% coinsurance or $50	50% coinsurance or $50 copayment[5]
Intensive Cardiac Rehabilitation	50% coinsurance or $100	50% coinsurance or $65 copayment[6]
Pulmonary Rehabilitation	50% coinsurance or $30	50% coinsurance or $35 copayment[7]
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)	50% coinsurance or $30	50% coinsurance or $30 copayment[8]
Urgently Needed Services	50% coinsurance or $65	50% coinsurance or $65 copayment[9]
Home Health	50% coinsurance or $9,999.99	$0.00[10]
Primary Care Physician	50% coinsurance or $35	50% coinsurance or $65 copayment[11]
Chiropractic Care	50% coinsurance or $20	50% coinsurance or $25 copayment[12]
Occupational Therapy	50% coinsurance or $40	50% coinsurance or $60 copayment[13]
Physician Specialist	50% coinsurance or $50	50% coinsurance or $95 copayment[14]
Physical Therapy and Speech-language Pathology	50% coinsurance or $40	50% coinsurance or $95 copayment[15]
Therapeutic Radiological Services	20%[3]	20% or $90
DME-Equipment	50% coinsurance or $9,999.99	20% coinsurance[16]
DME-Prosthetics	20% coinsurance or $9,999.99	20% coinsurance[16]
DME-Medical Supplies	20% coinsurance or $9,999.99	20% coinsurance[16]
DME-Diabetes Monitoring Supplies	50% coinsurance or $9,999.99	20% coinsurance[16]
DME-Diabetic Shoes or Inserts	20% coinsurance or $9,999.99	20% coinsurance or $10 copayment[17]
Dialysis Services	20%[3]	20% or $65
Part B Drugs-Insulin	20% coinsurance or $35.00	$35.00[18]
Part B Drugs-Chemotherapy/Radiation	20%[3]	20% or $345
Part B Drugs-Other	20% coinsurance or $120.00	20% coinsurance or $350.00 copayment[19]

[1]The limits in this column reflect longstanding cost sharing PBP data validations applied to Cost Plans.

[2]The dollar values in this column are illustrative (based on the most recent data available at the time of developing this proposal: contract year 2025 Medicare FFS data projections). The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)). CMS would set actual contract year 2026 and future year dollar and copayment limits annually based on updated Medicare FFS data projections if finalized.

[3]Per § 417.454(e), the cost sharing limits for skilled nursing facility, dialysis, and Part B drugs – chemotherapy/radiation drugs are subject to cost sharing no greater than original Medicare. Those values are used in this table to reflect current policy.

[4]These dollar limits reflect values that are actuarially equivalent to 100% of estimated Medicare FFS cost sharing for each inpatient hospital length of stay scenario per proposed § 417.454(e).

[5]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per cardiac rehabilitation session (based on HCPCS codes 93797 and 93798), weighted by the type of setting (such as, hospital outpatient departments and provider offices).

[6]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per intensive cardiac rehabilitation session (based on HCPCS codes G0422 and G0423 and APC code 5771), weighted by the type of setting (such as, hospital outpatient departments and provider offices).

[7]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per pulmonary rehabilitation session (based on CPT codes 94625 and 94626 and APC code 5733), weighted by the type of setting (such as, hospital outpatient departments and provider offices).

[8]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per SET for PAD session (based on CPT code 93668 and APC code 5733), weighted by the type of setting (such as, hospital outpatient departments and provider offices).

[9]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per urgent care visit, weighted by the number of visits rendered. This amount includes Medicare's payment plus the out-of-pocket cost for the visit code as well as the other services rendered and Part B drug costs.

[10]This copayment amount reflects cost sharing in Traditional Medicare that applies to MA plans that establish a mandatory or intermediate MOOP type per proposed § 417.454(e).

[11]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per primary care visit (excluding drug costs), weighted by utilization of the following provider specialty types: family practice, general practice, internal medicine, and geriatric medicine.

[12]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per visit (excluding drug costs) for the provider specialty type: chiropractor.

[13]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per visit (excluding drug costs) for the provider specialty type: occupational therapist in private practice.

[14]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per physician specialist visit (excluding drug costs), weighted by utilization of the following provider specialty types: cardiology, gastroenterology, nephrology, and ENT (otolaryngology).

[15]This copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount per physical therapy or speech-therapy visit (excluding drug costs), weighted by utilization of the following provider specialty types: physical medicine and rehabilitation and speech-language pathologists.

[16]This coinsurance amount reflects cost sharing in Traditional Medicare that applies to MA plans that establish a mandatory MOOP type per proposed § 417.454(e). CMS may choose to set copayment limits that are actuarially equivalent to the coinsurance listed for these service categories for contract year 2026 and future years if this proposal is finalized and sufficient data is available from the OACT.

[17]This cost sharing amount reflects cost sharing in Traditional Medicare that applies to MA plans that establish a mandatory MOOP type per proposed § 417.454(e). The copayment amount is based on the CY 2025 projected total average Medicare FFS allowed amount for diabetic shoes or inserts (without Part B deductible adjustment), weighted by utilization of the following DME shoes, inserts, and shoe modifications HCPCS codes: A5500 through A5501, A5507, and A5512 through A5514.

[18]This dollar limit reflects cost sharing in Traditional Medicare and MA that applies from the Part B Insulin Cost Sharing Cap of the Inflation Reduction Act (IRA) per proposed § 417.454(e). However, if this proposal is finalized and Traditional Medicare changes the cost sharing amount for a Part B rebatable drug subject to § 417.454(e), the new Traditional Medicare cost sharing amount would apply as the limit for that category.

[19]These cost sharing amounts reflects cost sharing in Traditional Medicare that applies to MA plans (all MOOP types) per proposed § 417.454(e).

(2) Potential Impacts To Plan Behavioral Health Cost Sharing Amounts

CMS considered the potential impact this proposal, if finalized, may have on plans and enrollees related to their behavioral health service category cost-sharing amounts. Tables 6 through 11 use contract year 2024 MA and Cost Plan data and contract year 2025 Medicare FFS data projections to roughly estimate these potential plan and enrollee impacts. We excluded D–SNPs from this data as states cover Medicare cost sharing for many dually eligible enrollees. However, we believe our proposal will have a beneficial effect on access to care for dually eligible individuals by increasing revenue for behavioral health providers in any instances in which states do not cover the full cost sharing amounts on their behalf. There could be state savings directly attributable to behavioral health benefits as well if utilization remains stable, which we expect given state coverage of dually eligible beneficiary cost sharing.

Organizations establish plan copayment amounts based on many variables that may change annually (including provider contracting arrangements, managed care practices, and scope of supplemental benefit offerings). As a result, CMS expects the values in tables 6 through 11 would be different in future years based on updated data (for example, contract year 2025 MA plan data). In addition, CMS cannot fully predict plan behavior and the MA organizations' reactions to the new behavioral health cost sharing limits. Due to these inherent uncertainties, we emphasize the potential plan and enrollee impacts discussed in this section are rough estimates and solicit comment on the scope of changes MA plans may make in response to this proposal if finalized.

Table 6 identifies the average MA plan cost sharing (weighted by enrollment) by behavioral health service category of all contract year 2024 plans. CMS considered the difference between the MA plan cost sharing values in table 6 and the proposed cost-sharing standards in table 3 as an initial estimate of how likely this proposal would be to require significant cost sharing changes by most MA plans for each category. For example, all of the weighted average MA plan cost sharing amounts for the three length-of-stay scenarios for the inpatient hospital psychiatric service category are less than the proposed and illustrative dollar limits in table 3. In contrast, as shown in table 6, the weighted average MA plan cost-sharing amount (25 percent coinsurance or $36 copayment) for the ''outpatient substance use disorder services'' service category exceeds the proposed 20 percent coinsurance or $30 copayment limit in table 3. As a result, we consider these comparisons as supportive evidence that this proposal would directly result in most MA plans: (1) lowering their cost sharing for the ''outpatient substance use disorder services'' category; and (2) making nominal or no changes to their cost sharing for inpatient hospital psychiatric services. We make additional comparisons and interpretations based on contract year 2024 MA plan cost sharing values in tables 8 and 10 to better understand the scope of changes certain MA plans may make in response to this proposal for each category.

TABLE 6: CONTRACT YEAR 2024 WEIGHTED AVERAGE MA PLAN COST SHARING BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Contract Year 2024 Weighted Average Percent Cost Sharing (Coinsurance or Estimated Medicare FFS Cost Sharing)	Contract Year 2024 Weighted Average Dollar Cost Sharing (Copayment or Dollar Amounts)
Mental Health Specialty Services[1]	14.7% coinsurance per visit	$25.05 copayment per visit
Psychiatric Services[1]	15.3% coinsurance per visit	$25.23 copayment per visit
Partial Hospitalization[1]	15.3% coinsurance per visit	$46.56 copayment per visit
Outpatient Substance Use Disorder Services[1]	24.6% coinsurance per day	$36.22 copayment per day
Opioid Treatment Program Services[1]	9.5% coinsurance per visit	$29.49 copayment per visit
Inpatient Hospital Psychiatric – 60 Days	44.5% of estimated Medicare FFS cost sharing for 60 days[2]	$1,461.44[3] dollars for 60 days
Inpatient Hospital Psychiatric – 15 Days	66.2% of estimated Medicare FFS cost sharing for 15 days[2]	$1,460.02[3] dollars for 15 days
Inpatient Hospital Psychiatric – 8 Days	71.4% of estimated Medicare FFS cost sharing for 8 days[2]	$1,454.63[3] dollars for 8 days

[1] Contract year 2024 weighted average MA plan coinsurance and copayment for the professional behavioral health service categories is based on: (1) maximum cost sharing for the service category; (2) plans with coinsurance or copayment amounts; and (3) normalizing the plan cost sharing amount (coinsurance or copayment) by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category

[2] Contract year 2024 weighted average percent of estimated Medicare FFS cost sharing is based on: (1) MA plans with dollar cost sharing amounts; and (2) normalizing the MA plan dollar cost sharing by calculating the equivalent percent of estimated Medicare FFS cost sharing it represents using contract year 2025 projected Part A deductible and Part B professional costs.

[3] Contract year 2024 weighted average MA plan dollar amount is based on: (1) maximum cost sharing for the service category; and (2) plans with dollar cost sharing amounts (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

Table 7 provides the same information as table 6 but for Cost Plans. CMS considered the difference between the Cost Plan cost sharing values in table 7 and the proposed cost-sharing standards in table 4 as an initial estimate of the likelihood this proposal would require significant cost sharing changes by most Cost Plans for each applicable category.[143] For example, as shown in table 7, the weighted average Cost Plan cost sharing amount for the ''opioid treatment program services'' service category exceeds the proposed zero cost sharing standard in table 4. In contrast, as shown in table 7, the weighted average Cost Plan cost sharing amount for the ''mental health specialty services'' service category is lower than the proposed cost-sharing standard in table 4. As a result, we consider these comparisons as supportive evidence that this proposal would directly result in most Cost Plans: (1) lowering their cost sharing for the ''opioid treatment program services'' category; and (2) making nominal or no changes to their cost sharing for mental health specialty services. We make additional comparisons and interpretations based on contract year 2024 Cost Plan cost sharing values in tables 9 and 11 to better understand the scope of changes certain Cost Plans may make in response to this proposal for each applicable category.

[143] Cost Plans are not required to report information for all Medicare and non-Medicare services, including Part A inpatient hospital psychiatric services. Due to this lack of data, in comparing the information in tables 4 and 7 we are only able to evaluate potential professional behavioral health service category cost sharing impacts for Cost Plans.

TABLE 7: CONTRACT YEAR 2024 WEIGHTED AVERAGE COST PLAN COST SHARING BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Contract Year 2024 Weighted Average Percent Cost Sharing (Coinsurance or Estimated Medicare FFS Cost Sharing)[2]	Contract Year 2024 Weighted Average Dollar Cost Sharing (Copayment or Dollar Amounts)[3]
Mental Health Specialty Services[1]	3.8% coinsurance per visit	$6.54 copayment per visit
Psychiatric Services[1]	8.1% coinsurance per visit	$13.30 copayment per visit
Partial Hospitalization[1]	4.5% coinsurance per visit	$13.83 copayment per visit
Outpatient Substance Use Disorder Services[1]	7.5% coinsurance per day	$11.02 copayment per day
Opioid Treatment Program Services[1]	3.8% coinsurance per visit	$11.86 copayment per visit

[1] Contract year 2024 weighted average Cost Plan coinsurance and copayment for the professional behavioral health service categories is based on: (1) maximum cost sharing for the service category; (2) plans with coinsurance or copayment amounts; and (3) normalizing the plan cost sharing amount (coinsurance or copayment) by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category.

[2] Contract year 2024 weighted average percent of estimated Medicare FFS cost sharing is based on: (1) Cost Plans with dollar cost sharing amounts; and (2) normalizing the plan dollar cost sharing by calculating the equivalent percent of estimated Medicare FFS cost sharing it represents using contract year 2025 projected Part A deductible and Part B professional costs.

[3] Contract year 2024 weighted average Cost Plan dollar amount is based on: (1) maximum cost sharing for the service category; and (2) plans with dollar cost sharing amounts (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

Table 8 identifies the number and percent of contract year 2024 MA plans and enrollees with cost sharing greater than the proposal by behavioral health service category. As shown in table 8, the behavioral health service category with the most contract year 2024 MA plans that have cost sharing greater than cost sharing in Traditional Medicare is opioid treatment program services. CMS considers the information in table 8 to be a rough estimate of the proportion of continuing MA plans and enrollees that may experience lower behavioral health cost sharing (by service category) if this proposal is finalized. For example, based on information in table 8, we estimate that about 42 percent of MA plans (and 41 percent of MA enrollees) may experience lower cost sharing for outpatient substance use disorder services in contract year 2026 if this proposal is finalized. In contrast, we expect a greater proportion of MA plans and enrollees would experience lower professional behavioral health cost sharing if this proposal is finalized. For example, based on table 8, we estimate that about 42 percent of MA plans (and 41 percent of MA enrollees) may experience lower cost sharing for outpatient substance use disorder services in contract year 2026 if this proposal is finalized. The information in table 8 aligns with our general expectation that the greater the decrease to existing cost-sharing standards from this proposal, the more plans, enrollees, and provider contracts that will be directly affected. The prior examples fit with this expectation as this proposal would lower MA cost-sharing standards for—

- Inpatient hospital psychiatric services from 125 percent to 100 percent of estimated Medicare FFS cost sharing (only for MA plans with the lower MOOP type); and
- Outpatient substance use disorder services from 50 percent coinsurance to 20 percent coinsurance (or an actuarially equivalent copayment) for all MA plans (regardless of MOOP type).

TABLE 8: PERCENT OF CONTRACT YEAR 2024 MA PLANS AND ENROLLEES WITH COST SHARING GREATER THAN THE PROPOSED COST-SHARING STANDARD BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Percent of Plans	Percent of Enrollees
Inpatient hospital psychiatric services – 60 days	0.0%	0.0%
Inpatient hospital psychiatric services – 15 days	0.5%	0.6%
Inpatient hospital psychiatric services – 8 days	4.3%	4.5%
Mental Health Specialty Services	24.4%	21.4%
Psychiatric services	24.9%	21.6%
Partial hospitalization	23.1%	16.4%
Outpatient substance use disorder services	41.7%	40.7%
Opioid treatment program services	70.7%	62.3%

Table 9 provides the same information as table 8 but for Cost Plans. In comparison to the findings from table 8, table 9 shows that substantially fewer Cost Plans and enrollees would be impacted by this proposal. For example, based on information in table 9, we estimate that 5 percent of Cost Plans (and about 1 percent of their enrollees) may experience lower outpatient substance use disorder services cost sharing in contract year 2026 (compared to the cost sharing they experience in contract year 2024) if this proposal is finalized. In contrast, this is

substantially less than the 42 percent of MA plans that may lower cost sharing for this service category (as shown in table 8). As a result, based on the findings in table 9, we believe Cost Plans would not be substantially incentivized to leave the market if this proposal is finalized given the likely limited breadth of impact.

TABLE 9: PERCENT OF CONTRACT YEAR 2024 COST PLANS AND ENROLLEES WITH COST SHARING GREATER THAN THE PROPOSED COST-SHARING STANDARD BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Percent of Plans	Percent of Enrollees
Mental Health Specialty Services	8.3%	3.1%
Psychiatric services	13.3%	13.2%
Partial hospitalization	0%	0%
Outpatient substance use disorder services	5.0%	0.7%
Opioid treatment program services	50.0%	60.6%

Column D in table 10 reflects the difference between: (1) the weighted average MA plan cost sharing by behavioral health service category of the plans identified in table 8; and (2) the proposed cost-sharing limit for each category. Table 11 shows the same information as table 10 but for Cost Plans. If this proposal is finalized, CMS considers the values in Column D of tables 10 and 11 as a rough estimate of how much, on a weighted average basis, enrollee cost sharing may decrease for each behavioral health service category in continuing plans that did not previously establish cost sharing amounts equal to or less than Traditional Medicare. For example, as shown in table 10, $30.38 is the estimated average difference in cost sharing for the ''outpatient substance use disorder services'' service category between: (1) the $60.38 weighted average cost sharing for this service category of contract year 2024 MA plans with cost sharing amounts greater than the proposed standard; and (2) this proposal's $30 illustrative copayment limit for that category (which reflects the actuarially equivalent copayment value to the 20 percent coinsurance standard in Traditional Medicare for this benefit, based on contract year 2025 Medicare FFS data projections). In comparison for this same service category, table 11 reflects a $10.00 difference in cost sharing between Cost Plan cost sharing amounts (those above the proposed limit identified in table 9) and the $30 illustrative copayment limit for the ''outpatient substance use disorder services'' service category (based on contract year 2025 Medicare FFS data projections). Comparing tables 10 and 11 in this manner supports our belief that Cost Plans will be less impacted by this proposal if finalized compared to MA plans.

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TABLE 10: ILLUSTRATIVE COMPARISON OF PROPOSED COST-SHARING STANDARDS FOR MA PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH COST SHARING ABOVE PROPOSED COST-SHARING STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Proposed Standards and Illustrative Cost-Sharing Limits (All MOOP Types)[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing (Plans with Cost Sharing Above Values in Column B)	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$3,284.00	N/A[2]	N/A
Inpatient Hospital Psychiatric – 15 Days	$2,204.00	$2,322.62[3]	($118.62) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$2,036.00	$2,143.22[3]	($107.22) for 8 days
Mental Health Specialty Services	20.0% / $35.00	24.6% / $41.92[4]	($6.92) or (4.6%) per visit
Psychiatric Services	20.0% / $35.00	25.4% / $41.91[4]	($6.91) or (5.4%) per visit
Partial Hospitalization	20.0% / $60.00	26.5% / $80.86[4]	($20.86) or (6.5%) per visit
Outpatient Substance Use Disorder Services	20.0% / $30.00	41.1% / $60.38[4]	($30.38) or (21.1%) per day
Opioid Treatment Program Services	0.0% / $0.00	15.3% / $47.32[4]	($47.32) or (15.3%) per visit

[1]Proposed cost-sharing standards include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in this section and section VII.E.3.d.(3). of this proposed rule; and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]No contract year 2024 plans established cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario greater than the proposed illustrative dollar limit for that service category.

[3]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario; and (2) only plans with dollar cost sharing amounts that are greater than the illustrative proposed standard for that length of stay scenario. In addition, these dollar amounts exclude the few plans with coinsurance percentages for inpatient hospital psychiatric services.

[4]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the proposed standard for that service category; (2) the plan maximum cost sharing for the service category; and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 11: ILLUSTRATIVE COMPARISON OF PROPOSED COST-SHARING STANDARDS FOR COST PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF COST PLANS WITH COST SHARING ABOVE ALTERNATIVE 3 COST-SHARING STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY[1]

Column A: Service Category	Column B: Proposed Standards and Illustrative Cost-Sharing Limits[2]	Column C: Contract Year 2024 Weighted Average Cost Sharing (Plans with Cost Sharing Above Values in Column B)	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Mental Health Specialty Services	20.0% / $35.00	23.5% / $40.00[3]	($5.00) or (3.5%) per visit
Psychiatric Services	20.0% / $35.00	28.9% / $47.66[3]	($12.66) or (8.9%) per visit
Partial Hospitalization	20.0% / $60.00	N/A[4]	N/A
Outpatient Substance Use Disorder Services	20.0% / $30.00	27.2% / $40.00[3]	($10.00) or (7.2%) per day
Opioid Treatment Program Services	0.0% / $0.00	6.3% / $19.57[3]	($19.57) or (6.3%) per visit

[1] Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.

[2] Proposed cost-sharing standards include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in this section and section VII.E.3.d.(3). of this proposed rule; and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(l)(6)(ii).

[3] Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the proposed standard for that service category; (2) the plan maximum cost sharing for the service category; and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment reflects all plans with cost sharing above the proposed cost sharing limits rather than plans with solely copayments or coinsurance.

[4] No contract year 2024 plans established cost sharing for the partial hospitalization service category greater than the proposed cost sharing limit for that service category.

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Based on tables 6, 8, and 10, CMS expects this proposal (if finalized) may result in a large proportion of continuing MA plans making significant

changes to their cost sharing for the ''opioid treatment program services'' service category in comparison to the other behavioral health service categories (on average). This is because, as shown in tables 6, 8, and 10, the ''opioid treatment program services'' service category has the:

- Highest percent of contract year 2024 MA plans and enrollees with cost sharing above the proposed standard (coinsurance percentage and illustrative actuarially equivalent copayment or dollar limit).
- Of the professional behavioral health service categories, largest cost sharing difference between the weighted average MA plan cost sharing and the proposed limit for that category for: (1) all MA plans; and (2) MA plans with cost sharing above the proposed cost-sharing standard.

Similar findings may be made for this service category for Cost Plans based on the information in tables 7, 9, and 11. As a result, this proposal (if finalized) has the potential to meaningfully improve access to opioid treatment programs as a significant proportion of MA and Cost Plan enrollees would likely experience substantively lower cost sharing for these services. While a decrease of $47 on average may be substantial for some MA plans (or $20 on average for Cost Plans), research finds that patients with severe alcohol and other drug problems report completing only two serious recovery attempts (median) before remission.[144] As a result, we expect lower cost sharing will increase utilization of opioid treatment program services and thus provide more beneficiaries with the services they need to achieve remission. In addition, a study shows that every dollar spent on substance use disorder treatment saves $4 in health care costs.[145] Finally, we note that over the past two decades, the number of overdose deaths in the older adult population has quadrupled.[146] As a result, applying the Traditional Medicare limit of zero cost sharing could have a significant positive impact on enrollees' ability to access those services and address the opioid use disorder crisis. We acknowledge this proposal of zero cost sharing also increases the cost liability for MA and Cost Plan organizations to cover opioid treatment program services. However, we believe this increase in cost liability is not as much of a concern as it otherwise would be for a highly utilized service (such as physical therapy). In other words, we find the increase in cost liability for MA and Cost Plan organizations to cover opioid treatment program services as outweighed by the potential positive enrollee outcomes described previously in this section. Given the expected positive impacts of applying the Traditional Medicare limit of zero cost sharing to opioid treatment program services, this proposed limit reflects an additional term or condition necessary and appropriate for the MA program, and not inconsistent with the Part C statute, which CMS has the authority to impose under section 1857(e)(1) of the Act.

We also believe tables 6 through 11 support the proposed MA and Cost Plan cost-sharing standard changes for the other behavioral health service categories. For instance, the MA data suggests that this proposal would result in either: (1) somewhat nominal reductions to plan cost sharing amounts for several behavioral health service categories across a substantive proportion of plans and enrollees or (2) substantive reductions to plan cost sharing amounts for certain inpatient hospital psychiatric length of stay scenarios for a small proportion of plans and enrollees. Similarly, for Cost Plans, we find that the data in tables 7, 9, and 11 suggest that this proposal would result in either: (1) moderate reductions to plan cost sharing amounts for opioid treatment program services across a substantive proportion of plans and enrollees or (2) nominal reductions to plan cost-sharing amounts for most of the other behavioral health service categories for a small proportion of plans and enrollees. For example, based on tables 8 and 10, approximately 24 percent of MA plans (or 4.5 million or 21 percent of MA enrollees) could have a reduction in cost sharing by about $7 per visit on average for mental health specialty services based on this proposal and contract year 2024 plan data. In comparison, based on tables 9 and 11, approximately 8 percent of Cost Plans (or 5,070 or 3 percent of Cost Plan enrollees) could have a reduction in cost sharing by about $5 per visit on average for this service category. CMS finds either of these consequences for mental health specialty services plan cost sharing amounts would further our progress towards improving access to behavioral health services across MA and Cost Plans. As a result, we find the burdens or costs that this proposal would impose on MA and Cost Plans are outweighed by the potential positive beneficiary outcomes.

By reducing costs for mental health specialty services by nominal amounts for each visit, we expect an increase in utilization of these services. This service category includes costs from social workers and psychologists, which are the behavioral health providers most utilized by enrollees in 2023.[147] Considering the combined effects of lower MA and Cost Plan cost sharing amounts across the behavioral health service categories, we also expect positive health outcome effects and improved enrollee access to these services.

We reiterate that the information in tables 6 through 11 reflects an estimate of this proposal's potential impact to MA and Cost Plans and enrollees in contract year 2026 based on the most recent data available at the time of developing this proposal. If this proposal is finalized, plans may make changes to their plan designs within the limits of applicable statutes and regulatory requirements discussed in the following section.

(3) Statutory and Regulatory Limitations on Benefit Design Changes

In the annual MA bids or for a new contract year for Cost Plans, plan benefit design changes may be made in response to multiple factors, including new cost-sharing requirements. If this proposal is finalized, MA and Cost Plan organizations have the flexibility to offset any potential cost changes related to providing behavioral health services (if they were not already establishing cost-sharing amounts at or below cost sharing in Traditional Medicare). For example, MA and Cost Plan organizations may choose to change aspects of their benefit designs in a manner that would distribute the impact across all enrollees such as changing

[144] Kelly JF, Greene MC, Bergman BG, White WL, Hoeppner BB. How Many Recovery Attempts Does it Take to Successfully Resolve an Alcohol or Drug Problem? Estimates and Correlates From a National Study of Recovering U.S. Adults. Alcohol Clin Exp Res. 2019 Jul;43(7):1533–1544. doi: 10.1111/acer.14067. Epub 2019 May 15. PMID: 31090945; PMCID: PMC6602820.

[145] Substance Abuse and Mental Health Services Administration (US); Office of the Surgeon General (US). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health [internet]. Washington (DC): US Department of Health and Human Services; 2016 Nov. CHAPTER 7, VISION FOR THE FUTURE: A PUBLIC HEALTH APPROACH. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK424861/*.

[146] Chatterjee, Rhitu. ''Mental health care is hard to find, especially for people with Medicare or Medicaid.'' April 2024. Retrieved from: *https://www.npr.org/sections/health-shots/2024/04/03/1242383051/mental-health-care-shortage-medicare-medicaid-hhs-inspector-general*.

[147] HHS Office of Inspector General. ''A Lack of Behavioral Health Providers in Medicare and Medicaid Impedes Enrollees' Access to Care'' April 2024. Retrieved from: *https://oig.hhs.gov/reports-and-publications/all-reports-and-publications/a-lack-of-behavioral-health-providers-in-medicare-and-medicaid-impedes-enrollees-access-to-care/*.

premium, supplemental benefits, and MOOP amount, as applicable, or make cost-sharing changes to other service categories. However, it is also possible that market forces will play a role in the organization deciding among potential plan benefit design changes. In addition, these organizations may choose to adjust profit margins rather than change benefits and/or premiums.

MA organizations may make changes to their plan benefit design that comply with existing statutory and regulatory requirements. This includes sections 1852(a)(1)(B)(i) and 1852(b)(1) of the Act. Section 1852(a)(1)(B)(i) of the Act provides that the MA organization must cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined at § 422.100(c)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in original Medicare in the aggregate; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented this requirement in several regulations, including §§ 422.100(j)(2), 422.102(a)(4), and 422.254(b)(4).

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. We have relied on this to establish certain minimum standards for MA plans, including cost sharing standards, designed to ensure that MA cost sharing designs and structures are not established in a way that discourages enrollment by Medicare beneficiaries with high health needs (whether overall or for specific categories of covered benefits).

In addition, section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is also authorized to deny a plan bid if the bid proposes too significant an increase in enrollee costs or a decrease in benefits from one plan year to the next. While this proposal does not limit our negotiation authority with respect to MA organizations' bid submissions (§ 422.256), it would provide cost-sharing standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids.

MA and Cost Plan organizations must also comply with applicable Federal civil rights laws that prohibit discrimination, including those that prohibit discrimination on the basis of race, color, national origin, sex, age, and disability, such as section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

None of the proposals in this proposed rule limit application of such anti-discrimination requirements. As a result, CMS believes these existing statutory antidiscrimination requirements, regulatory actuarial equivalence requirements for MA plans, and the competitive nature of the MA and Cost Plan programs will prevent potentially concerning changes organizations could otherwise make in response if this proposal is finalized. However, as discussed in the following section, we solicit comment on whether implementing this proposal beginning in contract year 2026 would sufficiently protect enrollees from potentially disruptive changes in access to care (including cost sharing and benefits) and coverage options from one year to the next.

(4) Comment Solicitations

As discussed in sections III.L.e.(2). and (3). and VII.E.3. of this proposed rule, CMS believes applying cost sharing no greater than Traditional Medicare as the cost-sharing standard for the behavioral health service categories will not result in significant negative disruption to many enrollees or MA and Cost Plan organizations. This is in part because as shown in:

- *Table 6:* The weighted average behavioral health cost sharing—of all contract year 2024 MA plans—reflects amounts that are less than the proposed standards for the behavioral health service categories, with two exceptions for the ''opioid treatment program services'' and ''outpatient substance use disorder services'' service categories.
- *Table 7:* The weighted average behavioral health cost sharing—of all contract year 2024 Cost Plans—reflects amounts that are less than the proposed standards for the behavioral health service categories, with one exception for ''opioid treatment program services'' service category.
- *Table 10:* The weighted average behavioral health cost sharing of contract year 2024 MA plans for only plans with cost sharing above the proposed standard is not significantly greater than our proposal for most of the professional service categories.
- *Table 11:* The weighted average behavioral health cost sharing of contract year 2024 Cost Plans for only plans with cost sharing above the proposed standard is not significantly greater than our proposal for most of the professional service categories.

As shown in table 6, the weighted average contract year 2024 MA plan cost sharing is about 9.5 percent coinsurance or $29 copayment for the ''opioid treatment program services'' and about 25 percent coinsurance or $36 copayment for ''outpatient substance use disorder services'' service categories. In comparison, as shown in table 10, the proposed behavioral health cost-sharing standards for these categories would eliminate cost sharing for ''opioid treatment program services'' and establish 20 percent coinsurance or a $35 copayment limit (illustrative dollar value that is actuarially equivalent to 20 percent coinsurance based on contract year 2025 Medicare FFS data projections) for the ''outpatient substance use disorder services'' categories. As a result, if the proposed behavioral health cost-sharing standards are finalized, we expect most continuing MA plans will not have to significantly adjust their benefit designs to come into compliance. In addition, based on our findings from tables 7 and 11 we also expect most continuing Cost Plans will not be significantly impacted by this proposal as most plans are currently in compliance with the proposed requirements.

Conversely, there are a subset of plans that established cost sharing amounts significantly above the weighted average values in table 6. Specifically, 3 percent of MA plans (impacting 3 percent of enrollees) established cost sharing greater than 30 percent coinsurance (or approximately $92 copayment) for partial hospitalization. In these cases, this proposal may have a more significant impact by lowering the cost sharing limit for this service category to 20 percent coinsurance or $60 copayment. Given the potential for this proposal to impact some MA and Cost Plans more significantly, we considered whether CMS should apply—

- These proposed changes beginning in contract year 2026 or 2027; or
- A transition period from the existing contract year 2025 behavioral health cost-sharing limits to the proposed cost-sharing standard for select behavioral health service categories, and if so, how long the transition should be.

For example, CMS considered whether a potential transition period is warranted for service categories with substantial changes to the cost sharing standard so MA and Cost Plans have sufficient time to address potential changes in bidding that stem from this proposal (if finalized) and other,

unrelated policy changes occurring at the same time (such as, new changes stemming from IRA Part D requirements and CMS's annual updates to the risk adjustment model and plan payments). In making this consideration, CMS evaluated MA encounter data to determine the potential impact this proposal may have on enrollee utilization of these behavioral health services. This data was not available for Cost Plans. Specifically, we compared the average length of stay and the percent of enrollees with any utilization of the various behavioral health service categories based on whether the MA enrollee's plan had cost sharing amounts for those services equal to, or less than, cost sharing in Traditional Medicare. The results of this analysis are provided in tables 12 and 13 for the most recent year of MA encounter data available at the time of developing this proposal, contract year 2023.

TABLE 12: CONTRACT YEAR 2023 MA ENCOUNTER DATA ANALYSIS OF ENROLLEE UTILIZATION OF BEHAVIORAL HEALTH SERVICES BASED ON PLAN COST SHARING

Service Category	Percent of Enrollees with Any Utilization in MA Plans with Cost Sharing Greater than Traditional Medicare	Percent of Enrollees with Any Utilization in MA Plans with Cost Sharing Equal to or Less than Traditional Medicare
Inpatient Psychiatric	0.3%	0.3%
Partial Hospitalization	0.03%	0.03%
Mental Health Specialty	2.6%	2.8%
Psychiatric	1.5%	1.8%
Opioid Treatment Program	0.1%	0.1%
Outpatient Substance Abuse	0.5%	0.6%

TABLE 13: CONTRACT YEAR 2023 MA ENCOUNTER DATA ANALYSIS OF AVERAGE LENGTH OF STAY OR NUMBER OF VISITS OF BEHAVIORAL HEALTH SERVICES BASED ON PLAN COST SHARING

Service Category	Average Length of Stay or Number of Visits by Enrollees in MA Plans with Cost Sharing Greater than Traditional Medicare	Average Length of Stay or Number of Visits by Enrollees in MA Plans with Cost Sharing Equal to or Less than Traditional Medicare
Inpatient Psychiatric	12.8 days	11.6 days
Partial Hospitalization	14.6 days	13.5 days
Mental Health Specialty	5.1 visits	4.9 visits
Psychiatric	4.0 visits	3.7 visits
Opioid Treatment Program	25.8 days	28.2 days
Outpatient Substance Abuse	2.1 days	2.0 days

Based on the information in tables 12 and 13, CMS finds that the data suggests that this proposal may result in small increases to per-enrollee utilization of certain behavioral health services but could also decrease the average duration or length of stay of these services. For example, table 12 shows that the percent of MA enrollees with any utilization of mental health specialty services, psychiatric services, and outpatient substance abuse services increased nominally if the enrollee was in a plan with cost sharing equal to or less than Traditional Medicare in comparison to plans with cost sharing greater than Traditional Medicare. For these same service categories, table 13 shows that enrollees in plans with cost sharing equal to or less than Traditional Medicare had shorter average length of stays or number of visits in comparison to enrollees in plans with cost sharing greater than Traditional Medicare for these services. As a result, we believe this proposal will not produce an immediate drastic change in utilization of the behavioral health service categories to the extent that a transition period is warranted. However, we solicit comment on this assumption.

f. Proposed Regulation Changes

Thus, we propose the following changes to §§ 417.454 and 422.100:

- Revise language at § 417.454(e) to clarify: (1) when the proposed new cost sharing limits—that is, the additional categories of basic benefits for which cost sharing may not be greater than cost sharing in original Medicare for that benefit—would apply and (2) the methods by which Cost Plan organizations (HMO or CMP) may abide by the requirements in this paragraph when they use coinsurance or copayment structures for these basic benefits.

- Revise language at § 417.454(e)(1) to match terminology of chemotherapy administration services with language at § 422.100(j)(1)(i)(A) applying the same cost sharing limit to MA plans.
- Add § 417.454(e)(5) to reflect proposed cost-sharing standard that Cost Plans may not establish cost sharing that exceeds cost sharing in Traditional Medicare for the following behavioral health service categories: intensive outpatient services, mental health specialty services, opioid treatment program services, outpatient substance use disorder services, partial hospitalization, and psychiatric services.
- Add § 417.454(e)(6) to reflect proposed cost-sharing standard that Cost Plans may not establish cost sharing for inpatient hospital acute and psychiatric services (all length of stay scenarios) that exceeds cost sharing for these services in Traditional Medicare.
- Add § 417.454(e)(7) through (e)(9) to reflect proposed cost-sharing standard that Cost Plans may not establish cost sharing for home health services, certain categories of DME, and drugs covered under Part B other than chemotherapy drugs that exceeds cost sharing for these services in Traditional Medicare.
- Add § 417.454(f) to codify and clarify our longstanding policy for Cost Plans that in-network cost sharing be no greater than the 50 percent coinsurance (or actuarially equivalent copayment) standard applied to MA plans for basic benefits without otherwise specified cost-sharing standards.
- Replace the partial hospitalization example with occupational therapy at § 422.100(f)(6)(iii)(A) to reflect the proposed cost-sharing standard of cost sharing no greater than original Medicare for the partial hospitalization service category.
- Add a regulation reference to paragraph (j)(1)(i)(H) at § 422.100(f)(6)(iv)(A) to reflect the proposed new paragraph which would apply cost sharing no greater than original Medicare to inpatient hospital psychiatric services.
- Remove language specific to inpatient hospital psychiatric services and associated lengths of stay scenarios at § 422.100(f)(6)(iv)(B) and (D) to reflect the proposed cost-sharing standard.
- Remove language at § 422.100(f)(6)(iv)(D) that the total inpatient benefit cost sharing must not exceed the MA plan's MOOP amount for clarity.
- Add language to § 422.100(j)(1)(i) that the requirement for cost sharing to not exceed cost sharing under original Medicare applies on different dates for different benefits categories as proposed in paragraphs under paragraph (j)(1)(i).
- Add language to § 422.100(j)(1)(i)(C) that the Part A deductible amount referred to is for the year.
- Remove § 422.100(j)(1)(i)(C)*(2)* and move language from paragraph (j)(1)(i)(C)*(1)* to paragraph (j)(1)(i)(C) to consolidate skilled nursing facility cost-sharing standard information.
- Add § 422.100(j)(1)(i)(G) to reflect proposed cost-sharing standard of cost sharing no greater than original Medicare for the following behavioral health service categories: intensive outpatient services, mental health specialty services, opioid treatment program services, outpatient substance use disorder services, partial hospitalization, and psychiatric services for contract year 2026 and subsequent years.
- Add § 422.100(j)(1)(i)(H) to reflect proposed cost-sharing standard of cost sharing no greater than original Medicare for inpatient hospital psychiatric services (all length of stay scenarios) for contract year 2026 and subsequent years.
- Revise language at § 422.100(o)(2) that references paragraph (j)(1)(i)(C)*(2)* to reference paragraph (j)(1)(i)(C) in relation to regional PPO dual eligible special needs plans.

We solicit comment on these proposals.

M. Ensuring Equitable Access—Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 422.137)

On January 20, 2021, President Biden issued Executive Order 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (E.O. 13985).[148] E.O. 13985 describes the Administration's policy goals to advance equity across Federal programs and directs Federal agencies to pursue a comprehensive approach to advancing equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Consistent with this Executive Order, in 2022, CMS announced ''Advance Equity'' as the first pillar of its Strategic Plan.[149] This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health care system. CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [150]

In April 2024, CMS published the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' [151] final rule (89 FR 30448) (hereinafter referred to as the April 2024 final rule). In the April 2024 final rule, CMS explained that we have received feedback from interested parties, including people with Medicare, patient groups, consumer advocates, and providers that utilization management (UM) practices in Medicare Advantage (MA), including the use of prior authorization, can sometimes create a barrier for patients in accessing medically necessary care. Further, as explained in detail in the April 2024 final rule, some research indicated that the use of prior authorization may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality (89 FR 30566).[152] [153]

Under section 1852 of the Act, MA organizations are generally allowed to use utilization management tools, such as prior authorization.[154] Authority for

[148] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[149] *https://www.federalregister.gov/d/2022-26956/p-228.*

[150] *https://www.cms.gov/pillar/health-equity.*

[151] *https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit.*

[152] *https://www.hmpgloballearningnetwork.com/site/frmc/commentary/addressing-health-inequities-prior-authorization*; and *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/.*

[153] *https://www.federalregister.gov/d/2023-24118/p-600.*

[154] Sections 1852(c)(1)(G) and (c)(2)(B) of the Social Security Act, and the MA regulations at 42 CFR 422.4(a)(1)(ii) and 422.138, expressly reference a MA plan's application of utilization management tools, like prior authorization and other ''procedures used by the organization to control utilization of services and expenditures.'' MA plans may require prior authorization on medical items and services, except for certain services, including emergency services, urgent care, and stabilization services. For preferred provider organization (PPO) plans, prior authorization is prohibited on plan-covered services from out-of-network providers (see § 422.4(a)(1)(v)(D)).

MA organizations to use utilization management policies and procedures regarding basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA statutory provisions. In addition, the MA statute and MA contracts cover both the basic and supplemental benefits covered under MA plans, so additional contract terms added by CMS pursuant to section 1857(e)(1) of the Act may also address supplemental benefits. Additionally, per section 1852(b) of the Act and § 422.100(f)(2), plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. These requirements apply to both basic and supplemental benefits. We consider utilization management policies and procedures to be part of the plan benefit design, and therefore they cannot be used to discriminate or direct enrollees away from certain types of services.

In the April 2024 final rule, CMS added two health equity related requirements to § 422.137. First, at § 422.137(c)(5), to require that beginning January 1, 2025, the UM committee must include at least one member with expertise in health equity. Second, at § 422.137(d)(6), we finalized that the UM committee must conduct an annual health equity analysis of the use of prior authorization. The analysis must examine the impact of prior authorization at the plan level, on enrollees with one or more of the specified social risk factors (SRF).[155] The analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Further, the analysis must use the outlined metrics, aggregated for all items and services, calculated for enrollees with the specified SRFS, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis. Finally, by July 1, 2025, and annually thereafter, the health equity analysis must be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website.

[155] Section 422.137(d)(6)(ii): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability.

During the public comment period, CMS received a significant number of comments on the requirement that the metrics for the health equity analysis be aggregated for all items and services (89 FR 30569). Some commenters expressed concern that because the proposed analysis would consist of prior authorization metrics aggregated for all items and services, it would not provide enough detail for true accountability and could allow plans to hide disparities. For that reason, commenters recommended that CMS require a further level of granularity to ensure that potential disparities could be identified. Specifically, commenters suggested that CMS require disaggregation by item and service to ensure that CMS can identify specific services that may be disproportionately denied. At the time, we believed that there was significant value in establishing baseline data because we recognized that there was little publicly available information regarding the use of prior authorization and its potential impact on specific populations.

In the April 2024 final rule, we signaled our intent to propose reporting and posting of disaggregated (that is, more granular) data on these topics in the future. Furthermore, we stated that we agree that disaggregation of the reported metrics for all items and services could assist in increasing transparency and ensuring the most accurate data regarding prior authorization is available.[156] By proposing to require the data to be disaggregated, CMS and MA organizations may more readily identify trends related to the use of prior authorization and, therefore, be able to more fully identify and address the impact of prior authorization on enrollees with the specified SRFs. This disaggregated data also will help inform future policymaking.

For these reasons, we propose at § 422.137(d)(6)(iii)(A) through (H) to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the following:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.
- The percentage of standard prior authorization requests that were denied, reported by each covered item and service.
- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

We also seek comment on alternative ways to group items and services for the purpose of reporting on these metrics, while still allowing for meaningful disaggregation to increase transparency, identify trends, and address the impact of prior authorization on enrollees with the specified SRFs.

Because the required metrics are to be reported based on percentage of prior authorization requests, and average and median time elapsed, CMS does not believe the health equity analysis and accompanying report will result in potential enrollee privacy issues. However, out of an abundance of caution, CMS is considering whether to include a provision to allow suppression of certain data points should disaggregation present an issue regarding enrollee privacy. For example, if reporting by each covered item and service would result in such a small data set that it could put enrollee privacy at risk, an MA plan would be permitted to suppress that data set. CMS solicits feedback on whether cell suppression is necessary in order to ensure that enrollee privacy is protected and on how to ensure that this suppression would be done in a uniform manner. Based on feedback received during the public comment period, we may consider revising any potential final policy to account for these potential privacy concerns.

We also received comments on the April 2024 final rule stating concerns that the analysis would be challenging for enrollees and the public to navigate and understand. At the time, we determined that this would not present

[156] *https://www.federalregister.gov/d/2024-07105/p-1232.*

a significant issue because the data was required to be aggregated for all items and services. However, because we are now proposing that MA organizations report the metrics by each covered item and service, we believe an executive summary of the results of the analysis is necessary to ensure that the public and plan enrollees can navigate and understand the data more fully. Therefore, we propose at § 422.137(d)(7)(v) that the results of the health equity analysis include an executive summary. The executive summary must include the following elements: additional context that may be necessary or helpful for understanding the results of the analysis; clarifying information that is relevant to the results of the analysis, or that could help the public understand the analysis more fully; and an overview of the information produced by the analysis, including key statistics and results. We propose that MA plans must also ensure that accompanying language is not misleading or misrepresentative of the findings of the analysis. We solicit comment on additional requirements to be included in the executive summary, including, but not limited to, how this information could be formatted and presented in a uniform manner across all MA plans, adherence to plain language principals and accessibility standards, and consumer centered design standards. We also solicit comment on how the data produced by the analysis could be formatted to ensure consistency and uniformity across MA plans, and to ensure usability by enrollees and the public.

CMS is considering adding ''having a mental health or substance use disorder diagnosis'' to the list of social risk factors that MA plans must use to conduct the annual health equity analysis. We solicit comment on this addition and whether this appropriately addresses a gap in the existing social risk factors. We also solicit comment on whether this is something that MA plans would be able to operationalize, any potential barriers or challenges CMS should consider in policy development and reporting, and how MA plans might overcome these barriers.

We welcome comment on the proposal and may revise the final policy based on comments received.

N. Medicare Advantage Network Adequacy (§ 422.116)

Section 1852(d)(1)(A) of the Social Security Act allows MA organizations to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and in a manner that assures continuity in the provision of benefits. 1852(d)(1)(D) of the Act requires MA organizations to provide access to appropriate providers for medically necessary treatment and services. In § 422.116, CMS codified a means of compliance with these statutory requirements by requiring network-based MA plans to demonstrate that they have an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in 1852(d)(1) and in §§ 422.112(a)(10) and § 422.114 and by meeting the network adequacy standards at § 422.116(a)(2). MA organizations must maintain an adequate contracted network of providers regardless of whether a provider or facility type is included in the network adequacy standards at § 422.116.

1. Defining County

Network adequacy is assessed at the county level, including county-equivalents, across all geographic areas in the United States and its territories. CMS uses the county level for purposes of determining the number and type of providers and facilities, based on time and distance, that an MA organization must contract with to ensure there is adequate access to Part A and B services for beneficiaries. The minimum number, specialty type, and time and distance requirements are codified at § 422.116(d) and (e). CMS's longstanding policy and interpretation of existing network adequacy regulations uses the term ''county'' to mean the areas designated by the Census Bureau as the primary political and administrative division of States. The Census Bureau also considers certain geographic areas as county-equivalents. County-equivalents include, but are not limited to, boroughs, certain designated cities, parishes, municipalities and the District of Columbia. CMS uses the Census Bureau's designation of counties and county-equivalents in establishing network adequacy standards to ensure consistency in the application of CMS' network adequacy requirements across the country.

For purposes of network adequacy, CMS is proposing to codify its longstanding policy of treating county equivalents the same as counties for network adequacy purposes by defining ''county'' in § 422.116. In § 422.116, we propose to create a new (a)(1) and redesignate the current (a)(1) through (a)(4) as (a)(2) through (a)(5). We further propose to define ''county'' in new (a)(1) as ''the primary political and administrative division of most States and includes functionally equivalent divisions called ''county equivalents'' as recognized by the United States Census Bureau (for economic census purposes)''. Note that we have also proposed to modify the definition of service area in § 422.2 in C–E of this section to incorporate the proposed definition of ''county'' in § 422.116(a)(1).

2. Limiting Exception Request Rationales

Under its authority to set standards to implement and carry out the MA statute (in section 1856(b)(1) of the Act), CMS codified network adequacy standards at § 422.116 under the final rule, Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the June 2020 final rule. CMS has also adopted specific access requirements in §§ 422.100(b), 422.112, 422.113 and 422.114 to ensure that MA enrollees in various types of MA plans have access to covered services.

In the June 2020 final rule, we codified regulations allowing MA organizations to submit exceptions to the network adequacy standards in § 422.116, including, the circumstances under which an MA organization may request an exception (§ 422.116(f)(1)) and the factors that CMS considers when evaluating an MA organization's request for an exception (§ 422.116(f)(2)), including examples of how it would be applied. We indicated that we would interpret the regulation such that the MA plan would have to contract with telehealth providers, mobile providers, or providers outside the time and distance standards, but accessible to most enrollees (or consistent with the local pattern of care), in order for the MA plan to request an exception by CMS (85 FR 33858).

Currently, subregulatory guidance, the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance,[157] indicates that organizations may request exceptions utilizing the following valid rationales:

- Provider is no longer practicing (for example, deceased, retired).

[157] *https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance12-12-2023.pdf.*

- Provider does not provide services at the office/facility address listed in the supply file.
- Provider does not provide services in the specialty type listed in the supply file, and for which this exception is being requested.
- Provider has opted out of Medicare.
- Provider does not contract with any organizations or contracts exclusively with another organization.
- Sanctioned provider on List of Excluded Individuals and Entities.
- Provider is at capacity and is not accepting new patients.
- Other: Use of Original Medicare telehealth providers, mobile providers, specific patterns of care in a community

We have explained in our Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance, that while the time and distance standards vary by county and specialty type, and are generally attainable across the country, there are unique instances where a given county's supply of providers/facilities is such that an organization would not be able to meet the network adequacy criteria. The exceptions process allows MA organizations to provide evidence to CMS when the health care market landscape has changed or is not reflected in the current CMS network adequacy criteria. The organization must include conclusive evidence in its exception request that the CMS network adequacy criteria cannot be met because of changes to the availability of providers/facilities, resulting in insufficient supply.

Per § 422.116(f)(1)(i), an MA plan may request an exception to network adequacy criteria when both of the following occur: (A) certain providers or facilities listed in the Provider Supply file are not available for the MA plan to meet the network adequacy criteria for a given county and specialty type; and (B) the MA plan has contracted with other providers and facilities who are located beyond the limits in the time and distance criteria, but are available and accessible to most enrollees, consistent with the local pattern of care.

As part of CMS's evaluation of MA networks using § 422.116, MA organizations must first submit their Health Service Delivery (HSD) tables, containing all their network providers, to CMS. CMS processes and reviews the network submissions against our established regulatory standards through use of an automated system located in the Health Plan Management Systems (HPMS) network management module. This automated module within HPMS evaluates the networks based on CMS' current network time and distance standards. Once the evaluation is complete, CMS, through HPMS, provides MA organizations with an Automated Criteria Check (ACC) report. The ACC report contains CMS's determination of whether the standards in § 422.116 have been met or not met, and the report displays where the MA organization's specific county/specialty combinations, within the given service area, are passing and failing those standards. MA organizations may decide to submit an exception request for those parts of their network submission that were found to be failing our standards by using the exception request template found in the HPMS in accordance with CMS procedural instructions.

After submission, CMS evaluates exception requests based on the criteria noted in § 422.116(f)(2), including whether the current access to providers and facilities is different than that in the HSD reference and provider supply files for the year (see § 422.116(a)(4)(ii)), whether the organization demonstrates that the network access is consistent with or better than the original Medicare pattern of care, and whether approval is in the best interest of the beneficiaries. The exception request is then either approved or denied. Once the CMS exception request review is complete, the results of CMS's determination are uploaded into HPMS with an approval or denial status for MA organizations to view. If an exception request is denied, CMS will provide feedback with the exception disposition, including, as applicable, a sampling of the providers that CMS lists in the Provider Supply File that are available for the MA organization to contract with that would allow the organization to meet the time and distance standards for the specific county/specialty type. MA organizations must resubmit all previously approved exception requests whenever CMS requests an organization to upload its HSD tables to review an MA organization's network(s).

To continue to strengthen our network adequacy process and the rules related to exception requests to our network adequacy standards, CMS is proposing to codify our long-standing network adequacy exception request rationales, with one change. We propose to eliminate the rationale that the ''provider does not contract with any organization or contracts exclusively with another organization'' (meaning MA organization) as a basis for an exception. It is important for CMS to ensure consistent and equitable access to healthcare services for all Medicare Advantage enrollees. In removing this rationale, CMS aims to limit the reasons that an organization could be able to bypass the established network adequacy criteria for a given specialty/county and provide greater incentives for MA organizations to establish contracts with providers that are located within our established time and distance standards.

Therefore, CMS is proposing to codify the following as valid rationales when an MA plan submits substantial and credible evidence, in the form and manner requested by CMS, to demonstrate that an exception request under § 422.116(f)(1)(i) should be considered:

- Provider is no longer practicing (for example, deceased, retired).
- Provider does not provide services at the office or facility address listed in the Provider Supply file in paragraph (a)(4)(ii) of this section.
- Provider does not provide services for the specialty type listed in the Provider Supply file in paragraph (a)(4)(ii) of this section.
- Provider has opted out of Medicare (in compliance with § 422.204(b)(4)).
- Provider is a sanctioned provider on the List of Excluded Individuals and Entities (in compliance with § 422.204); or provider is on the CMS preclusion list (in compliance with § 422.222);
- Provider is at capacity and is not accepting new patients.

One of the listed rationales may be used to explain the reason that an MA plan has failed to demonstrate that its network meets the minimum requirements of § 422.116(a) through (e) but MA organizations should provide CMS with as fulsome of an explanation as possible, including supporting documentation, regarding why an exception should be granted under the standards in § 422.116(f).

Our current subregulatory guidance states that CMS considers certain exception rationales under an ''other'' category. Currently, the ''other'' category permits organizations to request an exception for ''provider does not contract with any organization'', ''the provider has the potential to cause beneficiary harm'', and ''the provider is inappropriately credentialed.'' CMS is proposing to eliminate the ''other'' category and eliminate the exception rationale of ''provider does not contract with any organization,'' as described above. CMS is also eliminating ''provider has the potential to cause beneficiary harm'' because this exception rationale is already covered under CMS' evaluation of any exception, which includes ensuring the exception is in the best interest of the beneficiary as noted in § 422.116(f)(2)(iii). Finally, CMS is retaining the last exception currently

under ''other'' in guidance. This exception ''the provider is not properly credentialed'' is being incorporated under the proposed exception rationale of provider does not provide services for the specialty type listed in the Provider Supply file.

Our current subregulatory guidance also describes as exception rationales factors such as use of Original Medicare telehealth providers, mobile providers, and specific patterns of care in a community. When CMS evaluates these exception rationales, we consider whether network access is consistent with or better than the Traditional Medicare pattern of care and whether approval of an exception is in the best interest of beneficiaries, under § 422.116(f)(2). These factors may be relevant to demonstrate that network access is consistent with or better than the Traditional Medicare pattern of care (§ 422.116(f)(2)(ii)) or that approval of the exception is in the best interests of beneficiaries (§ 422.116(f)(2)(iii)). Our guidance states that for organizations using Traditional Medicare telehealth providers, services must meet the requirements for ''telehealth services'' under section 1834(m) of the Act (for example, provider types, eligible originating sites, geography, and currently approved list of Medicare telehealth services), as well as the requirements for ''communication technology-based services'' not subject to the section 1834(m) limitations (brief communication technology-based service/virtual check-in, remote evaluation of pre-recorded patient information, and inter-professional internet consultation). The MA organization must demonstrate that it meets all applicable requirements. Our guidance also states that if an MA organization uses mobile providers (for example, mobile x-ray suppliers, orthotics and prosthetics mobile units), they must be qualified and furnish services through scheduled appointments. In addition, organizations requesting an exception using the ''pattern of care'' rationale described in § 422.116(f)(2)(ii) are required to providesubstantial and credible evidence that shows that the supply of providers/facilities is insufficient, as well as the reason that the MA organization does not contract with the available providers/facilities within the time and distance. The MA organization must show that the pattern of care in the area is unique and can demonstrate their contracted network is consistent with or better than the Original Medicare pattern of care. CMS will consider an MA organization's reason for not contracting with an available provider/facility if such a contract is not in the best interest of the beneficiaries in the applicable service area.

We note that, as we have indicated in our subregulatory guidance, CMS will not accept an organization's assertion that it cannot meet current CMS network adequacy criteria because of an ''inability to contract,'' meaning they could not successfully negotiate and establish a contract with a provider/facility. The non-interference provision at section 1854(a)(6)(B)(iii) of the Act states that the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, we are not assuming the role of arbitrator or judge regarding the bona fides of contract negotiations between an MA organization and available providers or facilities.

CMS notes that with these proposals we are codifying long-standing rules related to network adequacy exception request rationales, with one change to eliminate the rationale that a ''provider does not contract with any organization or contracts exclusively with another organization''; therefore, we do not believe there is any additional paperwork burden to be considered. We welcome comment on these proposals, including the exhaustive list of exception request rationales proposed here, and whether there are additional rationales to consider that are in the best interest of beneficiaries. In addition, we are soliciting comment on potential unintended consequences from this proposal, including potential changes in the provider landscape, that could limit plan choice and/or availability in certain areas of the country.

3. Plan Benefit Package Level Reviews

Finally, CMS is considering whether conducting network adequacy reviews at the MA plan benefit package level would provide greater assurances regarding the adequacy of an MA organization's network at the more discrete, plan level service area. Our current practice is to conduct network adequacy reviews of an MA organization's network at the contract level, by county type. Reviewing the plan-level network may result in a more accurate portrayal of an enrollee's experience since, for example, while an MA organization's contract may exceed CMS's minimum provider number requirements some providers and facilities that participate in a contract's network may not be available to enrollees in a particular plan under that contract. This situation could therefore result in some MA contracts satisfying current network adequacy requirements, but an individual plan not satisfying current network adequacy requirements, resulting in a beneficiary having access to an inadequate number of providers in a given plan. We note that the CMS network adequacy time and distance standards in § 422.116 would not change but would instead be applied at the plan benefit package level.

In the June 2020 final rule, CMS indicated in preamble that we conduct network adequacy reviews at the contract level, meaning we evaluate the adequacy of the MA organization's network across all the plan benefit packages within the contract for the plan types as defined in § 422.2 offered for that contract; we do not separately or singularly evaluate the network of a specific plan benefit package. We indicated at the time that conducting network reviews at the contract level allowed us to consider the broadest availability of contracted providers and facilities for an MA organization while also providing administrative efficiency for both MA organizations and CMS. While this is still our current practice, we are considering whether network evaluations at the plan benefit package level, for active contracts only, would be more appropriate to help CMS ensure more consistent and thorough oversight of MA provider networks.

We point out that CMS already has the authority to conduct plan benefit package level reviews based on our current regulatory language. Section 422.116(a)(1)(i) requires that a network-based MA plan as described in § 422.2, but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards. We solicit comment on this potential change in methodology and the impact on the counties served by MA organizations, including any considerations for rural counties, and whether there could be additional ways for CMS to strengthen our evaluation of an adequate network for MA organizations, specifically individual plans within a contract. We also solicit comment on the effort required by MA organizations to submit network data at the individual plan benefit package level. In addition, we solicit comment on whether SNP PBPs, as part of product offerings within a contract, offer limited network options that meet our standards or contract with the same provider network as non-SNP PBPs under the same contract. If CMS chooses

to review active contracts at the plan benefit package level, we will indicate that change by updating the associated Paperwork Reduction Act (PRA) CMS–10636 forms, where we can seek public comment on proposed collections of information.

O. Promoting Informed Choice—Expand Agent and Broker Requirements Regarding Medicare Savings Programs, Extra Help, and Medigap (§§ 422.2274 and 423.2274)

Sections 1852(c) and 1860D–4(a) of the Act require MA organizations and Part D sponsors to provide certain information to current MA and Part D plan (PDP) enrollees concerning MA plan and PDP benefits, coverage, plan rules, and other information that could inform potential enrollment changes. Additionally, section 1851(h)(4) requires MA organizations to conform to fair marketing standards in relation to marketing activities for MA plans, including standards that CMS may establish pursuant to section 1856. Likewise, section 1860D–1(b)(1)(B)(vi) of the Act extends these fair marketing standard requirements to Part D sponsors. These statutory provisions provide CMS the authority to implement regulatory requirements on MA organizations and Part D sponsors to ensure plan benefits and cost sharing information are discussed with beneficiaries to ensure they have an accurate picture of their enrollment options and help them make informed decisions when considering their health care coverage. We note that such requirements are also consistent with CMS's own statutory obligation, at section 1851(d) of the Act, to disseminate information to current and prospective Medicare beneficiaries on coverage options, including information comparing MA plans' premiums and cost sharing, to promote informed decision-making. Section 1860D–1(c) of the Act specifies corresponding dissemination requirements for current and prospective Part D eligible individuals regarding PDP comparisons.

As described in the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22120), hereinafter referred to as the April 2023 final rule, CMS listened to a considerable number of marketing and enrollment audio calls between agents and brokers and beneficiaries (both current and prospective beneficiaries). Many of these calls indicated that agents and brokers failed to ask pertinent questions to help a beneficiary enroll in a plan that best fits their health care needs. During our review, we repeatedly heard instances in which agents only reviewed the beneficiary's health care providers and prescription drugs with them, which likely is not sufficient information for a beneficiary to consider when determining which health care option might best fit their needs. Other examples we heard included agents failing to ask the beneficiary if they had a preferred primary care provider or specialist, failing to confirm whether or not the preferred provider was in the plan's network, failing to discuss what pharmacies are in-network, as well as failing to ask if the beneficiary preferred copays or coinsurance, or preferred lower monthly premiums, or slightly higher monthly premiums as a trade-off for lower out of pocket costs for appointments, as an example. Before enrolling a beneficiary in an MA, MA–PD, or Part D plan, in addition to discussing topics like the beneficiary's health care providers, prescription drugs, copays, coinsurance, monthly premiums, and out of pocket costs prior to enrolling a beneficiary in an MA, MA–PD, or Part D plan, agents and brokers should also discuss costs of other healthcare services, plan benefits, and the beneficiary's specific health needs. Covering these topics with each beneficiary prior to their enrollment in a new plan, as discussed in the April 2023 final rule, helps ensure the beneficiary is enrolling into a plan that best meets their needs.

Based on these considerations, CMS finalized a new paragraph (c)(12) of §§ 422.2274 and 423.2274 in the April 2023 final rule, which defined a CMS-developed list of topics that MA organizations and Part D sponsors must ensure agents and brokers of first tier, downstream, and related entities (FDRs) that represent the MA organizations and Part D sponsors discuss with beneficiaries during the marketing and sale of an MA or MA–PD plan or PDP and prior to their enrollment in a new plan. Since the finalization of §§ 422.2274(c)(12) and 423.2274(c)(12), as part of our monitoring and oversight of the MA program, we have listened to and evaluated marketing and enrollment audio calls to understand the effectiveness of the new rule's implementation. As part of our monitoring and review efforts, we proactively evaluate the issues we uncover and consider appropriate revisions to our rules that may help improve the beneficiary experience so they have a more accurate picture of their enrollment options as they pertain to making an MA or Part D enrollment decision and can make more informed health care choices. For instance, after reviewing audio calls, we noticed gaps in information provided to beneficiaries surrounding low-income subsidy (LIS) eligibility and Medicare Savings Programs (MSPs) that would be beneficial to make an informed enrollment choice. We have also received feedback during meetings with State Health Insurance Assistance Program (SHIP) counselors who expressed concerns with beneficiaries not fully understanding how enrollment into an MA or MA–PD plan can impact future availability of Medicare Supplement Insurance (Medigap) coverage. In addition, a Commonwealth Fund study involving agents and brokers found that beneficiaries who work with agents and brokers are often unaware of their guaranteed issue (GI) rights or the rules around underwriting with Medigap when switching from an MA plan to traditional Medicare, which can lead to significant confusion.[158] We believe expanding upon the CMS-developed lists provided at §§ 422.2274(c)(12) and 423.2274(c)(12) to require this additional information will help beneficiaries better understand how their health care choice will address their individual needs.

Sections 422.2274(c)(12) and 423.2274(c)(12) require that MA organizations and Part D sponsors, as part of their oversight of their FDRs, ensure that agents and brokers operating on their behalf discuss a specified list of questions and topics with a potential beneficiary prior to completing an enrollment. In the following paragraphs, we propose adding three topics, LIS, MSP, and Medigap, to that list. In addition, we are proposing to update §§ 422.2274(c)(12) and 423.2274(c)(12) to also provide that agents and brokers pause to ask whether a beneficiary has any outstanding questions prior to an enrollment decision being made. And finally, we are proposing corresponding technical changes to §§ 422.2274(c)(12) and 423.2274(c)(12) to put the newly proposed and existing requirements into a more organized and reader-friendly format.

1. Low-Income Subsidy (LIS)

CMS regulations at § 423.773 define the requirements for full and partial LIS Part D eligible individuals in accordance with section 1860D–14 of the Act as amended by section 11404 of

[158] *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents.*

the Inflation Reduction Act of 2022 (IRA). This recent statutory change provided the full LIS for those who only qualified for the partial LIS prior to 2024, which means an increased number of beneficiaries are eligible to receive ''Extra Help'' paying their monthly premium, yearly deductible, and prescription drug cost sharing. In the April 2023 final rule, in accordance with the IRA of 2022, CMS amended § 423.773(b)(1) to require that, to be eligible for the full LIS for plan years beginning on or after January 1, 2024, an individual must have an income below 150 percent of the Federal poverty line (FPL). To coordinate with this change, CMS also amended § 423.773(d) to specify that the requirement that an individual have an income below 150 percent of the FPL to be eligible for the partial LIS applies only to plan years beginning before January 1, 2024, effectively sunsetting the partial LIS after 2023 and significantly increasing the number of beneficiaries who can get full help paying for their prescription drugs.

Since the new requirements at § 423.773 went into effect, as of January 1, 2024, LIS eligibility criteria have increased the number of beneficiaries who can get full extra help paying for their premium, deductible, and prescription drugs costs. We believe that agents and brokers have a responsibility to inform a beneficiary of the new LIS eligibility criteria prior to their enrollment in an MA, MA–PD or Part D plan because being LIS eligible may impact a beneficiary's premium, coinsurance, deductibles, and other costs. Therefore, we are proposing to modify §§ 422.2274(c)(12) and 423.2274(c)(12) to include LIS eligibility criteria as an additional topic that agents and brokers must address before enrolling a beneficiary in an MA, MA–PD or Part D plan, so that all eligible beneficiaries can make fully informed enrollment decisions including decisions about applying to receive extra help in paying for this important coverage. Specifically, at § 422.2274(c)(12), we propose to add the phrase ''low-income subsidy eligibility (that is, at a minimum, explaining the eligibility requirements as defined at § 423.773 and the effect on drug costs if eligible, and identifying resources where they can get more information on applying)'' to the existing list of required topics, before the phrase ''costs of health care services.'' At § 423.2274(c)(12), we propose to add the phrase ''low-income subsidy eligibility (that is, at a minimum, explaining the eligibility as defined at § 423.773 and the effect on drug costs if eligible, and providing resources to the beneficiary about where they can go for more information on applying)'' to the existing list of required topics, before the term ''premiums.'' We believe that agents and brokers should provide this additional information since it may impact a beneficiary's enrollment decision. As part of this proposed requirement, agents and brokers would be required to identify resources to the beneficiary about where the beneficiary can obtain more information regarding their potential eligibility for LIS or get help applying for LIS. For example, agents and brokers could offer existing CMS links and resources that provide guidance on eligibility on LIS and how a beneficiary can apply for LIS.[159] This information may be an essential factor in a beneficiary's decision to enroll in an MA, MA–PD or Part D plan, or Medicare Savings Programs (MSP).

We also are proposing to add a requirement that agents and brokers review, prior to a beneficiary's enrollment in an MA, MA–PD, or Part D plan, existing resources for state programs, including MSPs, that can help with health care costs. MSPs are Medicaid eligibility groups through which states cover Medicare premiums and, in many cases, cost sharing for eligible beneficiaries. This proposed requirement to discuss resources for state programs is a relevant addition alongside the proposed LIS eligibility requirement because most LIS-eligible beneficiaries may find other information about additional help with health care costs useful for making an informed decision about their health care coverage and enrollment options. Most beneficiaries eligible for LIS are also eligible for MSPs. With this new requirement, we would not expect agents and brokers to provide all necessary details for a beneficiary to make a final decision about applying for help from a state program.[160] However, we would expect agents and brokers to explain that state programs that can help with premiums and cost sharing costs exist, and additionally expect agents and brokers would be equipped to offer contact information for the state as a resource for a beneficiary to receive more information about their options and eligibility for those states where the agent is licensed and appointed to sell, as required under §§ 422.2274(b)(1) and 423.2274(b)(1). We would encourage agents and brokers to use CMS-developed materials to communicate important information to beneficiaries about relevant state programs. For instance, the CMS MSP web page describes Federal limits for each MSP and contains a link to easily contact state representatives.[161] Specifically, we propose to create §§ 422.2274(c)(12)(v) and 423.2274(c)(12)(iv) to add the phrase ''resources for state programs, including Medicare Savings Programs,'' to the existing list of required topics.

2. Medicare Supplemental Insurance (Medigap)

In addition to LIS eligibility and resources for state programs, to further promote informed decision-making for beneficiaries, we are proposing that agents and brokers be required to discuss with beneficiaries the potential impact enrolling into a MA plan can have on Medigap Federal guaranteed issue rights. If a beneficiary chooses to enroll in Traditional Medicare with a Medigap plan during their Medigap Open Enrollment Period OEP) or in certain limited situations outside of their Medigap OEP, they have Medigap protections or Medigap Federal GI rights. In situations where the Medigap Federal GI rights apply, the Medigap insurance company must sell the beneficiary a Medigap policy, must cover all of the beneficiary's preexisting health conditions, and cannot charge more for a Medigap policy because of the beneficiary's past or present health problems.[162]

Over the years, CMS has received feedback from congressional offices, SHIPs and Medicare beneficiary advocacy organizations from or on behalf of Medicare beneficiaries who have enrolled into an MA plan without understanding the impact doing so can have on selecting a Medigap plan in the future. For example, we have heard about beneficiaries who, based on personal preference, have decided to enroll into Traditional Medicare with a Medigap plan after having previously enrolled in an MA plan, only to find that they are unable to do so, or that the cost outside of the MA ''trial right'' periods, which are some of the situations where the Medigap Federal GI rights apply,[163] is not affordable. To

[159] *https://www.cms.gov/medicare/enrollment-renewal/part-d-plans/low-income-subsidy/eligibility-low-income-subsidy.*

[160] See section 1144(c)(3) of the SSA. Under Federal law, when an individual applies for LIS benefits and consents, their information is transmitted to the state to initiate an application of the individual for MSP benefits.

[161] United States Centers for Medicare & Medicaid Services, *Medicare Savings Programs, https://www.medicare.gov/basics/costs/help/medicare-savings-programs.*

[162] See section 1882(s)(3)(A) of the SSA.

[163] The MA ''trial right'' period and other Federal Medigap GI rights are described in CMS' Choosing

better ensure that beneficiaries are equipped with pertinent information on the impact on their Medigap Federal GI rights when making an MA plan enrollment decision, at § 422.2274(c)(12)(vi), we are proposing to require than an agent or broker convey information regarding Medigap Federal GI rights to beneficiaries who are enrolling into an MA plan when first eligible for Medicare, or those who are dropping a Medigap plan to enroll into an MA plan for the first time. Specifically, at § 422.2274(c)(12)(vi)(A)(1), we are proposing to require that an agent or broker convey that the beneficiary generally has a 12-month period under Federal law in which they can disenroll from the MA plan and switch back to Traditional Medicare and purchase a Medigap plan with Medigap Federal GI rights.[164] For purposes of this discussion and proposal, we refer to both of these situations that trigger Medigap Federal GI rights as ''MA 'trial right' periods.'' As noted previously, when seeking to purchase a Medigap plan in a situation where the Medigap Federal GI rights apply, the insurance company selling it must cover all preexisting health conditions and can't charge a beneficiary more for a Medigap policy because of past or present health problems. It is therefore important that beneficiaries have information about the impact on their Medigap Federal GI rights when making an MA plan enrollment decision.

Under this proposal, at § 422.2274(c)(12)(vi)(A)(*2*), the agent or broker would also be required to explain that, in general, if a beneficiary enrolled in an MA plan decided to switch back to Traditional Medicare outside of their MA ''trial right'' period, they are not guaranteed the right under Federal law to purchase a Medigap plan and if they do, the insurance company can take all previous and preexisting health conditions into consideration, resulting in the beneficiary likely paying more. In addition, under this proposal, we would encourage agents and brokers to use and refer a beneficiary to beneficiary-focused CMS materials, like the annual Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare, which includes information on MA ''trial right'' periods and Federal Medigap GI rights.[165] We note that while this proposal focuses on the Medigap Federal GI rights for beneficiaries in their MA ''trial right'' periods, agents and brokers would be encouraged to also provide information on state laws regarding Medigap GI rights for those states where the agent or broker is licensed and appointed to sell, as proposed under § 422.2274(c)(12)(vi)(B), as states can, and many do, offer additional GI rights. We note that, unlike the first two proposed topics discussed (LIS and MSP), the proposed requirement for agents and brokers to discuss the Medigap Federal GI rights for beneficiaries in their MA ''trial right'' periods would only be applicable to the sale an MA or MA–PD plan and would not be applicable to PDP sales.

3. Pausing for Additional Questions

We are also proposing to add a requirement that agents and brokers pause to ask the beneficiary, prior to finalizing the enrollment, whether the beneficiary has any remaining questions related to the beneficiary's enrollment in a plan. During our review of audio calls between agents and brokers and beneficiaries, CMS has learned that agents and brokers do not always ask beneficiaries if they have any questions about the topics discussed or other related questions that may not have been mentioned. Agents and brokers are required to cover a number of different topics prior to enrolling a beneficiary into an MA, MA–PD or Part D plan. The required topics are designed to ensure the beneficiary is fully informed about the choice they are making. The breadth of information that is presented during enrollment appointments may be intimidating to a beneficiary, and CMS has observed indications of this in our review of audio calls. We noticed some beneficiaries were confused regarding whether their current coverage would be ending, which was not addressed by the agent prior to the enrollment being completed. In other calls, some beneficiaries appear to be confused about plan networks and if their provider is part of a plan's network. We observed that a beneficiary may not feel comfortable or empowered to ask questions of an agent and broker unprompted. Additionally, mirroring what we heard in our review of audio calls, a recent United States Senate Committee on Finance report found that beneficiaries were sometimes confused because they enrolled into a new plan but were unaware that their provider was not in the plan's network until they started using the new plan.[166] In addition, a Commonwealth Fund study reported that one significant complexity for beneficiaries when choosing a plan is that they ''make decisions that result in trade-offs they are not likely to fully understand.'' [167] Therefore, we believe that requiring agents and brokers to pause to proactively ask beneficiaries about whether they have questions about the topics the agent and broker has discussed, or other questions related to enrollment in an MA, MA–PD or Part D plan will further promote informed decision-making among beneficiaries. We understand that many agents and brokers may do this already as a routine part of sales calls with beneficiaries. However, through our observations, we have seen enough instances where this does not happen effectively or at all, with a detrimental impact to the beneficiary who is then enrolled in a plan that does not best fit their health needs in part because they did not have a clear opportunity to ask questions, that we believe this proposed regulation is appropriate. Specifically, at § 422.2274(c)(12), we propose to delete the ''and'' that comes before ''specific health care needs'' and create § 422.2274(c)(12)(xi) to say, ''conclude by pausing to ask if the beneficiary has any questions about the topics discussed in paragraph (c)(12) of this section or others, including those related to enrollment.'' At § 423.2274(c)(12), we propose to delete the ''and'' that comes before ''services and incentives'' and create § 423.2274(c)(12)(vii) to say, ''conclude by pausing to ask if the beneficiary has any questions about the topics discussed in paragraph (c)(12) of this section or others, including those related to enrollment.'' Similar to the rationale described in the April 2023

a Medigap Policy: A Guide to Health Insurance for People with Medicare. *See* section 3 of the Centers for Medicare & Medicaid Services, *Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare, https://www.medicare.gov/publications/02110-medigap-guide-health-insurance.pdf.*

[164] See sections 1882(s)(3)(b)(v) and (vi) of the SSA. Under Federal law, this trial right period may be extended for up to 2 years in certain circumstances involving involuntary termination of the beneficiary's MA plan coverage within the first 12 months of enrollment. See section 1882(s)(3)(F) of the SSA.

[165] Centers for Medicare & Medicaid Services and National Association of Insurance Commissioners, *Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare, https://www.medicare.gov/publications/02110-medigap-guide-health-insurance.pdf.*

[166] United States Senate Committee on Finance, *Deceptive Marketing Practice Flourish in Medicare Advantage,* page 9. [*https://www.finance.senate.gov/imo/media/doc/Deceptive%20Marketing%20Practices%20Flourish%20in%20Medicare%20Advantage.pdf*] (November 2, 2022).

[167] Riaz Ali, Aimee Cicchiello, Morgan Hanger, Lesley Hellow, Ken Williams, Gretchen Jacobson, *How Agents Influence Medicare Beneficiaries' Plan Choices,* (Commonwealth Fund, [April 21, 2021]) [*https://www.commonwealthfund.org/publications/fund-reports/2021/apr/how-agents-influence-medicare-beneficiaries-plan-choices*] (August 21, 2024).

final rule regarding §§ 422.2274(c)(12) and 423.2274(c)(12), if agents and brokers are required to cover the topics described in this proposal with beneficiaries prior to their enrollment, we expect that beneficiaries will be more knowledgeable about their Medicare options as well as the MA, MA–PD or Part D plans that are available to them together with the associated costs, and thus better prepared to make an informed choice. Agents and brokers are uniquely positioned to help beneficiaries select and enroll in a Medicare option that best fits their health care needs. Given the complex nature of Traditional Medicare, and the Parts C and D programs, we believe our proposed additional topics to discuss with a beneficiary, together with the proposed requirement to pause to ask if the beneficiary has any additional questions is critical to ensuring beneficiaries make fully informed enrollment decisions.

4. Technical Changes

We are also proposing technical changes to §§ 422.2274(c)(12) and 423.2274(c)(12) to put the newly proposed and existing requirements into a more organized and reader-friendly format. Specifically, we are proposing to create §§ 422.2274(c)(12)(i) through (iii) and (vii) through (x) and 423.2274(c)(12)(i) and (ii) and (vi) and (vii) to list the requirements individually instead of in paragraph form. We are then proposing to include those three new topics (LIS, MSP, Medigap), as discussed in this proposal, to be included as new §§ 422.2274(c)(12)(iv) through (vi), respectively. The two newly proposed topics (LIS, MSP) under § 423.2274(c)(12) will be included as new §§ 423.2274(c)(12)(iii) and 423.2274(c)(12)(iv), respectively. Finally, the newly proposed requirement that an agent pause to ask the beneficiary if they have any questions would be included as new paragraphs § 422.2274(c)(12)(xi) and 423.2274(c)(12)(vii).

In addition, we are also proposing a minor technical correction to § 422.2274(c)(12) to delete the redundant word ''regarding'' before ''pharmacies.''

We expect these proposed changes to impose a negligible amount of additional information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) on impacted organizations in terms of the updating of their existing processes related to their oversight of FDRs to ensure agents and brokers communicate information about LIS, MSPs, and Medigap to beneficiaries and discuss the beneficiary's enrollment-related questions before they enroll in a new plan. Including these proposed requirements under §§ 422.2274(c)(12) and 423.2274(c)(12) requires four additional items for agents and brokers to cover, but they can be covered during calls or appointments they already have prior to a beneficiary's enrollment in an MA, MA–PD or Part D plan. We are not proposing that agents and brokers use standardized language to review LIS eligibility, resources for state programs, or Medigap, nor that they must schedule a separate appointment to meet this requirement. We do not expect these proposed requirements to require significant additional training for agents and brokers or MA organizations. Also, adding beneficiary questions as a required topic further clarifies the purpose of paragraph (c)(12), which is that FDRs that represent the MA organization must fully discuss a beneficiary's needs in a health plan prior to enrollment.

Furthermore, we believe this burden does not need to be submitted to the Office of Management and Budget (OMB) based on the currently approved control number 0938–0753 (CMS–R–267), which states the following in relation to § 422.2274: ''The time, effort, and financial resources necessary to comply with the following collection of information requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered usual and customary business practices. Consequently, the information collection requirements and burden are exempt (5 CFR 1320.3(b)(2)) from the requirements of the PRA.'' Consequently, there is no need for review by OMB under the authority of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

We welcome comment on our proposed amendments to §§ 422.2274(c)(12) and 423.2274(c)(12), and we thank commenters in advance for their feedback.

P. Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (§§ 422.111 and 422.2265)

CMS continues to take steps to improve the usability of Medicare Plan Finder, strengthen oversight of plan marketing materials, and require agents and programs share information intended to ensure enrollees are able to make informed choices about their Medicare, Medicare Advantage, and Part D coverage. Policymakers, MedPAC, and other researchers have raised concerns about the increase in the number of plans having a detrimental impact on choice and competition, leading to confusion and difficulty for beneficiaries as they compare plans and choose an option.[168] [169] [170] [171] Plans differ on multiple dimensions, including covered services, premiums, service-specific cost-sharing, and provider networks, and evidence shows that too much choice complexity, particularly on financial dimensions, hinders beneficiaries' ability choose a plan that best meets their needs.[172] [173] [174] [175] [176] Moreover, even modest increases in the number of options can further impair consumer choice,[177] reduce enrollment,[178] and can lead to premium increases.[179] On

[168] MedPAC (2023). ''Report to Congress: Medicare and the Health Care Delivery System'' June 2023.

[169] Rollins, Eric (2023). ''Standardized benefits in Medicare Advantage plans'' MedPAC presentation, September 7, 2023. Downloaded from *https://www.medpac.gov/document/standardized-benefits-in-medicare-advantage-plans/* on September 11, 2024.

[170] Lieberman, Steven M., Loren Adler, Erin Trish, Joseph Antos, John Bertko, Paul Ginsburg (2018). ''A Proposal to Enhance Competition and Reform Bidding in the Medicare Advantage Program.''

[171] Pearson, Joshua and Rayna Stoycheva (2023). ''Medicare vs. Medicare Advantage: Trends and Challenges for Older Adults in Navigating Medicare Enrollment Decisions'' Harkin Institute Report, October 2023, Number 23–2.

[172] Taylor, Erin Audrey, Katherine Grace Carman, Andrea Lopez, Ashley N. Muchow, Parisa Roshan, Christine Eibner (2016). ''Consumer Decisionmaking in the Health Care Marketplace.'' Rand Research Report.

[173] Johnson. Eric, Ran Hassin, Tom Baker, Allison T. Bajger, Galen Treuer (2013). ''Can Consumers Make Affordable Care Affordable? The Value of Choice Architecture.'' *PLoS ONE* 8(12): e81521.

[174] Abaluck, Jason and Jonathan Gruber (2011). ''Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program.'' *American Economic Review* 101 (June 2011): 1180–1210.

[175] Kling, Jeffrey, Sendhil Mullainathan, Eldar Shafir, Lee Vermeulen, Marian Wrobel (2012). ''Comparison Friction: Experimental Evidence from Medicare Drug Plans'' *The Quarterly Journal of Economics,* Volume 127, Issue 1, February 2012, Pages 199–235.

[176] Bhargava, S., Loewenstein, G. & Sydnor, J. (2017). Choose to lose: Health plan choices from a menu with dominated options. Quarterly Journal of Economics, 132(3), 1319–1372.

[177] Bundorf, M. Kate, and Helena Szrek, ''Choice Set Size and Decision Making: The Case of Medicare Part D Prescription Drug Plans,'' *Medical Decision Making,* Vol. 30, No. 5, September–October 2010, pp. 582–593.

[178] McWilliams JM, Afendulis CC, McGuire TG, Landon BE (2011). Complex Medicare advantage choices may overwhelm seniors—especially those with impaired decision making. *Health Affairs* Sep;30(9):1786–94.

[179] Ericson, Keith (2014). ''Consumer Inertia and Firm Pricing in the Medicare Part D Prescription

the other hand, facilitating plan comparison shopping through reduced complexity can lead to improved plan selection and more effective competition. CMS continues to consider opportunities to support consumer choice as part of broader efforts to strengthen the MA program.

To reiterate, it is important that, when Medicare beneficiaries are exploring their options, they have the information they need to make the best choice for their needs. When deciding between Traditional Medicare and MA, one key factor is that CMS requires MA plans to have a provider network. Provider directories allow beneficiaries and their caregivers to weigh Medicare options and decide if a certain provider network meets their needs, such as to check if their existing physicians are in the network, what other contracted providers are available to deliver other medical care, amongst a myriad of other factors. As the landscape of MA has evolved, CMS has implemented rules, and made modifications to those rules, to ensure that people with Medicare and the trusted individuals they rely on to aid in their decision making, have the information necessary to make decisions about their Medicare options, including many of the required materials and disclaimers found under § 422.2267(e), as well as the requirements under § 422.2265(b) and (c) that certain content and materials are made available on the MA organization's website.

We believe that additional regulatory changes are now required to allow the agency to ensure that CMS is leveraging technological methods to streamline the beneficiary experience so that beneficiaries have the information they need to make the best choice for their needs, including MA provider directories. CMS proposes to make changes that will allow MA provider directories to be viewable on Medicare Plan Finder (MPF) for the 2026 Annual Enrollment Period (AEP). In addition, to ensure the accuracy of the data being submitted, we propose to require MA organizations to attest to the accuracy of the provider directory data being submitted. In total, we believe these proposed changes will result in an advancement of informed beneficiary choice and transparency benefitting people with Medicare, while also promoting robust competition within the Medicare market, aligned with the President's July 2021 Executive Order on Promoting Competition in the American Economy.[180]

Section 1851(d)(1) of the Act states that the Secretary shall provide for activities to broadly disseminate information to current and prospective Medicare beneficiaries on MA plan coverage options to promote an active, informed selection among such options. Specifically, per section 1851(d)(2)(A)(ii) of the Act, at least 15 days before the beginning of each annual, coordinated election period, the Secretary shall provide MA-eligible individuals with a list identifying the MA plans that are (or will be) available to residents of the areas in which they reside, including certain information concerning such MA plans, presented in a comparative form. This information is described in section 1851(d)(4) of the Act and includes plan benefits, premiums, service area, quality and performance indicators, and supplemental benefits. Section 1851(d)(4)(A)(vii) of the Act, also sets forth that information comparing MA plan options must specifically include the extent to which an enrollee may select among in-network providers and the types of providers participating in the plan's network. In addition, section 1851(d)(7) of the Act provides that MA organizations shall provide CMS with such information about the MA organization and each MA plan that it offers, as may be required for the preparation of the information described in section 1851(d)(2)(A) of the Act.

Section 1852(d)(1) of the Act requires access to services and states that MA organizations offering an MA plan may select the providers from whom the benefits under the plan are provided if the MA organization complies with several conditions including access to appropriate providers (section 1852(d)(1)(D) of the Act). Regulations at § 422.116(a)(1) further clarify this obligation by providing network adequacy access requirements for MA plans. Specifically, network-based MA plans must demonstrate an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards at section 1852(d)(1) of the Act. Additionally, MA organizations must attest that they have an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year (§ 422.116(a)(1)(i)).

Section 1852(c)(1)(C) of the Act further requires MA plans to disclose the number, mix, and distribution of plan providers. Based on this statutory requirement, CMS has implemented regulations at § 422.111(b)(3)(i) that require MA plans disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office. Together, these regulations establish the overarching requirements for the MA provider directory content.

The Interoperability and Patient Access final rule (85 FR 25633) became effective on June 30, 2020, and requires MA organizations, beginning on January 1, 2021, to make standardized information about their provider networks accessible through a Provider Directory Application Programming Interface (API) that conforms with CMS/HHS technical standards at § 422.119(c). The Interoperability and Patient Access final rule, also included in § 422.120 that the Provider Directory API must be accessible via a public-facing digital endpoint on the MA organization's website to ensure that this information is viewable and accessible to prospective and current enrollees as well as third-party application developers, who can create services to help patients find providers for care and treatment. Requirements at § 422.120 further specify that the MA plan's directory of contracted providers must be complete and accurate and include names, addresses, phone number, specialties and (as applicable for MA–PDs) the number of pharmacies in the network and mix of pharmacy types. MA organizations must ensure this information is updated within 30 calendar days of receiving provider directory information or updates. Provider Directory API technical standards were also modified for more specificity in the Interoperability and Patient Access final rule (89 FR 8974) which was effective on February 8, 2024.

To comply with the previously referenced statutory and regulatory requirements, CMS has taken a two-prong approach. CMS implemented MPF as an online resource where current and prospective beneficiaries and their caregivers can explore their Medicare coverage options. On MPF, individuals can look for Medicare Advantage and Part D plans and make informed choices based on the

Drug Insurance Exchange.'' *American Economic Journal: Economic Policy,* February 2014, 6(1): 38–64.

[180] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.*

information provided, such as plan benefits, premiums, deductibles, and star ratings to name a few. While CMS has implemented improvements to MPF over the years to incorporate more data, MPF does not currently include information on MA plans' contracted provider networks, such as the specific providers with which a plan contracts and from which an enrollee may receive health care services. In addition to creating MPF, CMS has implemented regulations that require each MA organization to disclose or otherwise make available certain required information, including hardcopy and electronic provider directory requirements under § 422.2267(e)(11), as well as a searchable online directory as required under § 422.2265(b)(4). Through these requirements, the provider directory information is made available to prospective and existing MA plan enrollees so they may view MA plans' in-network providers and other relevant information as required under § 422.111(b)(3)(i), such as the provider's specialty, location, and cultural and linguistic capabilities in the MA organization's online PDF or printable version (§ 422.2265(b)(3)). While this schema meets the statutory requirements using plan websites and MPF, in their current form to make enrollment decisions, is cumbersome. When prospective and current MA plan enrollees use provider directories and MPF today to help them make enrollment decisions, they must toggle between different MA plan websites and MPF to find and review the plans' provider directories to determine if the providers they currently see are in the various plans' networks, as well as review the information provided by MPF.

In order to simplify and streamline the Medicare beneficiary experience when shopping for an MA plan, we are proposing to expand on the existing requirements applicable to MA organizations regarding their provider directories at a newly established § 422.111(m) to include a new provision to require MA organizations to submit or otherwise make available their plan provider directory data, that is the requirements found under § 422.111(b)(3)(i), available to CMS/HHS in a format, manner, and timeframe that CMS/HHS determines in order for the MA organization's provider directory data to be integrated online by CMS/HHS for display on MPF. In addition, we are proposing to include a requirement that MA organization update the provider directory data that is submitted or otherwise make available to CMS for this purpose within 30 days of receiving information from providers of a change, which mirrors the current standard for updating provider directory data found under § 422.2267(e)(11).

As previously noted, CMS has adopted regulations to implement requirements applicable to MA organizations for publicly accessible, accurate, and timely provider directory information through the Interoperability and Patient Access final rule. The provider directory requirements of the Interoperability and Patient Access final rule aide in establishing the groundwork for MA plan provider directory information to be readily accessible for MA organizations to submit to CMS for inclusion on MPF.

While publishing MA plan provider directory information on MPF is an important step, doing so in a way that ensures that beneficiaries are accessing accurate information, is a critical part of improving the Medicare beneficiary experience while using MPF. In order to enhance the accuracy of the information that will be published online by CMS/HHS on MPF, we are also proposing to add new subparagraph § 422.111(m)(4), which would require an MA organization attest that the information being submitted to CMS/HHS under this new requirement is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements at § 422.116(a)(1)(i). Given the significance of the choice that a beneficiary is making based on the information provided by the MA organization, it is critical to include this attestation requirement to ensure that the information being submitted by MA organizations is accurate and consistent with data submitted to comply with CMS's MA network adequacy criteria when it is submitted to CMS for the purpose of incorporating it into MPF. It is imperative that MA organizations' provider directory data remains consistent with the contracted provider network data submitted to CMS in order to provide sufficient access to covered services.

Furthermore, with regard to the attestation, because provider directory data changes so frequently, we understand that it may be impractical to require an attestation with each update. CMS is considering how to best balance the need for accountability of accurate data with the burden of the attestation. If this proposed rule is finalized, we will operationalize it by publishing a provider directory data submissions guide that would include operational guidance, which will explain how the attestation process will be implemented. We currently envision an attestation when the data is first made available to CMS, and then a yearly attestation thereafter. We ask commenters for feedback on the attestation process, including the intervals for the attestation.

It is important to highlight that our proposals at new proposed § 422.111(m) would closely mirror the provider directory submission requirements at 45 CFR 156.230(c) for Qualified Health Plan (QHP) issuers on the federally facilitated Exchange (FFE). Currently, 45 CFR 156.230(c) requires issuers seeking certification to offer QHPs on the FFE to submit provider and formulary information in a format and manner and at times determined by HHS/CMS to HHS/CMS. This information is then used to feed *HealthCare.gov* and its Direct Enrollment partner websites to allow consumers to filter available QHPs based on the providers and drugs covered by those QHPs. As discussed previously, we are proposing to take a substantially similar approach for MA organizations. Given that many health insurance carriers offer both MA plans an QHPs, we believe this is a reasonable approach. We note that these proposals apply only to MA organizations (not Part D sponsors). Additionally, to operationalize the proposed Format Provider Directories for Medicare Plan Finder provision at § 422.111(m), we anticipate that 2025 plan year directory data will need to be made available online for testing purposes in the summer of 2025, and 2026 plan year data would need to be available online on October 1, 2026. We therefore propose an applicability date of July 1, 2025, for this provision.

Additionally, this proposed rule fits within one of the important pillars of CMS's Strategic Plan to ''Advance Equity'' as it will help ensure that provider directory information, including a provider's cultural and linguistic capabilities (as CMS currently requires for MA provider directories), which are especially important to underserved communities, will be more readily available to people with Medicare when considering their Medicare choices. Ultimately, we believe our proposal would streamline the MPF online platform and promote informed beneficiary choice and market competition.

We welcome comment on our proposed creation of § 422.111(m) and we thank commenters in advance for their feedback.

Q. Promoting Informed Choice—Enhancing Review of Marketing & Communications (§§ 422.2260 and 423.2260)

Over the past decade and a half, as the MA and Part D marketing and communications landscape has changed and evolved, CMS has modified our regulations, including our marketing and communications standards, definitions, and submission requirements, to strengthen and enhance CMS' ability to monitor and oversee MA organizations and Part D sponsors, including the different modalities and distribution channels used by the MA and Part D industry to market and communicate information about product offerings. However, additional regulatory changes are required for CMS to keep pace with the ever-changing MA and Part D marketing and communications landscape.

Section 1851(h)(1) of the Act prohibits MA organizations from distributing marketing materials and application forms to (or for the use of) MA eligible individuals unless the document has been submitted to the Secretary at least 45 days (10 days for certain materials) prior to use and the document has not been disapproved. Additionally, section 1851(h)(4) requires MA organizations to conform to fair marketing standards in relation to marketing activities for MA plans, including standards that CMS may establish pursuant to section 1856. While the Act requires the submission and review of the marketing materials and applications, it does not provide a definition of what materials fall under the term marketing. Section 1856(b)(1) of the Act authorizes CMS to adopt, through rulemaking, standards that are consistent with, implement and carry out the Medicare Advantage statutory provisions. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) to Part D sponsors in the same manner as such provisions apply to MA organizations.

With regard to 1876 cost plans, similar to section 1851(h) of the Act, section 1876(c)(3)(C) of the Act focuses on CMS's review and approval process for marketing materials rather than providing an exhaustive list of the types of materials that are considered marketing or promotional information and materials. Specifically, section 1876(c)(3)(C) of the Act states that no brochures, application forms, or other promotional or informational material may be distributed by cost plans to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review; and (ii) the Secretary has not disapproved the distribution of the material. Consistent with these statutory requirements, CMS reviews all such materials submitted by section 1876 cost plans and disapproves such materials upon determination that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation. As part of the implementation of section 1876(c)(3)(C) of the Act, the regulation governing marketing activities for cost plans at 42 CFR 417.428(a) refers to the MA marketing procedures and requirements set forth in 42 CFR part 422, subpart V. Consequently, pursuant to CMS's authority in section 1876(c)(3)(C) to regulate section 1876 cost plan marketing, as well as the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, and as established in § 417.428, the proposed changes regarding MA and Part D marketing discussed in this section would also apply to section 1876 cost plans.

Under current regulations at §§ 422.2260 and 423.2260, communications ''means activities and use of materials created or administered by the MA Organization or Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.'' In regulations at §§ 422.2260 and 423.2260, marketing ''means communications materials and activities that meet both the following standards for intent and content.'' The intent standard, as defined under §§ 422.2260(1)(i) and 423.2260(1)(i), are communications materials and activities that intend, ''as determined under paragraph (1)(ii) of this definition, to do any of the following'' to ''(A) draw a beneficiary's attention to a MA or Part D plan or plans, (B) influence a beneficiary's decision-making process when making a MA or Part D plan selection, (C) influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).'' In addition, §§ 422.2260(1)(ii) and 423.2260(1)(ii) state that, ''In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's or Part D sponsor's stated intent.''

The current content standards, as defined under §§ 422.2260(2) and 423.2260(2), provide that to meet the regulatory definition of marketing, communications materials and activities must also include or address content regarding (i) the plan's benefits, benefits structure, premiums or cost sharing, (ii) measuring or ranking standards (for example, Star Ratings or plan comparisons), or (iii), for MA plans only, rewards and incentives as defined under § 422.134(a). Communications that do not meet both of these regulatory intent and content standards do not fall within the current regulatory definition of marketing, and as a result, such materials are not subject to the specific submission, review, and distribution requirements for marketing materials provided in §§ 422.2261(b) and 423.2261(b).

Prior to 2018, for over two decades, CMS had a broad regulatory definition of marketing at §§ 422.2260 and 423.2260 which stated that marketing materials include any informational materials targeted to Medicare beneficiaries which: promote the MA organization or Part D plan, or any MA plan offered by the MA organization, inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA or Part D plan offered by the MA or Part D organization, explain the benefits of enrollment in an MA or Part D plan, or rules that apply to enrollees, explain how Medicare services are covered under an MA or Part D plan, including conditions that apply to such coverage and may include, but are not limited to a broad list of materials defined in the regulation (from general audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet to letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.). The marketing materials definition excluded certain ad hoc enrollee communications materials that were targeted to current enrollees, were customized or limited to a subset of enrollees or apply to a specific situation, did not include information about the plan's benefit structure; and applied to a specific situation or cover claims processing or other operational issues. This broad definition of marketing meant that MA organizations and Part D sponsors prospectively submitted to CMS for review the majority of beneficiary-facing materials they used.

In the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule, published in the **Federal Register** on April 16, 2018, (83 FR 16440), hereinafter referred to as the ''April 2018 final rule,'' CMS included and defined ''communication requirements'' in the scope of part 422, subpart V, and part 423, subpart V, and amended §§ 422.2260 and 423.2260 to add a new definition of ''marketing'' alongside the original definition of ''marketing materials.'' With this change, marketing became a subset of communications and was defined as ''activities and use of materials that meet the following: conducted by the MA organization or downstream entities, intended to draw a beneficiary's attention to a MA plan or plans, intended to influence a beneficiary's decision-making process when selecting a MA plan for enrollment or deciding to stay enrolled in a plan (that is, retention-based marketing).'' CMS also revised the list of marketing materials excluded from submission to CMS and subject to review, to encompass all materials that ''do not include information about the plan's benefit structure or cost sharing or do not include information about measuring or ranking standards (for example, star ratings).'' [181] In creating this delineation, only those communications that met the new definition of marketing and marketing materials were subject to more stringent requirements, including the need for submission to and review by CMS.

To better focus CMS's review of such marketing materials, the April 2018 final rule aimed to narrow the scope of materials that fell under the marketing definition to those that had the highest likelihood of misleading or confusing beneficiaries into making an adverse enrollment decision. Such materials were subject to the more stringent marketing requirements, including submission requirements, hence allowing CMS the ability to focus on materials most likely to negatively impact a beneficiary's enrollment experience. In this April 2018 final rule, CMS reasoned that certain materials in existence at the time, that fell within the definition of marketing materials, ''pose[d] little to no threat of a detrimental enrollment decision,'' [182] and would be unlikely to lead a beneficiary to request additional information or make an enrollment decision, such as those that did not mention certain types of content such as benefit structure, cost sharing, measuring or ranking standards.[183] Thus, CMS excluded from the new definition of marketing materials those materials that did not contain such information and aimed to focus the material submission requirements ''on materials and activities that aim to influence enrollment decisions'' [184] and ''that present the greatest likelihood for a negative beneficiary experience.'' [185] In addition, the April 2018 final rule said that materials that included certain content tied to the updated definition of marketing, such as information about the plan's benefit structure or cost sharing or information about measuring or ranking standards (for example, star ratings), but did not otherwise meet the marketing definition, would not be considered marketing.[186] As the final rule explained, ''the goal of this proposal is to exclude member communications that convey important factual information that is not intended to influence the enrollee's decision to make a plan selection or to stay enrolled in their current plan.'' [187] An example of this in practice would be a postcard mailed to current enrollees letting them know that they can obtain a flu shot at zero cost sharing, which prior to the April 2018 final rule, would have been considered a marketing material and submitted to CMS for review even though it was likely to have had little impact on an enrollment decision.

In September 2018, CMS further clarified these definitions, in section 20.1 of the Medicare Communications & Marketing Guidelines (MCMG). The MCMG provided examples to distinguish between marketing and communications and explained that CMS would evaluate the intent and content of all marketing activities and materials to ensure they met the definition of marketing. The MCMG clarified that marketing activities and materials are distinguished from communications activities and materials based on these standards.[188] These standards were subsequently codified in the ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, published in the **Federal Register** on January 19, 2021 (86 FR 5864), hereinafter known as the ''January 2021 final rule.'' In addition to codifying the guidance from the MCMG, CMS further revised and streamlined the communications and marketing definitions and the intent and content standards. At that time, our objective in updating the intent and content standards of the marketing definition, and the stricter submission and review requirements associated with these new, revised standards, was to enable CMS to more effectively focus CMS's review on the materials that were most likely to impact a beneficiary's enrollment decision.

In 2023, CMS continued to pursue rulemaking to further strengthen beneficiary protections to address the growth of misleading advertising practices, including by those entities that circumvent our rules by carefully crafting advertisements with messaging that by design, allowed these entities to avoid our requirements for submission to and approval by CMS prior to their use in the marketplace. In the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120), hereinafter referred to as the ''April 2023 final rule,'' CMS codified provisions that prohibit marketing ads from including the mention of benefits not available in a service area [189] and requiring third-party marketing organizations (TPMOs) to state the number of organizations and plans they represent in the service area in which they are marketing.[190]

Yet, even with these changes, CMS continues to see, through CMS monitoring efforts, marketing misrepresentation complaints from beneficiaries and outreach from stakeholders that we consider to be related to advertisements on television, mail, and the internet. For example, CMS has observed television ads that instill a sense of urgency combined with a narrative that leads the beneficiary to believe they are not receiving important benefits they are entitled to by touting the availability of information about Medicare options if the viewer calls a

[181] 83 FR 16627.

[182] 83 FR 16626.

[183] 83 FR 16626–83 FR 16627.

[184] 83 FR 16626.

[185] 83 FR 16626.

[186] 83 FR 16627.

[187] 83 FR 16627.

[188] *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf.*

[189] 88 FR 22240.

[190] 88 FR 22253.

phone number. Yet, the information about Medicare options in such advertisements is described in such a broad, generic and non-specific manner that these advertisements are arguably considered communications rather than marketing under our current rules. These broad, generic and non-specific advertisements can potentially mislead and confuse beneficiaries. For example, advertisements positioned as an opportunity to review a beneficiary's options, or their current plan benefits or possible changes to their current plan, may pull potential enrollees into the ''chain of enrollment,'' even though the materials or the language used in the television advertisement are not considered to be marketing under our rules. Because these advertisements are so general and do not meet our current marketing definition, these are able to effectively circumvent CMS's more stringent marketing requirements under which the materials would be subject to CMS's review and approval prior to their use, or in the case of File and Use, as defined under §§ 422.2261(b)(3) and 423.2261(b)(3), not be used until 5 days following their submission.

As stated above, CMS is concerned that the current narrow definition of marketing has created a loophole that has been used by MA organizations, Part D sponsors and their downstream entities and resulted in the proliferation of misleading and confusing marketing practices that currently fall outside our scope of review. Specifically, since the time these rules that narrowed the definition of marketing were finalized, CMS has observed a shifting landscape of misleading marketing practices in MA and Part D, including television, web-based and direct mail advertisements that clearly attempt to draw a beneficiary's attention to a plan or plans, or influence a beneficiary's enrollment decisions, such as by alluding to potential plan or benefit changes, or touting ''new'' benefits or non-specific ''Medicare options.'' A common factor for such ads is that they encourage a beneficiary to call a 1–800 number. As noted earlier, these ads, that do not mention or address any of the subjects listed in the content standard within CMS's marketing regulations in §§ 422.2260 and 423.2260, such as plan benefits or ranking standards, do not technically meet the definition of marketing because these advertising practices use generic messaging that do not mention specific benefits and therefore do not require submission to CMS. However, such materials still include a call to attention, as described in the ''Advertisement (Ad)'' definition at §§ 422.2260 and 423.2260, like calling a 1–800 number for more information. Moreover, the ads initiate an enrollment trajectory by setting beneficiary expectations that the beneficiary will call a number and be presented with Medicare choice options, which invariably means Medicare Advantage plan choices since the TPMO that receives the calls may only be selling a select number of MA plans, which can then lead to a beneficiary making a Medicare Advantage plan enrollment decision. CMS has reviewed marketing misrepresentation complaints and listened to agent sales calls where a beneficiary contacts a 1–800 number to learn more information from an advertisement, only to be led to an enrollment into a plan that does not best meet their health care needs, ultimately resulting in a complaint to CMS.

To further illustrate this type of communication ad, CMS has seen TPMO television ads which, without mentioning an MA plan by name, ask the viewer to call a toll-free number to find out whether the viewer's Medicare plans will be changing and whether that change might include potential rising costs or changes to the provider networks. The ad will list a 1–800 number and encourage the viewer to call to find out the answers to whether there have been any changes to their Medicare plan. Similarly, CMS has seen TPMO websites that appear and purport to be educational, providing information on what MA or Part D is and how it works, while not mentioning any particular benefits and thus, not falling into the narrower definition of marketing. Yet, the website will also include an opportunity to collect and share a beneficiary's information with a third-party, in order to market MA or Part D plans to the beneficiary which leads to a beneficiary providing their consent to be contacted and likely marketed to. Unlike advertisements that meet the definition of marketing, these more generic advertisements do not mention specific plans or benefits, yet through tactics that can be misleading or confusing, encourage a beneficiary to contact a 1–800 number where they unknowingly step into a chain of enrollment they were likely not expecting.

Coinciding with these concerning trends, CMS has seen a sharp increase in beneficiary complaints of marketing misrepresentation since the issuance of the April 2018 final rule that made changes to and narrowed the marketing definition. These complaints corroborate the concerns with the marketing practices described in the previous paragraphs. Marketing misrepresentation complaints rose from approximately 9,000 complaints in 2018 to approximately 41,000 by 2021, a four-fold increase since 2018. While the volume of marketing misrepresentation complaints declined in 2022 to roughly 36,000, the number of complaints was still over three times greater, at approximately 32,000 in 2023, than in 2018.[191] As noted earlier, many of these complaints detail beneficiaries' negative enrollment experience after calling a 1–800 number based on an ad. In fact, through CMS monitoring efforts of agent sales beginning in 2022, CMS has reviewed a representative sample of over 400 agent sales calls and associated marketing misrepresentation complaints in the CTM. Of the calls CMS has reviewed to date, approximately 33% of the agent sales calls include beneficiaries mentioning that they saw an ad on television or received something in the mail which prompted them to call. Complaints by beneficiaries who called or were contacted by 1–800 numbers seen through an ad often detail the beneficiary having a negative enrollment experience and opting to change the enrollment that was transacted on the phone call. As examples, there are some beneficiary complaints where a beneficiary describes being unwittingly enrolled into a plan without their consent when they called for more information. Other beneficiaries describe receiving inaccurate information regarding the plan they were being switched into and later learning their providers were out of network. Yet, when CMS conducted further investigations into these ads, we found that many of the ads in question were not submitted to CMS as marketing materials, and generally would be considered to be communications that did not require submission to CMS under our narrower definition of marketing.

As previously mentioned, because the ads in question were not submitted to CMS, it hampers our ability to determine an ad's origin, and in the case of TPMO ads, what MA organizations or Part D sponsors are associated with the TPMO. Additionally, since these advertisements are not submitted to CMS, CMS is unable to review to confirm whether the advertisement contains any misleading information. CMS believes stronger oversight and collection of materials that can influence a beneficiary's decision making will ensure that CMS can better

[191] Complaints Tracking Module (CTM) Marketing Misrepresentation Reports from 2018 to 2024.

protect beneficiaries against misleading, inaccurate or confusing marketing tactics, in addition to expediting our ability to more quickly act on non-compliant ads associated with beneficiary complaints.

When CMS created the content and intent standards beginning with the April 2018 final rule, we did not foresee advertisements that did not, as an example, contain a plan's benefits, benefits structure, premiums, or cost sharing, leading to negative enrollment experiences. At the time, the bulk of advertisements were being created by a single plan, rather than a TPMO representing multiple plans. As stated earlier, the statutory requirements under section 1851(h)(1) of the Act provide CMS with the authority to review and approve materials most likely to mislead or confuse beneficiaries and lead to a negative enrollment experience. However, since the April 2018 final rule, CMS has observed a shifting MA and Part D marketing landscape, which alongside growing marketing misrepresentation complaints and changing marketing trends and tactics, requires an updated marketing definition that can better target the materials that mislead or confuse beneficiaries into making an adverse enrollment decision. This includes advertisements which encourage a beneficiary to call to review their plan changes or gather information, and sets a trajectory that ultimately leads to beneficiaries being unwittingly enrolled in a new plan with negative consequences. To date, CMS continues to receive concerning complaints related to misleading and confusing advertisements and marketing tactics, which are resulting in negative beneficiary enrollment experience.

To further emphasize the need to expand our oversight, in 2023, CMS disapproved roughly half of all television ads that were submitted by TPMOs to CMS for prospective review.[192] This begs the question, if this is true for materials that are being submitted to and reviewed by CMS under the current regulatory definition of marketing, what is the state of those materials that are not being submitted because of the limitations on the scope of our existing regulation? As noted earlier, CMS has received many complaints where a beneficiary calls a 1–800 number after viewing a TV ad and ends up being enrolled in a plan that results in adverse effects. According to a KFF report on the state of TV marketing activities, during the 2023 open enrollment period (10/1/2022 to 12/7/2022), English language Medicare ad airings totaled 643,852 with 86% or 556,068 of these television ads advertising MA plans.[193] The report cited that viewers of programs across the top 20 markets saw an average of between 4 to 6 ads per day, depending on the network affiliation, and regular viewers of specific TV programs could expect to see 6–8 ads per day.[194] It is clear from this report that beneficiaries are inundated with TV ads.

As previously mentioned, when CMS has investigated TV ads based on complaints or concerns expressed by advocacy organizations, the ads could not be found in the HPMS marketing module, the system used to collect and review marketing materials. The takeaway from this investigative work is that a number of TV ads, intended to draw a beneficiary's attention to MA or Part D plans and to ultimately influence a beneficiary's decision-making process when making a MA or Part D plan selection, were not submitted to CMS by the creator and MA and Part D plans associated with these ads determined that the ads were not marketing as defined under §§ 422.2260 and 423.2260. CMS believes broader oversight of the ads beneficiaries are confronted with, even if the ads do not contain content on specific topics such as benefits, co-pays or star ratings, will provide additional protections against misleading marketing practices. In these proposals, CMS is seeking to expand oversight over the materials that plans, and their downstream entities, use in their marketing activities that intend to draw a beneficiary to a plan or influence a beneficiary's enrollment decisions. CMS expects that this approach, if finalized, would provide CMS with greater insight into the shifting landscape of MA and Part D advertising and the materials that are outside of the scope of the materials currently submitted to CMS for review.

Similar trends were also reported by State oversight agencies, as detailed in a 2022 report from the United States Senate Committee of Finance titled *Deceptive Marketing Practices Flourish in Medicare Advantage.* The report shares data from State insurance commissioners and State Health Insurance Assistance Programs (SHIPs), with most of these entities reporting a similar increase in complaints from 2020 to 2021,[195] the same timeframe wherein CMS first reported that beneficiary complaints had doubled. In the report, which included data from 14 states, ''ten states reported that mail advertisements were a source for complaints, nine states reported that robocalls and telemarketers were a source for complaints, and eight states reported that television advertisements were a source for complaints.'' [196] As one of many examples that illustrate the misleading marketing beneficiaries experience, states reported complaints about mailers that would appear to be official Medicare notices and ''serve the explicitly misleading purpose of prompting beneficiaries to ''initiate contact,'' so that MA marketing prohibitions can be circumvented.'' [197] Based on these reports, alongside beneficiary complaints and CMS marketing oversight and review of agent sales calls, it appears that various entities, including TPMOs, have exploited the current content requirements of our marketing definition as a means of skirting CMS oversight, with detrimental effects for beneficiaries and the marketplace. CMS's existing regulations at §§ 422.2261(c)(2) and 423.2261(c)(2) provide that CMS may collect certain non-marketing communications materials. However, these mechanisms appear to be insufficient to provide appropriate oversight of MA and Part D marketing activities under the circumstances outlined above because without the requirement for these materials to be submitted, CMS is typically only able to address concerning materials of this nature after a complaint or concern has been received. In order to proactively monitor these materials and more efficiently review potentially misleading marketing materials before they are seen by beneficiaries, we believe that amending CMS's marketing regulations to allow

[192] HPMS Marketing Review Module Reports.

[193] Jeannie Fuglesten Biniek, Alex Cottrill, Nolan Sroczynski, Meredith Freed, Tricia Neuman, Breeze Floyd, Laura Baum, and Erika Franklin Fowler, *How Health Insurers and Brokers Are Marketing Medicare,* (KFF, [September 20, 2023]) [*https://www.kff.org/report-section/how-health-insurers-and-brokers-are-marketing-medicare-report/#flooded-with-ads*] (August 6th, 2024).

[194] *How Health Insurers and Brokers Are Marketing Medicare,* (KFF, [September 20, 2023]) [*https://www.kff.org/report-section/how-health-insurers-and-brokers-are-marketing-medicare-report/#flooded-with-ads*] (August 6th, 2024).

[195] United States Senate Committee of Finance, *Deceptive Marketing Practices Flourish in Medicare Advantage,* page 6. *https://www.finance.senate.gov/imo/media/doc/Deceptive%20Marketing%20Practices%20Flourish%20in%20Medicare%20Advantage.pdf.*

[196] *Deceptive Marketing Practices Flourish in Medicare Advantage, https://www.finance.senate.gov/imo/media/doc/Deceptive%20Marketing%20Practices%20Flourish%20in%20Medicare%20Advantage.pdf,* page 11.

[197] *Deceptive Marketing Practices Flourish in Medicare Advantage, https://www.finance.senate.gov/imo/media/doc/Deceptive%20Marketing%20Practices%20Flourish%20in%20Medicare%20Advantage.pdf,* page 11.

for a more comprehensive review of the materials used by MA organizations, Part D sponsors, and their TPMOs, to market MA and Part D plans is appropriate to ensure beneficiaries are protected.

In light of the facts and circumstances set forth above, and in accordance with our statutory authority to review marketing materials and application forms, and to develop marketing standards under these sections, we are proposing to eliminate the content standard, as described in §§ 422.2260(2) and 423.2260(2) of the marketing definition, so that all communications materials and activities that meet the existing intent standard are considered marketing for purposes of CMS's MA and Part D marketing and communications regulations. This proposed change would improve CMS oversight over the full scope of materials and activities that are intended to draw a beneficiary's attention to one or more specific MA plans, Part D plans or other plans, influence a beneficiary's decision-making process when making a MA or Part D plan selection or influence a beneficiary's decision to stay enrolled in a plan. CMS expects that this broader level of oversight will further strengthen beneficiary protections against misleading or confusing marketing tactics so that CMS can better ensure that MA organizations, Part D sponsors and their downstream entities are not providing misleading, inaccurate, or confusing information to current or potential enrollees, or engaging in activities that could misrepresent the MA organization or Part D sponsor, in accordance with §§ 422.2262 and 423.2262. By expanding CMS's oversight of these materials, CMS can more readily review ads related to marketing misrepresentation complaints and quickly act on them, without concern over whether the material has been submitted. Additionally, submission of all materials that are intended to draw a beneficiary's attention to a plan or influence a beneficiary's decisions will also enable CMS to more readily address materials that are attempting evade CMS submission requirements while attempting to influence beneficiary enrollment decision making. Further, by ensuring these materials are included in CMS submission and review processes, CMS can more effectively, speedily and reliably detect problematic materials that seem to be designed to circumvent CMS's existing submission requirements and may negatively impact a beneficiary's enrollment experience.

The MCMG provides a few scenarios to illustrate distinctions between communications or marketing materials under CMS's current regulatory definitions of those two terms. One scenario provided in the MCMG discussed a flyer that reads, ''Swell Health is now offering Medicare Advantage coverage in Nowhere County. Call us at 1–800–BE–SWELL for more information.'' As the MCMG explains, under the current marketing definition, this flyer would not be considered a marketing material because it does not include specific plan benefits, benefits structure, ranking standards or any other element of the current content standard within the marketing definition.[198] However, under the proposed update to the marketing definition, this material would be considered marketing because of its intent to draw a beneficiary's attention to a plan or plans. Alternatively, the MCMG discusses a scenario where a letter is sent to current enrollees reminding them to get their flu shot. In the letter, it says that ''Swell Health enrollees can get their flu shot for $0 copay at a network pharmacy . . .'' [199] Under the current definition of marketing, this material is not considered marketing as it does not meet the intent standard to ''draw a beneficiary's attention to a MA plan or plans, influence a beneficiary's decision-making process when making a MA plan selection, or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).'' Instead, the material is solely intended to encourage current enrollees to get the flu shot. Therefore, under the proposed changes to the marketing definition, this material would remain a communications material. If the plan were to be advertising this, say through a flyer, this would change the intent and hence be considered a marketing material as the intent would be to draw a beneficiary's attention to an MA plan through advertising their access to certain benefits. However, a material that is solely explaining benefits to a current enrollee for educational purposes would not be considered marketing under our proposed definition.

In the April 2018 final rule, when updating the marketing and communications definitions, we finalized ''an exclusion from marketing materials that provides that unless CMS provides otherwise, materials required under §§ 422.111 and 423.128 are not marketing materials.'' [200] While CMS is proposing to expand the materials defined as marketing, CMS intends to retain the material designations for required materials listed under §§ 422.2267(e) and 423.2267(e) and continue excluding those materials required under §§ 422.111 and 423.128, that are defined as communications, from requirements to submit for CMS review, unless otherwise noted in our regulation. Where relevant, all required materials listed under §§ 422.2267(e) and 423.2267(e), CMS required materials and content, have been defined as either marketing or communications. Since these materials are required, CMS has a clear understanding of the intent behind each material and whether it should be designated as communications or marketing. Therefore, we are also proposing to reference in the marketing definition the exception for required materials specified in §§ 422.2267(e) and 423.2267(e), which will maintain the material designation as provided by CMS. Those materials that are currently identified as communications will continue to be defined as communications and will continue to follow the same submission and review process as prior to this proposed rule. As an example, in §§ 422.2267(e)(4) and 423.2267(e)(4), the Pre-Enrollment checklist (PECL) is defined as a standardized communications material and is not currently required to be submitted to CMS for review. CMS wants to make it clear that even with the proposed changes to the marketing definition in this rule, the PECL would continue to be considered a communications material and not be required to be submitted to CMS for review. Separately, there are certain communications materials that CMS indicates in §§ 422.2267(e) and 423.2267(e) as required to be submitted for review (such as the Evidence of Coverage). This proposed rule will not include any changes to this process or to the non-marketing communications materials that are required to be submitted for review.

We are proposing conforming edits to the definition of ''Advertisement (Ad)'' in §§ 422.2260 and 423.2260 to align with the proposed updates to the definition of marketing. Specifically, we are proposing to remove the second sentence from the advertisement definition, as the content standard will be eliminated from the marketing definition. Advertisements, as with all other materials and activities, will be subject to the considerations set forth in

[198] *https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.**COM028*

[199] *https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.*

[200] 83 FR 16629.

the proposed revised definition of marketing. With that said, considering the nature of advertisements pertaining to MA and Part D, CMS believes that most, if not all, advertisements pertaining to MA and Part D created or administered by an MA organization or Part D sponsor or any downstream entity operating on their behalf, will fall under the proposed updated marketing definition. However, even though these materials will now need to be submitted to CMS, the overall burden will be tempered by the fact that we anticipate the majority of them will be accepted as File and Use per §§ 422.2261(b)(3) and 423.2261(b)(3) where plans may distribute or make available certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission. Additionally, we are proposing to consolidate the remaining definition of marketing to exclude extraneous numbering, which is no longer needed, as a result of the elimination of the content standard. Under §§ 422.2260 and 423.2260, we will consolidate the remaining portion of the definition currently under sections (1)(i) and (1)(ii) to simply be a two-sentence definition in line with the rest of this section.

Finally, to combat any ambiguity with the intent standard of the marketing definition, we emphasize that in evaluating the intent of an activity or material, CMS may look beyond and broadly consider the MA organization's or Part D sponsor's ''stated intent,'' as described under current §§ 422.2260(1)(ii) and 423.2260(1)(ii), which will be consolidated through the proposed update to the marketing definition. This means that, under this proposed rule, the activities or materials of an MA organization or Part D sponsor may meet the regulatory definition of marketing even if it is not immediately apparent to the recipient of such materials or activities that they are intended to be influencing a beneficiary's decision-making process when making a plan selection, influencing a beneficiary's decision to stay enrolled in a plan or drawing a beneficiary's attention to a plan or plans. In evaluating such activities and materials, CMS will continue to consider the corollary result of any call to attention that aims to ''draw a beneficiary's attention to a MA or Part D plan or plans, influence a beneficiary's decision-making process when making a MA or Part D plan selection, or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).'' As an example, if a television advertisement says, ''Questions about Medicare, call 1–800–LEARN–MORE,'' and the call results in MA or Part D plans being discussed as an option, the advertisement would fall under §§ 422.2260 and 423.2260 and be considered marketing under this proposed rule because the intent of the advertisement is ultimately to draw a beneficiary's attention to an MA or Part D plan or to encourage a beneficiary to call the number and speak to someone about enrollment and plan choice options.

In summary, this proposal would enhance CMS's oversight of the marketing and communications materials and activities most likely to influence a beneficiary's enrollment decision. CMS believes that the content standard within the marketing definition is limiting CMS's ability to review and target materials that are negatively influencing a beneficiary's enrollment experience. By removing the content standard from the marketing definition at §§ 422.2260 and 423.2260, CMS can better ensure that communications activities and materials that are intended to ''draw a beneficiary's attention to a MA plan or plans or Part D plans, influence a beneficiary's decision-making process when making a MA plan or Part D plan selection, or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing)'' will fall under the definition of marketing, and that materials are submitted to CMS and subject to review under §§ 422.2261 and 423.2261. Our goal is to ensure that beneficiaries are protected from misleading marketing so that they receive the best information to enroll in a plan that best meets their health care needs. We solicit comments on our proposed amendments to update the marketing definition at §§ 422.2260 and 423.2260, and we thank commenters in advance for their feedback. We are also soliciting specific comment on the potential or alternative financial impacts of this proposal.

R. Timely Submission Requirements for Prescription Drug Event (PDE) Records (§ 423.325)

CMS requires that Part D sponsors submit certain prescription drug claims information to CMS for specified Medicare Part D-related purposes as described in the Social Security Act (the Act). In accordance with the authority under sections 1860D–15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act, CMS conditions Medicare Part D program payments to Medicare Part D plans upon the disclosure and provision of information needed to carry out payment. In addition, section 1860D–15(f)(2)(A) of the Act allows CMS to utilize information collected under section 1860D–15(f) of the Act for the purposes of, and to the extent necessary in, conducting oversight, evaluation, and enforcement under Title XVIII of the Act and carrying out section 1860D–15 of the Act or the Medicare Drug Price Negotiation Program (''Negotiation Program'') under Part E of Title XI of the Act. Under sections 1860D–14A(c)(1)(C) and 1860D–14C(c)(3) of the Act, CMS collects information from Part D sponsors that allows for discounts under the Coverage Gap Discount Program and Manufacturer Discount Program, respectively, to be provided to applicable beneficiaries for applicable drugs. Part D sponsors submit this prescription drug claims information to CMS on prescription drug event (PDE) records through the CMS Drug Data Processing System (DDPS).[201]

A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.[202] CMS requires that PDE records are accurate, complete, and truthful since they are used for the purposes of obtaining Federal reimbursement.[203] These records are critical not only for accurate payment, but also for a wide range of sponsor compliance assessment activities, and other Part D program integrity audits. To that end, CMS performs checks (or edits) on the PDE data to validate and help ensure its accuracy.[204] This process results in the PDE records being accepted or rejected by CMS. Accepted PDE records may be subsequently adjusted or deleted by the Part D sponsor by submitting adjustment PDE records or deletion PDE records to CMS.[205] Rejected PDE records must be reviewed, resolved, and, if appropriate,

[201] OMB 0938–0982, CMS–10174, expiration February 28, 2025 (available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202403-0938-002*).

[202] The PDE file layouts are available at *https://www.csscoperations.com/internet/csscw3.nsf/DID/M7XCJKG0JI.*

[203] 42 CFR 423.505(k)(3).

[204] For PDE edits, see generally, DDPS Edit Lookup, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References* (click Download).

[205] For additional information and examples that result in adjustment and deletion PDE records, see HPMS memorandum, PDE Guidance for Post Point-of-Sale Claim Adjustments, July 3, 2013, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/post%20pos%20adjustments_247.pdf.*

resubmitted by the plan to CMS. The resubmitted PDE record goes through the same editing process and results in CMS accepting or rejecting the resubmitted PDE record.

CMS uses accepted PDE records in the Part D payment reconciliation described at § 423.336 and 423.343(c) and (d), reopenings of Part D payment reconciliations described at § 423.346, the Coverage Gap Discount Program invoicing process described generally at § 423.2315, and the Manufacturer Discount Program invoicing process.[206] PDE records for selected drugs (as described at section 1192(c) of the Act) will also be used to administer the Negotiation Program.[207] [208] In order for CMS to make payments, conduct oversight, administer the various programs under Medicare Part D and the Negotiation Program, as well as perform other statutory obligations, the PDE records must be received from Part D sponsors in a timely manner. Part D sponsors that do not submit PDE data in a timely manner (as explained in the following Background and Requirements sections) may be determined to be out of compliance consistent with § 423.505(n)(1)(i) and may be subject to compliance actions described at § 423.505(n)(3).

In this rule, we propose to codify the general PDE submission timeliness guidance that currently applies and that addresses three types of PDE submissions: initial PDE records submitted after a pharmacy claim is received by the Part D sponsor (hereinafter referred to as ''initial PDE records''), adjustment and deletion PDE records that update previously submitted records that have been accepted by CMS, and records to resolve PDE records that were rejected by CMS.[209] Further, we propose to codify a specific PDE submission timeliness requirement for initial PDE records when those PDE records are for selected drugs.

1. Background—General PDE Submission Timeliness

CMS has always required that Part D sponsors submit their PDE data to CMS in a timely manner. Timely PDE submissions assist in the effective quality review of PDE data prior to CMS using the data in payment reconciliations and invoicing to manufacturers for the Coverage Gap Discount Program and Manufacturer Discount Program (hereinafter referred to collectively as the discount programs). We conduct analysis and validation of PDE data on an ongoing basis and identify data quality issues for Part D sponsors' review and action. This pre-reconciliation data quality review initiative promotes accuracy in the plan-reported financial data used in the Part D payment reconciliation and the invoice and reconciliation processes for the discount programs.

Accordingly, in 2011, we released guidance on the timely submission of PDE records. On May 16, 2011, CMS released a memorandum ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'' [210] The guidance described the PDE submission timeframes for initial PDE records, adjustment and deletion records, and records to resolve PDE records that CMS rejected through the PDE editing process. After consideration of industry comments, CMS modified the PDE submission timeframes and released revised PDE submission timeliness guidance on October 6, 2011.[211] As described in that guidance, initial PDE records are due within 30 days following the date the claim is received by the Part D sponsor or the date of service, whichever is greater. Adjustment and deletion PDE records are due within 90 days following discovery of the issue requiring a change to the PDE. Resolution of rejected PDE records are due within 90 days following the receipt of rejected record status from CMS. We propose to codify PDE submission timeframes similar to those timeframes described in the October 2011 guidance and refer to those timeframes as the *General PDE Submission Timeliness Requirements.*

2. Background—Selected Drugs PDE Submission Timeliness

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. It established the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products (*i.e.,* selected drugs). The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA.

Under section 1193(a) of the Act, participating manufacturers must not only provide access to the MFP for a selected drug to MFP-eligible individuals (as defined in section 1191(c)(2) of the Act), but they must also provide access to the MFP to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug during a price applicability period (as defined in section 1191(b)(2) of the Act). This distinguishes the Negotiation Program from Part D programs such as the Coverage Gap Discount Program and the Manufacturer Discount Program where there is no such statutory requirement for the manufacturer to provide a specified price to a pharmacy or other dispensing entity. CMS stated in section 40.4 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191—1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (hereinafter referred to as the final guidance) that a Primary Manufacturer (as defined in section 40 of the final guidance) must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.[212]

[206] HPMS memorandum, Medicare Part D Manufacturer Discount Program Final Guidance, November 17, 2023 (available at *https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf*).

[207] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2026 *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.*

[208] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[209] HPMS memorandum, Revision to Previous Guidance Titled ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs'', October 6, 2011, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms_memo_pde_timeliness_clarification_240.pdf.*

[210] HPMS memorandum, Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs, May 16, 2011, available at *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-qtr1-4.*

[211] HPMS memorandum, Revision to Previous Guidance Titled ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs'', October 6, 2011, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms_memo_pde_timeliness_clarification_240.pdf.*

[212] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/*

Continued

To help operationalize dispensing entity access to the MFP, in section 40.4 of the final guidance, CMS stated it will engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between Primary Manufacturers and dispensing entities and to support the verification that the selected drug was dispensed to an MFP-eligible individual. The MTF will use the PDE records submitted by Part D sponsors to CMS through DDPS to verify that the selected drug was dispensed to an MFP-eligible individual. Additionally, the MTF will furnish Primary Manufacturers with certain claim-level data elements, including from PDE records, confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual. In the final guidance, unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.5 of the final guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, CMS requires that the Primary Manufacturer transmit payment of an amount that provides access to the MFP within 14 calendar days of when the MTF sends the claim-level data elements that verify the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer (''14-day prompt MFP payment window''). CMS notes that the 14-day prompt MFP payment window aligns with the timing requirement in the longstanding prompt pay rules in Part D for plan sponsors.[213] However, dispensing entities should be aware that they may not receive payment from a Part D plan sponsor for the Part D claim on the same date that the Primary Manufacturer provides a retrospective MFP refund to the dispensing entity. Due to operational differences between the Part D program and the Negotiation Program, the respective prompt payment windows for a particular dispensed prescription may start on different dates for the Part D sponsor and the Primary Manufacturer.

To help ensure prompt payments by Primary Manufacturers to dispensing entities to provide access to the MFP, initial PDE records for selected drugs under the Negotiation Program necessitate a PDE submission timeliness requirement that is different from the general PDE submission timeliness requirement for initial PDE records. Under the current general PDE submission timeliness requirements, dispensing entities could wait up to approximately six weeks to receive access to the MFP (*e.g.,* 30 calendar days for the Part D sponsor to submit PDE data to the DDPS, plus approximately one to three days for the PDE data to move from DDPS to the MTF to the Primary Manufacturer, plus up to an additional 14 days for the Primary Manufacturer to transmit an MFP refund payment). If the Primary Manufacturer does not prospectively make the MFP available to the dispensing entity, then the lag between when the dispensing entity receives payment from the Part D plan and when the dispensing entity receives the MFP refund payment from the Primary Manufacturer could impose a financial strain on dispensing entities given that anticipated MFP refunds could be a material percent of the dispensing entity's purchase price. To mitigate potential financial hardship on dispensing entities such as pharmacies, which could impact Part D beneficiary access to selected drugs, and more closely align MFP refund payments with the timing requirements in the longstanding prompt pay rules in the Part D program, CMS believes it is necessary to create a specific new requirement for PDE submission timeliness requirements for selected drugs. Therefore, CMS is proposing to shorten the PDE submission timeliness requirements for selected drugs to reduce the maximum amount of time a dispensing entity could wait to receive access to the MFP.

On May 3, 2024, when CMS released draft guidance describing the implementation of the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 (draft guidance), CMS noted that it was evaluating a PDE submission timeliness requirement for PDE records that is different from the general PDE submission timeliness requirement for initial PDE records.[214] To ensure that dispensing entities receive timely payment of MTF refunds, CMS stated that it was evaluating whether the 30-day window for Part D sponsors to submit PDE records should be shortened to 7 days of receipt of the claim to help ensure dispensing entities receive timely payment of MFP refunds.

CMS received and reviewed comments from interested parties on the draft guidance related to the consideration of a shorter PDE submission timeliness requirement for selected drugs and addressed those comments on page 53 of the final guidance.[215] To inform policy development for this rulemaking, CMS re-reviewed all comments received on the topic of PDE submission timeliness requirements. Many commenters supported CMS shortening the PDE submission window and agreed with the 7-day timeliness requirement or recommended other timeliness requirements shorter than 30 calendar days. Some commenters recommended CMS not change the PDE reporting general timeliness requirement and keep the 30-day window for selected drugs. Many commenters noted that shortening the PDE submission window could increase the volume of claim adjustments and reversals during and after the 14-day prompt MFP payment window. These commenters noted that it typically takes pharmacies up to 14 days to reverse a claim when a beneficiary does not pick up a prescription and asked CMS to provide more detail on how the MTF will address claim reversals and adjustments. One commenter noted that if CMS shortens the PDE submission window, plan sponsors would need additional implementation time to revise agreements and internal processes. While CMS addressed these comments in final guidance by stating that it intends to propose to shorten the current 30-day window for plans to submit PDE records for selected drugs to 7 calendar days, CMS also received several comments posing technical questions on the PDE reporting process and DDPS operations, and offering input on other PDE operational matters, which CMS considered out of scope for final guidance. However, CMS recognizes the importance of public feedback on potential operational concerns surrounding a shorter PDE submission window for selected drugs. CMS is soliciting comments in this proposed rule on the operational considerations of shortening the timeframe for initial PDE records for selected drugs to 7 calendar days, including potential challenges

medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[213] See 42 CFR 423.520, Prompt Payment by Part D Sponsors, which requires Part D sponsor to transmit payment to pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.

[214] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[215] Insert link to final guidance when it is available.

Part D sponsors may face in implementing the proposed timeframe.

CMS is also soliciting comments on whether it should shorten the submission timeline for selected drugs for adjustment and deletion PDE records, and for records to resolve PDE records that were rejected by CMS. CMS is particularly interested in comments on operational feasibility, as well as comments that address whether a shorter submission timeline would help facilitate timely payments by Primary Manufacturers to dispensing entities, or whether the 90-calendar day submission timeframe for adjustments and deletions and/or for the resolution of rejected records is sufficient for the purpose of the Negotiation Program.

We propose to codify this 7-calendar day timeframe for initial PDE records for selected drugs and refer to this timeframe as the *Selected Drugs PDE Submission Timeliness Requirement.*

3. Requirements—General PDE Submission Timeliness

We propose to codify the existing 30-day and 90-day general PDE submission timeframes, with two slight modifications. First, we propose that the 30-day and 90-day requirements refer to calendar days, as opposed to business days. Second, we propose to modify the timing of the initial PDE records submission, which currently begins from the date the claim is received by the Part D sponsor or the date of service, whichever is greater. Given that the claim cannot be received by the Part D sponsor (or its contracted first tier, downstream, or related entity (for example, pharmacy benefit manager (PBM))) until on or after the date of service, we propose to clarify that initial PDE records must be submitted within 30 calendar days of when the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

Based on our experience with the Part D program, these proposed 30-calendar day and 90-calendar day PDE submission timeframes are appropriate, striking a balance between allowing sufficient time for the Part D sponsors to submit PDE records while providing sufficient time for CMS to review and flag data quality issues that may require action from the Part D sponsor prior to the PDE record being used in the invoicing and reconciliation processes for the discount programs and the Part D payment reconciliations. These proposed timeframes, which CMS developed with industry feedback, have been in subregulatory guidance since 2011 and have worked well for Part D sponsors and CMS.

Therefore, we propose the following general PDE submission timeliness requirements. We propose that the Part D sponsor must submit an initial PDE record within 30 calendar days from the date the Part D sponsor receives the claim. We propose that the Part D sponsor must submit adjustment or deletion PDE records within 90 calendar days of the discovery or notification of an issue requiring a change to the previously submitted PDE records. We propose that the Part D sponsor must resolve rejected PDE records within 90 calendar days of the rejection. We propose that these general PDE submission timeliness requirements apply unless, for the initial PDE records submissions, the proposed selected drugs PDE submission timeliness requirement applies.

4. Requirement—Selected Drugs PDE Submission Timeliness

We propose to establish a selected drugs PDE submission timeliness requirement, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. The proposed PDE submission timeliness requirement is consistent with CMS' authority under section 1860D–15(f) of the Act, which authorizes CMS to collect PDE data for the purposes of, and to the extent necessary in, carrying out both section 1860D–15 of the Act and part E of title XI of the Act (*i.e.,* the Negotiation Program).

Figure 1 illustrates the general and selected drugs PDE submission timeline requirements.

FIGURE 1. PROPOSED PDE SUBMISSION TIMELINES FOR NON-SELECTED AND SELECTED DRUG CLAIMS

Submission Timeframe	Non-Selected Drug	Selected Drugs
Initial PDE	30 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity	7 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity
Resolution of Rejected Records	90 calendar days following receipt of rejected record status from CMS	
Adjustment and Deletion	90 calendar days following discovery of issue requiring change	

CMS believes Part D sponsors are compliant with the longstanding guidance pertaining to 30- and 90-day PDE submission timelines, and thus, CMS does not expect the proposed change to result in additional costs or savings and are not scoring these requirements in the Regulatory Impact Analysis section. We are not imposing any new reporting requirements for drugs other than selected drugs. We do not believe that our proposal pertaining to 7-, 30-, and 90-day PDE submission timeline will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

5. Severability

The general PDE submission timeliness requirements and the selected drugs PDE submission timeliness requirement provisions proposed herein are separate and severable from one another. If either provision, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it is our intention that such provision shall be severable from this rule and not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

S. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), enacted August 16, 2022, established the Medicare Drug Price Negotiation Program (hereinafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs

and biological products. The requirements for the Negotiation Program are described in sections 1191 through 1198 of the Social Security Act (hereinafter ''the Act''), as added by sections 11001 and 11002 of the IRA. Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the United States Department of Health and Human Services (hereinafter ''the Secretary'') to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS issued the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 on May 3, 2024 (hereinafter ''draft guidance''), and the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 on October 2, 2024 (hereinafter ''final guidance'').[216] In the final guidance, CMS noted that it also planned to engage in rulemaking to propose certain policies under Medicare Part D that relate to or have implications for the Negotiation Program but involve exercising authorities under the Act that are not subject to the IRA's program instruction requirement. Accordingly, as discussed in more detail below, in this rule, CMS proposes at § 423.505(q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Negotiation Program's Medicare Transaction Facilitator (MTF) Data Module (DM) (hereinafter ''MTF DM'').

1. Background on the Medicare Transaction Facilitator

Section 1193(a) of the Act instructs CMS to enter into agreements (a ''Medicare Drug Price Negotiation Program Agreement,'' hereinafter referred to as a ''Negotiation Program Agreement'') with willing manufacturers of selected drugs (as described in section 1192(c) of the Act) for a price applicability period (as defined in section 1191(b)(2) of the Act). After entering into a Negotiation Program Agreement with CMS and in accordance with section 1193(a) of the Act, any ''Primary Manufacturer'' (as defined in section 40 of the final guidance) of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act) and to pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D (hereinafter ''dispensing entities'') with respect to such MFP-eligible individuals. In section 40.4 of the final guidance, CMS stated that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP, or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Consistent with longstanding Part D prompt pay rules regarding payment by plan sponsors to network pharmacies,[217] CMS will require that a Primary Manufacturer transmit payment of an amount that provides access to the MFP within 14 calendar days of when certain claim-level data elements are sent to the Primary Manufacturer by the MTF DM.

In section 40.4 of the final guidance, CMS stated, based on CMS' continuous engagement with and extensive feedback from interested parties, for 2026 and 2027, CMS will engage with MTF contractors to facilitate the exchange of data and payment between pharmaceutical supply chain entities for the purposes of the Negotiation Program. The MTF will have two distinct modules, the MTF DM and the MTF Payment Module (hereinafter ''MTF PM''), a voluntary option to pass payment for MFP refunds from Primary Manufacturers to dispensing entities. The combined data and payment facilitation functionalities present in the MTF DM and the MTF PM will attempt to address the interests expressed by dispensing entities and manufacturers in a single platform for transmitting the data necessary for program administration and supporting MFP refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments.

The MTF DM will facilitate the exchange of certain claim-level data elements and claim-level payment elements for selected drugs to support the verification that the selected drug was dispensed to an MFP-eligible individual, as described in section 40.4.2 of the final guidance. The data supplied by the MTF DM to Primary Manufacturers will have been verified by both the Part D sponsor and CMS' Drug Data Processing System (DDPS) resulting in dual verification of both an individual's eligibility for Part D, and Part D coverage of the selected drug for each claim being transmitted. For context, when a Part D plan sponsor receives a claim for a selected drug from a dispensing entity, the Part D plan sponsor verifies that the beneficiary listed on the claim paid by the Part D plan sponsor is enrolled in Medicare Part D and coverage is provided under Part D for the dispensed drug. After the Part D plan sponsor verifies Medicare eligibility and coverage of the selected drug, the plan pays the dispensing entity no more than the MFP plus any dispensing fees for the selected drug. Then, the Part D plan sponsor sends the data on the Part D claim as a Prescription Drug Event (PDE) record (*i.e.,* claim summary records submitted by Medicare Part D plan sponsors to CMS for every prescription filled by a dispensing entity for a Medicare Part D beneficiary) to DDPS. CMS uses DDPS to perform verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim, as described in section 40.4.2.1 of the final guidance. After CMS verifies MFP eligibility for the individual related to the claim, DDPS will transmit the PDE record for the Part D claim for the selected drug to the MTF DM. Therefore, because MFP eligibility status has been twice validated before the data elements are sent from the MTF DM to the Primary Manufacturer, the data elements will have been verified as involving a selected drug that was dispensed to an MFP-eligible individual.

As stated in section 40.4.2.1 of the final guidance, enrollment in the MTF DM will be mandatory for Primary Manufacturers. CMS will require all Primary Manufacturers to register with the MTF DM by a deadline to be specified by CMS and to maintain the functionality necessary to receive certain claim-level data elements from the MTF DM and return certain claim-

[216] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[217] See 42 CFR 423.520, Prompt Payment by Part D Sponsors, which requires the Part D sponsor to transmit payment to network pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.

level payment elements to the MTF DM. Each Primary Manufacturer will be required to sign data use, privacy, and security agreements with CMS and comply with data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF.

As discussed in section 40.4.2.2 of the final guidance and in more detail below, dispensing entity enrollment in the MTF DM is also needed for necessary operations related to administration of the Negotiation Program and the Part D program. Dispensing entity enrollment in the MTF DM allows for several key functionalities that help ensure accurate Part D claims information and payment and continued access for beneficiaries and dispensing entities to selected drugs. These functionalities include the collecting and sharing of banking information from dispensing entities to Primary Manufacturers; creating and sending of Electronic Remittance Advice that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act of 1996 (hereinafter ''ERAs'') (for electronic transfer of funds) or remittances (for paper checks) to dispensing entities; a streamlined ability to submit complaints and disputes regarding selected drugs dispensed; and an opportunity for dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to selected drugs as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. Accordingly, CMS proposes to require Part D plan sponsors to include in their network pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM.

If a Primary Manufacturer elects to utilize the MTF PM, then the MTF PM will complement the data-related activities of the MTF DM and facilitate payment of an MFP retrospective refund on MFP-eligible claims of selected drugs from the participating Primary Manufacturer to the dispensing entity. Specifically, as discussed in section 40.4.3 of the final guidance, the MTF PM will (1) provide Primary Manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments from Primary Manufacturers to dispensing entities; and (2) provide Primary Manufacturers with a credit/debit ledger system to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system. Participation in the MTF PM will be voluntary for Primary Manufacturers, which will have the option of passing MFP refund payments to dispensing entities through the MTF PM or using their own processes outside of the MTF PM to effectuate the MFP. Primary Manufacturers that elect to use the MTF PM to pass through payments will be required to execute MTF agreements with the MTF PM outlining each party's rights, responsibilities, and potential liabilities associated with the transfer and receipt of funds through the MTF PM.

2. Network Pharmacy Contracts With Part D Plan Sponsors

CMS has broad contracting authority with respect to Part D plan sponsors under section 1860D–12 of the Act. As applied to the Part D program through section 1860D–12(b)(3)(D) of the Act, section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. Additionally, section 1860D–12(b)(3)(D)(i) of the Act specifies that information provided to the Secretary under the application of section 1857(e)(1) of the Act may be used (in relevant part) for the purposes of carrying out the Part D program or Part E of Title XI of the Act (*i.e.,* the Negotiation Program). Pursuant to these authorities, CMS proposes to require plan sponsors (or first tier, downstream, or related entities, such as PBMs, on the sponsors' behalf) to include in their network participation agreements with contracting pharmacies a provision that requires the pharmacy to be enrolled in the MTF DM (or any successor to the MTF DM) in a form and manner to be determined by CMS. CMS emphasizes that under the proposed regulation, such provision must require the pharmacy ''to be enrolled'' in the MTF DM, as opposed to merely requiring the pharmacy ''to enroll'' in the MTF DM, to establish an ongoing obligation that the pharmacy maintain its enrollment in the MTF DM. CMS also proposes that such provision must require the pharmacy to maintain and certify to CMS that the enrollment information provided in the MTF DM is accurate, complete, and up to date, pursuant to applicable terms and conditions of participation with the MTF DM, in a form and manner to be determined by CMS. CMS proposes amending § 423.505 by adding paragraph (q) to codify this requirement.

Consistent with section 1860D–12(b)(3)(D) of the Act, such a requirement would be necessary and appropriate and not inconsistent with the Part D statute. As previously mentioned, the MTF DM will contain several key functionalities that are necessary and appropriate for operations related to administration of the Negotiation Program and the Part D program. Through each of the functionalities outlined below, dispensing entity enrollment in the MTF DM would help ensure continued access to selected drugs that are covered under Part D for beneficiaries and dispensing entities and help maintain the accuracy of Part D claims information and payment.

First, the MTF DM will provide dispensing entities enrolled in the MTF DM with remittances or ERAs to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment to the dispensing entity through the MTF PM. Interested parties strongly requested that electronic MFP refunds be accompanied by an ERA or remittance. To meet standards in the creation of an accurate ERA or remittance, up-to-date banking information for a dispensing entity will be needed. Dispensing entities will be asked to provide up-to-date banking information during MTF DM enrollment. For Primary Manufacturers that make payments outside of the MTF PM, CMS plans to make available through the MTF DM dispensing entities' bank account information and designated destination for ERAs or remittances, as applicable.

These ERAs or remittances will assist dispensing entities in closing out their open accounts receivable, thereby minimizing cashflow interruptions. Specifically, the information contained in the ERA or remittance will connect claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. Consistent with each dispensing entity's own standard business practices, CMS expects dispensing entities to review their accounts receivables for each claim for which a Primary Manufacturer owes an MFP refund and determine whether a Primary Manufacturer has paid all the claims the dispensing entity believes are MFP-eligible claims, in the amounts the dispensing entity believes are sufficient to effectuate the MFP. Moreover, CMS has consistently heard from interested parties that without an ERA or remittance, MFP refund payments may be rejected, and, in these scenarios, dispensing entities would not have means to reconcile received payments against outstanding MFP-eligible claims.

Second, there will be streamlined access for dispensing entities enrolled in the MTF DM to submit complaints and disputes within the MTF DM to

help identify issues with timely MFP refund payment, supporting dispensing entities to continue efficient operations and prevent undue financial hardship, while maintaining accuracy of Part D claims information and payment. Allowing dispensing entities streamlined access to this system will support the administration of the Negotiation Program and Part D program. Through the MTF DM, a dispensing entity can submit a complaint concerning claims for selected drugs that potentially require an MFP refund, which CMS will review. Additionally, all Primary Manufacturers will be required to utilize the MTF DM to report to the MTF DM information (claim-level payment elements) about how the Primary Manufacturer has made the MFP available for each claim for which the Primary Manufacturer received data from the MTF DM or indicate why no MFP refund payment has been made on a claim. While dispensing entities are encouraged to remediate with the manufacturer directly if they believe that they have not received a retrospective refund payment that effectuates the MFP, dispensing entities may use the complaints process within the complaint and dispute system in the MTF DM to alert CMS.

Third, the MTF DM will serve as a central repository for information about dispensing entities enrolled in the MTF DM that anticipate material cashflow concerns due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. Interested parties have noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP refund. Based on this input, CMS is concerned that this challenge will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective (*i.e.,* at the start of a price applicability period with respect to a selected drug). CMS does not anticipate this challenge to continue with respect to a selected drug once MFP refunds for that selected drug are flowing and dispensing entities become accustomed to the 14-day prompt MFP payment window. Consider a scenario in which the dispensing entity purchases a selected drug at a price discounted from the wholesale acquisition cost (WAC), for example, at WAC minus four percent, for ten units. Initially, this expenditure creates a temporary cashflow gap. However, upon receiving the MFP refund payment, the dispensing entity's upfront cost is offset, effectively restoring its financial position. Assuming a consistent utilization rate for the drug, any temporary negative cashflow should be balanced by the subsequent MFP refund payment. The timing and consistency of this pattern should lead to stable cashflow and avoid a long-term cash deficit over time. During MTF DM enrollment, CMS will ask dispensing entities to self-identify whether they are a dispensing entity that anticipates having material cashflow concerns. CMS expects dispensing entities of the types that have raised material concerns about cashflow related to the effectuation of MFP—such as sole proprietor rural and urban pharmacies with high volume of Medicare Part D prescriptions dispensed, pharmacies who predominantly rely on prescription revenue to maintain business operations, long-term care pharmacies, 340B covered entities with in-house pharmacies, and I/T/U pharmacies—may self-identify through this process. This information will be provided to Primary Manufacturers to assist in the development of their MFP effectuation plans, which must include a process for mitigating material cashflow concerns for dispensing entities. The MTF DM will also be available to dispensing entities enrolled in the MTF that need to update their self-identification with respect to material cashflow concerns, as CMS anticipates that indication could change over time.

Fourth, CMS intends that dispensing entities will be able to view the status of MFP refunds from Primary Manufacturers through the MTF DM. The ability to track MFP refunds could also help dispensing entities better manage their cashflow or aid their financial planning to meet other administrative burdens or operational costs.

Fifth, the MTF DM will collect and share bank account information belonging to dispensing entities enrolled in the MTF DM with Primary Manufacturers that pay MFP refunds to dispensing entities outside the MTF PM. Through CMS' engagement with interested parties, both manufacturers and dispensing entities have expressed the concern that they typically do not have direct financial relationships with one another, increasing dispensing entities' risk of experiencing payment delays. As such, during MTF DM enrollment, CMS will ask dispensing entities to provide their bank account information. CMS believes that the collecting and sharing of dispensing entities' bank account information with Primary Manufacturers will address interested parties' concerns related to the lack of an established channel to support MFP refund payments made outside the MTF PM, and help dispensing entities to continue efficient operations.

In sum, CMS believes that enrollment in the MTF DM by dispensing entities would facilitate continued beneficiary and dispensing entity access to selected drugs that are covered Part D drugs. Manufacturers and dispensing entities have asked the agency to undertake a role in assuring that MFP refund payments to dispensing entities can be made efficiently, and the development of an MTF DM has an important role in that process. With less financial uncertainty, dispensing entities are better positioned to keep dispensing selected drugs covered under Part D. Given the wide number and scope of dispensing entities that dispense drugs to Part D beneficiaries—which is currently approximately 60,000-plus community pharmacies and 80,000-plus dispensing entities in total—this proposed requirement will help reach the maximum number of entities that serve Medicare beneficiaries. Requiring network pharmacy agreements to require enrollment by pharmacies in the MTF DM will help promote successful MFP effectuation under the Negotiation Program and facilitate continued access to selected drugs covered under Part D for Medicare beneficiaries.

For the reasons stated above, CMS proposes to require plan sponsors (or first tier, downstream, or related entities, such as PBMs, on the sponsors' behalf) to include in their network participation agreements with contracting pharmacies a provision that requires the pharmacy to be enrolled in the MTF DM (or any successor to the MTF DM), which would entail an ongoing obligation that the pharmacy maintain its enrollment in the MTF DM, in a form and manner to be determined by CMS. CMS also proposes that such provision must require the pharmacy to maintain and certify to CMS that the enrollment information provided in the MTF DM is accurate, complete, and up to date, pursuant to applicable terms and conditions of participation with the MTF DM, in a form and manner to be determined by CMS. CMS seeks comment on this proposal.

3. Overview for Dispensing Entity Enrollment in the MTF DM

As of the date of the publication of this proposal in the **Federal Register**, CMS is still determining the exact process for enrollment of dispensing entities in the MTF DM and welcomes feedback on factors CMS should incorporate into this process. Currently, for 2026 and 2027, CMS may use existing databases to identify contact information for dispensing entities that dispense prescription drugs to Medicare beneficiaries or participate in one or more parts of the Medicare program. CMS may use that information to facilitate the process for dispensing entities to enroll in the MTF DM. CMS may also use that information to conduct outreach activities to dispensing entities such that they are aware of the MTF, including the benefits, functions, and process for enrollment, and, if finalized, this proposed contractual requirement to be enrolled in the MTF DM. Regardless of whether CMS conducts any outreach to dispensing entities, under this proposal, the plan sponsor would remain responsible for ensuring that its network agreements with pharmacies include a provision that requires the pharmacy to be enrolled in the MTF DM in a form and manner to be determined by CMS.

When enrolling in the MTF DM, the dispensing entity would enter, certify, and maintain its enrollment information, including but not limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or NPI; (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) deposit or account number with financial institution; (6) type of registered financial account; and (7) secure location for making available the ERA or remittance, as applicable. During MTF DM enrollment, CMS would allow dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to selected drugs as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. The dispensing entity's (and, as applicable, their third-party support entity's) banking information would be shared with Primary Manufacturers to establish accurate ERA for electronic MFP refund payments (or remittance advice for paper checks) made outside of the MTF PM.

CMS would require each dispensing entity to execute an agreement package during the MTF enrollment process, which, for example, may include an MTF agreement with CMS and a participation agreement with CMS' MTF DM contractor. Under the terms and conditions of participation in the MTF DM, the dispensing entity would be responsible for maintaining MTF enrollment information in the MTF DM and be subject to audits conducted by CMS or its agents. If any of the dispensing entity's enrollment information in the MTF DM changes, the dispensing entity would also be required to update and recertify the information in the MTF DM. CMS intends to publish copies of draft MTF terms and conditions of the agreement package on the CMS IRA website.[218]

T. Proposed Regulatory Changes to Medicare Advantage (MA) and Part D Medical Loss Ratio (MLR) Standards (§§ 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2460, 422.2480, 422.2490, 423.2401, 423.2420, 423.2430, 423.2450, 423.2452, 423.2454, 423.2480, 423.2490)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013, **Federal Register**, we published a final rule titled ''Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule), in which we codified the MLR requirements for MA organizations and Part D prescription drug plan sponsors (''Part D sponsors'') (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X.

Generally, the MLR for each MA and Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on the following categories of expenditures: incurred claims for all enrollees, prescription drug costs for those enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts used to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR for MA and Part D (*see* §§ 422.2401 and 423.2401; 422.2420(b)(4) and 423.2420(b)(4); 422.2430(b) and 423.2430(b)).

The MLR calculation, prior to any credibility adjustment, can be depicted as the following general formula:

MRL = (Incurred Claims + Quality Improving Activities) ÷ (Revenue − Certain Taxes and Fees)

In the May 2013 Medicare MLR final rule, we codified at §§ 422.2410 and 423.2410 the requirements for 2014 and subsequent years that MA organizations and Part D sponsors are subject to financial and other sanctions for failure to meet the requirement that they have an MLR of at least 85 percent. Specifically, CMS set forth that, if we determine that a contract of an MA organization or Part D sponsor has an MLR that is less than 0.85 for a contract year, the contract has not met the MLR requirement and the MA organization or Part D sponsor must remit to CMS an amount equal to the product of (1) the total revenue of the MA or Part D contract for the contract year multiplied by (2) the difference between 0.85 and the MLR for the contract year (*see* §§ 422.2410 and 423.2410). We also established at §§ 422.2460 and 423.2460 that, for each contract year, each MA organization and Part D sponsor must submit an MLR Report to CMS that included the data needed from the MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract such as the amount of incurred claims, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS under § 422.2410 or § 423.2410.

To facilitate the submission of MLR data, CMS developed a standardized MLR Report template that MA organizations and Part D sponsors are

[218] See: *https://www.cms.gov/inflation-reduction-act-and-medicare.*

required to populate with their data and upload to the Health Plan Management System (HPMS), starting with contract year (CY) 2014 MLR reporting. For any given reporting year (calendar year), MA organizations and Part D sponsors must submit their MLR Reports in December of the year following the reporting year, or another time as determined by CMS. Based on the data entered by the MA organization or Part D sponsor for each component of the MLR numerator and denominator, the MLR reporting software would calculate an unadjusted MLR for each contract. The MLR reporting software would also calculate and apply a credibility adjustment provided for in §§ 422.2440 and 423.2440, based on the number of member months entered into the MLR Report, in order to calculate the contract's adjusted MLR and remittance amount (if any). The credibility adjustment takes into account the specific circumstances of contracts with lower enrollment and reduces the probability that an MA organization or Part D sponsor with relatively smaller enrollment has to pay a remittance in a given year due to the propensity for random fluctuations in claims each year. In addition to the numerical fields used to calculate the MLR and remittance amount, the MLR Report template included narrative fields in which MA organizations and Part D sponsors provided detailed descriptions of the methods used to allocate expenses, including how each specific expense met the criteria for the expense category to which it was assigned.

In the final rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (83 FR 16440), which appeared in the April 16, 2018, **Federal Register** (hereinafter referred to as the April 2018 final rule), we finalized a proposal to modify the MLR reporting requirements by significantly reducing the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, starting with contract year 2018. Specifically, the reporting requirement was changed to collect the minimum amount of information needed for Medicare MLR reporting: the organization name, contract number, adjusted MLR, and the remittance amount.

In light of subsequent experience overseeing the administration of the Medicare MLR program while relying on the simplified MLR reporting requirements, and after further consideration of the potential impacts on beneficiaries and costs to the government and taxpayers when CMS has limited access to detailed MLR data, we proposed to reinstate the detailed MLR reporting requirements that were in effect for contract years 2014 through 2017. This detailed reporting required the submission of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. We also proposed some modifications to the reinstated reporting requirements. These modifications included three types of changes to the MLR Reporting Tool. First, the MLR Reporting Tool's formulas were revised to incorporate changes to the MLR calculation such as adding categories for fraud reduction expenses in the section for Activities that Improve Healthcare Quality. Second, CMS separated out certain items that were consolidated, for example, the low-income cost-sharing subsidy amounts were added as an information-only line in the MLR Reporting Tool. Third, CMS included expenditures related to supplemental benefits in the MLR Reporting Tool. These modifications were proposed in the rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (87 FR 1842), which appeared in the March 7, 2022, **Federal Register** (hereinafter referred to as the March 2022 proposed rule) and finalized in the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (87 FR 27704), which appeared in the May 9, 2022, **Federal Register** (hereinafter referred to as the May 2022 final Medicare rule).

The factors that led us to make these changes included the growth of the MA and Part D programs, the related growth in MLR remittances, and the growth in the number of contracts that failed to meet the MLR requirement during the period when MA organizations and Part D sponsors had reduced reporting requirements. When the proposed rule titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56336), which appeared in the November 28, 2017, **Federal Register** (hereinafter referred to as the November 2017 proposed rule), to eliminate the detailed Medicare MLR reporting requirements was released, MA organizations and Part D sponsors had submitted MLR data for CYs 2014 and 2015. Total remittances for all contracts for the two years averaged $29.6 million, and an average of 16 contracts failed to meet the minimum Medicare MLR requirement. By the time CMS issued the April 2018 final rule, annual average remittances for CYs 2014 through 2016 totaled $91.8 million, and an annual average of 21 contracts failed to meet the MLR requirement. Thereafter, for CYs 2017 through 2019, the average amount of annual remittances more than doubled to $204.9 million, and the average number of contracts that failed to meet the MLR requirement nearly doubled to 40 contracts per year.

In the May 2013 Medicare MLR final rule, we also codified sanctions at §§ 422.2410 and 423.2410 as set forth in statute. Specifically, the statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately, contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the revenue received by plan sponsors and helps ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

Section 1001(5) of the 2010 Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the 2010 Health Care and Education Reconciliation Act (Pub. L. 111–152), also established new MLR reporting and rebate requirement under section 2718 of the Public Health Service Act that applies to health insurance issuers (issuers) of private health insurance coverage in the employer group and individual markets as of CY 2011. We will refer to the MLR requirements that apply to issuers of private insurance as the ''commercial MLR rules.'' Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

In a 2016 rule titled ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party

Liability'' (81 FR 27853), which appeared in the May 6, 2016, **Federal Register**, we also established Medicaid and CHIP managed care regulations at §§ 438.8(k) and 457.1203(f) respectively, that require managed care plans to annually submit reports of their MLR to States, and, at §§ 438.74 and 457.1203(e) respectively, we require States to submit annually a summary of those reports to CMS based on our authority under sections 1903(m)(2)(A)(iii), 1902(a)(4), and 2101(a) of the Act.

In the May 2013 Medicare MLR final rule, we stated that we would use the commercial MLR rules as a reference point for developing the Medicare MLR requirements because the intent of the provisions is comparable. We observed that maintaining consistency between the commercial MLR rules and Medicare MLR rules serves to limit burden on organizations that participate in both markets and makes commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. In the March 2022 proposed rule, we reiterated our longstanding policy of attempting to align the Medicare MLR requirements with the commercial MLR requirements to limit burden on organizations that participate in both markets.[219] We also cited this policy when we amended our regulations to authorize the public release of the Part C and Part D MLR data that we collect for a contract year under §§ 422.2460 and 423.2460 in the rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' (81 FR 80170), which appeared in the November 15, 2016, **Federal Register**. At the same time, in developing the Medicare MLR regulations, we have recognized that some aspects of the regulation for commercial plans needed to be tailored to fit the unique characteristics of the MA and Prescription Drug plan (PDP) markets. For example, Medicare MLRs are reported on a contract basis, rather than by state and market.

In this proposed rule, we propose to make certain modifications to the MLR reporting requirements and to add requirements based upon MLR audit examinations in the Medicare Part C and Part D programs. The overall goal of the modifications is to do all of the following:

- Further align the Medicare MLR program with the commercial and Medicaid MLR programs.
- Improve the accuracy of MA and Part D MLR reporting.
- Safeguard the integrity of the Medicare program.
- Ensure beneficiaries receive value from the MA and Part D programs.

Specifically, we propose to amend § 422.2420(b)(2)(xi) to establish clinical or quality improvement standards for provider incentives and bonus arrangements included in the MA MLR numerator. We propose to amend §§ 422.2430(a) and 423.2430(a) to prohibit administrative costs from being included in quality improving activities in the MA and Part D MLR numerators. We also propose to amend §§ 422.2420(d)(2)(i) and 423.2420(d)(2)(i)) to impose additional requirements for the allocation of expenses in the MLR. Additionally, we propose to add new paragraphs §§ 422.2450, 422.2452, 422.2454, 423.2450, 423.2452, and 423.2454 to establish new audit and appeals processes for MLR compliance. We also propose to add §§ 422.2490(b)(6) and 423.2490(b)(6), to add an exclusion to the data release, to exclude from release the DIR information reported within the MLR data as part of incurred claims. Furthermore, we propose to exclude unsettled balances from the Medicare Prescription Payment Plan from the MLR numerator at § 423.2420(b)(4)(iii). We are issuing a request for information on whether CMS could and should adopt policies regarding how the MA and Part D MLRs are calculated to help enable policymakers to address concerns surrounding vertical integration in MA and Part D. Finally, we are proposing to amend §§ 422.2460(a) and 422.2490(b) to explicitly provide that the MLR reporting includes detailed information regarding provider payment arrangements. These proposals are described in detail below.

2. Proposal To Require Clinical or Quality Improvement Standards for Provider Incentive and Bonus Arrangements To Be Included in the MA MLR Numerator (§ 422.2420)

Section 1857(e)(4) of the Act requires the Secretary to determine for a contract year whether an MA organization has failed to have an MLR of at least 85 percent. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. However, the statute does not specify how the Secretary must calculate the MLR. Accordingly, in the May 2013 Medicare MLR final rule, we established regulations specifying how we calculate the MLR for MA and Part D contracts.

For MA and Part D contracts, we identify the elements that are required to be included in the MLR numerator for a contract at §§ 422.2420(b) and 423.2420(b). Specifically, under §§ 422.2420(b)(1) and 423.2420(b)(1), MA organizations and Part D sponsors must include in the MLR numerator incurred claims (as defined in paragraphs (b)(2) through (b)(4) for both programs); expenditures under the contract for activities that improve health care quality, which are referenced at paragraph (b)(1)(iii), and described in detail at §§ 422.2430 and 423.2430; and, under § 422.2420(b)(1)(ii), for the MA program, the amount to reduce the Part B premium, if any, for all MA plans under the contract for the contract year.

For the MA program, incurred claims include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services that are provided to all enrollees under the contract. Under § 422.2420(b)(2)(xi), incurred claims for clinical services and prescription drug costs must include ''the amount of incentive and bonus payments made to providers,'' which includes paid and accrued medical incentives and bonuses. Currently, incentive and bonus payments made to providers are included as incurred claims in the MLR numerator regardless of whether they are tied to clinical or quality improvement standards for providers.

While many types of provider incentives and bonuses can reward higher-quality care to enrollees, MLR examinations in other markets have found some incentive or bonus payments to providers are not based on quality or performance metrics. For example, as noted in the final rule titled ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023'' (87 FR 27208), which appeared in the May 6, 2022, **Federal Register** (hereinafter referred to as the May 2022 commercial final rule), commercial examinations have found issuers reporting incentive or bonus payments to affiliated providers that are not based on quality or performance metrics, but rather, involve transferring excess premium revenue to providers to circumvent MLR rebate requirements. In addition, as discussed in the final rule titled ''Medicaid Program; Medicaid and

[219] *https://www.federalregister.gov/d/2022-00117/p-656.*

Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality'' (89 FR 41002), which appeared in the May, 10, 2024, **Federal Register** (hereinafter referred to as the May 2024 Medicaid final rule), Medicaid reviews of States' oversight of managed care plan MLR reporting found many managed care plans' contracts with network providers did not base incentive payments on a requirement for the provider to meet quantitative clinical or quality improvement standards or metrics.

Given these findings, we revised the commercial MLR regulations at 45 CFR 158.140(b)(2)(iii) to only permit issuers to include provider incentive and bonus payments in their MLR numerator if they are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards for these costs to qualify as expenditures in the MLR numerator in the May 2022 commercial final rule.[220] Similarly, effective July 9, 2024, we revised the Medicaid and CHIP regulations at 42 CFR 438.3(i), 438.8(e)(2), 457.1201, and 457.1203 to specify that only those provider incentives and bonuses tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting in the May 2024 Medicaid final rule.

Given the similarities between the commercial MLR regulations when these findings were made and current MA MLR regulations, we believe that the concerns identified about incentive or bonus payments to providers not being based on quality or performance metrics in the commercial market are also applicable to the MA market. If MA organizations or Part D sponsors use incentive or bonus payments to providers to inflate their MLRs by including such payments for the sole purpose of meeting the MLR and not for clinical or quality improvement purposes, that would conflict with the purpose of the MLR requirement. Generally, the purpose of the MLR requirement is to create incentives for MA organizations and Part D sponsors to reduce administrative costs, as well as reduce funding for activities such as marketing, profits, and other business functions and thereby ensure that taxpayers and enrolled beneficiaries receive maximum value from Medicare health plans. If incentive and bonus payments are not tied to clinical or quality improvement purposes, taxpayers and enrolled beneficiaries would not receive any value from such payments.

Furthermore, we believe that aligning our regulations with the commercial and Medicaid regulations would be consistent with our longstanding policy of modeling Medicare MLR rules on commercial MLR rules and would limit the burden on organizations that participate in multiple markets and promote comparability of commercial, Medicaid, and Medicare MLRs for comparison and evaluation purposes.

As such, we propose to amend § 422.2420(b)(2)(xi) such that only those provider incentives and bonuses made, or expected to be made, that are tied to clearly defined, objectively measurable, and well documented clinical or quality improvement standards that apply to providers may be included in incurred claims in the numerator for MA MLR reporting and remittance purposes.

While we believe that concerns about incentive or bonus payments to providers not based on quality or performance metrics in the MA market and our longstanding policy of alignment with the commercial MLR rules support amending the MA MLR rules to reflect the commercial MLR rules for provider incentive and bonus payments, we believe that certain unique characteristics of the Part D program may counsel against a similar change for that program at this time. Specifically, under § 423.2420(b)(2)(i), for MA contracts that include MA–PD plans and for PDP contracts, incurred claims include only drug costs that are ''actually paid'' by the Part D sponsor. The concept of ''actually paid'' is defined at § 423.308 and refers to Part D costs that must be actually incurred by the Part D sponsor, net of any direct or indirect remuneration (DIR) from any source. Therefore, the amount reported in the MLR numerator as direct drug costs incurred by the sponsor must be net of all DIR (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor.

DIR that serves to increase the costs incurred by the Part D sponsor—referred to as *negative DIR*—is included in the MLR numerator when it meets the requirements at § 423.308 for amounts that are actually paid.[221] Negative DIR includes incentive and bonus payments made to pharmacies and other Part D providers. Because incentive and bonus payments made under the Part D program are already accounted for as DIR, Part D sponsors are not subject to a separate requirement to include such payments in the MLR numerator. Revising the Part D MLR regulations to require that incentive and bonus payments be tied to clinical or quality improvement standards could potentially require changes to the definition of drug costs that are ''actually paid,'' which, in turn, could affect other processes outside of the MLR that rely on that definition which is out of the scope of this provision. Furthermore, CMS believes that incentive and bonus payments made under the Part D program are generally tied to pharmacy performance metrics. Accordingly, we do not believe that it is necessary to amend the Part D MLR regulations at this time. However, we seek comments on whether interested parties believe there are additional considerations that should motivate CMS to consider adding § 423.2420(b)(2)(x) to mirror the proposed change to § 422.2420(b)(2)(xi).

We seek comment on these proposals, including whether any modifications to the credibility adjustment may be necessary.

3. Proposal To Prohibit Administrative Costs From Being Included in Quality Improving Activities in the MA and Part D MLR Numerator (§§ 422.2430 and 423.2430)

Under §§ 422.2420(b)(1)(iii) and 423.2420(b)(1)(ii), MA organizations and Part D sponsors must include expenditures under the contract for activities that improve health care quality, also known as quality improvement activities (QIAs), in the numerator for MA and Part D contract MLRs. QIAs are described in detail for both programs at §§ 422.2430 and 423.2430, respectively. As specified at paragraph (a)(2) of §§ 422.2430 and 423.2430, a QIA must be designed to improve health outcomes, implement activities to prevent hospital readmissions, implement activities to improve patient safety, implement wellness and health promotion activities, or enhance the use of health care data to improve quality, transparency, and outcomes.

[220] *https://www.govinfo.gov/content/pkg/FR-2022-05-06/pdf/2022-09438.pdf.*

[221] For additional discussion of negative DIR, please review the Final Medicare Part D DIR Reporting Guidance, which is released by CMS annually.

As specified at paragraph (a)(3) of §§ 422.2430 and 423.2430, a non-claims expense incurred by an MA organization or Part D sponsor may be accounted for as a quality improvement activity only if the activity falls into one of the categories described previously and meets all of the following requirements:

- It must be designed to improve health quality.
- It must be designed to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.
- It must be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.
- It must be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

In addition, under paragraph (a)(4) of §§ 422.2430 and 423.2430, QIAs include Medication Therapy Management Programs that meet the requirements of § 423.153(d), as well as fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

Sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act require MA organizations and Part D sponsors to report to CMS the MLR for each contract for each contract year and meet a minimum MLR requirement of 85 percent. Under §§ 422.2460(a) and 423.2460(a), the MLR report to CMS must include the data needed by the MA organization or Part D sponsor to calculate and verify the MLR, including the incurred claims, quality improving activity expenditures, non-claims costs, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS. However, §§ 422.2430 and 423.2430 do not specify the types of expenses that may be reported as a QIA expense or the extent to which the expenses must relate to a QIA.

The commercial MLR audit examinations have found QIA expenses to be a high-risk reporting area with ''wide discrepancies in the types of expenses that issuers include in QIA expenses and creates an unequal playing field among issuers.'' [222] The commercial MLR examinations found some issuers were including only direct expenses such as salaries of the staff performing the quality improving functions in QIA expenses, while other issuers were including indirect expenses such as overhead, the full salaries of employees who were conducting QIA only part of the time, IT infrastructure that supports regular business functions such as billing, office space, marketing, lobbying, third-party vendor profits, and company parties and retreats, including catering and travel.[223] These examinations also found that some issuers allocated indirect expenses such as overhead, marketing, lobbying, and third-party vendor profits to count as QIA expenses. In addition, many issuers did not have an accurate method to quantify the actual cost attributable to each QIA expense category and were often arbitrarily reporting or apportioning indirect expenses without adequate documentation or support. As discussed in the May 2024 Medicaid final rule, including such indirect expenses not directly related to activities that improve health care quality inflates the MLR numerator, and inconsistent MLR reporting undermines the integrity of the MLR programs.[224]

To clarify the types of QIA costs that may be included in MLR calculations, in the May 2022 commercial final rule, we amended the commercial regulations for QIA expenditures in 45 CFR 158.150(a), effective July 1, 2022, to provide that ''only expenditures directly related to activities that improve health care quality may be included in QIA expenses.'' In addition, we updated the Medicaid and CHIP MLR QIA reporting requirements in the May 2024 Medicaid final rule to add a reference to the same commercial regulation that prohibits the inclusion of overhead or indirect expenses that are not directly related to health care quality improvement activity expenditures. As stated in the May 2024 Medicaid final rule, the difference in standards could have posed a potential administrative burden for managed care plans that participate in Medicaid, CHIP, and the commercial markets because managed care plans and issuers may include different types of expenses in reporting QIA.[225]

Given the similarities between current Medicare MLR rules and the commercial and Medicaid MLR rules in place when we identified discrepancies in the types of expenses issuers of commercial plans and Medicaid managed care plans reported in QIA, we believe that the concerns identified are also applicable to the MA and Part D markets. Furthermore, we believe that aligning our regulations with the commercial and Medicaid requirements would be consistent with our longstanding policy of modeling Medicare MLR rules on commercial MLR rules and would limit the burden on organizations that participate in multiple markets and promote comparability of commercial, Medicaid, and Medicare MLRs for comparison and evaluation purposes. For these reasons, we propose to amend §§ 422.2430(a) and 423.2430(a) to specify that only expenditures directly related to activities that improve health care quality may be included as quality improving activity expenses for purposes of MA and Part D MLR reporting.

We seek comment on these proposals.

4. Proposal To Codify Current Requirements That MA and Part D MLR Reports Include a Description of How Expenses Are Allocated Across Lines of Business (§§ 422.2420 and 423.2420)

Under §§ 422.2420(d) and 423.2420(d), MA organizations and Part D sponsors, respectively, must allocate each MLR expense under one category and allocation to each category must be based on generally accepted accounting methods. MA organizations and Part D sponsors must also report expenditures that benefit multiple contracts on a pro rata or proportional share basis.

Current Medicare MLR reporting instructions require MA organizations and Part D sponsors to include descriptions of the methodologies used to allocate expenses included in the calculation of the MLR. More specifically, as described in the MA and Part D MLR reporting instructions, the MLR Report workbook should be ''used by organizations to describe the methods used to allocate expenses, as reported on the MLR Report, including incurred claims, health care quality improvement expenses, Federal and state taxes and licensing or regulatory fees, and non-claims costs.'' [226] The MLR reporting instructions further state that ''a detailed description of each expense element should be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized.''

Commercial regulations at 45 CFR 158.170(b) and Medicaid and CHIP

[222] *https://www.federalregister.gov/d/2022-09438/p-1778.*

[223] *https://www.federalregister.gov/d/2022-09438/p-1779.*

[224] *https://www.federalregister.gov/d/2024-08085/p-1255.*

[225] *https://www.federalregister.gov/d/2024-08085/p-1297.*

[226] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

regulations at 42 CFR 438.8(k)(1)(vii) and 457.1203(f) similarly require details on expense allocation in MLR reporting around the types of expenditures that were allocated, how the expenses met the criteria for inclusion in the MLR, and the methods used to allocate expenses. Like the Medicare MLR regulations, the commercial and Medicaid and CHIP regulations further require that issuers and managed care plans that operate multiple lines of business must submit information on the types of expenditures allocated to each line of business.

As noted in the April 2018 final rule (82 FR 56459), consistent with our general approach when developing the original Medicare MLR requirements of aligning those requirements with the commercial MLR requirements to the greatest extent possible, we attempted to model the Medicare MLR reporting format on the tools used to report commercial MLR data in order to limit the burden on organizations that participate in both markets. As a result, the fields in the MA and Part D MLR Report workbook are similar to the fields on the commercial MLR reporting form, including fields for descriptions of the methodologies used to allocate expenses included in the calculation of the MLR.

We are proposing to align the Medicare MLR regulations with the commercial and Medicaid MLR requirements related to information on allocation of expenses and with current Medicare MLR reporting practices. Specifically, we propose to codify requirements that MA organizations and Part D sponsors report a detailed description of the methods used to allocate expenses, including incurred claims, expenditures on QIA, licensing and regulatory fees, and State and Federal taxes and assessments. Furthermore, we propose that the detailed description of each expense element must include how each specific expense meets the criteria for the type of expense in which it is categorized as well as the method by which it was aggregated and allocated. We propose adding this requirement to the Medicare MLR regulations at §§ 422.2420(d)(2)(i) and 423.2420(d)(2)(i).

We seek comment on these proposals.

As proposed, this provision is consistent with our current Medicare MLR reporting guidance and the requirements that were in place for CYs 2014 through 2017. This provision codifies an existing requirement in the reporting instructions and makes a clarification that is not expected to place additional requirements on MA organizations and Part D sponsors. As such, the proposed regulations §§ 422.2420(d)(2)(i) and 423.2420(d)(2)(i) do not create any additional burden for MA organizations or Part D sponsors. MA organizations' and Part D sponsors' compliance with the MLR reporting requirements is already evaluated through the current MLR desk review process described at §§ 422.2480 and 423.2480. In addition, the burden associated with the submission of MLR data is already approved under the OMB control number 0938–1232 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10476)). We have not incorporated this provision in the Collection of Information section of this proposed rule, nor are we are scoring this provision in the Regulatory Impact Analysis section because MA organizations and Part D sponsors are already complying with the proposed regulations.

5. Proposal To Establish Standards for MA and Part D MLR Audit Examinations (§§ 422.2401, 422.2450, 422.2452, 422.2454, 422.2480, 423.2401, 423.2450, 423.2452, 423.2454, and 423.2480)

As stated in 42 CFR 422.503(d), 422.504(d)–(e), 422.2480, 423.504(d), 423.505(d), and 423.2480, MA organizations' and Part D sponsors' MLR reports are subject to review and audit by CMS or by any person or organization that CMS designates. As part of the review and audit process, CMS or its representative may request additional documentation supporting the information contained in the MLR report. MA organizations and Part D sponsors must provide this information in a timely manner.

Currently, as described at §§ 422.2480 and 423.2480, CMS conducts desk reviews and analyses of the reported MLR data to identify omissions or suspected inaccuracies and communicate findings to MA organizations and Part D sponsors in order to resolve potential compliance issues. If an issue is identified during desk review, the MLR report may be corrected and resubmitted in order to resolve the identified issue, or the inquiry may be resolved by the MA organization or Part D sponsor providing additional explanation or supporting information sufficient to satisfy the inquiry and complete the desk review.

With the growth of the MA and Part D programs, greater scrutiny to ensure that MA organizations and Part D sponsors are appropriately spending funds to provide care to enrollees is increasingly important. Given the findings from the commercial and Medicaid MLR audit examinations, such as for QIA reporting, as discussed previously, we expect there may be similar reporting issues in the Medicare MLR program. In addition to ensuring compliance with the applicable requirements for calculating and reporting MLR information, we believe that audit examinations could help identify areas where submitters might be able to reduce reporting errors. MLR audits will improve the accuracy of MA organizations' and Part D sponsors' annual MLR submissions, safeguard the integrity of the Medicare program, and ensure beneficiaries receive value from the MA and Part D programs.

We propose new regulations and amendments to existing regulations to establish standards for the MA and Part D MLR audit examinations. These changes would more fully align the Medicare MLR regulations with longstanding operational practices of commercial and Medicaid MLR oversight, which consists of audit examinations, an appeal process for remittances determined to be owed as the result of an audit, and compliance actions when necessary.

More specifically, we propose specifications for how CMS will conduct MA and Part D MLR audit examinations in addition to the MLR desk review process discussed previously and in regulations §§ 422.2480 and 423.2480. Under our existing authority, we propose requiring MA organizations and Part D sponsors selected for MLR audit examinations to provide detailed MLR data and underlying records that can be used to substantiate amounts included in the calculation of each contract's MLR. We also propose calling audit examinations for only those contracts with an MLR greater than 85 percent. Currently, CMS provides MA organizations and Part D sponsors with opportunities to correct MLR data through the MLR desk review process or through other self-reporting mechanisms, such as contacting CMS directly. Following the completion of the desk review process, consistent with the MLR regulations at §§ 422.2460(d) and 423.2460(d), the MLR is considered to have been reported once and is not reopened as a result of any payment reconciliation process. In addition, as stated in the May 2013 Medicare MLR final rule, if an MA organization or Part D sponsor reports that a contract's MLR for a contract year does not meet the 85 percent standard, a remittance amount is collected and that MLR is considered final. As such, the MLR audit examinations would not include

contracts that previously paid remittances as the result of an MLR below 85 percent. As described further in this proposed rule, if through the audit process, it is determined that a contract did not meet the 85 percent threshold, we would recalculate the MLR based on audit examination findings to determine appropriate remittances and would not reopen MLR reports for submission of corrections. CMS may conduct Medicare MLR audit examinations in 2025 and the compliance actions that result from the audits and provisions in this rule would take effect in 2026.

The following sections outline our proposal to establish regulations for an MA and Part D MLR audit process, an MLR audit remittance calculation and payment process if an MLR audit remittance is determined to be owed, and an appeal process for MA organizations and Part D sponsors to dispute the MLR audit remittance if requested. The last section outlines the compliance actions CMS may take as the result of MLR audit findings and proposed modifications to existing regulations to allow for future flexibility to pursue additional compliance actions if necessary.

a. MA and Part D MLR Audit Process

We propose to add §§ 422.2450 and 423.2450 to regulations to establish the audit process to validate MA organization and Part D sponsors' MLR compliance. At §§ 422.2450(a) and 423.2450(a) we propose that CMS will provide at least 15 calendar days advance notice of its intent to conduct an audit of an MA organization or Part D sponsor. At §§ 422.2450(b) and 423.2450(b), we propose that all audits would include an entrance conference during which the scope of the audit would be presented and an exit conference during which the initial audit findings would be discussed. At §§ 422.2450(c) and 423.2450(c), we propose that all requested audit documentation would be provided by MA organizations or Part D sponsors to CMS within 30 calendar days of the audit entrance conference. CMS may extend, at CMS's discretion, the time for an MA organization or Part D sponsor to provide the documentation requested.

At §§ 422.2450(d) and 423.2450(d), we propose that CMS would share its preliminary audit findings with the MA organization or Part D sponsor, and the MA organization or Part D sponsor would then have 30 calendar days to respond to such findings. CMS may extend, at CMS's discretion, the time for an MA organization or Part D sponsor to submit such a response. At §§ 422.2450(e) and 423.2450(e), we propose that if the MA organization or Part D sponsor does not dispute the preliminary findings within the 30-day timeframe proposed at §§ 422.2450(d) and 423.2450(d), then the audit report becomes final. However, if the MA organization or Part D sponsor disputes the preliminary findings within the 30-day timeframe proposed at §§ 422.2450(d) and 423.2450(d), CMS would review and consider such response before finalizing the audit findings. At §§ 422.2450(f) and 423.2450(f), we propose that CMS would send a copy of the final audit report to the MA organization or Part D sponsor as well as issue corrective actions that the MA organization or Part D sponsor must undertake as a result of the audit findings. At §§ 422.2450(g) and 423.2450(g), we propose that if CMS determines as the result of an audit that an MA organization or Part D sponsor has failed to pay remittances it is obligated to pay pursuant to §§ 422.2470 and 423.2470, CMS may order the MA organization or Part D sponsor to pay those remittances in a manner consistent with new regulations §§ 422.2452 and 423.2452 described in the subsequent section of this proposed rule.

We seek comment on these proposals.

b. MLR Audit Remittance Process and Payment of MLR Audit Remittance

We propose to add §§ 422.2452 and 423.2452 to establish the process for notifying MA organizations and Part D sponsors of the MLR audit remittance and how the MLR audit remittance would be collected in association with MLR audit examinations.

To support these new regulations, we propose to amend §§ 422.2401 and 423.2401 to add two definitions relevant for the establishment of the MLR audit remittance process.

We propose to add a definition for the term *MLR audit remittance process,* which is the process by which CMS would calculate the MLR audit remittance for a contract that has failed to meet the 85 percent minimum MLR requirement as the result of an MLR audit examination and notify the MA organization or Part D sponsor about the remittance. The process includes collecting the MLR audit remittance indicated in the final audit report issued by CMS, receiving responses from MA organizations or Part D sponsors requesting an appeal of the MLR audit remittance, and taking actions to adjudicate an appeal (if requested) and receive MLR remittances from MA organizations and Part D sponsors.

Per these definitions, CMS would calculate and notify MA organizations and Part D sponsors of the MLR audit remittance associated with the MLR audit examination findings. In the new regulations, at paragraph (a) of §§ 422.2452 and 423.2452, we propose that CMS would send the final audit report to MA organizations and Part D sponsors with the MLR audit remittance, if applicable. Specifically, proposed paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) state that, if applicable, the notice would contain the following information: a MLR audit remittance; relevant banking and financial mailing instructions for MA organizations and Part D sponsors that owe CMS an MLR audit remittance that would be transferred to the Treasury General Fund; relevant CMS contact information; and a description of the steps for the MA organizations or Part D sponsor to request an appeal of the MLR audit remittance calculation.

At paragraph (b) of §§ 422.2452 and 423.2452, we propose to establish that MA organizations and Part D sponsors would have 15 calendar days from the date of issuance of the final audit report to request an appeal. We propose at paragraphs (b)(1) and (b)(2) of these new sections that, if an MA organization or Part D sponsor agrees with the MLR audit remittance, no response from the MA organization and Part D sponsor for that part of the audit report would be required, and that, if an MA organization or Part D sponsor does not request an appeal within 15 calendar days, CMS would not consider any subsequent requests for appeal of the MLR audit remittance.

At paragraph (c) of §§ 422.2452 and 423.2452, we propose to establish the actions that would take place if an MA organization or Part D sponsor does not appeal the MLR audit remittance. At paragraph (c)(1), we propose that an MA organization or Part D sponsor that owes money and does not appeal would have to remit payment in full within 120 calendar days from issuance of the final audit report. We further specify that an MA organization or Part D sponsor that does not appeal and does not remit payment within 120 calendar days of issuance of the final audit report would be subject to having any debts owed to CMS referred to the Department of the Treasury for collection.

If an MA organization or Part D sponsor does not appeal the MLR audit remittance indicated in the final audit report within 15 calendar days of the issuance of the final audit report, no subsequent requests for appeal would be considered.

We seek comment on these proposals.

c. Process for Appealing the MLR Audit Remittance

We propose to add §§ 422.2454 and 423.2454 to regulations to establish that an MA organization or Part D sponsor may request an appeal of the calculation of the MLR audit remittance amount and the process and requirements for making such a request associated with MLR audit examination findings.

At paragraph (a) of §§ 422.2454 and 423.2454, we propose to establish requirements that would apply to MA organizations' and Part D sponsors' requests for appeal of the MLR audit remittance calculation.

Specifically, at paragraph (a)(1), we propose to establish the process under which an MA organization or Part D sponsor could request reconsideration of the MLR audit remittance. We propose to specify that the 15 calendar day period for filing the request would begin on the date the final audit report from CMS is issued. We believe that would provide organizations with sufficient time to request an appeal, as MA organizations and Part D sponsors would be aware of the amounts that factor into the MLR audit remittance at the time the final audit report is issued. Requiring a request for appeal within this timeframe would help ensure accurate and timely payment of the MLR audit remittance.

CMS would not accept requests for appeal that are submitted more than 15 calendar days after the date of issuance of the final audit report. As noted previously, if an MA organization or Part D sponsor does not reply within 15 calendar days, they would be deemed to accept the MLR audit remittance indicated in the final audit report.

If an MA organization or Part D sponsor agrees with the MLR audit remittance, no response to that part of the audit exam report would be required. Failure to request an appeal within 15 calendar days of the date of issuance of the final audit report would indicate acceptance of the MLR audit remittance.

We also propose that MA organizations and Part D sponsors would have to include in their request: (1) the calculation with which they disagree and (2) evidence supporting the assertion that the CMS calculation of the MLR audit remittance is incorrect. We further specify that CMS would not consider, and MA organizations and Part D sponsors should not submit, new data or data that was submitted to CMS after the final audit report was issued, unless requested by CMS.

In addition, to establish a review process under which MA organizations and Part D sponsors may request a reconsideration of CMS's MLR audit remittance calculation, we propose to add two additional levels of appeal: (1) an informal hearing conducted by the CMS Office of Hearings to review CMS's determination, following a request for appeal of the reconsideration of CMS's determination, and (2) a review by the CMS Administrator of the hearing officer's determination if there is an appeal of the CMS hearing officer's determination. We believe that these levels of appeal would afford MA organizations and Part D sponsors sufficient opportunities to present objections to the calculation of the MLR audit remittance in MLR audit examinations.

At paragraph (a)(1)(iii), we propose to establish that the CMS reconsideration official would review the MLR audit remittance calculation and evidence timely submitted by the MA organization or Part D sponsor supporting the assertion that the CMS calculation of the MLR audit remittance is incorrect. We further propose to establish that the CMS reconsideration official would inform the MA organization or Part D sponsor of their decision on the reconsideration in writing and that their decision would be final and binding unless the MA organization or Part D sponsor requests a hearing officer review.

At paragraph (a)(2), we propose to establish that MA organizations and Part D sponsors that disagree with CMS's reconsideration decision under paragraph (a)(1) of this section would be able to request an informal hearing by a CMS hearing officer.

Specifically, at paragraph (a)(2)(i), we propose that MA organizations and Part D sponsors would have to submit their requests for an informal hearing within 15 calendar days from the date of issuance of the reconsideration decision. At paragraph (a)(2)(ii), we propose that MA organizations and Part D sponsors would have to include in their request a copy of CMS's reconsideration decision, the specific findings or issues with which they disagree, and the reasons for which they disagree. At paragraph (a)(2)(iii), we propose to establish the informal hearing procedures. Specifically, we propose that the CMS hearing officer would provide written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date and the CMS reconsideration official would provide a copy of the record of the reconsideration decision to the hearing officer. We further propose that the hearing would be conducted by a hearing officer who would neither receive testimony nor accept new evidence. We finally propose that the hearing officer would be limited to the review of the record that the CMS reconsideration official had when making the reconsideration decision. At paragraph (a)(2)(iv), we propose that the CMS hearing officer would send a written decision to the MA organization or Part D sponsor explaining the basis for the decision. At paragraph (a)(2)(v), we propose to establish that the hearing officer's decision would be final and binding, unless the decision is reversed or modified by the CMS Administrator.

We further propose to establish at paragraph (a)(3) that MA organizations and Part D sponsors that disagree with the hearing officer's decision would be able to request a review by the CMS Administrator.

At paragraph (a)(3)(i), we propose that MA organizations and Part D sponsors would have to submit their requests for a review by the Administrator within 15 calendar days of the date of the decision and may submit written arguments to the Administrator for review but would not be able to submit evidence in addition to the evidence submitted during CMS's reconsideration. At paragraph (a)(3)(ii), we propose that the CMS Administrator would have the discretion to elect or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. We further propose that if the Administrator declines to review the hearing officer's decision, the hearing officer's decision would be final and binding.

We propose at paragraph (a)(3)(iii) that, if the Administrator elects to review the hearing officer's decision within 30 calendar days of receiving the request, the Administrator would review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written arguments submitted by the MA organization or Part D sponsor, and determine whether to uphold, reverse, or modify the decision. At paragraph (a)(3)(iv), we propose that the Administrator's determination would be final and binding and no other requests for review would be considered.

At paragraph (b), we propose to establish the matters subject to appeal and that an MA organization or Part D sponsor bears the burden of proof. At paragraph (b)(1), we propose to establish that the MA organization or Part D sponsor appeal would be limited to CMS's calculation of the MLR audit remittance. At paragraph (b)(2), we propose that the MA organization or Part D sponsor would bear the burden

of proof by providing evidence demonstrating that CMS's audit examination findings for the MLR audit remittance are incorrect.

At paragraph (b), we propose to establish the matters subject to appeal and that an MA organization or Part D sponsor bears the burden of proof. At paragraph (b)(1), we propose to establish that the MA organization or Part D sponsor appeal would be limited to CMS's calculation of the MLR audit remittance. At paragraph (b)(2), we propose that the MA organization or Part D sponsor would bear the burden of proof by providing evidence demonstrating that CMS's audit examination results for the MLR audit remittance require further review. The MA organizations and Part D sponsors may not challenge the underlying methodology for the MLR audit remittance calculation.

Proposed paragraph (d) would clarify that nothing in this section would limit an MA organization or Part D sponsor's responsibility to comply with any other applicable statute or regulation.

We seek comment on these proposals.

d. MLR Audit Compliance Actions

To address issues of noncompliance as identified through an MLR audit, CMS would pursue certain actions depending on the audit results. If an audit examination finds inaccurate MLR data was reported and that the recalculated MLR (based on the audit finding(s)) is less than 85 percent, CMS proposes to determine remittances owed, send a remittance notice, issue a Corrective Action Plan (CAP) consistent with regulations §§ 422.504 and 423.505, and require a detailed response from the MA organization or Part D sponsor outlining how the plan would address the audit finding(s).

If an audit examination finds inaccurate MLR data was reported but the MLR remains greater than 85 percent when recalculated based on the audit finding(s), CMS proposes to issue progressive noncompliance actions consistent with the regulations at §§ 422.504(m) and 423.505(n), depending on the plan's previous record of compliance and the gravity of the violation (for example, violation frequency, level of financial impact). CMS also proposes to require the MA organization or Part D sponsor to address the audit finding(s) and explain the corrective actions they have taken or plan to take. CMS reserves the right to review the actual implementation of the MA organization's or Part D sponsor's plan to provide correct MLR data in future MLR annual reporting forms, examinations, or as otherwise may be appropriate, to ensure noncompliance issues are being or have been addressed.

Finally, we propose to amend §§ 422.2480(d) and 423.2480(d) to establish that if CMS finds MLR data to be reported in an untimely and inaccurate manner, we may pursue intermediate sanctions in accordance with 42 CFR part 422, subpart O and 42 CFR part 423, subpart O. This amendment will provide us with flexibility in the future to take additional actions if audit examinations uncover instances where MLR data is not reported in a timely and accurate manner in compliance with 42 CFR part 422, subpart X and part 423, subpart X. It will also encourage MA organizations and Part D sponsors to approach their MLR calculations with greater precision. We seek comment on this proposal.

6. Proposal To Change Medicare MLR Regulations Authorizing Release of Part C and Part D MLR Data (§§ 422.2490 and 423.2490)

Part C MLR data defined at § 422.2490(a) and Part D MLR data defined at § 423.2490(a) refers to the data the MA organizations and Part D sponsors submit to CMS in their annual MLR Reports, as required under existing §§ 422.2460 and 423.2460. For the purpose of the data release under §§ 422.2490 and 423.2490, we currently exclude certain categories of information from the release of Part C and Part D MLR data, as described at §§ 422.2490(b) and 423.2490(b). Specifically, CMS excludes four categories of information from the release of Part C and Part D MLR data. First, at §§ 422.2490(b)(1) and 423.2490(b)(1), we exclude from release any narrative information that MA organizations and Part D sponsors submit to support the amounts that they include in their MLR Reports, such as descriptions of the methods used to allocate expenses. Second, at §§ 422.2490(b)(2) and 423.2490(b)(2), we exclude from release any plan-level information that MA organizations and Part D sponsors submit in their MLR Reports. Third, at §§ 422.2490(b)(3) and 423.2490(b)(3), we exclude from release any information that could be used to identify Medicare beneficiaries or other individuals. Fourth, at §§ 422.2490(b)(4) and 423.2490(b)(4), we exclude from release any MLR review correspondence.

At §§ 422.2490(b)(6) and 423.2490(b)(6), we propose to add an exclusion to the data release, to exclude from release the DIR information reported within the MLR data as part of incurred claims. We are proposing this exclusion to align with the disclosure requirements regarding DIR data as required by section 1860D–15(f) of the Act.

7. Proposal To Exclude Medicare Prescription Payment Plan Unsettled Balances From the MLR (§§ 422.2420 and 423.2420)

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) made several additions and amendments to the Act that affect the structure of the defined standard Part D drug benefit. Section 11202 of the IRA (Maximum Monthly Cap on Cost-Sharing Payments under Prescription Drug Plans and MA–PD Plans) added a new section 1860D–2(b)(2)(E) to the Act requiring all Medicare prescription drug plans to offer their Part D enrollees the option to pay out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year instead of at the pharmacy point of sale (POS) beginning January 1, 2025. Section 1860D–2(b)(2)(E)(v)(VI) of the Act specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan ''shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.''

Section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS released guidance establishing critical operational and technical, and communication requirements for the Medicare Prescription Payment Plan for 2025. In the Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of section 1860D–2 of the Social Security Act for 2025, and Response to Relevant Comments, CMS established that, consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid, unsettled balances from the Medicare Prescription Payment Plan will be considered administrative costs for purposes of the MLR calculation and therefore be excluded from the MLR numerator.

CMS does not have program instruction authority to implement the Medicare Prescription Payment Plan beyond 2025, so we are pursuing rulemaking to codify the requirements of the program for 2026 and subsequent years. In this proposed rule, with respect to the treatment of unsettled balances from the Medicare Prescription Payment Plan, we propose to exclude unsettled balances from the Medicare Prescription Payment Plan from the

MLR numerator at §§ 422.2420(b)(4)(i)(D) and 423.2420(b)(4)(i)(D).

8. Request for Information on MLR and Vertical Integration

MLR reporting may be less transparent for integrated medical systems where the MA organization or Part D sponsor is a subsidiary, owner, or affiliate in such a system. In these situations, there may be reduced transparency when an MA organization or Part D sponsor reports an MLR based only on their own direct expenditures due to the relationships between these related entities and the potential that payments made to related parties may, in some cases, be inflated to ensure the MA organization or Part D sponsor meets its MLR reporting requirements, obscuring the actual MA and Part D-related profits made by the integrated system as a whole. Policymakers, MedPAC, and other researchers have raised concerns that large MA organizations are becoming more vertically integrated by acquiring hospitals, physician practices, pharmacy benefit managers, specialty pharmacies, and other related health care businesses.[227] [228] Furthermore, there is evidence that this vertical integration is associated with higher health and prescription drug expenditures.[229] [230]

In addition to the proposed regulatory changes, we are issuing a request for information seeking comment from the public on whether CMS could and should adopt policies, and if so, what potential policies it could or should adopt, regarding how the MA and Part D MLRs are calculated to help enable policymakers to address concerns surrounding vertical integration in MA and Part D. Based on the information we receive, CMS will consider additional rulemaking or guidance for future contract year rulemaking. Specifically, we are requesting comment, data, and examples regarding the following potential policies:

- Establish parameters in MLR reporting that limit the amount of transfer payments that are incurred between related parties that can be included in the numerator, such as by limiting the amount for any service included in the numerator to be under a relative benchmark.
- Revise definition of incurred claims to include profits earned by related parties as indirect remuneration to a Part D sponsor or MA organization and not allowable for inclusion in the MLR numerator.
- Revise definition of incurred claims to include payments that are net of direct or indirect remuneration by or to the Parent Organization, in addition to the Part D sponsor.
- Establish a framework for assessing transfer payments made to or by related parties by expanding related-party reporting requirements in the MLR. CMS specifically invites comment on the kind of information CMS could collect about transfer payments to be able to assess what portions of such payments should be reported in the MLR numerator.
- We also request comment on the type of information we could collect to better define types of vertical integration or related party relationships that exist in the health insurance market.
- Other frameworks or policies not enumerated here.

Please note that this is a request for information only and is issued solely for information and planning purposes.

9. Technical Correction (§ 422.2420)

In the course of this rulemaking, we noticed the need for a technical correction at regulation § 422.2420(c)(2)(iv), which specifies that Federal income tax-exempt MA organization community benefit expenditure payments may be deducted up to a specific limit when calculating the MLR. The regulation text currently refers to Part D sponsors in two places when it should refer to MA organizations, and thus we propose to make the correction.

10. Proposal To Add Provider Payment Arrangement Reporting in the Medicare MLR Reporting Regulations (§§ 422.2460 and 422.2490)

Alternative payment models (APMs) have become increasingly prevalent in the health care system.[231] In addition, CMS continues to test different value-based programs to pay providers based on quality, rather than quantity of care.[232] [233] [234] APMs are arrangements under which providers have added incentives to provide high-quality and cost-effective care, which can apply to a clinical condition, episode of care, or patient population.[235] Researchers and stakeholders, through the Request for Information on MA data, have raised concerns that there is limited public information available about APMs outside of Traditional Medicare.[236] [237] In addition, researchers have raised concerns that these payment arrangements may not be transparent and could lead to increases in reported claims spending in the Medicare MLR, particularly when the insurer and provider are the same business entity or very closely tied together.[238] Furthermore, stakeholders have called on CMS to collect more data on value-based payment arrangements between providers and plans. [239]

Therefore, to improve transparency and oversight of the use of Medicare Trust Fund dollars, we are proposing to collect additional details regarding plan expenditures categorized by different provider payment arrangements.[240] Building on the existing Medicare Part C reporting requirements, we propose simplified provider payment arrangement categories for ease of reporting as we believe the streamlined categories will provide sufficient information to help inform the accuracy of MLR submissions, and value of services provided to MA enrollees.[241] Specifically, we propose to amend § 422.2460(a) so the regulation text explicitly provides that the MLR report submitted to CMS includes aggregate expenditures by provider payment arrangement type in MA. Under our proposed amendment, paragraph (a) of § 422.2460 would state that, except as provided in paragraph (b), for each contract year, each MA organization must submit to CMS, in a timeframe and manner we specify, a report that includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract,

[227] *https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers.*

[228] *www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf,* page 45.

[229] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf,* page 17.

[230] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf,* page 365.

[231] *https://www.techtarget.com/revcyclemanagement/answer/Value-Based-Reimbursement-Grows-as-Providers-Take-on-More-Risk.*

[232] *https://hcp-lan.org/workproducts/apm-methodology-2023.pdf.*

[233] *https://www.cms.gov/medicare/quality/value-based-programs.*

[234] *https://www.cms.gov/priorities/innovation/about#:~:text=The%20CMS%20Innovation%20Center's%20models,Advantage%20or%20Medicare%20Part%20D.*

[235] *https://qpp.cms.gov/apms/overview.*

[236] *https://www.ajmc.com/view/all-payer-value-based-contracting-in-organizations-with-medicare-acos.*

[237] *https://www.regulations.gov/document/CMS-2024-0008-0001/comment.*

[238] *https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation/.*

[239] *https://www.govinfo.gov/content/pkg/FR-2024-01-30/pdf/2024-01832.pdf.*

[240] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-X/section-422.2420.*

[241] *https://www.cms.gov/files/document/cy2024-part-c-reporting-requirements.pdf.*

including the amount of incurred claims for Medicare-covered benefits, supplemental benefits, provider payment arrangements, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410.

If our proposal to amend our regulations to require additional MLR data is finalized, we intend to make changes to the MLR Reporting Tool. We will revise the MLR Reporting Tool to add separate fields to capture various categories of expenditures for provider payment arrangements. Specifically, we propose to collect the following sample list of three categories of provider payment arrangements ordered from lowest to highest financial accountability for providers: FFS, APMs, and population-based payments. These proposed categories of provider payment arrangements are based on the Health Care Payment Learning & Action Network (HCPLAN) APM framework and ongoing measurement effort in order to reduce the reporting burden on stakeholders.[242] FFS payment arrangements are typically based on FFS payments in which providers are paid for each service that is billed by the patient's insurer and may or may not be linked to pay-for-performance or quality payments to improve quality performance such as care coordination fees or bonuses for reporting data. APMs may include upside and/or downside risk such as shared-savings linked to utilization, a clinical episode, or procedure-based bundled payments. Providers who meet quality, and cost or utilization targets may receive shared savings, and/or be held financially accountable for missing performance measures designed to deliver care to patients at the right time, place, and level of intensity. Finally, in population based payments providers are paid through capitated payments for comprehensive treatment of specific conditions, bundled services such as oncology care, or a global budget that is not condition specific, but is linked to quality. These comprehensive payment arrangements are designed to pay providers a percentage of, or the full premium. Providers are then fully financially accountable for the delivery of person-centered care through coordinated preventive health, health improvement, acute and chronic care services.[243] [244]

We believe it is appropriate for CMS to retain flexibility to modify the scope of the data fields and the specific list of provider payment arrangements required to be reported on the MLR Reporting Template. Maintaining this flexibility will allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures and verify and increase accountability for the accuracy of MLR calculation. We believe the proposed amendment to § 422.2460(a) will provide us with the flexibility to modify the scope of data fields and categories required for expenditures under various provider payment arrangements. The intent of this proposed rule is not to create a static MLR report; rather this rule is intended to enable reporting requirements that support the program needs, such as supporting MLR calculation, verifying data reporting accuracy, gaining insight into expenditures under various provider payment arrangements, and providing transparency into program expenditures.

Modifications to the MLR data requirements for expenditures under provider payment arrangements will be set forth in a revision to the MLR Paperwork Reduction Act package (CMS–10476, OMB 0938–1232) and made available to the public for review and comment under the standard PRA process which includes the publication of 60- and 30- day **Federal Register** notices and the posting of the collection of information documents on our PRA website. The sample list of provider payment arrangements in the proposed rule should be viewed as examples of the types of categories CMS is interested in collecting based on the APM framework described above. We will set forth data reporting requirements in a revised package as required by the PRA. This package will be published in the **Federal Register** and be available for public comment.

We solicit comment on whether the sample list of categories of provider payment arrangements include the appropriate breakouts for separating out incurred claims in the MLR Reporting Tool. We are interested in feedback that addresses whether we should increase or decrease the number of categories, as well as suggestions for clarifications, alternative categories, or for consolidating categories. Given the differences in provider payment arrangements between MA and Part D, CMS is not proposing to add these requirements to the Medicare MLR reporting for the Part D portion of MA–PD plans or standalone Part D plans at this time at § 423.2460(a). We are interested in the extent to which the proposed payment arrangement reporting in the Medicare MLR report applies to Part D and potential provider payment arrangements for Part D.

Finally, we do not intend to release the provider payment arrangements data we collect publicly unless it is deidentified and reported as aggregate totals. Specifically, we propose to add an exclusion to the data release at § 422.2490(b)(7) to exclude any provider payment arrangement data that is not reported on a deidentified basis and that is not reported on an aggregate total basis. We solicit comment on whether there is additional sensitivity around expenditures under provider payment arrangements, such that public release of data concerning those expenditures would be harmful.

U. Enhancing Rules on Internal Coverage Criteria § 422.101

In the final rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) (hereinafter referred to as the ''April 2023 final rule''), we codified regulations that clarified the obligations and responsibilities for MA organizations in covering basic benefits and established guardrails for when MA organizations may develop and use coverage criteria to achieve better alignment with Traditional Medicare.[245] We clarified at § 422.101(b)(2) that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of basic benefits that must be covered by MA plans.[246] We codified requirements for making medical necessity determinations at § 422.101(c)(1), which includes using applicable coverage criteria in Traditional Medicare laws, CMS's national coverage determinations (NCDs), applicable local coverage determinations (LCDs), and—when Traditional Medicare coverage criteria are not fully established—internal coverage criteria. We also codified

[242] *https://www.cms.gov/priorities/innovation/innovation-models/health-care-payment-learning-and-action-network.*

[243] *https://hcp-lan.org/workproducts/apm-methodology-2023.pdf.*

[244] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

[245] 88 FR 22189.

[246] 88 FR 22187.

specific requirements at § 422.101(b)(6) that determine when MA organizations may use internal coverage criteria, what the criteria must be based on, and rules for making the internal coverage criteria publicly accessible. Finally, we codified enrollee protections related to the use of prior authorization (at § 422.112(b)(8)) and required MA organizations to establish a utilization management committee that reviews and approves all plan utilization management policies (at § 422.137). These rules were applicable to coverage for MA organizations beginning January 1, 2024.

Since the issuance of the April 2023 final rule, CMS has received numerous questions about the application of these rules. As a result, we issued a memo titled ''Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS–4201–F),'' on February 6, 2024 (hereinafter referred to as the ''February 2024 HPMS memo'') to provide answers to commonly asked questions and provide additional clarifying information to MA organizations about how these new rules apply to basic benefits. Additionally, through CMS account manager engagement with MA organizations, incoming inquiries from industry stakeholders, and our ongoing 2024 program audits, we have learned a great deal about common misunderstandings related to these new rules and where these new policies could be further clarified with additional rulemaking to achieve the intended goal of ensuring access to medically necessary care for MA enrollees. Therefore, we are proposing here to build upon and enhance the regulations from the April 2023 final rule, specifically those related to the use of internal coverage criteria, by defining the phrase ''internal coverage criteria,'' establishing policy guardrails to preserve access to basic benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites. MA organizations' coverage of and responsibility to provide basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA provisions. These proposals will further implement the requirements set forth in section 1852 of the Act and §§ 422.100 and 422.101, which require MA organizations to furnish all reasonable and necessary Part A and B benefits and are therefore proposed pursuant to CMS's authority under section 1856(b) of the Act.

1. Using Internal Coverage Criteria To Interpret or Supplement General Provisions

In the April 2023 final rule, we codified at § 422.101(b)(6)(i) that MA organizations may apply internal coverage criteria when coverage criteria under Traditional Medicare are not fully established in three specific circumstances. In § 422.101(b)(6)(i)(A), we explained that one circumstance when it is appropriate to use internal coverage criteria is when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. We required that MA organizations must demonstrate that the additional criteria the MA organizations apply provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. The NCDs and LCDs that MA plans must follow are developed through rigorous evidence review processes [247] with public input to identify gaps or lack of clarity in a proposed policy; as a result, the evidence-based coverage criteria are as specific as possible upon finalization. It is only in the rare instance when an NCD or LCD is lacking in specificity or clarity, that we would consider internal coverage criteria to be permissible to interpret or supplement general provisions under 422.101(b)(6)(i)(A). Our intent with this requirement was to allow MA organizations to interpret or supplement the *plain language* of existing and applicable Medicare coverage and benefit criteria (as stated in applicable Medicare statutes, regulations, NCDs, or applicable LCDs) when needed, but also only when the additional criteria protect patient safety and outweigh any risks of harm or decreased access to the items or services. However, we believe this regulatory text needs to be refined to more clearly state our intent about interpreting existing policies and to achieve our goal of protecting patients without decreasing access to medically necessary care.

First, we propose to replace the term ''general provisions'' at § 422.101(b)(6)(i)(A) with ''the plain language of applicable Medicare coverage and benefit criteria.'' The term ''general provisions'' was meant to encapsulate all forms of applicable Medicare coverage and benefit rules that exist in statute, regulation, NCD, or applicable LCD. These general provisions already exist as Medicare coverage policies at the time that the MA organization is required to apply them to make a determination about coverage. We propose to add the term ''plain language'' in regulation text to make it explicitly evident that internal coverage criteria may only be used to supplement or interpret already existing content within these Medicare coverage and benefit rules. In other words, internal coverage criteria cannot be used to add new, unrelated (that is, without supplementary or interpretive value) coverage criteria for an item or service that already has existing, but not fully established, coverage policies. This also supports the current requirement at § 422.101(b)(6)(ii)(C) that MA organizations must ''identify the general provisions that are being supplemented or interpreted'' in the publicly accessible material. It was our intent that the MA organization identify the *plain language* of the applicable Medicare coverage and benefit criteria that they are interpreting or supplementing in the publicly available material and provide an explanation of the rationale that supports the adoption and application of the internal coverage criteria. Therefore, we also propose to make conforming edits to the ''publicly accessible'' requirements at § 422.101(b)(6)(ii)(C) to replace the term ''general provisions'' with ''the plain language of applicable Medicare coverage and benefit criteria.''

Second, we propose to remove the existing requirement at § 422.101(b)(6)(i)(A) that the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. In our examination of publicly available internal coverage criteria since the rule became effective on January 1, 2024, we have found that an assessment about whether the criteria provide clinical benefits that are *highly likely to outweigh* any clinical harms is difficult to definitively prove through evidence and, as a result, enforce as a policy. We have observed numerous instances of MA organizations simply

[247] CMS National Coverage Analysis Evidence Review Guidance Document (August 7, 2024) *available at https://www.cms.gov/files/document/cms-evidence-review2024pdf.pdf;*; Revised Process for Making National Coverage Determinations 78 FR 48164 (August 7, 2013) *available at https://www.cms.gov/medicare/coverage/determinationprocess/downloads/fr08072013.pdf;* and Medicare Program Integrity Manual Chapter 13-Local Coverage Determinations (February 2, 2019) *available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.*

and baldly stating that their internal coverage criteria provide clinical benefits that are highly likely to outweigh any clinical harms, but we have not seen much in the way of evidence in the information provided by the MA organizations that definitively proves this to be true. Often, the clinical benefits that are cited by the MA organizations are simply the avoidance of potential risks or harms associated with the relevant healthcare item or service at issue. We have found that it is difficult to measure the probability that the criteria cited and applied by the MA organizations will (or may) have a net positive effect over the potential risks of not applying the criteria. Further, the qualitative explanations that the MA organizations have asserted as to why the benefits of the criteria used are highly likely to outweigh any harms are not often supported with reliable evidence. For these reasons, we propose to remove the ''clinical benefits that are highly likely to outweigh any clinical harms'' requirement in both § 422.101(b)(6)(i)(A) and (ii)(C), and replace it with two important policy guardrails in new paragraph (iv) that will apply to all internal coverage criteria adopted under paragraph (b)(6)(i)—not just internal coverage criteria that are authorized under § 422.101(b)(6)(i)(A).

As a possible alternative, we solicit comment on replacing the existing requirement at § 422.101(b)(6)(i)(A) that the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms with a requirement that the MA organization must demonstrate through evidence that the additional criteria explicitly support patient safety. We solicit comment on whether this approach is clearer than the current standard and how we could define patient safety in a way that MA organizations understand how to comply with the rule.

Finally, unrelated to our policy proposal to modify paragraph (A), we propose to make a minor change at § 422.101(b)(6)(i)(B) to state that NCDs or applicable LCDs include flexibility that explicitly allows for *discretionary* coverage by the MA organization in circumstances beyond the specific indications that are listed in an NCD or applicable LCD. The addition of the word ''discretionary'' is meant to make clear that when an NCD or applicable LCD provides flexibility for the Medicare Administrative Contractor (MAC) to cover or not cover the item or service beyond the specific indications listed, the coverage or non-coverage of the item or service by the MA organization is purely discretionary and is not guaranteed.

2. Definition of Internal Coverage Criteria

In the April 2023 final rule, we codified at § 422.101(b)(6) that MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. We further defined what we meant by ''coverage criteria are not fully established'' and ''publicly accessible'' at § 422.101(b)(6)(i) and (ii), respectively, but we did not provide a definition of ''internal coverage criteria.'' Over the past year, through engagements with stakeholders, we have found that various MA organizations have interpreted the meaning of ''internal coverage criteria'' differently. For example, some MA organizations are not aware that coverage criteria from third parties (entities other than CMS or the MA organization) can be considered internal coverage criteria of the MA organization when the organization adopts the criteria (or criterion) that contain policies or measures that cannot be found in Medicare laws, NCDs, or LCDs. Another MA organization believed that evidence found in articles or studies cited in the bibliography section of an LCD, but not discussed or listed in the coverage guidance section, could be applied as part of the LCD and not considered internal coverage criteria of the MA plan. A different MA organization wondered whether criteria and policies found in CMS manual guidance should be considered internal coverage criteria. Finally, some organizations are just not aware that their long-established coverage policies contain internal coverage criteria because they have been supplementing existing Traditional Medicare policies for years to fill in gaps where coverage criteria do not specify all possible circumstances where coverage of a Part A or Part B item or service may be available for a beneficiary. These are just some of the examples that we have been made aware of, and we believe there are other misunderstandings throughout the plan community. Therefore, we are proposing additional rules to define the term and clarify what CMS considers ''internal coverage criteria.''

We propose new regulatory text at § 422.101(b)(6)(iii) to provide clarity on these topics for MA organizations and to further protect beneficiaries by ensuring equal access to these basic benefits. More specifically, we propose to define internal coverage criteria as any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination at § 422.101(c)(1). We explain in regulation text that this includes any coverage criteria that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care.

First and foremost, we find it important to reiterate that internal coverage criteria are inherently ''internal'' to the MA plan that utilizes them because they are a policy, measure, tool, or guideline that does not exist in applicable Medicare coverage or benefit rules. Further, other MA plans are not required to use the criteria and therefore it would be an element of coverage specific to the MA plan. This includes criteria used to further interpret or supplement the plain language of applicable Medicare coverage and benefit criteria because any coverage criteria or guidelines that are not contained in the actual statutes, regulations, NCDs, or applicable LCDs, or addressed in CMS manual guidance interpreting or explaining such criteria or guidelines would be considered non-Medicare criteria. For example, using information or evidence to form coverage criteria not found in the plain language of an LCD, but found in an article or study cited in the bibliography of an LCD, would be an example of an MA plan using internal coverage criteria. Only coverage criteria and policies found in the NCD, applicable LCD, related statutes or regulations, or addressed in CMS manual guidance interpreting related statutes or regulations, are not subject to the rules at § 422.101(b)(6); all other coverage criteria applied by an MA organization would be considered internal coverage criteria.

Based on this proposed definition, we do not consider content and information found in CMS published manuals (*e.g.,* Medicare Managed Care Manual, Medicare Program Integrity Manual, Medicare Benefit Policy Manual) to be internal coverage criteria under § 422.101(b)(6). As we explained in the April 2023 final rule, these manuals contain significant explanations and interpretations of Traditional Medicare laws governing Part A and Part B benefits, most of it longstanding, to

provide instructions and procedures for day-to-day operations for those responsible for administering the Medicare program and making coverage decisions on individual claims. We expect that MA plans will consult these manuals without the burden of having to justify their clinical or evidentiary value as required for internal coverage criteria under § 422.101(b)(6) (both currently and under the revisions we are proposing).

We have also received questions from MA organizations about whether information in Referenced Local Coverage Determination articles are considered internal coverage criteria when used to make coverage decisions. Referenced Local Coverage Determination articles are issued by Medicare Administrative Contractors (MACs) to provide coding/billing guidelines and instructions for a particular LCD and do not contain coverage criteria; that is the role of the LCD. We have observed that MA organizations sometimes use these articles to see if specific item or service codes are contained in the article, and when the code is not listed, use the article as a basis to deny coverage. This is inappropriate because the LCD provides the criteria that must be satisfied for Medicare coverage; not the Referenced Local Coverage Determination article. Simply because an item or service code is not listed in the Referenced Local Coverage Determination article does not mean the item or service is not covered by the LCD. Additionally, Referenced Local Coverage Determination articles do not meet the standard of ''current evidence in widely used treatment guidelines or clinical literature'' because they do not exist to provide any clinical value. As a result, we clarify here that information contained in Referenced Local Coverage Determination articles may not be used as internal coverage criteria when making coverage decisions on basic benefits.

We clarify in the proposed regulation text at § 422.101(b)(6)(iii) that criteria developed by a third-party may be considered internal coverage criteria when used by an MA organization in making medical necessity determinations. If the third-party coverage criteria contain additional policies, measures, tools or guidelines that do not exist in Medicare statute, regulation, manual, NCD or LCD, it would be internal coverage criteria of the MA organization when used or relied upon for the purpose of making a medical necessity decision regardless of who developed or created the coverage criteria. We note that many third-party developers of coverage criteria have synthesized existing Medicare coverage criteria found in statute, regulation, or NCD/LCD into proprietary workflows or tools and have filled in gaps or supplemented the Medicare coverage policies with additional measures, parameters, or policies in an attempt to more clearly identify and specify when the item or services should be covered. We clarify in this proposal that the application of additional measures or policies or more specific parameters that further define Medicare coverage policies are the application of internal coverage criteria under § 422.101(b)(6)(i)(A) and, therefore, must meet all regulatory requirements at § 422.101(b)(6). In some circumstances, there may be multiple parts of an NCD or applicable LCD that are being supplemented or interpreted with internal coverage criteria by an MA plan. Every instance where the plain language of a Medicare coverage rule is interpreted or supplemented is considered internal coverage criteria, and each instance must be based on current evidence in widely used treatment guidelines or clinical literature and must be publicly accessible. Therefore, we expect MA organizations to work closely with these third parties to understand whether the proprietary third-party criteria contain any standards or requirements that go beyond what is found in existing Medicare coverage criteria. Later in this preamble, we will discuss proposed requirements for how MA organizations should identify items and services that contain internal coverage criteria by listing them on their internal websites.

One of the ways that internal coverage criteria can go undetected, and therefore would fail to be made publicly available by the MA organization as required by § 422.101(b)(6), is when the criteria are built into an algorithm or software tool that generates a decision without an explicit understanding by the MA organization of the underlying factors that were considered by that algorithm or software tool in the making of the decision. As mentioned in the February 2024 HPMS memo, an algorithm, artificial intelligence, or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made.[248] In section K of this proposed rule, we propose to define ''automated system'' as any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques, and exclude passive computing infrastructure. Considering this definition of automated system in the context of the February 2024 HPMS memo, the MA organization must understand whether any internal coverage criteria have been built into an automated system, and if so, the specific details of the criteria that are built into the tool must be publicly accessible and meet our evidentiary standards at § 422.101(b)(6). Furthermore, we are concerned that many automated systems can exacerbate discrimination and bias. An MA organization cannot avoid or evade responsibility for compliance with MA regulations and the MA contract by using these automated systems and the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all regulations and terms and conditions of the MA organization's contract with CMS.

In the proposed definition of internal coverage criteria to be added at § 422.101(b)(6)(iii), we use a non-exhaustive list of types of internal coverage criteria—called policies, measures, tools, or guidelines—that we have seen MA organizations use when making medical necessity determinations. Use of other terms to describe the internal coverage criteria would not change their underlying function and how they are used by MA organizations. Under the proposed definition at § 422.101(b)(6)(iii), internal coverage criteria include any coverage policies that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care. Again, these types of policies are only considered internal when they are not articulated in applicable Medicare coverage and benefit criteria. It is common that MA organizations have policies such as these for health care items or services that are not covered by applicable Medicare statutes, regulations, NCDs, or LCDs. These types of policies are often used to comply with section 1862(a)(1)(A) of the Act, which requires that Part A and Part B benefits be reasonable and necessary for

[248] February 2024 HPMS memo, page 2.

the diagnosis or treatment of illness, or injury, or to improve the functioning of a malformed body member. Additionally, MA organizations are required to have measures that prevent, detect, and correct fraud, waste, and abuse.[249] Since internal coverage criteria may be used to assess the appropriateness of the health care service and could result in the denial of a medical necessity decision, it is important that they be based on current evidence in widely used treatment guidelines or clinical literature and made publicly available.

It is important that we distinguish aspects of MA plan coverage that do not qualify as internal coverage criteria under the proposed definition. Utilization management processes and procedures are interventions that take place before, during, and after the clinical encounter[250] and include prior authorization (or pre-authorization), concurrent review, retrospective review, and claim review. MA organizations are required by section 1852(g)(1)(a) of the Act to have procedures for making determinations regarding whether an individual enrolled in the plan is entitled to receive a health service. Unless expressly prohibited by statute or regulation (for example, prior authorization for emergency services), MA organizations can decide which utilization management processes they wish to employ and are not required to follow or practice the same utilization management processes conducted by MACs in Traditional Medicare. These types of utilization management decisions about when to apply these interventions are not considered internal coverage criteria under § 422.101(b)(6); but internal coverage criteria applied during one of these interventions (*i.e.,* prior authorization) are subject to the rules at § 422.101(b)(6). For example, Traditional Medicare may not require prior authorization for a specific healthcare service, but an MA organization may require prior authorization to confirm the presence of diagnoses and ensure the service is medically necessary. (See § 422.138.) In this case, any internal coverage criteria applied as part of the prior authorization process will be subject to rules related to internal coverage criteria, but the ability of the MA organization to decide which items and services are subject to prior authorization is not subject to rules on internal coverage criteria at § 422.101(b)(6). Utilization management programs are necessary for MA organizations to manage the utilization of covered item and services and ensure that benefits are medically necessary in accordance with the statute and applicable regulations.

Another example of coverage policies that fall outside the scope of internal coverage criteria are coverage requirements that are based on whether a provider is in-network or out-of-network. An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services, are available and accessible under the plan. In other words, network-based MA plans may limit access to Medicare-covered items and services via networks, as long as those networks provide adequate enrollee access (see for example, §§ 422.112(a)(1) and 422.114(a)) to services consistent with standards required by section 1852 of the Act (and other applicable laws) and established by CMS. Therefore, if an enrollee obtains a health care service outside of the plan's specified network, it may be subject to non-coverage depending on the type of plan being offered (that is, Health Maintenance Organization, Preferred Provider Organization) and the MA plan's written policies on provider network coverage. Coverage limitations based on network status are not internal coverage criteria under the proposed definition.

3. Prohibitions

CMS understands that MA organizations need to have coverage policies to make consistent medical necessity decisions and that appropriate limitations on the use of these policies is necessary, so we are relying on our authority under sections 1856(b) and 1857(e)(1) of the Act to adopt regulatory limitations designed to implement and carry out the obligations of MA plans to cover benefits while protecting beneficiaries and ensuring their access to medically necessary covered benefits. Section 1852(a) of the Act requires MA plans to cover basic benefits and authorizes coverage of supplemental benefits. Ensuring access to covered benefits is an important policy goal for CMS in administering the MA program and we have concluded that it is necessary and appropriate to adopt specific requirements for how basic benefits are covered to ensure that MA enrollees receive the items and services for which benefits are available under Parts A and B. Therefore, based on these authorities, we are proposing two requirements that prohibit the use of all internal coverage criteria.

First, we propose at § 422.101(b)(6)(iv)(A) that a coverage criterion is prohibited when it does not have any clinical benefit, and therefore, exists to reduce utilization of the item or service. Section 1862(a)(1)(A) of the Act requires Traditional Medicare benefits to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. In the absence of an NCD or LCD, these decisions are made on a case-by-case basis after considering the individual's particular factual situation. MA plans must consider clinical circumstances in making a decision as to whether Part A and Part B items and services are reasonable and necessary as well. Under this proposed requirement that the criterion must have a clinical benefit, the internal criterion must have a value that contributes to a determination of whether the benefit is reasonable and necessary under the statute. For example, if the evidence supporting use of an internal coverage criterion is rooted in managing care to reduce utilization of an item or service to a less costly alternative without any clinical value to the patient, the internal coverage criterion would be a violation of this proposed rule.

Secondly, we propose at § 422.101(b)(6)(iv)(B) that internal coverage criterion is prohibited when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination as required at § 422.101(c)(1)(i). Internal coverage criteria that neither considers the individual medical necessity of the patient nor the clinical effectiveness of the care would be inconsistent with sections 1862 and 1852(g)(1)(A) of the Act. For instance, a coverage criterion that establishes a blanket policy to automatically deny access to a covered benefit in every circumstance without consideration of the enrollee's medical history, physician's recommendations, clinical notes, and when appropriate, involvement of the organization's medical director would be a violation of this rule. Unless there is current evidence as described at § 422.101(b)(6) that the health care item or service is experimental or investigational, we would view this blanket policy as being designed to reduce the utilization of the item or service, establishing a barrier to potentially medically necessary care without the MA organization making an individual medical necessity

[249] 42 CFR 422.503(b)(4)(vi).

[250] *https://www.ncbi.nlm.nih.gov/books/NBK560806/.*

determination as required by law. This proposed rule is intended to ensure that MA enrollees have equal access to Part A and Part B benefits as other Medicare beneficiaries and that any coverage criteria used by the MA plan is done so in accordance with principles that support the reasonable and necessary standard under the Act.

Both prohibitions being proposed herein at 422.101(b)(6)(iv), which apply to all internal coverage criteria used by an MA organization, provide important guardrails to ensure appropriate access to benefits in a way that CMS can objectively measure with evidence. We solicit comment on whether there are other prohibitions on internal coverage criteria that CMS should consider that support and promote access to medically necessary care in the MA program. We remind MA organizations that section 1852(b) of the Act and § 422.110(a) prohibit an MA organization from denying, limiting, or conditioning the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status. Additionally, § 422.100(f)(2) provides that plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. As a result, an MA organization that uses internal coverage criteria must comply with section 1852(b) of the Act, § 422.110(a), and § 422.100(f)(2) and may not discriminate on the basis of any factor that is related to the enrollee's health status. CMS will continue to conduct routine monitoring and auditing of MA organizations, and through these processes, may discover that internal coverage criteria are being used that do not comply with rules at § 422.101(b)(6) or the anti-discrimination rules mentioned herein. In these circumstances, CMS will utilize its current compliance and enforcement processes to determine if any action should be taken for the non-compliance and to remediate the issue. We have strengthened our audit processes and will consider new compliance and reporting activities to examine MA organization's compliance with these proposed rules.

4. Public Availability

In the April 2023 final rule, we codified at § 422.101(b)(6)(ii) that when MA organizations use internal coverage policies, they must provide the internal coverage criteria in use, a summary of evidence that was considered during the development of the criteria, a list of sources of such evidence, and an explanation of the rationale that supports the adoption of the coverage criteria in a publicly accessible way. We did not require specific mechanisms for how the information must be made publicly accessible in an effort to provide MA organizations flexibility in complying with these new requirements. We further explained in the February 2024 HPMS memo that MA organizations are required to have a website under § 422.111(h)(2) and that use of that website for purposes of posting this information is appropriate. We further elaborated in the memo that publicly accessible means generally accessible to CMS, enrollees, providers, researchers, and other stakeholders without undue burden. Transparency in this area provides a measure of protection for enrollees and assurances that the coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature.

With the importance of this protection in mind, we propose to add more structure and detail to the public accessibility requirements to ensure that MA organizations are making this information available in a manner that is routinized and easy to follow. However, before we discuss the details of newly proposed requirements, first we propose to make an update to the terminology used in § 422.101(b)(6) to change the term ''accessible'' to ''available.'' We understand that ''accessible'' has other meanings and there are specific requirements for accessibility of online materials under section 504 that could make the term particularly confusing in this context. We believe that ''available'' more accurately describes our intent, which is that the information is publicly available to the people who need it. Therefore, we propose to update § 422.101(b)(6) and § 422.101(b)(6)(ii) by replacing the word ''accessible'' with ''available.'' This change does not negate or alter the obligations of MA organizations to ensure accessibility of online materials in accordance with section 504 or other laws.

Over the course of the past year, we have reviewed numerous MA organization websites to observe how they are posting the currently required content. We have seen a variety of different approaches; some with dedicated web pages that organize the Medicare item or service by vendor, and others that build the required content into very detailed coverage policy documents. Both approaches often include hyperlinks to vendor criteria that contain the content required under § 422.101(b)(6)(ii). In total, we have found that the average person faces difficulty accessing an MA organization's website for the purpose of determining whether or not the MA plan applies internal coverage criteria to the particular Medicare item or service. Therefore, we are proposing requirements to make this required information more understandable, readable, and easier to locate.

First, for consistency in terminology, we propose to update § 422.101(b)(6)(ii) which currently states, ''For internal coverage policies . . .'' to read ''For internal coverage *criteria.*'' Second, we are proposing to update the requirements in paragraphs (b)(6)(ii)(A)–(C) to be more specific about the information that must be publicly accessible. In paragraph (A), which requires posting each internal coverage criterion in use, we are adding that each internal coverage criterion used by the MA organization in making medical necessity decisions on Part A and Part B benefits must be clearly identified and marked as internal coverage criterion of the MA plan within coverage policies. We often see internal coverage criteria that are intertwined with, or that expand upon, NCD or applicable LCD coverage policies without any acknowledgement that the MA plan is applying additional criteria beyond what is found in the applicable NCD or LCD. Therefore, we are requiring that MA organizations examine and identify each internal coverage criterion being used and mark or label it as such within their policy documents for readers to understand that the specific internal criterion noted is being applied and may be specific to the MA plan. We are updating the word ''criteria'' to ''criterion'' to make it clear that we expect each single coverage criterion used to be listed and identified, noting that there may be more than one criterion that is applied to a given regulation, NCD, or applicable LCD. In paragraph (B), we are proposing to add to the list of evidence that supports the coverage criterion by requiring that the evidence be connected to the internal coverage criterion with a corresponding footnote. This will allow readers to understand which evidence supports the use of which internal coverage criterion within the coverage policies. In paragraph (C), we are making corresponding edits to mirror the proposed changes previously discussed in § 422.101(b)(6)(i)(A) by replacing ''general provisions'' with ''the plain language of applicable Medicare coverage and benefit criteria'' and

removing the ''clinical benefits that are highly likely to outweigh any clinical harms'' requirement. Additionally, we are changing ''criteria'' to ''criterion'' in § 422.101(b)(6)(ii)(C) to make it clear that we require an explanation of the rationale that supports adoption of each individual internal coverage criterion in use.

In new paragraph (D), we are proposing that by January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. The list of items and services on the website must include the information in paragraph (b)(6)(ii)(A) through (C) (explicitly or by connecting directly to that information through a hyperlink) and include the vendor's name when using a third-party vendor's criteria. The MA organization's internal coverage criteria web page must be displayed in a prominent manner and clearly identified in the footer of the website. The web page must be easily available to the public, without barriers, including but not limited to ensuring the information is available free of charge, without having to establish a user account or password, without having to submit personal identifying information, in a machine-readable format with the data contained within that file being digitally searchable and downloadable, and include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access. We believe that by making this information more easily available to automated searches and data pulls, it will help third-parties and researchers conduct studies to examine the clinical value of the internal coverage criteria being used by MA plans.[251]

In addition to the public posting of this content, we are considering an annual reporting to CMS of the information in § 422.101(b)(6)(ii)(A)–(D) under our reporting requirements listed at § 422.516(a). We believe this information is critical to ensuring appropriate access to Part A and Part B benefits in the MA program and there is value in comparing use of internal coverage criteria across all MA organizations. CMS would specify the format and collection of this information through the normal Paperwork Reduction Act (PRA) process. Further, we solicit comment on whether CMS should require a specific format for the information posted on the MA organization website and whether a standard template for the posted information would be helpful.

Finally, we do not expect that any of the regulatory changes proposed in this section will have an impact on the Medicare Trust Fund. Use of internal coverage criteria by MA organizations is optional, and when used, helps MA organizations make consistent medical necessity decisions that are aligned with coverage rules in Traditional Medicare. We believe that most MA organizations are using internal coverage criteria that are supported by current evidence in widely used treatment guidelines or clinical literature, and therefore we do not believe that these regulatory proposals will significantly change utilization patterns of Part A or Part B items or services. These changes and protections promote transparency across MA organizations so enrollees can make informed choices on plan selection and know when to appeal an adverse coverage decision, and providers can be informed about the criteria they must satisfy when seeking coverage of items and services on behalf of their patients.

If finalized, these proposed rules would be applicable beginning January 1, 2026. We solicit comments on all aspects of these proposals.

V. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, 422.572, 422.616, and 422.631)

We are proposing four modifications to existing regulations at 42 CFR part 422, subpart M, to clarify and strengthen existing rules related to organization determinations. First, we are proposing to clarify the rule that if an enrollee has no further liability to pay for services furnished by a Medicare Advantage (MA) organization, a determination regarding these services is not subject to appeal. Specifically, we are clarifying that an enrollee's further liability to pay for services cannot be determined until an MA organization has made a determination on a request for payment. Second, we are proposing to modify the definition of an organization determination to clarify that a coverage decision made by an MA organization contemporaneously to when an enrollee is receiving such services, including level of care decisions (such as inpatient or outpatient coverage), is an organization determination subject to appeal and other existing requirements. Third, we are proposing to strengthen the notice requirements to ensure that a provider who has made a standard organization determination or integrated organization determination request on an enrollee's behalf, or when it is otherwise appropriate, receives notice of the MA organization's decision. Finally, we are proposing a change to the reopening rules to curtail an MA organization's authority to reopen and modify an approved authorization for an inpatient hospital admission on the basis of good cause for new and material evidence. We address each of these proposals in detail below.

1. Clarifying When a Determination Results in No Further Financial Liability for the Enrollee (§ 422.562)

Section 1852(g)(1)(A) of the Social Security Act (the Act) requires an MA organization to have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) that the individual is required to pay with respect to such service. Under section 1852(g)(2) of the Act, an MA organization must provide for reconsideration of an adverse determination upon an enrollee's request. The existing regulations at part 422, subpart M set forth the administrative appeals process available to enrollees who wish to dispute an organization determination made by an MA organization. Section 422.562(c) describes limits on the applicability of the administrative appeals process in part 422, subpart M. The limitation in § 422.562(c)(1) states that if an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care, then the enrollee is not entitled to review of that issue by the MA organization. The second limitation at § 422.562(c)(2) states that if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

The organization determination and reconsideration regulations of part 422, subpart M broadly distinguish between two categories of decisions: coverage decisions (that is, a decision on whether the MA organization will furnish, authorize, or arrange for an item, service, or Part B drug) and payment decisions (that is, a decision whether to pay or deny payment for services furnished to an enrollee). These divergent categories of organization determinations have distinct requirements related to processing timeframes (including the applicability of processing timeframe extensions), the

[251] We also note that the requirements for accessibility of online materials under Section 504 of the Rehabilitation Act apply to this information as well. See 29 U.S.C. 794; 45 CFR pt. 84.

parties eligible to submit an organization determination or reconsideration request, notice requirements, and whether an MA organization must expeditiously process an organization determination or reconsideration request upon receiving a valid request.

When a coverage request is received, or when the MA organization issues an unsolicited coverage decision related to ongoing services, the MA organization will apply applicable coverage criteria and either approve, furnish, arrange for, or deny coverage for the services at issue. An approved coverage decision should result in the enrollee receiving the services at issue and the MA organization making payment to the treating provider when a request for payment is eventually submitted. When a request for payment for furnished services is received without a previously approved coverage decision, the MA organization will apply coverage criteria and must either make payment or deny the request within the timeframes specified in the ''prompt payment'' provisions of § 422.520. In addition, the MA organization must calculate the enrollee's applicable cost-sharing and/or financial liability for the furnished service (when issuing a partially or fully adverse decision) including considering applicable beneficiary protections related to plan-directed care. ''Plan-directed care'' occurs when a contracted provider furnishes a service or refers an enrollee for a service that an enrollee reasonably believes is a plan-covered service. Upon receiving plan-directed care, an enrollee cannot be financially liable for more than the applicable cost-sharing for that service (see § 422.105). Accordingly, under existing § 422.562(c)(2), if a payment determination related to services furnished by a MA organization results in no remaining financial liability for the enrollee, including adverse decisions that fall within the plan-directed care beneficiary protections, the decision is not subject to the appeal requirements of part 422, subpart M.[252] This means that neither the enrollee nor any other party may appeal an adverse payment decision under subpart M after an MA organization determines the enrollee is not financially liable for more than the applicable cost-sharing of the services for which payment was requested.[253]

CMS has historically interpreted the limitations of § 422.562(c)(2) to apply to payment determinations, not coverage decisions (that is, those addressed under § 422.566(b)(3) and (4)). From a practical perspective, a coverage decision will affect the care an enrollee is to receive or is receiving in addition to the enrollee's cost-sharing liability. Nevertheless, we have identified that some MA organizations misapply the appeal limitation provision of § 422.562(c)(2) to certain coverage decisions, specifically those related to an enrollee's inpatient admission or level of care. These MA organizations often improperly label these adverse coverage decisions as ''contractual denials'' or ''payment decisions'' even though no request for payment has been submitted and, oftentimes, the services are still being rendered at the time of the MA organization's decision. We have seen instances, for example, where an MA organization will deny an enrollee coverage for ongoing inpatient services being received in a contracted hospital and take the position that because MA beneficiary protection policies on plan-directed care prevent the enrollee from being financially liable for more than their applicable cost-sharing, when a request for payment is ultimately submitted, § 422.562(c)(2) prevents the enrollee from appealing the coverage denial. Consequently, these enrollees are left without an avenue to appeal decisions that directly affect their immediate medical care and may also alter the amount of their applicable cost-sharing if the enrollee's level of care is changed from inpatient to outpatient during their hospital stay. Further, the application of § 422.562(c)(2) in this manner may also contravene section 1852(g)(2) of the Act which requires MA organizations provide reconsideration of denials of enrollee coverage, in whole or in part, upon request by the enrollee involved.

To eliminate potential confusion related to identifying when organization determinations may not be appealable due to the lack of enrollee financial liability, we propose modifying § 422.562(c)(2) to clarify that the provision is only applicable to contracted provider payment disputes arising from a claim payment decision in which the enrollee has no additional financial liability. The reference to ''no further liability to pay'' in 422.562(c)(2) means the enrollee's financial liability will not be affected by whether the payment determination is upheld or overturned. In scenarios where an enrollee may still have a balance due for their cost sharing amount, this amount would not be considered ''further liability to pay'' if this amount would not be affected by resolution of the payment dispute.

Specifically, we are proposing to modify this paragraph to state that, based on an MA organization's determination on a request for payment, if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal. In other words, we are proposing to clarify that this limitation is only applicable if there's been a claim payment determination, which necessarily requires a submission of a claim or other request for payment from a contracted provider or enrollee. Coverage decisions, whether approved or denied, will continue to be subject to the subpart M appeals process. Under our proposal, an enrollee would be considered potentially liable to pay for a service until the MA organization makes a determination in response to a request for payment, including the submission of a provider's claim for the furnished service.

We believe the proposed clarification to § 422.562(c)(2) properly reestablishes the intent to exclude contracted provider payment appeals from the subpart M administrative appeals process when the enrollee no longer has any interest in the dispute because the enrollee has received the services in question and has no further liability to pay for those services. In addition, the proposed clarification would safeguard enrollees' right to appeal adverse coverage decisions that may affect the type, duration, or level of services to be, or being, furnished. However, simply because a payment decision does not implicate the subpart M administrative appeals process, an MA organization is not discharged of its obligation to pay its contracted providers for services

[252] We note that a state Medicaid agency has a specific right to appeal an adverse payment decision for a qualified Medicare beneficiary (QMB) or other full-benefit dually eligible individual for services in which the state Medicaid agency has made payment or may be liable, pursuant to § 405.908 and incorporated into part 422, subpart M through § 422.562(d)(1). The right for a state Medicaid agency to appeal an adverse payment decision may exist even when § 422.562(c)(2) would otherwise preclude the right to appeal.

[253] We note that the provision at § 422.562(c)(2) only applies to services ''furnished by an MA organization'' which, as we have explained, generally occurs when a contracted provider, as an agent of the MA organization, renders covered services to an MA organization's enrollee. Section 422.562(c)(2) does not limit the right for parties to appeal adverse payment determinations related to services provided by a non-contracted provider as non-contracted providers are not considered agents of an MA organization due to the lack of a mutual contractual relationship. Instead, non-contracted providers may become assignees of an enrollee by formally agreeing to waive any right to payment from the enrollee, in accordance with § 422.574(b), and then may utilize the administrative appeals process established at §§ 422.578 through 422.616 to appeal adverse payment determinations in their capacity as an assignee of the enrollee.

rendered. Section 1852(a)(1) of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or *making payment for* (emphasis added), all items and services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. We expect MA organizations to establish networks of providers to deliver plan-covered benefits and pay them in accordance with terms of the contracts established. Failure to abide by contract terms and contract disputes can have a negative impact on providers, their ability to properly deliver benefits, and ultimately adversely impact patients in the health care system.

2. Clarifying the Definition of an Organization Determination To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138 and 422.566)

Section 1852(g)(1)(A) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive health services or payment under the program. In accordance with section 1852(g)(1)(A) of the Act, §§ 422.566 through 422.572 establish the requirements related to organization determinations. Existing § 422.566(b) defines an organization determination as any determination made by an MA organization that falls within a prescribed set of discrete actions. These include, at subsection (b)(3), an ''MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization'' and, at subsection (b)(4), the ''[r]eduction, or premature discontinuation, of a previously authorized ongoing course of treatment.'' Taken collectively, this means an organization determination may be made prior to the receipt of services (for example, prior authorization), after the receipt of services (for example, payment requests), or during receipt of services (for example, continuation or termination of services) the enrollee receives from either contracted or non-contracted providers.

An ''organization determination,'' as defined by § 422.566, is a decision ''regarding the benefits an enrollee is entitled to receive under an MA plan . . . and the amount, if any, that the enrollee is required to pay for a health services'' to include, among other actions, ''the MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.'' When an MA organization makes an adverse organization determination (for example, denying coverage for a service), it must adhere to certain requirements that include providing notice of the decision to the enrollee in a format prescribed by CMS (see § 422.568(e)), within designated timeframes (see §§ 422.568 and 422.572), and, if the adverse decision was based on medical necessity, ensuring the decision was reviewed by a physician or other appropriate heath care professional with expertise in the field of medicine appropriate for the services at issue (see § 422.566(d)). In accordance with § 422.576, an ''organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.'' An enrollee or physician who is acting on behalf of the enrollee (regardless of their affiliation with an MA organization) may request an expedited reconsideration of an adverse organization determination concerning the type or level of services that the enrollee believes they should receive (see §§ 422.578 and 422.584(a)). However, pursuant to § 422.562(c)(2), if an ''enrollee has no further liability to pay for services that were furnished by the MAO, a determination regarding these services is not subject to appeal.''

Historically, we have interpreted the definition of an organization determination to include when an MA organization makes a coverage decision on the appropriateness of an inpatient admission, or the appropriateness of inpatient services (that is, a level of care determination), contemporaneously with an enrollee's receipt of the services at issue. This would be true whether the MA organization ultimately approved the enrollee's admission to a facility, determined that the enrollee's level of care in the same facility should be reduced, or determined that the enrollee should be discharged (see §§ 422.620 through 422.624). Accordingly, these decisions would have to comply with all applicable notice and appeal requirements for organization determinations and would be binding on all parties unless they are reconsidered under §§ 422.578 through 422.596 or are reopened and revised under § 422.616.

We acknowledge that many MA organizations understand these decisions are organization determinations subject to the existing rules in subpart M including, but not limited to, timely notice of the decision. However, through routine audits, feedback from the provider community, and discussions with MA organizations, CMS has identified circumstances where some MA organizations have misinterpreted the organization determination provisions to exclude decisions that rescind a previously authorized inpatient admission, deny coverage for inpatient services, or downgrade an enrollee's hospital coverage from inpatient to outpatient (often either simultaneously denying inpatient coverage while approving coverage for outpatient observation services or instructing the provider to only bill for outpatient services when submitting a subsequent claim), when the decision is made concurrently to the enrollee receiving such services. These types of decisions most often occur while enrollees are receiving inpatient services in an in-network hospital and are at times referred to as ''concurrent review decisions,'' ''level of care determinations,'' ''clinical utilization review decisions,'' or ''inpatient authorization denials.'' For the sake of clarity and consistency in describing these types of decisions, we will use the term ''concurrent review'' for purposes of this rulemaking.

We understand MA organizations conduct concurrent review on hospitalizations and other services that require review for continued care, such as long-term care stays in SNFs, LTACHs, or IRFs, HHA services, partial hospitalizations, or intensive outpatient programs. Such review includes utilization management activities that occur during inpatient level care, post-acute care, or an ongoing outpatient course of treatment. In general, the concurrent review process includes obtaining necessary clinical information from the treating physician and other providers to determine medical necessity based on the clinical status of the enrollee and applicable Medicare coverage criteria. Concurrent review involves the evaluation of the appropriateness of the ongoing level of care, including decisions related to the extension of previously approved care.

We offer the following example to illustrate a common scenario we have seen, although we note that certain details may vary depending on the MA organization making the decision. An enrollee will present to an in-network hospital and the treating physician will order the enrollee admitted to an inpatient status. During the admission process, the hospital will provide the enrollee's MA organization with a Notice of Admission, in accordance with the contract between the hospital

and MA organization, that alerts the MA organization of the admission but (in most circumstances) does not request approval for the admission. After receiving the Notice of Admission, the MA organization will monitor the enrollee's condition by reviewing the medical documentation on its own accord and, when applicable, will notify the hospital that it has made an adverse concurrent review decision related to the enrollee's inpatient admission or receipt of inpatient services on the basis that the enrollee's condition does not meet certain inpatient coverage criteria. Accordingly, if the hospital submits an inpatient claim for the services, whenever it ultimately submits a request for payment, the MA organization will automatically deny payment for inpatient services based on the concurrent review decision. In its concurrent review decision, the MA organization may either approve outpatient observation services for the enrollee or suggest that the hospital bill the entire hospital stay as outpatient services. If the treating physician disagrees with the decision, the physician may engage the MA organization in a peer-to-peer discussion with a plan physician or may appeal using the plan's internal dispute resolution processes.[254] It is important to note that in many circumstances the MA organization does not inform the enrollee of the concurrent review determination and the enrollee is not afforded the opportunity to appeal the decision (or have an appeal submitted on their behalf) as required. The result of the concurrent review is the hospital may either continue to provide non-covered inpatient services or it may reclassify the enrollee's hospital status from inpatient to outpatient. Many times, the enrollee does not know a change in status has occurred until they are required to pay the outpatient deductible and applicable cost-sharing.[255]

We have seen several different justifications for why an MA organization may not process a determination to deny an enrollee's inpatient admission, or deny coverage for inpatient services, made concurrently to the provision of such services under the requirements for other organization determinations. Some MA organizations have posited that these concurrent reviews are outside the definition of an organization determination because the timing of the decision is made during an ongoing course of treatment. These MA organizations appear to mistakenly believe that the existing definition of an organization determination is limited to decisions made before services begin and payment decisions that are made after a claim is submitted, and thus, a decision on inpatient coverage made concurrent to the services being rendered does not meet the definition of an organization determination or need to comply with the applicable organization determination notice and appeal right requirements.

We have also seen other situations where an MA organization appropriately considers the downgrading of an enrollee from receiving inpatient to outpatient services as an organization determination and yet will still fail to provide proper notice of the decision to the enrollee, process a timely appeal request, or both. We have received many complaints from the provider community that when the enrollee's treating physician requests an expedited reconsideration of an adverse concurrent review decision, pursuant to § 422.578, the MA organization will not process the appeal for a myriad of reasons. Some MA organizations have concluded that a level of care denial is not an appealable subject matter, while others believe reconsideration requests may not be processed while an enrollee is receiving the services at issue. The most common reason cited by plans for not processing appeals of adverse concurrent review decisions is the erroneous view that concurrent reviews made while an enrollee is being treated in an in-network hospital are ''contractual denials'' that are ineligible for review under the administrative appeals process of part 422, subpart M. This line of reasoning relates to the provision at § 422.562(c)(2) which states that ''[i]f an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.'' MA organizations reason that because contracted providers are contractually restricted from billing the enrollee for denied services and must accept the contractual payment as ''payment in full,'' coupled with the enrollee protections against financial liability at §§ 422.504(g) and 422.562(c)(2), a concurrent review decision will ultimately result in the enrollee having no further financial liability for the inpatient services being rendered so there is no right to appeal the decision. As we have explained in section III.W.1. of this proposed rule, this interpretation overlooks the fact that the MA organization has made an adverse decision on the authorization or provision of inpatient services which not only impacts the type of care the enrollee receives but also directly impacts the amount of deductible and cost-sharing for which the enrollee is liable, when a request for payment is eventually submitted.

CMS does not agree with the above interpretations of the existing organization determination and appeal regulations of part 422, subpart M. In the past, we have addressed these types of misinterpretations and non-compliance by MA organizations on a case-by-case basis as those issues were presented to us. However, we realize that the inconsistent application or misapplication of MA policies governing concurrent review is becoming increasingly varied and widespread across the industry, creating substantial confusion to MA organizations and, at times, variable outcomes to providers and enrollees. In addition, we recognize that the direct consequence of the misapplication of MA policies is that many enrollees do not receive notice of a decision to downgrade their level of care from inpatient to outpatient, nor are they given opportunity to appeal such decisions as provided under § 422.562(b)(4) (the right to a reconsideration of an adverse organization determination by an MAO). After considering other options available to CMS to clarify this matter, including increasing outreach and updating non-regulatory guidance, we decided the most appropriate and effective manner to address this issue is to clarify and strengthen the existing

[254] We have received conflicting information on the nature of peer-to-peer discussions from MA organizations. Some describe the process as solely educational in nature and that it has no bearing on the prior decision. Other MA organizations appear to use the discussion either to supplement or as a part of a contracted provider's appeal.

[255] We note that because an adverse concurrent review decision is a denial of inpatient hospital coverage, such a decision could also affect an enrollee's eligibility for covered post-hospital extended care services furnished in a skilled nursing facility (SNF). Section 1861(i) of the Act requires Medicare beneficiaries receive at least 3 consecutive days in a covered inpatient hospital stay within the preceding 30 calendar days in order to qualify for covered skilled SNF care. While we understand that most, if not all, MA organizations currently waive this coverage requirement, they are not required to continue to do so in future plan years. Therefore, if an MA organization that does not waive the 3-day inpatient hospital stay requirement makes an adverse concurrent review decision, the enrollee may not accrue the 3-day inpatient hospital stay necessary to receive covered skilled SNF care they otherwise could receive. A similar impediment to covered skilled SNF care could occur for enrollees that have opted into Traditional Medicare for the following year when an adverse concurrent review is made in the last 30 days of the plan year.

requirements related to organization determinations.

We, therefore, propose to clarify that decisions made based on the review of an enrollee's need for continued care, commonly known as concurrent review, are organization determinations under the rules at § 422.566(b). Specifically, we are proposing to revise § 422.566(b)(3) to clarify that a decision by an MA organization made pre-service, post-service, or concurrent with the enrollee's receipt of services in an inpatient or outpatient setting is an organization determination subject to the rules in part 422, subpart M which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights. We note that while the primary focus of the above discussion relates to the denial of inpatient hospital coverage as a result of an MA organization's concurrent review, our proposed clarification to the definition of an organization determination is inclusive of all other types of services.

In addition to adding a reference to decisions made concurrently to the enrollee's receipt of services, we are also proposing to add to § 422.566(b)(3) a reference regarding applicable decisions made prior to the enrollee's receipt of services and after the services have been completed. Similar to our previous discussion related to concurrent review, we propose these additions to clarify that the subject-matter of an MA organization decision dictates whether it has made an organization determination, regardless of when in the continuum of an enrollee seeking and receiving covered medical care the decision is made. We use the term pre-service in proposed § 422.566(b)(3) to refer to a request for an MA organization to approve coverage for a service before the service is received by the enrollee. An enrollee, enrollee's representative, or a provider on behalf of an enrollee, has the right to request the enrollee's MA organization approve an item, service, or Part B drug in circumstances where there is a question whether the item, service, or Part B drug will be covered. This right to receive prior approval applies to services for which an MA organization may require prior authorization as a condition for coverage as well as services for which there is no prior authorization requirement. When an MA organization receives a request for an item, service, or Part B drug, it must process the request according to the timeframes at § 422.568(b) or § 422.572(a).[256]

The reference to post-service in our proposed addition to § 422.566(b)(3) refers to applicable decisions that have been requested (or made by an MA organization in the absence of an organization determination request) after the enrollee has finished receiving the services at issue. The vast majority of post-service organization determinations are made in response to receiving a claim or other request for payment from an enrollee or provider. We are, however, aware that some MA organizations are denying payment for services before receiving a claim or other request for payment. More specifically, we have seen MA organizations decide on the appropriateness of an enrollee's inpatient admission, or the appropriateness of inpatient services, after an enrollee has been discharged from the hospital but before a request for payment has been received. These decisions have been referred to as ''retrospective reviews'' and, similar to our previous discussion on concurrent review decisions, many MA organizations making these decisions fail to comply with all applicable organization determination requirements, including providing appropriate notice and appeal rights to enrollees.

As a point of clarity, we regularly observe MA organizations making retrospective organization determinations when performing a post-payment review (a review that occurs after payment is made on the selected claim in order to determine whether the initial determination for payment was appropriate (see definition at § 405.902)).[257] The retrospective review decisions we are discussing here, however, are not reviews of an MA organization's prior payment decisions but are initial determinations impacting payment for inpatient hospital services that are made after the enrollee has been released from a hospitalization, but before a request for payment is received.

We have primarily observed MA organizations make retrospective review decisions on inpatient hospital services in a similar fashion as concurrent review. For example, an enrollee may be admitted as an inpatient in a hospital contracted with the enrollee's MA organization. During the hospital stay (or shortly thereafter), the MA organization will become aware of the inpatient admission, generally upon the hospital sending the MA organization a Notice of Admission. The hospital will finish providing services and discharge the enrollee in accordance with §§ 422.620–422.622. At some point after discharge, but before a claim for payment is submitted, the MA organization will notify the hospital that it is denying payment for all inpatient services and will instruct the hospital to submit an outpatient claim, while sometimes simultaneously approving the provider to bill for observation services. The MA organization does not send a notice of the denial to the enrollee. The hospital receives an opportunity to dispute the decision under the MA organization's internal dispute resolution processes, but the enrollee has no opportunity to dispute the decision under the rules of part 422 subpart M.

We find that retrospective reviews are conducted very similarly to concurrent reviews in that both reviews involve obtaining necessary clinical information from the treating physician or other providers to determine medical necessity for the services rendered, using the clinical status of the enrollee and applicable Medicare coverage criteria. In addition, both concurrent and retrospective review decisions are often made without the MA organization first receiving a request for coverage or payment. The primary difference between the two review types is that concurrent review occurs while the services are being rendered while retrospective review occurs after the services at issue are fully furnished. This means that a concurrent review decision concerns the delivery of care being received by the enrollee, while a retrospective review decision concerns whether the MA organization will make payment for the services the enrollee received. Put simply, a concurrent review decision (whether made unsolicited or in response to a request) is a coverage decision while a retrospective review decision (whether made unsolicited or in response to a request) is a payment decision.

[256] Beginning January 1, 2026, a request for a service or item that is subject to an MA organization's prior authorization requirement must be processed within 7 calendar days. The timeframe for processing requests for items and services not subject to an MA organization's prior authorization requirement remains 14 calendar days. See CMS–0057–F (89 FR 8976).

[257] Post-payment reviews are performed under the reopening rules at §§ 405.980–405.986 and 422.616 (see § 405.929). Pursuant to § 422.616(d), when a payment determination is revised on reopening (including through post-payment review), any party may file an appeal of the revised determination. However, similar to initial payment determinations, when an MA organization revises a contracted provider payment determination that results in no additional financial liability or cost-sharing for the enrollee, § 422.562(c)(2) precludes any party from appealing the revised payment determination under the administrative appeals processes of part 422, subpart M. Contracted providers may appeal adverse payment determination revisions under the terms of the contract between the provider and the MA organization.

An MA organization's refusal to pay for services, in whole or in part, including the type or level of services, the enrollee believes should be furnished or arranged for by the MA organization is an organization determination under the rules at existing § 422.566(b)(3). As we mentioned above, we have proposed adding references to § 422.566(b)(3) to clarify that the definition of an organization determination includes decisions made before, during, and after the enrollee's receipt of the services at issue. Under our proposed clarifications to what actions constitute an organization determination, a post-service payment decision, even if made without the MA organization first receiving a payment request, is subject to the rules in subpart M. In addition, as we explained in section III.W.1. of this proposed rule, the regulations of part 422, subpart M treat organization determinations related to coverage for services to be or contemporaneously being rendered (coverage decisions) differently from determinations related to payment for services already furnished (payment decisions). As such, a retrospective review decision would be subject to all applicable subpart M requirements related to payment organization determinations, including those related to notice and appeal rights.[258]

In accordance with § 422.568(d)(1), an MA organization must give the enrollee written notice when denying payment in whole or in part. The payment denial notice must use approved language in a readable and understandable form (§ 422.568(e)(1)), state the specific reasons for the denial (§ 422.568(e)(2)), inform the enrollee of their right to appeal (§ 422.568(e)(3)), describe the standard reconsideration process and the rest of the appeal process (§ 42.568(e)(4)(ii)), and comply with any other notice requirements specified by CMS (§ 422.568(e)(5)). CMS created the Notice of Denial of Medical Coverage or Payment (form CMS–10003–NDMCP), more commonly known as the Integrated Denial Notice (IDN), as a standardized notice for MA organizations to use when making adverse coverage or payment decisions. Alternatively, an MA organization may use the model Explanation of Benefits (EOB), when making an adverse payment decision as long as it includes the approved standard language from the IDN.[259] We explain in subregulatory guidance that an MA organization must provide notice of an adverse payment decision to an enrollee using the IDN or EOB when the enrollee submitted the request or through an EOB when the payment request was submitted by a provider (the provider would receive a corresponding remittance notice or similar notice).[260] We have not previously considered the proper notice for MA organizations to use when making payment decisions without first receiving a request for payment.

As we previously discussed, it is our understanding that retrospective review decisions are most often, if not exclusively, made on inpatient services performed by hospitals that are contracted with the MA organization. In most instances (excluding those which fall outside the plan-directed care beneficiary protection), when an MA organization makes a payment decision on contracted provider services, existing § 422.562(c)(2) would preclude a party's appeal of a decision as the enrollee would generally have no additional financial liability under the terms of the contract between the MA organization and the provider. However, as we discussed in section III.W.1. of this proposed rule, proposed § 422.562(c)(2) would not be applicable until an MA organization makes a decision on an enrollee's financial liability in response to a request for payment. Under proposed § 422.562(c)(2), an enrollee would not be precluded from appealing an adverse retrospective review decision as the MA organization would not yet have received a request for payment when the retrospective review decision is made. We believe this would be an appropriate outcome as an adverse retrospective review decision on inpatient hospital services typically results in the MA organization instructing the hospital to submit an outpatient claim (at times including an approval for observation services), thereby changing the cost-sharing amount for which the enrollee would be responsible. Cost-sharing, which may include deductibles, co-payments, and co-insurance, varies across the MA program, but most often has different requirements for inpatient and outpatient hospital services. Therefore, whether a hospitalization is billed as an inpatient or an outpatient stay would likely result in different out-of-pocket costs for the enrollee. We note that the difference in cost-sharing liability could be higher or lower for an enrollee after an adverse retrospective review decision on inpatient hospital services. The exact difference in amounts would depend on the enrollee's cost-sharing requirements of their particular plan, the length of their hospitalization, and, potentially, the amount and types of services which were rendered. We believe that ensuring an enrollee has adequate notice of an adverse MA organization payment decision, which may negatively affect their out-of-pocket expenses for a hospitalization, is paramount for providing a meaningful opportunity to appeal. However, because we have not previously considered which existing notice type (that is, the IDN or an EOB) would be most appropriate for MA organizations to use when making a retrospective review decision without first receiving a request, we are requesting comments on the type of notice MA organizations should utilize to ensure enrollees have adequate notice of the organization determination and its implications on the enrollee's cost-sharing responsibilities. Based on this feedback, CMS may consider clarifying in future guidance how MA organizations can ensure compliance with existing notice requirements when issuing retrospective review decisions prior to receiving a request for payment.

Finally, we also propose to make a corresponding change at § 422.138(c), to include concurrent reviews as a type of determination subject to the rules at § 422.138(c). Per CMS regulations at § 422.138(c), if the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis

[258] While the focus of this discussion is on unsolicited retrospective reviews, we acknowledge that enrollees or providers may, at times, submit a request for ''authorization'' for services which have already been fully rendered. Indeed, we understand that some MA organizations currently permit the submission of late ''authorization'' requests for certain services subject to prior authorization requirements within designated timeframes after a service has been rendered and, if approved, would consider the applicable prior authorization requirements met when separately considering payment. However, as we have explained above, once a service has been fully furnished, the only matter for an MA organization to decide is whether to make payment and any resulting enrollee financial liability or cost-sharing. Thus, similar to unsolicited retrospective review decisions, post-service authorization requests, whether permitted by MA organizations or not, must be processed as payment requests, under the applicable payment timeframes and policies. We note that our proposed policies do not prevent MA organizations from waiving prior authorization requirements on a case-by-case basis, based on good cause or any other consideration, during the claim adjudication or subsequent appeal processes when such processes are described in their EOC.

[259] An EOB is a model communication material which must also contain the information required under § 422.111(k).

[260] See section 40.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. We propose to add concurrent review decisions to § 422.138(c) as subject to this requirement. In the same way that a provider and patient reasonably rely upon an MA organization's approval of a prior authorization before services are rendered, an approval of inpatient or outpatient services during a concurrent review is an organization determination that is relied upon by the patient and provider to continue delivering medically necessary services that they expect to be covered and paid for by the MA organization. As a result, an MA organization should not be able to later deny the services based on a lack of medical necessity if the continued treatment had already been approved during a concurrent review.

3. Strengthening Requirements Related to Notice to Providers (§§ 422.568, 422.572, and 422.631)

Section 1852(g)(1)(B) of the Act requires MA organizations to provide an explanation of determinations regarding whether an individual enrolled with a plan is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. In accordance with section 1852(g)(1)(B) of the Act, § 422.568 establishes the timeframe and notice requirements for standard organization determinations. Section 422.568(e)(5) establishes an additional framework for promulgating expanded notice requirements. Under § 422.568(f), if a MA organization fails to timely meet applicable notice requirements, the failure constitutes an appealable adverse organization determination.

Existing § 422.568(d) requires MA organizations to provide enrollees written notice if an MA organization decides to deny coverage for a service or an item, Part B drug, or payment in whole or in part, or decides to reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment. Section 422.568(e) specifies that an MA organization's written notice of a coverage denial must use approved notice language, state the specific reasons for the denial, inform the enrollee of their right to request and the procedures for requesting a standard or expedited reconsideration, and must also comply with other notice requirements specified by CMS.[261] CMS created the Notice of Denial of Medical Coverage or Payment (*Form 10003–NDMCP*), also known as the Integrated Denial Notice (IDN) as a standardized denial notice that MA organizations may use to comply with the written notice requirements of § 422.568(e). This notice is approved by the Office of Management and Budget, subject to Paperwork Reduction Act procedures and is posted on the CMS website.[262] While MA organizations are required to provide timely notice of an approved organization determination, written notice is not required. This means that MA organizations may provide oral notice of approved coverage decisions.

The existing notice requirements for standard organization determinations at § 422.568(b)(1) only specify that MA organizations must provide the enrollee with notice of its decisions. This is a notable difference from the requirements related to expedited organization determinations at existing § 422.572(a) and (b) that require MA organizations to provide timely notice of any expedited organization determination to the enrollee and the physician or prescriber involved, as appropriate. Likewise, for Part B drug requests, regulations at § 422.568(b)(3) require notice to the prescribing physician or other prescriber involved, as appropriate.

However, existing CMS guidance instructs MA organizations to notify the provider, as well as the enrollee, whenever a provider submits an organization determination on behalf of the enrollee (see section 40.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.[263]) Similar references are also made in the text of the IDN, as CMS explains to enrollees that ''If your doctor requested coverage on your behalf, [the MA organization has] sent a copy of this decision to your doctor.''

We do not find a compelling reason that a provider should not receive notice of a standard organization determination when the provider submitted a request on behalf of an enrollee or when it is otherwise appropriate for the provider to receive notice of the determination. Indeed, under existing regulations at § 422.566(c)(1)(ii), a provider is already permitted to request an organization determination on an enrollee's behalf. This longstanding policy is premised on a reasonable belief that an enrollee will welcome and be informed of their provider or physician's willingness to pursue an organization determination on their behalf. We see no reason that a provider or physician to whom an enrollee has already entrusted their care or has sought to request coverage for their care, should not receive notice of an organization determination that directly affects such care. In fact, we believe an enrollee's provider is often in the best position to receive, explain, and timely act upon the MA organization decision for an enrollee.

Similar requirements for integrated organization determinations apply to applicable integrated plans at § 422.631. Under § 422.631(d)(1)(i), applicable integrated plans are required to send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in § 422.631(d)(2). Existing § 422.631(d)(1)(ii) states that an integrated organization determination not reached within the timeframes specified constitutes a denial and thus is an adverse decision. Section 422.631(d)(1)(iii) specifies the integrated organization determination notice requirements for applicable integrated plans must be written in plain language, available in a language and format accessible to the enrollee, include the date the determination was made and will take effect, the reason for the determination, the enrollee's right to an integrated reconsideration and to have someone file an appeal on their behalf, procedures for an integrated reconsideration, circumstances for an expedited resolution and enrollee's rights to continue benefits while their appeal is pending. CMS created the coverage decision letter (CDL) (*Form CMS–10716*), an OMB approved notice, for use by applicable integrated plans to comply with the written notice requirements at § 422.631(d)(1)(iii). The existing notice requirements at § 422.631(d)(1)(i) only specify that an applicable integrated plan must provide the enrollee with notice of its decisions. However, integrated organization determinations for Part B drug requests are governed by the provisions at § 422.568(b)(3) that require notice to the

[261] Section 422.568(e) also regulates the notice requirements for payment denials, which are largely the same, with the exception that payment denial notices do not need to include information on expedited reconsideration processes.

[262] *https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative/ma-denial-notice.*

[263] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

prescribing physician or other prescriber involved, as appropriate. Likewise, existing CMS guidance instructs applicable integrated plans to notify the provider, as well as the enrollee.

We, therefore, propose strengthening requirements related to notice of a standard organization determination at § 422.568 in paragraph (b)(1) and the introductory text for paragraph (d) and integrated organization determinations at § 422.631(d)(1)(i) to require MA plans and applicable integrated plans to notify an enrollee's physician or provider, as appropriate, of an organization determination or integrated organization determination on a request for a non-drug item or service (in addition to the existing requirement related to notifying an enrollee). Note that ''as appropriate'' means, as with similar requirements in §§ 422.568(b)(3) and 422.572(a), that notice should be given to the provider or prescriber who submitted an organization determination request on behalf of an enrollee or in other circumstances where it would be in the enrollee's best interest for their provider or prescriber to receive notice of a decision related to an enrollee-submitted request.

We are also proposing corresponding amendments to §§ 422.568(f), 422.572(f), and 422.631(d)(1)(ii) to state that if the MA organization or applicable integrated plan fails to provide the enrollee, physician, or provider involved, as appropriate, with timely notice of an organization determination or integrated organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed. We note that the proposed change at § 422.572(f) is a technical change to expedited organization determination requirements. Under existing rules at § 422.572(a), MA organizations are required to provide notice of an expedited organization determination to the physician or prescriber, as appropriate. However, existing § 422.572(f), which establishes that a MA organization's failure to timely meet expedited organization determination notice requirements constitutes an adverse decision, only refers to the MA organization's responsibility to provide timely notice to the enrollee. We, therefore, propose a technical change to § 422.572(f) to clarify that the failure to provide timely notice of an expedited organization to the enrollee and the physician or prescriber, when appropriate, would itself constitute an appealable adverse organization determination.

In addition, we are proposing a technical change at § 422.631(a) to reference the correct Part B drug regulation at § 422.568(b)(3) rather than the current reference to § 422.568(b)(2) to govern the timeframes and notice requirements for integrated organization determinations for Part B drugs. The final rule titled the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,'' which appeared in the February 8, 2024, **Federal Register**, redesignated § 422.568(b)(2) as § 422.568(b)(3).

We do not believe this proposal will have a substantial impact on the practices of MA organizations or applicable integrated plans as we are codifying longstanding guidance that we believe the majority of plans already implement this practice based on the relatively few complaints from providers and enrollees. In addition, we also understand that due to the contractual relationship MA organizations have with their providers, most contracted providers should already receive notice of relevant organization determinations, including those that the provider submitted on behalf of the enrollee. However, we note that the few complaints that we do receive on this issue reinforce how disruptive the lack of provider notice can be for enrollees attempting to promptly receive covered medical services. When an enrollee is the only party to receive written notice of a decision, not only can this result in a delay in their receipt of approved medical care but could also delay the submission of a valid appeal when coverage is denied.

We also believe this proposal will positively support our proposed modification of the definition of an organization determination at § 422.566(b) by ensuring providers will always receive notice of a decision notwithstanding when in the continuum of care the decision is made. As discussed in section III.W.2. of this proposed rule, CMS has identified that some MA organizations routinely misinterpret existing organization determination provisions related to decisions that rescind prior authorization of an inpatient admission, deny coverage for inpatient services, or downgrade an enrollee's hospital coverage, from inpatient to outpatient, when the decision is made concurrently to the enrollee receiving such services. In these cases, the MA organizations are not providing enrollees or their providers proper notice of the adverse organization determination or providing appeal rights. Our proposed clarifications to the definition of an organization determination at § 422.566(b)(3) seek to clarify that applicable decisions made before, during, or after the enrollee's receipt of services are organization determinations and thus are subject to notice requirements pursuant to §§ 422.568, 422.572 and 422.631. Our proposal at §§ 422.568 and 422.631 would, therefore, require the MA organization or applicable integrated plan to provide notice to the enrollee and physician or provider that must comply with the standard organization determination or integrated organization determination requirements. We note, however, that in the case of an MA organization conducting pre-service or concurrent review for inpatient services, our expectation is that the facts and circumstances around that type of review will often satisfy the medical exigency standard. Therefore, we expect in most circumstances an MA organization must provide an expedited determination because applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, consistent with the provisions at §§ 422.570(c)(2) and 422.631(c)(3).

4. Modifying Reopening Rules Related to Decisions on an Approved Hospital Inpatient Admission (§§ 422.138 and 422.616)

Under the regulations at § 422.576, an organization determination is binding on all parties unless it is reconsidered under the rules at §§ 422.578 through 422.596 or is reopened and revised under § 422.616. The reopening rules at § 422.616 permit an organization or reconsidered determination made by an MA organization that is otherwise final and binding to be reopened and revised by the MA organization under the applicable rules in part 405, subpart I at §§ 405.980 through 405.986. The reopening rules in part 405, subpart I are based on § 1869(b)(1)(G) of the Act which states that the Secretary may reopen or revise any initial

determination or reconsidered determination described in this subsection under guidelines established in regulations. While the reopening rules in §§ 405.980 through 405.986 are applicable to the Traditional Medicare program, the regulatory provisions at 42 CFR part 405 historically have been cross-referenced in the managed care regulations and have been applied to the MA program consistent with the provisions at §§ 422.562(d) and 422.616 since the inception of the MA program (and to MA's predecessor, the Medicare+Choice program). Thus, the ability of an MA organization to reopen and revise an organization determination for the reasons set forth in regulation is well established in the MA program. For purposes of this proposal, the discussion is specific to the application of the reopening rules to organization determinations made by an MA organization that involve inpatient hospital admission decisions.

Section 422.616(b) permits a reopening at the instigation of any party and, in accordance with § 422.616(d), once an adjudicator issues a revised determination, any party may file an appeal. Pursuant to the applicable reopening regulations at § 405.980(b), an organization determination or reconsideration may be reopened by an MA organization within 1 year from the date of the initial determination or redetermination for any reason. However, in recently promulgated prior authorization rules at § 422.138(c), if an MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616.[264] Under § 422.138(c), in the case of an approved organization determination for the furnishing of a covered item or service made through prior authorization or a pre-service determination, an MA organization is not permitted to reopen that decision within 1 year from the date of determination for any reason as is otherwise permitted at § 405.980(b)(1). While the rules at § 422.138(c) currently allow for reopening of a favorable prior authorization decision within 4 years from the date of the initial determination or redetermination for good cause, as defined in § 405.986, we believe a proposed modification to the MA reopening rules at § 422.616 is necessary with respect to favorable organization determinations on inpatient hospital admissions.

We are aware that some MA organizations are reopening and revising or otherwise rescinding a prior approval for an inpatient hospital admission based on a medical necessity determination during the enrollee's receipt of the previously authorized services or during the adjudication of the subsequent inpatient claim for payment. For example, when deciding to admit an enrollee, the hospital requests and receives approval for the admission from the enrollee's MA organization. Later, however, the MA organization obtains and reviews additional medical documentation and determines that the enrollee does not meet the necessary criteria to support payment for inpatient hospital services and rescinds or overrides its prior approval. As discussed in the context of our proposal to strengthen the notice requirements in § 422.568, some MA organizations are not consistently providing notice or appeal rights to the enrollee for these decisions.

The rules at § 405.980(b) permit reopening of a decision if there is a finding of good cause as defined in § 405.986. If good cause is found, an organization determination may be reopened within 4 years from the date of the determination. Under the rules at § 405.986, good cause may be established when (1) there is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or (2) the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. New and material evidence is evidence that was not readily available or known to the person or entity requesting or initiating the reopening at the time the initial determination was made by the MA organization and may result in a different conclusion than reached in the initial determination. Such evidence may include any record used in the furnishing of care and supporting the medical necessity of such care. This includes, but is not necessarily limited to, medical records, progress notes, and physician orders. Under the reopening rules, a change of legal interpretation or policy by CMS in a regulation, ruling, or general instruction is not a basis for reopening an organization determination.

Under existing rules at § 422.138(c), in cases where an enrollee's inpatient admission into the facility is approved prior to admission, this decision is binding and may not be reopened and revised by the MA organization unless there is good cause for a reopening pursuant to the rules at § 405.986. The inpatient hospital admission rules at § 412.3(d)(1) and (3) are clear that the coverage criteria set forth therein are based on the admitting physician's expectation at the time of admission about whether the hospital care will cross two-midnights or is otherwise appropriate, as supported by the medical record. Since the physician's expectation at the time of admission is based on the clinical information known at that time as well as the documented medical record at the time of admission, any subsequent clinical information obtained after an MA organization has made its initial organization determination would not have the effect of creating a good cause reopening on the basis of new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion. As part of the organization determination process, it is incumbent on the MA organization to obtain and review all relevant clinical information to make an organization determination on a request for inpatient hospital admission and to comply with requirements for basic benefits as described in § 422.101(b)(2).

Due to the ongoing issues we have seen with previously approved inpatient hospital admissions later being inappropriately revised or rescinded, and to augment the rules at § 422.138(c), we propose to amend § 422.616(a) to state that the reopening provisions are subject to the rules at § 422.138(c) and propose a new paragraph (e) of § 422.616 that would place a limitation on reopening determinations related to favorable inpatient hospital admissions. Specifically, proposed § 422.616(e) would state that if an MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) or (3), any additional clinical information obtained after the initial organization determination cannot be used as new and material evidence to establish good cause for reopening the determination.

We believe these proposed amendments to the reopening rules at § 422.616 present a reasonable approach to curtailing the reopening of approved hospital admission decisions and are consistent with the rules on inpatient admission decision-making. Decisions on inpatient admissions under § 412.3(d)(1) or (d)(3) are based on whether the complex medical factors documented in the clinical record

[264] See 88 FR 22120, 22185–22217.

support the admitting physician's clinical expectation or judgment. Section 412.3(d)(1) states that, except as specified in paragraphs (d)(2) and (3) of § 412.3, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights. Section 412.3(d)(1)(i) states that the expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record to be granted consideration (with respect to determining the appropriateness of payment for an inpatient stay). Section 412.3(d)(1)(ii) states that if an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least two midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A. The exception in § 412.3(d)(2) relates to inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n). The exception in § 412.3(d)(3) states that where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross two midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision is based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

Based on these rules, we believe it is appropriate to limit reopening of a decision involving inpatient hospital admission by prohibiting reopening for good cause based on new and material evidence. Any additional clinical information obtained after the initial organization determination cannot have the effect of creating a good cause reopening because the determination was made based on what was known by the physician and documented in the medical record at the time of admission. Under the rules at § 405.986(a)(2), good cause for reopening may also be established if the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination or decision. This proposed rule does not seek to modify or limit the applicability of reopening for obvious error per the rules at § 405.986(a)(2) with respect to favorable inpatient hospital admission decisions. For example, there could be a situation where the admitting physician documents something related to the enrollee's condition incorrectly into the clinical record that the plan relied upon when making the favorable decision and the facts and circumstances of such a mistake, including the significance and materiality of the error, may support a reopening of the favorable decision on the basis of obvious error. We believe the need for a plan to reopen a favorable inpatient hospital admission decision on the basis of obvious error under the rules at § 405.986(a)(2) should be a rare occurrence given the breadth of clinical documentation that is considered when making a decision on an inpatient hospital admission.

We acknowledge that our proposed limitation on the type of clinical information that may be considered new and material evidence to form the basis to reopen a favorable determination related to an inpatient hospital admission is a departure from corresponding Traditional Medicare reopening policies and would, at times, restrict certain clinical information from forming the basis of new and material evidence to reopen that would otherwise be available in Traditional Medicare. While we strive to create and apply policies consistently between the MA program and Traditional Medicare, the programs' inherent differences require a tailored approach in this scenario. In particular, under Traditional Medicare, an initial determination related to an inpatient admission would only be made after a beneficiary had received the service and a claim for payment has been submitted (see § 405.920) and, therefore, generally after a beneficiary's medical record supporting that service has been fully developed. In contrast, MA enrollees may receive a favorable determination related to an inpatient hospital admission before or contemporaneously to the enrollee's receipt of services (see § 422.566(b)(3)). This means the enrollee's medical records are continuing to be updated to reflect the changing medical circumstances. Thus, it is more likely that clinical information obtained after an initial organization determination could lead to an MA organization reopening a decision for an enrollee than a beneficiary in Traditional Medicare, even though the inpatient admissions criteria in § 412.3 apply in the same manner to both programs. MA enrollees should be able to rely upon an approved inpatient admission made in advance of the receipt of services, or concurrently with the receipt of services, despite changing medical circumstances. They should not be concerned that an MA organization may revise or rescind an approved admission due to clinical information that was not available or in existence when the provider determined the need for admission and the MA organization approved the admission.

Finally, for clarity in the applicability of the reopening rules to prior authorization and pre-service determinations, we are proposing a technical amendment to the parenthetical text in paragraph (c) of § 422.138 to add a cross reference to the rules at § 422.616, including proposed new paragraph (e) related to decisions to approve an inpatient hospital admission.

We are soliciting comments on the above proposals and will consider the need to revise one or more of these approaches based on relevant stakeholder feedback. With respect to the proposal to clarify that an organization determination includes decisions made by an MA plan concurrent with an enrollee's receipt of services and on a retrospective basis after services have ended, we are specifically soliciting comments on whether a notice other than the existing EOB may be needed to convey written information to an enrollee on the anticipated impact of the decision on the enrollee's financial liability and the right to appeal.

W. Formulary Inclusion and Placement of Generics and Biosimilars

Multiple recent reports, actions, and findings published or taken by entities outside CMS have raised concerns that Part D sponsors and their PBMs engage in practices that favor, intentionally or unintentionally, more expensive brand drugs and reference products over generics, biosimilars, and other lower cost drugs in terms of formulary placement or non-placement. For example, a March 2022 HHS OIG report titled, ''Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions with Increased Biosimilar Use,'' found that, since biosimilars were introduced in 2015,

use of and spending on these drugs in Part D has steadily increased. However, the report also found that biosimilars are still used far less frequently than their higher-cost reference product alternatives, and that Part D spending on biologics with available biosimilars could have decreased by $84 million in 2019, if all biosimilars had been used as frequently as the most-used biosimilars. The report asserted that a lack of biosimilar coverage on Part D formularies could limit the potential for these drugs to reduce costs for Part D and beneficiaries. The report noted that, in 2019, not all plan formularies covered available biosimilars, and those formularies that did cover biosimilars rarely encouraged their use over reference products through preferential formulary tier placement and utilization management (UM) tools.[265]

In addition, a July 2024 Federal Trade Commission (FTC) report titled, ''Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies'' stated that an FTC review of a number of contracts, including both commercial and Part D contracts, and internal documents summarizing such contracts, revealed ''that some rebate contracts explicitly premise high rebates on the exclusion of AB-rated generics. These generic exclusions can be accomplished through 'NDC blocks' of generic equivalents—that is, a contractual prohibition on payments for generic drugs, as identified by their National Drug Code or 'NDC' number. These findings are consistent with public comments that identify the practice of PBMs preferring higher point-of-sale price branded products over generics, which may raise out-of-pocket costs for patients.'' [266]

Furthermore, in September 2024, the FTC filed an Administrative Complaint against certain PBMs and related entities asserting violations of the FTC Act based upon formulary and manufacturer rebate practices relating to disfavoring certain lower cost insulin products (some of which are biosimilars).[267] Among other things, the complaint alleges that these PBMs ''systematically prefer high list price insulin products, with high rebates and fees, over similar low list price products, with low rebates and fees, on formularies to inflate the perceived value of their commercial drug formularies and offer higher rebate guarantees.'' [268] While this complaint did not involve the Medicare Part D program, it is instructive as to PBM practices generally, since the respondents also operate in the Part D space as contractors to Part D sponsors.

In addition to external organizations highlighting this issue, CMS has previously stated that it had identified instances when Part D sponsors did not include on their formularies generic alternatives when available and issued guidance to address this issue. In the final CY 2020 Call Letter,[269] in the section ''Improving Access to Generic and Biosimilar Medicines'' that discussed tier composition policy, CMS stated, ''The use of cost-effective therapeutic alternatives like generic and biosimilar medicines is critical to the current and long-term success of Medicare Part D. . . .CMS will continue to encourage Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products. . . . [W]hile CMS analysis of CY 2019 formularies shows robust access to cost-effective generic medications and that Part D sponsors have been achieving very high generic dispensing and substitution rates, we do note that there are limited instances when Part D sponsors are not including generic alternatives when available. Instead, sponsors are only covering the brand drugs, which decreases generic substitution and increases beneficiary costs.'' [270]

In the final CY 2020 Call Letter, CMS also stated that we would continue to monitor beneficiary access to generic alternatives, utilization of multi-source brand drugs when generics are available, and situations where the brand drug is situated more favorably in comparison to the generic with regards to tiering and UM, and that we would consider future policy changes should this trend continue.[271] As part of such monitoring, CMS has identified cases when an equivalent generic or biosimilar is not included on the formulary when it is available. There are also occasions when the generic is included on the same or higher formulary tier as the brand drug, and occasions when a biosimilar is included on the same or higher formulary tier as the reference product.

These reports, actions, and findings continue to be concerning because of the potential for higher out-of-pocket prescription drug costs for Medicare beneficiaries when lower cost generics and biosimilars are excluded from formularies or are placed on the same or higher formulary tiers as the more expensive brand-name drug or reference product. Furthermore, the patterns described in the reports, actions, and findings may exist for other lower cost drugs. Because such formulary decisions risk increasing out-of-pocket costs for enrollees, CMS believes these reports, actions, and findings may be indicative of UM programs that are not cost-effective and therefore out of compliance with Part D requirements.

We remind sponsors that section 1860D–4(c)(1)(A) of the Act requires a Part D sponsor to have in place, directly or through appropriate arrangements, with respect to covered Part D drugs, ''[a] cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act).'' This statutory requirement is codified at § 423.153(b), which states that Part D sponsors must have established ''a reasonable and appropriate drug utilization management program'' that, among other requirements, ''[i]ncludes incentives to reduce costs when medically appropriate.''

Given the concerns highlighted by the preceding reports, actions, and findings, CMS finds it necessary to clarify that, to be compliant with Part D requirements, Part D plan formularies must provide beneficiaries with broad access to generics, biosimilars, and other lower cost drugs. We view such access as a necessary component of a reasonable and appropriate drug UM program that is cost-effective and that includes incentives to reduce costs when medically appropriate. In other words, the plain language in section 1860D–4(c)(1)(A) of the Act and current § 423.153(b) makes clear that a UM program cannot be considered cost-effective or inclusive of incentives to reduce costs if it broadly excludes or restricts access to generics, biosimilars, and other lower cost drugs that can reduce costs in a medically appropriate manner and improve the cost efficiency

[265] *https://oig.hhs.gov/reports/all/2022/medicare-part-d-and-beneficiaries-could-realize-significant-spending-reductions-with-increased-biosimilar-use/.*

[266] *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (page 68).*

[267] Compl., *In re Caremark Rx, LLC et al.,* FTC Dkt. No. 9437, *https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx_zinc_health_services_et_al_part_3_complaint_public_redacted.pdf.*

[268] *Id.* at ¶ 256.

[269] *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2020.pdf* (*pages 210–211*).

[270] With respect to generic substitution, CMS noted that a significant number of states have passed legislation requiring pharmacies to substitute lower cost generic drug products for brand name drug products where available, and that there are laws to encourage generic and biosimilar uptake, including the Hatch-Waxman Act and state generic substitution laws.

[271] Id.

of drug utilization. This does not mean that a sponsor is required to include all generics and biosimilars associated with a brand drug or reference product on the formulary, or if they are included, that they all be placed on a more preferred formulary tier relative to the brand drug or reference product. Nor do we require that a sponsor forego UM edits (for example, prior authorization (PA) and step therapy (ST)) on generics and biosimilars. Instead, we are making it a point of emphasis that broad access to generics, biosimilars, and other lower cost drugs is a necessary component of having a reasonable, appropriate, and cost-effective UM program.

Broad access to generics, biosimilars, and other lower cost drugs, refers not only to formulary inclusion, but also tier placement and UM practices such as PA, ST, and quantity limits (QL). This is because a drug UM program may not be cost-effective even if the plan broadly includes generics, biosimilars, and other lower cost drugs on the formulary, if tier placement and other UM restrictions effectively limit access to these drugs compared to their more expensive branded versions and reference products. The idea that a cost-effective UM program includes formulary placement and tiering, and UM practices (including PA, ST, and QL), is consistent with the plain text of section 1860D–4(c)(1)(A) of the Act. For example, a plan that generally includes on formulary higher cost drugs and biologicals, while broadly excluding their lower cost generics and biosimilar alternatives, cannot reasonably claim to have a ''cost-effective'' UM program that incentivizes reduced costs, when medically appropriate, including through the use of multiple source drugs. The concept of the UM program encompassing formulary inclusion, tier placement, and various UM practices has been a fundamental component of the Part D program since its inception. The January 2005 final rule establishing the Part D program stated, ''While drug utilization management is common practice, plans appropriately employ a number of different approaches (for example, formularies, step therapy, tiered cost sharing, prior authorization) and different combinations of those approaches. . .'' 70 FR 4277–4278. Also, the Prescription Drug Benefit Manual, Chapter 7, Section 60.1—General Rule (Effective 9–1–2008), states that ''Common utilization management tools include formularies, prior authorization requirements, and promotion of lower cost generics.'' [272]

CMS currently conducts an extensive formulary review process to ensure Part D sponsors provide an adequate formulary consistent with § 423.120(b)(2). Although we have been monitoring beneficiary access to generics and biosimilars, we now plan to include an additional step in the formulary review process to check that Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs. Specifically, CMS will holistically review whether a plan's formulary and UM practices with respect to these drugs constitute a drug UM program that is ''cost-effective,'' ''reasonable and appropriate,'' and inclusive of ''incentives to reduce costs.'' This review would encompass an evaluation of whether the formulary includes generics, biosimilars, and other lower cost drugs, when available, for brand drugs and reference products, and whether the generics, biosimilars, and other lower cost drugs are placed on a lower formulary tier than the brand drugs or reference products. In addition, CMS would review whether a formulary incorporates fewer utilization controls on brand drugs and reference products than on lower cost alternatives. CMS would use its authority to negotiate the terms and conditions of submitted Part D sponsors' bids under section 1860D–11(d)(2) of the Act if a plan's proposed formulary does not appear to provide broad access to generics, biosimilars, and other lower cost drugs in order to ensure such access for Part D beneficiaries and compliance with Part D requirements in section 1860D–4(c)(1)(A) of the Act and § 423.153(b)(1).

In conjunction with our formulary review process, CMS intends to continue to monitor and analyze plan sponsors' inclusion of generics, biosimilars and other lower cost drugs on formularies. CMS seeks comments on: (1) the prevalence of manufacturer rebates and the extent to which such rebates influence formulary decisions that reduce Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs; and (2) whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generics, biosimilars, and other lower cost drugs. Based on this feedback, CMS may consider further steps in future rulemaking or guidance to promote broad access to generics, biosimilars, and other lower cost drugs for Part D beneficiaries.

[272] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf* (page 28).

IV. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,[273] more commonly referred to as Medicare Advantage (MA), and Part D plans as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. We use multiple data sources based on the collection of different types of quality data under section 1852(e) of the Act to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, and information provided directly from health and drug plans. CMS regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA/Part C and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the Parts 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526 and 16527). As a result, the policies and regulatory changes proposed here will apply to the quality ratings for MA plans, cost plans, and Part D plans.

We have continued to identify enhancements to the Star Ratings program to ensure it is aligned with the CMS Quality Strategy as that Strategy [274] evolves over time. To support the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality and value-based care programs. Across our programs,

[273] We generally use ''Part C'' to refer to the quality measures and ratings system that apply to MA plans and cost plans.

[274] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

where applicable, we are considering including the Universal Foundation [275] of quality measures, which is a core set of measures that are aligned across CMS programs. CMS is committed to aligning a core set of measures across all our quality and value-based care programs and ensuring we measure quality across the entire care continuum in a way that promotes the best, safest, and most equitable care for all individuals. Improving alignment of measures across Federal programs and with private payers would reduce provider burden while also improving the effectiveness and comparability of measures. Using the Universal Foundation of quality measures would focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The Universal Foundation is a building block to which programs would add additional aligned or program-specific measures. This core set of measures would evolve over time to meet the needs of individuals served across CMS programs. We submitted the following Part C measures to the 2024 Measures under Consideration list as part of the Pre-Rulemaking Measure Review process as a step toward proposing use of these Universal Foundation measures in the Star Ratings system through future rulemaking: Adult Immunization Status, Depression Screening and Follow-Up for Adolescents and Adults, and Social Need Screening and Intervention.[276] We have previously solicited feedback regarding potentially proposing these measures as Star Ratings measures in the future through both the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. CMS is continuing to consider ways to streamline the measurement set for the Part C and D Star Ratings program. We currently plan to solicit comments through the 2026 Advance Notice and Rate Announcement process on ways to focus the measurement set to improve the impact of the Star Ratings program.

In this proposed rule, we are proposing to add or update the following measures:

- Initiation and Engagement of Substance Use Disorder Treatment (IET) (Part C)
- Initial Opioid Prescribing for Long Duration (IOP–LD) (Part D)
- Breast Cancer Screening (Part C)
- Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C)

We are also proposing how the health equity index (HEI) reward will be calculated for contracts that are required by a state Medicaid agency to move one or more D–SNP plan benefit packages from an existing MA contract to an MA contract that only includes one or more D–SNPs with a service area limited to that state, consistent with § 422.107(e), beginning with the 2029 Star Ratings. Additionally, we are proposing to clarify at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) that in order for Institutional Special Needs Plan (I–SNP)-only contracts to have the rating-specific HEI calculated, these contracts must have data for at least half the measures included in the rating-specific HEI for the subset of measures that I–SNP-only contracts are required to report.

We are also proposing a couple of technical clarifications of the existing rules related to how the HEI reward enrollment thresholds described at §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) are assessed in the case of contract consolidations for the second year following the consolidation and changes to how the HEI score would be calculated for contracts that have data discrepancies between their submitted patient-level detail and summary-level data for HEDIS measures included in the HEI. We are also proposing a clarification of how the improvement measure hold harmless for the highest rating is determined based on the rounded rating before the addition of the HEI reward, if applicable, at §§ 422.166(g) and 423.186(g), as well as proposing a technical clarification at §§ 422.162(b)(3)(iv)(A)(2) and (B)(2) and §§ 423.182(b)(3)(iv)(A)(2) and (B)(2) to provide details about how the enrollment-weighted measure score is calculated when a consumed or surviving contract is missing data for a measure.

In the proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' which appeared in the December 27, 2022, Federal Register (hereinafter referred to as the December 2022 proposed rule), we proposed to remove guardrails (that is, bi-directional caps that restrict upward and downward movement of a measure's cut points for the current year's measure-level Star Ratings compared to the prior year's measure-threshold specific cut points) when determining measure-specific thresholds for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures (87 FR 79625–79626). We are considering finalizing this proposal, in this rulemaking, to apply beginning with the 2026 measurement year and 2028 Star Ratings because with the implementation of Tukey outer fence outlier deletion, extreme outliers are removed before the clustering algorithm is applied, which minimizes the need for guardrails to achieve predictability and stability of cut points. Additionally, the removal of guardrails would allow cut points to adjust when there are unanticipated changes in performance across the industry. We intend to address comments received regarding the removal of guardrails to the December 2022 proposed rule in the final rule.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Part C and D Star Ratings program. In the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule which appeared in the **Federal Register** on April 16, 2018 (83 FR 16532) hereinafter referred to as the April 2018 final rule, we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-

[275] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539* and *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

[276] Information on the Measures Under Consideration list for 2024 will be available here: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

substantive updates. See also 83 FR 16534–16537. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings. In this rule, CMS is proposing to add the Initiation and Engagement of Substance Use Disorder Treatment (Part C) and Initial Opioid Prescribing for Long Duration (Part D) measures to the Star Ratings program and to update the Breast Cancer Screening (Part C), Plan Makes Timely Decisions about Appeals (Part C), and Reviewing Appeals Decisions (Part C) measures for performance periods beginning on or after January 1, 2026.

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. For example, we regularly review measures developed by the National Committee for Quality Assurance (NCQA) and Pharmacy Quality Alliance (PQA).

1. Adding Measures

a. Initiation and Engagement of Substance Use Disorder Treatment (IET) (Part C)

We propose to add the Initiation and Engagement of Substance Use Disorder Treatment (IET) measure beginning with the 2028 Star Ratings covering the 2026 measurement year. Adding the IET measure to the Part C Star Ratings would further align the Part C Star Ratings with the Universal Foundation as discussed in the CY 2024 and CY 2025 Rate Announcements.[277]

The IET measure is a composite measure that averages two separate rates: Initiation of Substance Use Disorder Treatment and Engagement of Substance Use Disorder Treatment. Prior to measurement year 2022, this measure was called Initiation and Engagement for Alcohol and Other Drug Abuse or Dependence Treatment and the individual rates have been reported on the Part C and Part D Star Ratings display page beginning with the 2012 performance period (2014 display page). For measurement year 2022, NCQA made several updates to the IET measure, including updating its name. Since many individuals with substance use disorder (SUD) attempt treatment multiple times before they are able to successfully engage, the measure was changed from ''member-based'' to ''episode-based'' to allow for each recovery attempt to count independently, which should result in a more valid representation of engagement with SUD treatment for health plan populations. The length of the negative SUD history period was increased from 60 days to 194 days to limit the number of members receiving ongoing treatment who fall into the denominator. Emergency department visits and medically managed withdrawal services were removed from the negative SUD history period because emergency department visits and withdrawal services alone are not suggestive of ongoing or planned treatment for individuals with SUD and thus do not signal that a member is already engaged in comprehensive care. The requirement that psychosocial treatment accompany pharmacotherapy was also removed to align with the most current clinical practice guidelines (for example, allowing for patients who may not accept concomitant psychosocial treatment). Finally, the adult age stratification was split between 18–64 years and 65+ years to better highlight any gaps in care between different age groups.

CMS began reporting the two indicators or rates included in the historical IET measure on the display page for the 2014 Star Ratings. However, starting with the display page for the 2024 Star Ratings covering the 2022 measurement year, we began reporting the updated measure being proposed here, including the separate rates for initiation and engagement that are part of the HEDIS measure and an average of the two rates. As provided at §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4), as new performance measures are developed and adopted, they are initially posted on the display page for at least 2 years. We intend to use the period that the updated IET measure was on the display page to meet this requirement.

To lessen the complexity in the Star Ratings program by minimizing the number of new Star Rating measures, CMS is proposing to average the initiation and engagement rates into one measure for reporting in the Star Ratings program. A contract must have scores on both rates to receive a score for this measure as we propose to use it in the Star Ratings program. This is similar to how the data are reported for the IET measure in the Quality Rating System for the Qualified Health Plans on the Exchanges.[278] The two rates of this composite measure will continue to be reported as separate measures on the display page so as to be available to plans for use in their quality improvement projects after the composite IET measure is added to the Star Ratings pending rulemaking.

We submitted the IET measure for inclusion in the 2023 Pre-rulemaking Measure Review (PRMR) process, required under *section 1890A* of the Act. The Consensus-Based Entity (CBE), which is currently Battelle, convenes interested parties that participate in committees to review measures as part of the PRMR process. Battelle utilized the Novel Hybrid Delphi and Nominal Group multi-step process, which is an iterative consensus-building approach aimed at a minimum of 75% agreement among voting members, rather than a simple majority vote. The final result from the committee's vote can be: Recommend, Recommend with conditions, Do not recommend, or Consensus not reached. Consensus not reached signals continued disagreement amongst the committee despite being presented with perspectives from public comment, committee member feedback, and discussion, and highlights the multi-faceted assessments of quality measures. More details regarding the CBE PRMR voting procedures may be found in Chapter 4 of the Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.[279] Although the committee did support the IET measure overall, there were diverging perspectives related to data collection burden, the effect of patients refusing treatment on measure performance, and exclusions. Approximately 29 percent (4 of the 14 voting members) [280] did not recommend this measure resulting in the committee not reaching consensus. Some members of the committee cited data collection burden as a challenge to the feasibility of the measure given interoperability barriers with electronic health record (EHR) systems across

[277] See Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (*cms.gov*) pages 162–163 and Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and D Payment Policies (*cms.gov*) page 137.

[278] The Quality Rating System public use file shows the averaged rate of initiation and engagement: *https://www.cms.gov/files/zip/qrs-nationwide-puf-py2023.zip.*

[279] *https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.*

[280] *PRMR–2023–MUC-Recommendations-Report-Final-.pdf (p4qm.org).*

providers and specialties; however, this concern was not shared by all committee members and some members noted that there was nothing specific related to this measure that would result in data collection issues. CMS has taken the CBE's input into consideration, but since MA contracts have been collecting and reporting this measure for over 10 years, we do not anticipate that data collection burden will be an issue with moving this measure from the display page to the Star Ratings. Additionally, the issue of members refusing treatment is not unique to this measure. Only one committee member, a patient representative, mentioned that some patients may choose not to initiate treatment and that this should not be counted against the plan; however, for this measure there are not significant clinical reasons for refusing treatment that would need to be accounted for in the measure specification. Having considered the CBE's input, we are proposing moving this measure from the display page to the Star Ratings beginning with the 2028 Star Ratings covering the 2026 measurement year.

b. Initial Opioid Prescribing for Long Duration (IOP–LD) (Part D)

As part of CMS' ongoing efforts to address the national opioid crisis, we have implemented balanced drug utilization review (DUR) policies and quality measurement strategies to help reduce prescription opioid misuse in the Medicare Part D population while maintaining medically necessary access. To support this goal, CMS proposes to add the IOP–LD measure for the 2028 Star Ratings (2026 measurement year) in accordance with § 423.184(c) because it is an important measure to promote safer prescription opioid use. The IOP–LD measure will be an additional tool for Part D sponsors to monitor initial opioid prescription exposure to reduce the risk for long-term opioid use and opioid use disorder. Adequate management of pain and assessment after opioid initiation is vital to minimize the risk of long-term opioid use, opioid misuse, and overdose.

CMS began reporting the IOP–LD measure to Part D sponsors through the Patient Safety reports starting in measurement year 2020 and has publicly reported the measure on the Part D display page [281] since 2023 (2021 performance data) in accordance with § 423.184(c)(3). Consistent with § 423.184(c)(2), we announced in the Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,[282] as well as in subsequent Rate Announcements, that the IOP–LD measure would be considered in the future for addition to the Star Ratings. The IOP–LD measure underwent further review and evaluation during the 2023 PRMR process by the CBE to provide recommendations for selecting quality and efficiency measures for use in CMS programs as required by section 1890A of the Act. A consensus for inclusion in the Part D Star Ratings was not reached during the PRMR process for the IOP–LD measure. Approximately 36 percent (5 of the 14 voting members) did not recommend this measure, resulting in the committee not reaching the 75 percent consensus threshold as summarized in the PRMR 2023 Recommendations Report.[283] As noted in the Report, committee members acknowledged the importance of having a measure that assesses opioid prescriptions as a method of harm reduction and that the measure may fill a gap in opioid safety in the Star Ratings program. Committee members sought clarification on the specifications and consideration of measure exclusions for patients with complex medical needs. Some members of the committee expressed concern for the adequacy of evidence and alignment with current clinical guidelines for opioid prescribing. The committee also discussed potential unintended consequences of measure implementation on prescriber hesitancy, the quality of pain management, and harm for patients who need long-term opioids. CMS discussed that the measure is not intended to guide clinical decision-making for individual patients and does not represent a prescribing limit.

We seek comments from a broad range of interested parties on the proposal to add the IOP–LD measure to the Part D Star Ratings. The IOP–LD measure is an important area of focus for the Medicare Part D program and is supported by evidence-based literature and national guidelines. The measure specifications are designed to reduce unintended consequences and complement Medicare Part D opioid-related policies.

Measure Specifications: The PQA is the measure steward. The IOP–LD measure was endorsed by the PQA's membership and included a review by the PQA's Patient and Caregiver Advisory Panel in 2018, with 100% voting members in favor of the measure as important to patients and caregivers.[284] The National Quality Forum (NQF) Patient Safety Standing Committee (NQF #3558) [285] also endorsed the measure in 2019, demonstrating that it meets high standards of evidence to impact healthcare quality. The NQF Patient Safety Standing Committee unanimously deemed the IOP–LD measure to meet the importance criterion, with zero votes for ''low'' on any importance-related sub-criteria.

CMS will use the PQA Measure Manual specifications and Value Sets.[286] The IOP–LD measure evaluates the percentage of Part D beneficiaries, 18 years or older with at least one initial opioid prescription for more than 7 cumulative days' supply. To prevent misapplication, the following beneficiaries are excluded: (i) those with cancer or sickle cell disease diagnoses and (ii) those who elected to receive hospice care or are in palliative care at any time during the measurement period or the 90 days prior to the index prescription start date, which is the earliest date of service (DOS) for an opioid medication during the measurement year. The IOP–LD period has a lookback period, which is 90 days prior to each opioid prescription claim. Therefore, beneficiaries with no opioid prescription claims in the lookback period are defined as having a negative medication history for opioids.

The initial opioid prescription is the earliest DOS for an opioid prescription claim during the measurement year following a negative medication history. The opioid initiation period is the 3-day period when the numerator is assessed and ensures a comprehensive view of initial opioid prescribing. The opioid initiation period includes the date of the initial opioid prescription plus 2 days. All prescription claims during the opioid initiation period are counted cumulatively towards the days' supply total to avoid situations where a patient is prescribed a long duration of opioids following a very brief initial duration (that is, 1–3 days).

[281] Display Page Technical Notes and Measure Data available at: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

[282] *https://www.cms.gov/files/document/2021-announcement.pdf.*

[283] Pre-Rulemaking Measure Review Measures Under Consideration 2023 Recommendations Report: *https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf.*

[284] The Pharmacy Quality Alliance Patient & Caregiver Advisory Panel Meeting Minutes. *https://www.pqaalliance.org/assets/docs/PQA_2018_PCAP_Excerpt.pdf.*

[285] The Patient Safety Final Technical Report—Spring 2020 Cycle. *https://www.qualityforum.org/Publications/2021/03/Patient_Safety_Final_Technical_Report_-Spring_2020_Cycle.aspx.*

[286] Licensing and Using PQA Measures. *https://www.pqaalliance.org/measure-licensing-use.*

The IOP–LD measure is intended for retrospective population-level performance measurement of Part D plan sponsors (at the contract-level) and not to guide clinical decision-making for individual patients. The measure does not address opioid dosage, only the duration of an initial opioid prescription. Medications used for opioid use disorder (MOUD) are not included in the IOP–LD measure; for methadone, only use for pain is included.

The measure is not intended to impact current long-term opioid use. Because this measure only captures initial opioid prescriptions in individuals with no opioid history in the preceding 90 days, it is not anticipated to result in unintended consequences related to discontinuation or abrupt tapering of opioid use in current, long-term users. We recognize that some beneficiaries may require a longer duration for their initial opioid prescription based on the acute pain condition being treated (for example, major surgery or injury). Subsequent fills for opioids after the initial opioid prescription are not factored into the measure. However, by design, the measure does encourage re-evaluation of the benefits and risks for continued opioid therapy, which is a recommendation in the updated Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain, 2022 [287] (''2022 CDC Guideline''). Based on Recommendation 6 of the 2022 CDC Guideline, when opioids are used to treat acute pain, no greater quantity of opioids should be prescribed than needed for the expected duration of pain that is severe enough to require opioids. However, when acute pain does continue longer than the expected duration, prescribers, practices, and clinicians ''should have mechanisms in place for the subset of patients who experience severe acute pain that continues longer than the expected duration. These mechanisms should allow for timely reevaluation to confirm or revise the initial diagnosis and adjust pain management accordingly.''

Evidence for Measure: The duration of initial opioid exposure is associated with a higher likelihood of long-term opioid use. There is a consistent body of empirical evidence that a greater days' supply for initial opioid prescriptions is associated with significant risks, including increased risk of long-term opioid use, opioid misuse, and overdose. In the 2022 CDC Guideline, the CDC reaffirmed their recommendation on initial opioid prescription duration that ''when opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.'' In the associated implementation consideration text, the updated CDC Guideline notes that ''when the diagnosis and severity of acute pain warrant use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids'' and ''for many common causes of nontraumatic, nonsurgical pain, when opioids are needed, a few days or less are often sufficient.'' Furthermore, the 2022 CDC Guideline references an analysis conducted in 2014 [288] that found that the median durations of initial opioid analgesic prescriptions for acute pain indications in primary care settings were 4 to 7 days, suggesting that in most cases, clinicians considered an initial opioid prescription of 4 to 7 days' duration sufficient. In April 2023, the Food and Drug Administration (FDA) announced that it was requiring updates to the prescribing information of opioid pain medicines to provide additional guidance on the use of opioids. In this Drug Safety Communication,[289] the FDA stated, ''Data also suggest that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, although the dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.''

Existing evidence-based literature reinforces the CDC's recommendations regarding the duration of initial opioid prescriptions. A retrospective cohort study by Shah et al., found that the probability of long-term opioid use increased with each additional day supplied when initiating opioid therapy, following the third day supplied.[290] The study examined 1,294,247 patients aged 18 years or older who met the inclusion criteria and received initial opioid prescriptions, defined as those with no opioid prescriptions in the preceding 6 months of continuous enrollment. The study found that the probability of long-term use was more than twice as high for individuals who received greater than 7 days' supply, when compared to those with at least one day's supply (13.5 percent vs. 6.0 percent).

A different retrospective study published by Shah et al., provided further evidence that a greater days' supply for initial opioid prescriptions was associated with a decreased likelihood of opioid discontinuation.[291] The study followed a total of 1,353,902 opioid naïve individuals who had at least one opioid prescription between June 1, 2006, and December 31, 2014 and at least six months of continuous pharmacy and medical enrollment without an opioid prescription before their first opioid prescription. Among the 1.3 million study participants, 993,935 were enrolled for at least 1 year. Out of the 993,935 study participants, 33,019 individuals (3.32 percent) continued opioid use for 365 days or longer. After controlling for patient factors and underlying pain etiologies, the authors' results suggested a dose-response relationship between days' supply and likelihood of discontinuation. The hazard ratios for discontinuation of opioids were 0.70 (95 percent confidence interval (CI) 0.70–0.71) for a 3–4 days' supply, 0.48 (95 percent CI 0.47–0.48) for a 5–7 days' supply, 0.37 (95 percent CI 0.37–0.38) for an 8–10 days' supply, 0.32 (95 percent CI 0.31–33) for an 11–14 days' supply, 0.29 (95 percent CI 0.28–0.29) for 15–21 days' supply, and 0.20 (95 percent CI 0.19–0.20) for 22 or more days' supply of opioids, where a 1–2 days' supply is the reference group. This study also narrowed the sample by further evaluating opioid-naïve individuals to only those individuals who were opioid naïve for 12 months. This decreased the sample to 955,371 individuals and the results found the relationship between the first opioid prescription and the likelihood of discontinuation from opioids showed similar trends to the original study population.

Another study by Hadlandsmyth replicated Shah et al.'s methodology and researched the relationship between initial opioid exposure and long-term

[287] *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

[288] Mundkur ML, Franklin JM, Abdia Y, et al. Days' supply of initial opioid analgesic prescriptions and additional fills for acute pain conditions treated in the primary care setting—United States, 2014. MMWR Morb Mortal Wkly Rep 2019;68:140–3. *https://doi.org/10.15585/mmwr.mm6806a3.*

[289] *https://www.fda.gov/media/167058/download.*

[290] Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015. *MMWR Morb Mortal Wkly Rep.* Mar 17 2017;66(10):265–269.

[291] Shah A, Hayes CJ, Martin BC. Factors Influencing Long-Term Opioid Use Among Opioid Naive Patients: An Examination of Initial Prescription Characteristics and Pain Etiologies. J Pain. Nov 2017;18(11):1374–1383. doi:10.1016/j.jpain2017.06.010 at *https://www.jpain.org/article/S1526-5900(17)30635-1/pdf.*

use.[292] There were 19,600 Veteran's Health Administration patients who received an initial opioid prescription (defined as the first prescription with no opioid prescriptions in the preceding year) and subsequently met the criteria for long-term opioid use within one year of follow-up. The authors of this study compared their 2011 and 2016 data. Their results corroborated Shah's study that an association exists between initial opioid exposure and the rate of long-term use. This long-term opioid use appeared to persist even though the overall rate of long-term opioid use may have decreased, therefore concluding that cumulative days' supply was a strong predictor of long-term use and limiting initial opioid use can potentially decrease the risk of long-term opioid use. The study results found that in 2016, the overall rate of continued opioid use 1 year after initial opioid exposure was 16.8 percent and in 2011 was 29.2 percent.

Additionally, a study by Mojtabai analyzed trends in prescription opioid use among adults in the United States from 1999–2000 to 2013–2014.[293] The study found a significant increase in the prevalence of prescription opioid use, driven by an increase in long-term use.[21] By 2013–2014, nearly 80 percent of opioid users were classified as long-term users.[21] Long-term opioid use was linked to poorer physical health status, concurrent use of benzodiazepines, and a history of heroin use.[21] These findings emphasize the growing prevalence and implications of long-term opioid use in the U.S.[21]

Medicare Part D Opioid-Related Policy Alignment: Medicare Part D sponsors must have concurrent DUR systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS) (that is, the pharmacy) or point of distribution as described in § 423.153(c)(2). To help prevent and combat prescription opioid overuse through improved concurrent DUR, sponsors are expected to implement real-time opioid safety edits at the POS, including an edit to limit initial opioid prescription fills for opioid naïve beneficiaries to no more than a 7 days' supply. Sponsors should *not* implement these edits so that beneficiaries' access to MOUD, such as buprenorphine, is impacted; sponsors should not include MOUD in this edit.

Sponsors should have procedures in place to allow the edit to be overridden at POS if an enrollee is already taking opioids or is exempt.[294] [295] For example, sponsors may not have opioid claims history for new enrollees, especially at the start of a new contract year, and they may experience a claim rejection due to the opioid naïve edit with their first opioid prescription over 7 days' supply. Furthermore, beneficiaries who are residents of a long-term care facility, are in hospice care or receiving palliative or end-of-life care or have cancer or sickle cell disease should be excluded from these reviews. A pharmacist can override a POS edit for an exemption or for the enrollee not being opioid naïve. A beneficiary or their prescriber may also request a coverage determination from the plan for a longer duration for their initial fill, including the right to request an expedited or standard coverage determination in advance of prescribing. Subsequent prescriptions filled within the plan's look back window are not subject to the 7 days' supply limit, as the enrollee will no longer be considered opioid naïve.[296] While the opioid safety edit may help plan sponsors reduce prescription opioid overuse across their enrollment population, it should not be implemented by Part D plans as a one-size-fits-all prescribing limit or as a substitute for individual clinical judgment. Implementation of opioid safety edits, including the opioid naïve edit, by Part D sponsors, is monitored through the CMS Part D Reporting Requirements (OMB 0938–0992), beneficiary complaints, and other sources of CMS administrative data.

The IOP–LD measure complements the opioid naïve safety edit because it is similarly focused on the duration of initial opioid prescriptions to reduce risks, but the IOP–LD measure is retrospective. Sponsors are also required to establish a drug management program (DMP) for beneficiaries at-risk for misuse or abuse of frequently abused drugs, and beneficiaries with potential patterns of opioid misuse or with a history of opioid-related overdose are to be included in DMPs per the established retrospective criteria. DMP requirements are codified at § 423.153(f). Under such programs, Part D sponsors engage in case management of such beneficiaries by contacting their prescribers to determine if a beneficiary is at risk.

The Medicare Part D opioid-related policies were carefully developed to balance the need to address opioid misuse with the need to maintain a positive patient-doctor relationship, to preserve access to medically necessary drug regimens, and to reduce the potential for unintended consequences. The IOP–LD measure is an additional tool for sponsors to assess the effectiveness of Medicare Part D opioid-related strategies to reduce the risk of long-term opioid use, opioid misuse, or overdose.

Data-Driven Need: CMS routinely monitors the impact of the Medicare Part D opioid-related policies. We have observed positive trends in our population, especially after the opioid DUR—safety edit and DMP—policies were enhanced beginning in 2019, but we must continue to use available tools to proactively address potential misuse and overdose, including quality measures.

The IOP–LD rates for Part D contracts can be improved. The average IOP–LD rate across all contracts was about 16 percent for the 2021 measurement year (2023 display page) and 2022 measurement year (2024 display page). The average rates were 17 percent for MA–PDs and 13 percent for PDPs in the 2021 measurement year and 17 percent and 14 percent for MA–PDs and PDPs, respectively, in 2022. There was a range of IOP–LD rates among contracts; some of the highest rates for this measure by contract are 43 percent, 53 percent, and 64 percent.

Furthermore, based on the internal analysis of Part D prescription drug event (PDE) data from 2018 to 2023 (extracted January 17, 2024), the percentage of non-MOUD opioid Part D claims with 7 days' supply or less positively increased from 18.4 percent in 2018 to 27.7 percent in 2023 after the implementation of enhanced opioid safety edits at POS in 2019, but the

[292] Hadlandsmyth K, Lund BC, Mosher HJ. Associations between initial opioid exposure and the likelihood for long-term use. *J Am Pharm Assoc (2003).* Jan–Feb 2019;59(1):17–22. doi:10.1016/j.japh.2018.09.005 at *https://www.sciencedirect.com/science/article/pii/S1544319118304059?via%3Dihub.*

[293] Mojtabai, R. (2018). National trends in long-term use of prescription opioids. *Pharmacoepidemiology and drug safety, 27*(5), 526–534 at *https://pubmed.ncbi.nlm.nih.gov/28879660/.*

[21] 73 FR 20489–20490 in ''Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit'' published April 15, 2008 (73 FR 20486). However, CMS's longstanding interpretation of the phrase ''[a]gents when used for. . .weight *gain* . . .'' (emphasis added) in the same section of the Act has not included drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia (73 FR 20490).

[294] HPMS memorandum, dated December 19, 2022, Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs) available at: *https://www.cms.gov/files/document/cy-2023-opioid-safety-edit-reminders-and-recommendations.pdf.*

[295] HPMS memorandum, dated July 5, 2024, Contract Year (CY) 2025 Medicare Part D Opioid Safety Edits—Submission Instructions, Recommendations, and Reminders available at: *https://www.cms.gov/files/document/cy-2025-opioid-safety-edit-submission-instructions.pdf.*

number of claims were 10 million (2018), 12 million (2019), 11.5 million (2020), 12 million (2021), 12 million (2022), and 9.4 million (2023).

The percentage of Part D enrollees who had at least one opioid Part D claim in the year in PDE data decreased from 28.6 percent in 2018 to 20.6 percent in 2023 (not including MOUD).[297] Similarly, the percentage of non-MOUD opioid Part D claims (out of all covered Part D claims) after exclusions decreased from 4.7 percent to 3.6 percent. However, the number of users and claims remains a concern. The number of non-MOUD opioid Part D users from 2018 to 2023 were 10.4 million (2018), 9.8 million (2019), 9.1 million (2020), 9.3 million (2021), 9.3 million (2022), and 9.4 million (2023). The number of non-MOUD opioid Part D claims from 2018 to 2023 were 55 million (2018), 51.3 million (2019), 49.3 million (2020), 47.5 million (2021), 45.9 million (2022), and 44.7 million (2023).

The PQA has developed other measures to address opioid misuse, including the Use of Opioids at High Dosage in Persons without Cancer (OHD), Use of Opioids from Multiple Providers in Persons without Cancer (OMP), and Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP) measures, which CMS has used for quality and performance oversight. In 2019, the PQA updated these three measures and CMS implemented the measure revisions in the Patient Safety reports to Part D sponsors for the 2019 measurement year. These three measures were added to the display page beginning in 2021 (then using 2019 data).[298]

These three measures share the same denominator criteria, based on the number of member-years (MYs) of enrolled Part D beneficiaries with two or more prescription claims for opioids, filled on at least two unique dates of service, for at least 15 total cumulative opioid days' supply over a period of 90 days or longer during the measurement period.[299] CMS currently adjusts Part D enrollment based on MYs [300] to account for enrolled beneficiaries for only part of the contract year. Upon reviewing the denominator data, there has been an increase in the number of MYs of enrolled beneficiaries from almost 35.6 million to about 42.7 million from 2017 to 2022 measurement years (respectively, from 2019 to 2024 display page). However, the proportion of MYs of enrolled beneficiaries receiving at least two fills of prescription opioids and at least 15 days of supply of opioids over a period of 90 days or longer has decreased from 17 percent in 2017 to 9 percent in 2022. Even with this reduction, roughly four million MYs of enrolled beneficiaries still demonstrate long-term use of opioid prescriptions.

There is also continued concern for long-term opioid and illicit opioid use leading to overdose and death. According to the CDC, there are widening disparities among various population groups for overdose death rates, which have recently been driven by illicitly manufactured fentanyl use.[301] In 2020, the overdose death rates per 100,000 people increased by 44 percent for the Black population and 39 percent for American Indian and Alaska Native (AI/AN) population compared to 2019. Additionally, among Black males 65 years and older, the overdose death rate was nearly seven times more than their White male counterparts of the same age group.

Additionally, officials from the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, and the National Institute on Drug Abuse published a study that followed a cohort of 136,762 Medicare beneficiaries who experienced an index nonfatal drug overdose in 2020.[302] This population consisted primarily of Hispanic (5.8 percent), non-Hispanic Black (10.9 percent), and non-Hispanic White (78.8 percent) beneficiaries. The researchers followed the beneficiaries 12 months after the initial index nonfatal drug overdose and found that 23,815 beneficiaries (17.4 percent) had at least one more nonfatal drug overdose and 1,323 beneficiaries (1.0 percent) died of a fatal overdose. The study found that opioids were involved in 72.2 percent of these fatal drug overdoses.

Differences are seen in the Medicare Part D population based on internal analysis of PDE and administrative claims data by CMS. In 2023, the percentages of non-MOUD opioid Part D users were 24 percent for Black beneficiaries, 24 percent for AI/AN beneficiaries, and 22 percent for White beneficiaries. We found that overall, the number of Part D beneficiaries with a primary opioid overdose claim decreased from 32,120 in 2018 to 28,365 in 2023 (0.83 per 1,000 to 0.62 per 1,000 Part D beneficiaries). The opioid overdose rates varied among the Part D population in 2023 (January 1, 2023 to December 31, 2023): 1.52 per 1,000 AI/AN Part D beneficiaries, 1.35 per 1,000 Black Part D beneficiaries, and 0.57 per 1,000 White Part D beneficiaries. The disparities in opioid overdose rates existing among different population groups, as highlighted by CMS's internal data analysis, underscore the urgency to address the widening gap in health outcomes. As discussed in this preamble section, there is room for improvement and variations in IOP–LD rates among Part D sponsors.

The IOP–LD measure is a preventative-focused quality measure that addresses initial prescription opioid exposure to reduce the likelihood of long-term opioid use and reduce the risk of opioid overdose. We propose to add the Part D IOP–LD measure to the Star Ratings for the 2028 Star Ratings (2026 measurement year) and solicit comments on this proposal.

2. Updating Measures

a. Breast Cancer Screening (Part C)

CMS is proposing a substantive update to the existing Breast Cancer Screening measure because the measure steward, NCQA, is updating the measure as a result of changes in the applicable clinical guidance. In April 2024, the U.S. Preventive Services Task Force (USPSTF) issued final updated guidance for the age at which breast cancer screenings should begin.[303] Subsequently, NCQA announced their intention to update their breast cancer

[296] Medicare Part D Opioid Policies: Information for Prescribers available at: *https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/improving-drug-utilization-review-controls-part-d.*

[297] CMS internal analysis excluded beneficiaries who elected to receive hospice care, are in palliative care, who have cancer or sickle cell disease, or who are in a long-term care setting.

[298] See Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter available at: *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2020.pdf.* The ODHMP measure was

[299] Refer to 2024 Medicare part C & D Display Measure Technical Notes available at: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

[300] These measures will use continuous enrollment beginning in measurement year 2025 (2027 display page) as announced in the Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies available at: *https://www.cms.gov/files/document/2025-announcement.pdf.*

[301] CDC Newsroom Release. Overdose death rates increased significantly for Black, American Indian/Alaska Native people in 2020: *https://www.cdc.gov/media/releases/2022/s0719-overdose-rates-vs.html.*

[302] JAMA Internal Medicine: Overdose, Behavioral Health Services, and Medications for Opioid Use Disorder After a Nonfatal Overdose at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2820177.*

[303] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#bcei-recommendation-title-area.*

screening measure for measurement year 2025 to include biennial mammography screening for women aged 40–74 years at average risk of breast cancer (see *https://www.ncqa.org/blog/updates-to-breast-cancer-screening-age-range-for-hedis-my-2025/*). As discussed in the CY 2025 Rate Announcement, CMS is proposing to expand the age range for the Breast Cancer Screening measure to women aged 40–49, for an updated age range of 40–74, for the 2027 and subsequent measurement years.[304] The expanded age range for this screening measure significantly increases the size of the population covered by this measure and is therefore a substantive measure specification change within the scope of § 422.164(d)(2). The legacy measure with the narrower age range of 50–74 years will remain available and used in Star Ratings until the updated measure has been on the display page for two years and has been adopted through rulemaking. For measures such as this, NCQA requires plans to submit the data as the total rate and rates for each age stratification so data will be available to calculate the legacy measure rate until the expanded rate is adopted through rulemaking for the Star Ratings. The updated measure will be on the display page for the 2027 and 2028 Star Ratings and will be included in the 2029 Star Ratings if finalized through rulemaking.

b. Plan Makes Timely Decisions About Appeals (Part C) and Reviewing Appeals Decisions (Part C)

CMS is proposing substantive updates to the Plan Makes Timely Decisions about Appeals (Part C) measure that evaluates the percent of appeals timely processed by the plan (numerator) out of all the plan's appeals decided by the Independent Review Entity (IRE) (includes upheld, overturned, partially overturned, and appeals not evaluated by the IRE because the plan agreed to cover) (denominator). Given the extent to which cases are now submitted electronically (via the portal) to the IRE, CMS has updated the Maximus Medicare Health Plan Reconsideration Process Manual Medicare Managed Care Reconsideration Project (that is, the IRE Manual) effective January 1, 2025 [305] to better align when submission of a case file to the IRE is considered timely with the existing regulations. First, CMS is eliminating the additional days the IRE allows for appeal files that are submitted electronically. Currently, the IRE includes additional days to make allowances for any mail delays. Because the IRE now receives over 99 percent of case files electronically via the portal, CMS has updated the language in the IRE Manual to use a deadline for timely portal (that is, electronic) submission that aligns with the timeliness requirements in § 422.590 for submission of standard, expedited, and Part B drug cases. Section 422.590(a)(2) requires Medicare health plans to submit an unfavorable standard service reconsideration to the IRE as expeditiously as the enrollee's health condition requires, or not later than 30 calendar days after the receipt of a valid reconsideration request, subject to an additional 14-calendar day extension if requested by the enrollee or otherwise justified and in the enrollee's interest as set forth in § 422.590(f). These timeframes apply as well to Medicare cost plans under § 417.600.

The regulations do not provide any additional time for mail delays and Medicare health plans are not required to use overnight delivery for non-expedited cases. For purposes of defining and calculating timeliness, the IRE currently adds five calendar days to the timeframes listed above for all appeal file submissions. For example, the IRE currently considers a standard service case, without an extension, to be submitted timely if it is received within 35 calendar days of the valid request for reconsideration; this means that for electronic submissions by the plan, the plan has an extra five days to submit the file to the IRE beyond the deadline established in the applicable regulation. Since CMS is eliminating this 5-day period for all cases submitted electronically starting on January 1, 2025, we are proposing to make this update to the Plan Makes Timely Decisions about Appeals measure to align the measure with the timeframe used by the IRE in processing appeal files submitted to it. CMS believes this change is justified due to the overwhelming majority of cases being submitted electronically; further, eliminating the 5-day grace period for electronic submissions aligns this measure with the regulation text, which does not provide for or require any grace period for submission of files to the IRE. Per § 422.590(a)(2), (b)(2), (c)(2) and (e)(5), submission of the written explanation of an adverse reconsideration decision and associated documentation to the IRE is required within the same timeframe as notice to the enrollee (that is, 30, 60, or 7 days or 24 hours, depending on the specific item or service under appeal). Please note these changes are only in effect for electronic submissions. The timeliness of case files submitted by mail would continue to be subject to the 5-day grace period.

The second update CMS is implementing starting January 1, 2025, is to use the electronic system receipt date and time as the date the appeal was received by the IRE, regardless of whether it is during the IRE's business hours, for electronic submissions through the IRE's secure web portal. Currently, the IRE uses the system receipt date as the date the appeal was received if it is during the IRE's normal business hours. If the system receipt time or date is outside of the IRE's normal business hours, the following business day is currently used as the receipt date. For example, if the appeal is received on a Sunday when the IRE offices are closed, the appeal would be considered received on Monday when the offices are open. With this change the receipt date would be Sunday rather than Monday. CMS has updated the IRE Manual and process to allow case files submitted via the electronic portal to be considered received on the date and time of portal submission, even if it is outside of normal business hours, starting January 1, 2025. This means that cases received up to 11:59 p.m. (Eastern Time) each day via the portal would be considered received on that day. (However, the processing timeframe for the IRE-level review would not commence until the following business day.) This update more closely reflects the process of the submission of electronic files than current practice; because the electronic submission is available to the IRE at the time the electronic submission process is complete and the portal system has the functionality to track the minute of submission and record that as part of the submission record, using that date and time will better reflect when the IRE has possession and the ability to use the submitted materials to perform its work. These proposed specification changes would only affect electronic submissions. If hard copies are delivered outside of the IRE's normal business hours, the following business day is used as the receipt date. We are proposing to incorporate this change as part of the Plan Makes Timely Decisions about Appeals measure. We are proposing to incorporate this change also in the Reviewing Appeals Decisions measure since the appeals used in this measure are based on the date in the

[304] See Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (*cms.gov*) page 138.

[305] *https://www.medicareappeal.com/sites/default/files/New%20Manual%20with%20Timefram%20Updates%2010%207%2024.pdf.*

calendar year the appeals were received by the IRE, and this proposed update could affect the received date.

We are proposing to adopt these measure updates as defined at § 422.164(d)(2) for the Plan Makes Timely Decisions about Appeals and the Reviewing Appeals Decisions measures for the 2026 measurement year. The legacy appeals measures would remain in the Star Ratings until the updated measures have been on the display page for at least 2 years. Then, the legacy measures would be retired, and the respecified appeals measures would move into the Star Ratings beginning with the 2029 Star Ratings.

3. Summary of Measure Changes for the Part C and D Star Ratings

Table 14 summarizes the additional and updated measures addressed in this proposed rule, beginning with the 2028 Star Ratings. The measure descriptions listed in this table are high-level descriptions. The annual Star Ratings measure specifications supporting document, the *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2028 are produced in the fall of 2027. If a measurement period is listed as ''the calendar year 2 years prior to the Star Ratings year'' and the Star Ratings year is 2028, the measurement period is referencing the January 1, 2026 to December 31, 2026 period. As noted earlier in section IV.B. of this proposed rule, CMS does not codify the specific measures for the Part C and Part D Quality Rating System in regulation; doing so would be unnecessarily lengthy and cumbersome due to the relative regularity with which measure specifications are updated.

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TABLE 14: SUMMARY OF NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2026

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Initiation and Engagement of Substance Use Disorder Treatment	The average of (A) the percentage of new substance use disorder (SUD) episodes that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth visit, or medication treatment within 14 days and (B) the percentage of new SUD episodes that have evidence of treatment engagement within 34 days of initiation.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	00394-06-C-PARTC	Clustering	MA-PD and MA-only
Breast Cancer Screening*	Percent of female plan members aged 40-74 who had a mammogram during the past 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	00093-02-C-PARTC	Clustering	MA-PD and MA-only
Plan Makes Timely Decisions about Appeals*	Percent of appeals timely processed by the plan (numerator) out of all the plan's appeals decided by the Independent Review Entity (IRE) (includes upheld, overturned, partially overturned appeals, and dismissed because the plan agreed to cover) (denominator).	Health Plan Customer Service	Access Measure Weight of 2	Independent Review Entity	The calendar year 2 years prior to the Star Ratings year	00562-01-C-PARTC	Clustering	MA-PD and MA-only
Reviewing Appeals Decisions*	Percent of appeals where a plan's decision was "upheld" by the Independent Review Entity (IRE) (numerator) out of all the plan's appeals (upheld, overturned, and partially overturned appeals only) that the IRE reviewed (denominator).	Health Plan Customer Service	Access Measure Weight of 2	Independent Review Entity	The calendar year 2 years prior to the Star Ratings year	00652-01-C-PARTC	Clustering	MA-PD and MA-only
Part D Measures								
Initial Opioid Prescribing for Long Duration	The percentage of beneficiaries, 18 years of age or older, with at least one initial opioid prescription for more than 7 cumulative days' supply.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	PDE	The calendar year 2 years prior to the Star Ratings year	01789-01-C-PARTD	Clustering	MA-PD and PDP

*Revised Measures

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C. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

The Health Equity Index (HEI) reward will be implemented beginning with the 2027 Star Ratings (measurement years 2024 and 2025) that will be released in October 2026. The HEI reward is an upside only reward for obtaining high measure-level scores for the subset of enrollees with the specified social risk factors (SRFs). The current SRFs include receipt of the low income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE), or having a disability as defined by the original reason for Medicare entitlement. Additional SRFs may be added over time through rulemaking. The goal of the HEI reward is to improve health equity by incentivizing MA, 1876 cost, and PDP contracts to perform well among enrollees with specified SRFs.

The methodology for the HEI reward is codified at §§ 422.166(f)(3) and 423.186(f)(3). The calculation of the HEI reward includes an assessment of contract enrollment against two enrollment thresholds as described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii). To qualify for the full HEI reward (which ranges from 0.0 to 0.4 on a linear scale), contracts must have percentages of enrollees with the specified SRFs combined greater than or equal to the contract-level median in the most recent year of data used to calculate the HEI. To qualify for one-half of the HEI reward (which ranges from 0.0 to 0.2 on a linear scale), contracts must have percentages of enrollees with SRFs greater than or equal to one-half of the contract-level median up to, but not including the contract-level median percentage of enrollees with SRFs in the most recent year of data used to calculate the HEI. Paragraph (f)(3)(viii) describes how the HEI reward is calculated, with paragraphs (f)(3)(viii)(A) and (B) addressing calculation of the HEI reward in cases of contract consolidation.

We propose to revise §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) to clarify how the HEI reward enrollment thresholds are assessed beginning with the 2027 Star Ratings in the case of calculating the HEI reward for contract consolidations for the second year following the consolidation. We also propose changes at §§ 422.166(f)(3)(viii)(C) and 423.186(f)(3)(viii)(C) to how the HEI reward will be calculated beginning with the 2029 Star Ratings for contracts that are required by a state Medicaid agency to move one or more D–SNP plan benefit packages from an existing MA contract to an MA contract that only includes one or more D–SNPs with a service area limited to that state, consistent with § 422.107(e). Finally, we propose to revise §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) to clarify that in order for I–SNP-only contracts to have the rating-specific HEI calculated, these contracts must have data for at least half the measures included in the rating-specific HEI for the subset of measures that I–SNP-only contracts are required to report.

In calculating the HEI reward for the surviving contract of a consolidation, we want to avoid masking the scores of contracts with low performance among enrollees with the specified SRFs under higher performing contracts. We also want to avoid rewarding contracts that serve relatively few enrollees with the specified SRFs as they consolidate with contracts serving relatively more of these enrollees, because we want to focus the HEI reward on contracts serving larger percentages of enrollees with the specified SRFs where improvement is most needed. Starting with the 2027 Star Ratings, for the second year following a consolidation, we propose at §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) to clarify that the combined enrollment from the consumed and surviving contracts from the most recent year of data used in calculating the HEI will be used to assess whether the surviving contract meets one of the enrollment thresholds as described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii). When two or more contracts consolidate, the enrollment data used for the second year following the consolidation are from prior to the consolidation since the HEI is measuring performance prior to the contracts combining. For example, if two contracts consolidate as of January 1, 2026, we would combine the enrollment of the surviving and consumed contracts when calculating the 2027 Star Ratings based on enrollment in the surviving and consumed contracts in 2025. This is similar to how enrollment is combined for the calculation of enrollment for the second year following a consolidation for the categorical adjustment index at §§ 422.166(f)(2)(i)(B)(*1*) and 423.186(f)(2)(i)(B)(*1*).

In the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the **Federal Register** on May 9, 2022 (87 FR 27704), we codified at § 422.107(e) a provision allowing D–SNPs with exclusively aligned enrollment to apply for and maintain MA contracts that only include one or more D–SNPs with a service area limited to a specific state. If states require such D–SNP-only contracts along with integrated materials described at § 422.107(e)(ii) through their state Medicaid agency contracts, CMS will facilitate operationalization of additional opportunities for integration. As we described in the May 2022 final rule (87 FR 27763), D–SNP-only contracts established under § 422.107(e) result in several benefits for states and dually eligible individuals, including greater transparency on the MA organizations' performance in serving dually eligible enrollees by establishing Star Ratings specific to D–SNPs. As of plan year 2025, five states have taken advantage of the opportunity at § 422.107(e) to require D–SNP-only contracts. We anticipate the number of states with D–SNP-only contract requirements to increase by another eight or nine states in 2026, with the majority of these new states a result of the transition of those participating in the capitated financial alignment model demonstrations. We expect a limited number of additional states may move in this direction over time.

As a result of these state requirements, some MA organizations have had to, or will have to, move D–SNP plan benefit packages from existing MA contracts (hereafter referred to as ''legacy MA contracts'') to D–SNP-only contracts established under § 422.107(e). These changes may make it more difficult for a legacy MA contract to meet either of the enrollment thresholds for the percentages of enrollees with the specified SRFs for the HEI reward as defined at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) while the specified SRFs included in the HEI are LIS/DE or having a disability as currently defined at §§ 422.166(f)(3)(i)(A) and 423.186(f)(3)(i)(A). As such, MA organizations operating in states that elected § 422.107(e) may not be eligible for the HEI reward if fewer enrollees with SRFs remain following the establishment of separate D–SNP-only contracts, potentially creating an incentive for these organizations to promote enrollment of individuals with the specified SRFs in the legacy MA contracts as opposed to the D–SNPs. This incentive runs counter to our goal of encouraging enrollment in high-quality integrated products that better

suit the dually eligible population. To address this, we propose at §§ 422.166(f)(3)(viii)(C) and 423.186(f)(3)(viii)(C) to modify the way eligibility for an HEI reward and the size of the HEI reward are determined for legacy MA contracts that no longer meet either of the percentage SRF enrollment thresholds due to state contracting requirements under § 422.107(e). As additional SRFs are added to the HEI reward through rulemaking, we anticipate that the need for this adjustment will no longer be necessary. Thus, we propose at §§ 422.166(f)(3)(viii)(C) and 423.186(f)(3)(viii)(C) that this change would be implemented every year after the D–SNP-only contract established under § 422.107(e) is required to be created until the Star Ratings year when additional SRFs are added to the HEI reward, after which time, legacy MA contracts will have the potential HEI reward calculated based on their own enrollment and performance following the methodology at §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii). There are no changes to how eligibility for, or the size of, the HEI reward are calculated for D–SNP-only contracts established under § 422.107(e).

We propose a series of rules that would be applied in order to determine whether the legacy MA contract would qualify for an HEI reward and the size of the reward if applicable. First, we propose at §§ 422.166(f)(3)(viii)(C)(*1*) and 423.186(f)(3)(viii)(C)(*1*) to follow the methodology for calculating the HEI reward at paragraphs §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) for legacy MA contracts that continue to meet either of the percentage SRF enrollment thresholds (*i.e.,* the contract-level median threshold or one-half of the contract-level median threshold) based on their own enrollment. For legacy MA contracts that do not meet either of the percentage SRF enrollment thresholds (*i.e.,* the contract-level median threshold or one-half of the contract-level median threshold) based on their own enrollment, we propose at §§ 422.166(f)(3)(viii)(C)(*2*) and 423.186(f)(3)(viii)(C)(*2*) to first determine whether the legacy MA contract can reliably have the rating-specific HEI score calculated based on its own enrollment as described at §§ 422.166(f)(3)(iv) and (vi) and 423.186(f)(3)(iv) and (vi). If the legacy MA contract cannot reliably have the rating-specific HEI score calculated based on its own enrollment, then the legacy MA contract would not qualify for an HEI reward for the given rating. We propose this to ensure that legacy MA contracts are not rewarded unless they are still providing relatively high quality care for their remaining enrollees with SRFs, and we cannot ensure this if the rating-specific HEI score cannot be reliably calculated.

Additionally, we propose at §§ 422.166(f)(3)(viii)(C)(*2*) and 423.186(f)(3)(viii)(C)(*2*) that if the D–SNP-only contract established under § 422.107(e) that received the D–SNP(s) from the legacy MA contract cannot have the rating-specific HEI score reliably calculated, then the legacy MA contract would not qualify for an HEI reward for the given rating. We propose this because without the HEI score from the D–SNP-only contract established under § 422.107(e), the potential HEI reward for the legacy contract would be based solely on its own performance among a relatively small percentage of enrollees with the specified SRFs. This would be inconsistent with our policy goals for the HEI reward, one of which is to focus the HEI reward on contracts serving larger percentages of enrollees with the specified SRFs, as this is where improvement is most needed. For example, the D–SNP-only contract established under § 422.107(e) that received the D–SNP(s) from the legacy MA contract would not be able to have a rating-specific HEI score reliably calculated if the D–SNP contract is too new or does not have enough data, and therefore the legacy MA contract in this instance also would not qualify for an HEI reward. To further illustrate this point using example measurement years, a D–SNP-only contract established under § 422.107(e) that begins operating in 2027 would first be eligible for a Star Rating as of the 2029 Star Ratings (measurement year 2027) and an HEI reward as of the 2030 Star Ratings (measurement years 2027 and 2028). For the 2027 and 2028 Star Ratings, the calculation of the enrollment thresholds and the HEI for the legacy MA contract would be based on measurement periods that were prior to the D–SNP-only contract transition. The 2029 Star Ratings are based on a measurement period following the D–SNP-only contract transition, and since the D–SNP-only contract cannot have an HEI reward calculated that rating year, the legacy MA contract would not be eligible for the HEI reward unless it qualifies solely based on its own enrollment.

We propose at §§ 422.166(f)(3)(viii)(C)(*3*) and 423.186(f)(3)(viii)(C)(*3*) that the legacy MA contract would not qualify for a rating-specific HEI reward if the legacy MA contract's performance on the rating-specific HEI based on its own enrollment does not meet the minimum index score of greater than zero defined at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) or if the legacy MA contract's performance on the rating-specific HEI based on its own enrollment is less than the performance on the rating-specific HEI of the D–SNP-only contract established under § 422.107(e).

If both the legacy MA contract and the D–SNP-only contract established under § 422.107(e) can reliably have the rating-specific HEI scores calculated as defined at §§ 422.166(f)(3)(iv) and (vi) and §§ 423.186(f)(3)(iv) and (vi) based on their own enrollment, and the legacy MA contract does not meet an enrollment threshold on its own, then we propose at §§ 422.166(f)(3)(viii)(C)(*4*) and 423.186(f)(3)(viii)(C)(*4*) the methodology to determine the potential HEI reward for the legacy MA contract for the given rating. Specifically, we propose at §§ 422.166(f)(3)(viii)(C)(*4*)(*i*) and 423.186(f)(3)(viii)(C)(*4*)(*i*) to base the enrollment threshold at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) on the combined enrollment from the legacy MA contract and the D–SNP-only contract established under § 422.107(e) from the most recent measurement year used in calculating the HEI. Additionally, we propose at §§ 422.166(f)(3)(viii)(C)(*4*)(*i*) and 423.186(f)(3)(viii)(C)(*4*)(*i*) that if the legacy MA contract's rating-specific HEI score based on its own enrollment meets the minimum index score of greater than zero defined at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii), and the legacy MA contract's rating-specific HEI score based on its own enrollment is greater than or equal to the rating-specific HEI score for the D–SNP-only contract established under § 422.107(e), then the legacy MA contract would qualify for an HEI reward for the given rating. This potential rating-specific HEI reward would be calculated following §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii) and would be based on the enrollment threshold using the combined enrollment from the legacy MA contract and the D–SNP-only contract established under § 422.107(e) as defined at §§ 422.166(f)(3)(viii)(C)(*4*)(*i*) and 423.186(f)(3)(viii)(C)(*4*)(*i*), and using the HEI score for the D–SNP-only contract established under § 422.107(e). We propose this because we want to avoid overly rewarding legacy MA contracts that are serving a smaller percentage of enrollees with SRFs and therefore may find it easier to perform well on the HEI.

We also propose at §§ 422.166(f)(3)(viii)(C)(*5*) and

423.186(f)(3)(viii)(C)(*5*) that when multiple legacy MA contracts move their D–SNP plan benefit packages to the same D–SNP-only contract established under § 422.107(e), the combined enrollment from the multiple legacy MA contracts and the D–SNP-only contract would be used to determine if a percentage SRF enrollment threshold is met for legacy MA contracts that do not meet an enrollment threshold based on their own enrollment.

Further, in calculating the rating-specific HEI, we require at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) that contracts must have at least 500 enrollees and meet the criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) for at least half of the measures included in the rating-specific HEI. Since I–SNP-only contracts are not required to report CAHPS, HOS, and certain HEDIS measures, there may be situations depending on the set of measures included in the HEI each year where I–SNP-only contracts cannot meet this half of measures requirement based on not being required to report some of the measures included in the HEI. To address this, we propose to revise §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) to clarify that starting with the 2027 Star Ratings, contracts that are I–SNP-only contracts in the rating year must meet the criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) for at least half of the measures included in the rating-specific HEI for the subset of measures that I–SNP-only contracts are required to report. For example if there were 20 measures included in a rating-specific HEI but only 16 of the measures were required to be reported by I–SNP-only contracts, then I–SNP-only contracts would need to meet the criteria specified at §§ 422.166(f)(3)(iv) and 423.186(f)(3)(iv) for at least half of the 16 measures or for 8 measures. We propose this to avoid situations where I–SNP-only contracts are not able to meet the half of measures requirement at §§ 422.166(f)(3)(vi) and 423.186(f)(3)(vi) based solely on reporting requirements. We are not proposing changes for other contract types, because we do not anticipate scenarios for other contract types where it is not possible to meet the half of measures requirement based solely on reporting requirements. We also propose at §§ 422.166(f)(3)(iv)(C) and 423.186(f)(3)(iv)(C) that for a measure to be included in the calculation of the HEI for a contract that is an I–SNP-only contract in the ratings year, the measure must be required to be reported by I–SNP-only contracts. We propose this to address situations where a contract may not have been an I–SNP-only contract in one of the measurement years and therefore has data on measures that are not required to be reported by I–SNP-only contracts and are not reflective of the population served by I–SNP-only contracts.

Finally, we propose changes at §§ 422.166(f)(3)(v)(A) and 423.186(f)(3)(v)(A) to how the HEI score would be calculated for contracts that have data discrepancies between their submitted patient-level detail and summary-level data for HEDIS measures included in the HEI beginning with the 2026 and 2027 measurement years used for the 2029 Star Ratings. For HEDIS measures included in the HEI we rely on the patient-level detail data that contracts submit to CMS. It is critical that these data are complete so we can accurately calculate performance for the subset of enrollees with the specified SRFs. We propose that for measures included in the HEI, if a contract's HEDIS measure score across all enrollees for a measure that is calculated by CMS using the contract's submitted patient-level detail HEDIS data does not match the contract's summary-level HEDIS score submitted to NCQA for either of the two measurement years used to construct the HEI as defined at §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B), the contract would receive −1 points for that measure (the same number of points assigned to the bottom third of the distribution of contract performance) in the calculation of the HEI as described at §§ 422.166(f)(3)(v) and 423.186(f)(3)(v). We also propose at §§ 422.166(f)(3)(v)(A) and 423.186(f)(3)(v)(A) that a contract that does not provide patient-level HEDIS data for a measure included in the HEI for which it has provided summary-level HEDIS data to NCQA would receive −1 points for that measure in the calculation of a contract's HEI score at §§ 422.166(f)(3)(v) and 423.186(f)(3)(v). For example, if the HEI is based on the 2026 and 2027 measurement years and a contract does not provide HEDIS patient-level data for a measure for either the 2026 or 2027 measurement years, the contract would receive −1 points for that measure in the calculation of its HEI score.

We solicit comments on these proposals, including whether these rules for calculating the HEI reward when an MA organization is required by a state, consistent with § 422.107(e), to establish and maintain a D–SNP-only contract that is limited to only D–SNPs offered by the MA organization in that state should apply for one year, multiple years, or every year after the D–SNP-only contract is required to be established by the state or until additional SRFs are added to the HEI.

D. Applying the Improvement Measure Scores (§§ 422.166(g) and 423.186(g))

We propose to clarify at §§ 422.166(g)(1)(i) and (ii) and §§ 423.186(g)(1)(i) and (ii) that the improvement measure hold harmless for the highest rating is determined based on the rounded rating before the addition of the HEI reward, if applicable. This is consistent with how the improvement measure hold harmless rules have historically been applied based on the rounded rating, and §§ 422.166(f)(3)(ix) and 423.186(f)(3)(ix) require that the HEI reward be added after the application of the improvement measures and before rounding to the nearest half star.

To operationalize this, CMS would determine the application of the improvement measures for the highest rating using the rating rounded to the nearest half star before the addition of the HEI reward, if applicable. Then when adding the HEI reward if applicable for the highest rating, CMS would go back to the unrounded rating either with or without the improvement measures as determined using the steps described at §§ 422.166(g) and 423.186(g), add the HEI reward, and then round to the nearest half star. This is our current (and historical) process and how the proposed regulatory clarification would be applied.

E. Contract Consolidations (§ 422.162(b)(3) and § 423.182(b)(3))

We are proposing a technical clarification of existing policy at §§ 422.162(b)(3)(iv)(A)(*2*) and (B)(*2*) and §§ 423.182(b)(3)(ii)(A)(*2*) and (B)(*2*) to provide details about how the enrollment-weighted measure score is calculated when a consumed or surviving contract is missing data for a measure. In the first year of the consolidation when a measure score for a consumed or surviving contract is missing as a result of not having enough data to meet the measure technical specification or for a CAHPS measure having reliability less than 0.6, CMS proposes to treat this measure score as missing in the calculation of the enrollment-weighted measure score. Similarly, in the second year of the consolidation for all measures, except HEDIS, HOS, CAHPS, and call center measures, when a measure score for a consumed or surviving contract is missing as a result of not having enough

data to meet the measure technical specification, CMS proposes to treat this measure score as missing in the calculation of the enrollment-weighted measure score. For § 423.182(b)(3)(ii)(A)(2) and (B)(2) we also removed reference to § 423.184(g)(1)(ii) since it was reserved in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) final rule (pages 30639–30642).

F. Burden

As described in this section of this proposed rule, we are proposing adding and updating certain measures. The proposed measure additions and updates are calculated from administrative data or entail moving existing measures from the display page to Star Ratings, which would have no impact on plan burden. We are also proposing a series of technical clarifications related to applying the improvement measure scores and calculating the health equity index, as well as proposing how the health equity index reward would be calculated for contracts that are required by a state Medicaid agency to move one or more D–SNP plan benefit packages from an existing MA contract to an MA contract that only includes one or more D–SNPs with a service area limited to that state, consistent with § 422.107(e). The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS's Star Ratings related PRA packages.

V. Improving Experiences for Dually Eligible Enrollees

A. Member ID Cards, Health Risk Assessments, and Individualized Care Plans (§§ 422.101, 422.107, 422.2267, 423.2267)

Dually eligible individuals face fragmentation in many parts of the health care system, including their experiences as enrollees of Medicare and Medicaid managed care plans. One way in which we seek to address such fragmentation is through policies that integrate care for dually eligible individuals. ''Integrated care'' refers to delivery system and financing approaches that (1) maximize person-centered coordination of Medicare and Medicaid services; (2) mitigate cost-shifting incentives between the two programs; and (3) create a seamless experience for dually eligible individuals.

In recent years, we have advanced integrated care by:

- Incorporating features of the Medicare-Medicaid Financial Alignment Initiative's (FAI) Medicare-Medicaid Plans (MMPs) into dual eligible special needs plan (D–SNP) requirements, including enrollee participation in plan governance, screening for social risk factors in health risk assessments (HRAs) (which applies to all SNPs), integrated enrollee materials, and mechanisms for joint Federal-State oversight;
- Implementing provisions of the Bipartisan Budget Act of 2018 to unify appeals and grievance processes across Medicare and Medicaid; and
- Increasing opportunities for enrollment in D–SNPs with aligned Medicaid managed care plans operated by the same parent organization.

However, there remain aspects of care for dually eligible individuals that can be misaligned, confusing, or duplicative even when a dually eligible individual is enrolled in Medicare and Medicaid managed care plans operated by the same parent organization.

In this section we describe proposals to establish new Federal requirements for D–SNPs that are applicable integrated plans (AIPs) to: (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated health risk assessment for Medicare and Medicaid, rather than separate HRAs for each program. These proposals continue our work to advance integrated care by applying MMP features into D–SNP requirements. More importantly, our proposals would improve and simplify experiences for dually eligible enrollees in AIP D–SNPs. We are also proposing to amend the requirements related to HRAs and individualized care plans (ICPs) for all SNPs (that is, D–SNPs, chronic condition SNPs, and institutional SNPs). Under this third proposal, we would codify timeframes for SNPs to conduct HRAs and develop ICPs and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs. Finally, we propose a related addition to requirements for D–SNP enrollee advisory committees. We describe each proposal in greater detail in the following sections.

a. Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D–SNPs

Sections 422.2267(e)(30) and 423.2267(e)(32) require MA and Part D plans, including D–SNPs, to provide member ID cards to enrollees. Medicaid managed care plans, which include managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) also send member ID cards to enrollees which they use to access the items and services provided under that plan. However, when a dually eligible individual is enrolled in both a Medicare Advantage (MA) plan and a Medicaid managed care plan, the plans usually issue the enrollee separate member ID cards—one for their MA plan and one for their Medicaid managed care plan—to access services for each program. This is administratively confusing, as providers may not always know which insurance to charge for which services, and confusing for enrollees, who may not always be aware of when to present which card.[306] Through studies and conversations with dually eligible enrollees, we have learned that individuals dually eligible for Medicare and Medicaid view having one insurance card instead of two as a benefit of integrated care.[307] As such, we are proposing to continue our effort to integrate materials for dually eligible enrollees by requiring that certain D–SNPs provide one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled.

In the past several years, we have partnered with States to make integrated materials more broadly available, with the goal of streamlining the managed care enrollee experience and reducing burden and confusion for dually eligible individuals. As of January 2024, approximately 846,000 dual eligible individuals were enrolled in integrated care plans that used integrated materials. That includes all MMPs in the FAI, which use integrated Medicare and Medicaid materials including the member ID card, annual notice of change, evidence of coverage (Member Handbook), Formulary (List of Covered

[306] CMS commissioned studies on experiences and terms pertaining to integrated care and solicited feedback from States and plans on integrated member ID cards.

[307] Rachelle Brill, Listening to Dually Eligible Individuals: Person-Centered Enrollment Strategies for Integrated Care. Center for Consumer Engagement in Health Innovation, June 2021. Online at *https://communitycatalyst.org/wp-content/uploads/2023/06/Person-Centered-Enrollment-Strategies-for-Integrated-Care.pdf.*

Drugs), Summary of Benefits, and Provider and Pharmacy Directory.

In the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the May 9, 2022, **Federal Register** (hereinafter referred to as the May 2022 final rule), we finalized a pathway at § 422.107(e) by which States can require D–SNPs with exclusively aligned enrollment (EAE) to use integrated Medicare and Medicaid materials including the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory—essential information for dually eligible enrollees to be able to understand and utilize their managed care benefits. Eleven States currently require D–SNPs that are AIPs, as defined at § 422.561, to use at least some integrated materials for CY 2025, as shown in table 15.

TABLE 15. STATES REQUIRING VARIOUS INTEGRATED MATERIALS AMONG AIPs

Material	Summary of Benefits	Provider and Pharmacy Directory	Formulary (List of Covered Drugs)	Annual Notice of Change	Evidence of Coverage (Member Handbook)
State(s)	CA, DC, ID, MA, MN, NJ, NY, TN, VA, WI	CA, DC, HI, ID, MA, MN, NJ, VA, WI	CA, DC, HI, ID, MA, MN, NJ, VA, WI	CA, MN, NJ, TN	CA, MN, NJ, TN

In addition, in some cases, dually eligible enrollees in D–SNPs and an affiliated Medicaid managed care plan with EAE receive a single ID card that serves as the ID card for both health plans. According to State Medicaid agency contracts (SMACs) for contract year 2024, nine States (California, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, Tennessee, and Wisconsin) currently require D–SNPs to use a single integrated member ID card for both Medicare and Medicaid benefits.

Establishing a Federal requirement for integrated member ID cards for AIP D–SNPs would improve experiences for dually eligible individuals (in such plans not already deploying an integrated ID card) and build on our past work to integrate Medicare and Medicaid. Therefore, under our authority to interpret, implement and carry out the Part C and D programs under sections 1851(h), 1852(c), 1860D–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(*l*) of the Social Security Act (the Act), we are proposing to add a requirement at §§ 422.2267(e)(30) and 423.2267(e)(32) that AIPs provide enrollees one integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which they are enrolled.

We are not proposing substantive changes to the Medicare or Medicaid requirements for the content of the ID cards. Therefore, the integrated ID cards would need to comply with the applicable Medicare requirements at §§ 422.2267(e)(30) and 423.2267(e)(32) and as further described in the Medicare Communications and Marketing Guidelines as well as applicable Medicaid requirements.

For example, we finalized a provision at § 438.3(s)(7) in the final rule titled ''Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program,'' which appeared in the September 26, 2024, **Federal Register** (hereinafter referred to as the September 2024 Medicaid final rule), requiring States that contract with MCOs, PIHPs, or PAHPs that provide coverage of Medicaid outpatient drugs to require those managed care plans to assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits to make the Medicaid drug program run more efficiently and improve the level of pharmacy services provided to Medicaid enrollees. Although Medicaid managed care plans are not Federally required to issue member ID cards, it is a standard business practice for the MCOs, PIHPs, and PAHPs to routinely issue identification cards for pharmacy benefits for Medicaid enrollees. To the extent AIPs cover outpatient drugs for which Medicaid (not Medicare) would be the primary payer, § 438.3(s)(7) would still apply to the AIP.

We note that the September 2024 Medicaid final rule states that § 438.3(s)(7) is effective for Medicaid managed care contracts (which would require compliance by MCOs, PIHPs, and PAHPs) no later than the first rating period for contracts with managed care plans beginning on or after 1 year following the effective date of the September 2024 Medicaid final rule, which is November 19, 2024. While our proposed updates to §§ 422.2267 and 423.2267 are applicable for contract year 2027, beginning October 1, 2026, the requirements at § 438.3(s)(7) would be applicable as is described in the September 2024 Medicaid final rule.

Our proposal would not add new requirements in the nine States that currently require integrated member ID cards in their SMACs. Similarly, we expect—independent of this proposal—several additional States will require integrated member ID cards when MMPs transition to D–SNPs in 2026 (because these States already require integrated member ID cards for the MMPs). If finalized, this proposal would require current AIPs in three additional States and Territories (District of Columbia, New York, and Puerto Rico) to implement integrated member ID cards, and if more plans become AIPs, this requirement would apply to any such plans as well. However, we do not believe that this proposed requirement to integrate member ID cards would create additional burden in these States and Territories as the issuance of member ID cards is a normal and customary practice throughout the insurance industry. Since we will be working with several States to update an array of integrated materials as we transition MMPs to become integrated D–SNPs in 2026, and to give AIPs time needed to implement such updates as appropriate during the annual material creation cycle, we propose to require the use of the integrated member ID card for enrollments effective January 1, 2027. Thus, our proposed updates to marketing and communication provisions at §§ 422.2267(e)(30) and 423.2267(e)(32) would be applicable for all contract year 2027 marketing and

communications beginning October 1, 2026.

We believe requiring that AIPs use integrated member ID cards is an important step to further integration and make enrollees' experience with Medicaid and Medicare less confusing, less burdensome, and more accessible. To our knowledge, this proposal represents the first time we have proposed a Federal requirement for any integrated materials for any type of D–SNP. We chose to focus on ID cards because having one ID card is important to dually eligible individuals [308] and—relative to integrating other materials—is operationally manageable for integrated plans and requires the least of State Medicaid agencies. We solicit comment on this proposal and feedback on successes, challenges, and other experiences to date with integrated member ID cards.

We are considering, and invite comment on, whether the final rule should provide that any requirement for integrated ID cards should apply to AIPs and *all* HIDE SNPs, including those that do not also qualify as AIPs. However, in this proposed rule, we chose to limit our proposal to AIPs because we assume that integrated member ID cards would be more complex to administer in situations where some D–SNP enrollees have aligned enrollment but others are enrolled in a Medicaid plan operated by a different organization or fee-for-service Medicaid. In contrast to an AIP, where all of the D–SNP's enrollees would receive the integrated ID card, a non-AIP would need a reliable and timely mechanism for differentiating among enrollees within the plan to determine which ID card to send. We are unaware of any D–SNPs or other MA plans that currently deploy the types of integrated ID cards envisioned in our proposal for plans that do not have exclusively aligned enrollment. We solicit comment on the accuracy of these assumptions and, as noted above, whether in the final rule to apply the proposed requirement to AIPs and *all* HIDE SNPs. We also welcome comments on different situations in which commenters believe that integrated member ID cards could be helpful to include in potential future rulemaking.

Finally, we welcome comment on other considerations for future rulemaking on ID cards, including ways to prevent stigma and ensure their security and utility for dually eligible enrollees.

b. Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D–SNPs

Medicare requirements at § 422.101(f)(1) require D–SNPs to conduct a comprehensive HRA for each enrollee, both at the time of enrollment and annually thereafter. Separately, Medicaid managed care regulations at § 438.208(b)(3) require Medicaid managed care plans to make a best effort to conduct an initial screening of enrollee needs within 90 days of their effective enrollment date, and States may require additional assessments such as long-term services and supports (LTSS) and home and community-based services eligibility screenings.

In the FAI, MMP enrollees complete a single integrated HRA, encompassing both Medicare and Medicaid requirements. In contrast, dually eligible individuals enrolled in both a D–SNP and a Medicaid managed care plan may end up completing multiple assessments during the year, some of which may be duplicative, as managed care plans aim to meet all applicable enrollee assessment requirements across both programs, and to gather information about enrollee needs and preferences and create individualized care plans. Completing two separate, but potentially overlapping, assessments creates unnecessary burden for enrollees, who may have to answer the same detailed personal questions more than once.

In the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the January 19, 2021, **Federal Register** (hereinafter referred to as the January 2021 final rule), we clarified that D–SNPs receiving capitation for Medicaid services may combine their Medicare-required HRA with a State Medicaid-required assessment to reduce burden for enrollees, as long as the assessment meets all applicable requirements (86 FR 5879). We also noted that, to the extent there is overlap and the HRA required by § 422.101(f)(1)(i) can be aligned with other assessments conducted by a SNP, the model of care (MOC) should describe that alignment, consistent with the standards in MOC 2, Element B in Chapter 5, section 20.2.2 of the Medicare Managed Care Manual. We explained that the factors outlined in the MOC guidelines allow SNPs the flexibility to align the HRA required by § 422.101(f)(1)(i) with other assessment tools. In addition, the contract year (CY) 2024 Medicare Part C Reporting Requirements, in which MA plans must report on HRA completion, allow D–SNPs to count a Medicaid HRA that is performed within 90 days before or after the effective date of Medicare enrollment as meeting the Part C obligation to perform an HRA, so long as the requirements in § 422.102(f) regarding the HRA are met.[309] As outlined in both the January 2021 rule and the most recent Part C Reporting Requirements, we have allowed a certain degree of flexibility for SNPs to streamline their Medicare and Medicaid assessments. However, we have not previously required that D–SNPs integrate Medicare and Medicaid enrollee HRAs into a single HRA for dually eligible individuals.

States have implemented their own requirements, through SMACs, to reduce burden and duplication. For example, Arizona requires D–SNPs to perform an integrated HRA for both Medicare and Medicaid. California requires D–SNPs with exclusively aligned enrollment to make their best effort to create a single unified HRA for enrollees, and New Jersey's SMAC includes requirements related to minimizing duplication of assessments.[310] Other States, while not explicitly requiring integrated HRAs, have implemented requirements to improve integration and coordination across Medicare and Medicaid HRAs and services. A 2019 Health Management Associates (HMA) report commissioned by the Medicaid and CHIP Payment and Access Commission (MACPAC) noted one State requires its D–SNPs to request a representative from an enrollee's Medicaid plan to participate in all needs assessments, and that another State requires integrating Medicaid LTSS assessments within the HRA.[311] We have also heard from a few D–SNP parent organizations that are actively working to reduce duplication between their Medicare and Medicaid HRAs.

Under our authority at section 1856(b) of the Act to establish standards for MA plans by regulation, we propose to adopt specific standards to implement the requirement at section

[308] Rachelle Brill, Listening to Dually Eligible Individuals: Person-Centered Enrollment Strategies for Integrated Care. Center for Consumer Engagement in Health Innovation, June 2021. Online at *https://communitycatalyst.org/wp-content/uploads/2023/06/Person-Centered-Enrollment-Strategies-for-Integrated-Care.pdf.*

[309] 2024 Part C Reporting Technical Specifications: *https://www.cms.gov/files/document/cy2024-part-c-technical-specifications-02222024.pdf.*

[310] CMS review and analysis of State SMACs.

[311] *https://www.macpac.gov/wp-content/uploads/2019/03/Care-Coordination-in-Integrated-Care-Programs-Serving-Dually-Eligible-Beneficiaries.pdf.*

1859(f)(5)(A)(ii)(I) of the Act that all MA SNPs conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs. We propose to add a new paragraph at § 422.101(f)(1)(v) that would require D–SNPs that are AIPs (as defined in § 422.561) to conduct a comprehensive HRA that meets all requirements at § 422.101(f)(1)(i) through (v) as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees in the AIP complete a single integrated HRA for Medicare and Medicaid. If this proposal is finalized, we believe it would meaningfully reduce assessment burden for dually eligible individuals and improve their experience as managed care enrollees (where States aren't already requiring something similar). It may also improve integration of care within D–SNP AIPs and their affiliated Medicaid managed care plans by collecting all enrollee assessment information in one place, potentially facilitating better care coordination across Medicare and Medicaid services. This proposal would also continue our efforts to incorporate MMP features into D–SNP requirements. Finally, we believe this proposal for a new Federal requirement would not create a significant burden for health plans because similar State requirements to integrate Medicare and Medicaid HRAs are already in place in some States, and at least a few health plans have taken on these efforts themselves.

We are proposing only to require D–SNPs that are AIPs to meet this new requirement because we believe it is most feasible for D–SNPs whose enrollees are exclusively aligned with an affiliated Medicaid MCO to implement a fully integrated HRA. Because all FIDE SNPs are AIPs beginning in 2025, the proposal encompasses all FIDE SNPs. Numerous HIDE SNPs and some coordination-only D–SNPs with exclusively aligned enrollment are also AIPs. We are considering whether we should apply this new requirement to *all* HIDE SNPs or all D–SNPs, even those without exclusively aligned enrollment. However, in a scenario where some D–SNP enrollees receive their Medicaid benefits from a different organization or through fee-for-service, it could be challenging for the D–SNP to assess aligned enrollees with an integrated HRA and to assess non-aligned enrollees with a different, Medicare-only assessment. We welcome comment on whether, in the final rule, this requirement should be applied to all HIDE SNPs or suggestions as to whether application to a different subset of D–SNPs should be proposed in future rulemaking.

This proposal would not change any specific Medicare or Medicaid requirements for the timing of or elements included in an HRA (although we address an issue related to the timing of required HRAs elsewhere in this proposed rule). Nor would this proposal preclude deployment of assessments that are modular (such as a base level assessment that meets all Medicare and Medicaid requirements with optional additional sections that are specific to people for substance use or other factors) or include additional elements for people with special needs. For example, some States may require more expansive assessment questions to develop a service plan for 1915(c) waiver services, or plans may conduct additional assessment for people who screen positive for substance use disorder or other conditions. Our proposal would not require that all enrollees complete such an assessment, nor would it preclude plans from conducting such additional assessments separately from the HRA. Rather, our proposal simply requires that the base HRA and screening applies across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid. We welcome comment on potential challenges that health plans and other stakeholders foresee, or have already experienced, in implementing HRAs that integrate LTSS assessments. We also welcome comment on any potential conflicts with State Medicaid assessment requirements our proposal may create.

In addition to separate Medicare and Medicaid managed care assessment requirements, different Medicare and Medicaid enrollment timeframes and effective dates can be a barrier to D–SNP AIPs administering a single, integrated HRA. In the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the April 23, 2024, **Federal Register** (hereinafter referred to as the April 2024 final rule), we noted at 89 FR 30704 that Medicare and Medicaid managed care enrollment start and end dates can be misaligned. Sections 1851(f)(2) and 1860D–1(b)(1)(B)(iv) of the Social Security Act, and regulations codified at §§ 422.68 and 423.40 respectively, generally require that Medicare enrollments become effective on the first day of the first calendar month following the date on which the election or change is made, although section 1851(f)(4) of the Act and §§ 422.68(d) and 423.40(c) allow CMS flexibility to determine the effective dates for enrollments that occur in the context of special enrollment periods.

Medicaid managed care regulations at § 438.54 do not specify the timelines or deadlines by which any enrollment must be effective. Some States have cut-off dates after which enrollment in a Medicaid managed care plan is not effectuated until the first day of the next month after the following month. In this scenario, a dually eligible individual requesting to enroll in an AIP D–SNP with an aligned Medicaid MCO on March 28 might be enrolled in the D–SNP effective April 1, but in the aligned Medicaid MCO effective May 1, leaving a month-long gap. We believe it would still be feasible to assess an enrollee using an integrated HRA in this scenario, given that the enrollee's Medicaid eligibility would already be verified. However, we are interested in hearing from stakeholders about whether this would present operational challenges to implementing an integrated HRA for AIP D–SNP enrollees.

We believe our proposal would reduce confusion, assessment burden, and fragmentation for dually eligible individuals enrolled in AIP D–SNPs and potentially lead to more effective coordination of care. We also believe our proposal would not be overly burdensome for AIP D–SNPs to implement, given there are existing requirements in eight States [312] either to use a single, integrated HRA or take action to reduce duplication in HRAs. We welcome comment on our proposal.

c. Promoting Person-Centeredness in SNP ICPs and Timeliness of HRAs and ICPs

(1) Medicare Context

Section 1859(f)(5)(A) of the Act requires SNPs to conduct an initial assessment and an annual reassessment of each enrollee's physical, psychosocial, and functional needs and ensure that the results are addressed in each enrollee's ICP. We codified this requirement at § 422.101(f)(1)(i), using the term ''health risk assessment,'' as a required component of the SNP MOC. Specifically, § 422.101(f)(1)(i) requires

[312] Based on CMS review of 2024 SMACs.

that MA organizations offering SNPs conduct a comprehensive initial HRA of the individual's physical, psychosocial, and functional needs as well as annual HRA, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals' individualized care plan.

In addition, § 422.112(b)(4)(i) requires that MA organizations offering coordinated care plans make a ''best effort'' attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment. In the CY 2024 Medicare Part C Reporting Requirements, as further defined by the Medicare Part C Technical Specifications Document Contract Year 2024,[313] CMS specifies that SNPs must provide CMS with the number of initial HRAs completed within 90 days of (before or after) the effective date of enrollment and annual HRAs performed within 365 days of the last HRA. As described in the Medicare Part C Technical Specification Document Contract Year 2024, SNPs may report an enrollee as unable to be reached if: the enrollee did not respond to at least three ''non-automated'' phone calls and a follow-up letter from the SNP where all the efforts were to solicit participation in the HRA, none of the efforts to solicit participation were automated calls (''robo'' or ''blast'' calls), and documentation of the enrollee's refusal and/or the SNP's inability to reach the enrollee is available at any time to CMS. The technical specifications include additional details regarding how to interpret the CY 2024 Medicare Part C Reporting Requirements.

In addition, § 422.101(f)(1)(ii) requires SNPs to develop and implement a comprehensive ICP through an interdisciplinary team in consultation with the beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided. There are no timeframe requirements for developing ICPs in § 422.101(f). Chapter 5 of the Medicare Managed Care Manual, section 20.2.2, MOC 2, Element C notes that SNPs must describe the process for developing the ICP, including specifying how often the ICP is modified as beneficiaries' health care needs change, in the SNPs' MOC, which are subject to review and approval by NCQA and subsequent CMS audits.

(2) Medicaid Context

Many D–SNPs have affiliated Medicaid managed care plans that deliver Medicaid services to D–SNP enrollees through their parent organization or another entity that is owned and controlled by the D–SNP's parent organization. For Medicaid managed care, § 438.208(b)(3) requires that MCOs, PIHPs, or PAHPs make a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful.

For individuals enrolled in certain Medicaid home and community-based services (HCBS) programs, we have adopted requirements for a person-centered care planning process. For section 1915(c) Medicaid HCBS waiver programs, these requirements are set forth at § 441.301(c)(1) through (3); for section 1915(k) Medicaid HCBS State plan amendments, these requirements are set forth at § 441.540; and for section 1915(i) Medicaid State plan HCBS benefits, these requirements are set forth at § 441.725. We refer readers to these regulations for more details.

Generally, these regulations require the State administering these Medicaid HCBS programs to ensure an individualized person-centered services plan, meeting certain minimum requirements, is developed for each individual beneficiary enrolled in a Medicaid HCBS program. This plan must reflect the services and supports that are important for the individual to meet their needs identified through an assessment of functional need, as well as what is important to the individual with regard to their preferences for the delivery of such services and supports (§§ 441.301(c)(2); 441.540(b); 441.725(b)). The process by which the person-centered service plan is developed must be led or driven by the individual. The individual's authorized representative should play a participatory role, as needed and as defined by the individual. If State law confers decision-making authority to the legal representative, the individual should still lead the person-centered service plan process to the extent possible. The plan must also meet other person-centered requirements, including: ensuring people chosen by the individual are included in the process; providing necessary information and support to ensure that the individual directs the process to the maximum extent possible; reflecting cultural considerations of the individual; and offering choices to the individual regarding the services and supports they receive and from whom (§§ 441.301(c)(1); 441.540(a); 441.725(a)). The resulting person-centered service plan must be tailored and individualized, and the approach must consider personal preferences and goals. Additionally, the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon reassessment of functional need at least every 12 months, when the individual's circumstances change significantly, or at the individual's request (§§ 441.301(c)(3)(i); 441.540(c); 441.725(c)).

(3) Medicare-Medicaid Plan (MMP) Context

Like Medicaid managed care plans, MMPs are subject to more requirements than SNPs on person-centeredness and timeliness of HRAs and ICPs. The MMP care coordination requirements for HRAs and ICPs for the FAI are included in the three-way contracts between CMS, State Medicaid agencies, and MMPs. In several States, the three-way contracts apply requirements on the person-centeredness of ICPs beyond what is required for SNPs and specific requirements for the timing of HRAs and ICPs. Most States participating in the FAI (Illinois, Massachusetts, Michigan, Ohio, South Carolina, and Texas) require MMPs to develop HRAs and ICPs within 90 days or less of enrollment and include enrollees in the development of the ICPs.

d. Opportunities for Improvement

Over the years, we have identified opportunities to improve person-centeredness in care planning and the need to codify the timeline for development of HRAs and ICPs. For example, we have learned of instances in which SNPs did not complete initial or annual HRAs timely, or it took several months to develop an ICP for enrollees after an HRA. In addition, we have reviewed ICPs that were only loosely related to the needs and preferences of enrollees or did not contain measurable outcomes. We have identified some similarities in our review of MMP care plans, such as care plans that do not include goals that are meaningful to enrollees. Through this proposed rule, we are seeking to address these opportunities for improvement, better align requirements across Medicare and Medicaid, and build on

[313] *https://www.cms.gov/medicare/enrollment-renewal/health-plans/part-c.*

our experiences in other programs and demonstrations.

We propose amendments to § 422.101(f)(1) to codify timeliness standards, improve the organization of the various HRA and ICP requirements, and strengthen these requirements. First, in § 422.101(f)(1)(i), we propose to specify that SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. This would better align with the Medicaid requirement at § 438.208(b)(3) and, for Medicare, conform to § 422.112(b)(4)(i) and the standard currently described for reporting HRA completion in the Part C Reporting Requirements. We also note that, as described in the Medicare Part C Technical Specifications, when a person enrolls, disenrolls, and re-enrolls into any SNP under the same contract number, the previous HRA is still considered valid and can continue to be used as long as it is not more than 365 days old. CMS will continue to provide guidance on these types of issues through the Medicare Part C Technical Specifications.

Second, we propose to move the requirement for a comprehensive annual HRA from § 422.101(f)(1)(i) to § 422.101(f)(1)(ii) based on the updates and to improve the flow of the rule.

Third, we propose to relocate the requirement for SNPs to use a comprehensive risk assessment tool that CMS may review during oversight activities that assesses the enrollee's physical, psychosocial, and functional needs and includes one or more questions from a list of screening instruments specified by CMS in subregulatory guidance on housing stability, food security, and access to transportation from § 422.101(f)(1)(i) to § 422.101(f)(1)(iii). This is a technical change to improve the organization of the rule.

Fourth, we propose a new § 422.101(f)(1)(iv)(A) through (C) to establish specific requirements for all SNPs related to outreach to enrollees regarding completion of the HRA. Consistent with the Medicare Part C Technical Specifications, we propose to require that the SNP must make at least three non-automated phone call attempts, unless an enrollee agrees or declines to participate in the HRA before three attempts are made. We propose to newly require that these attempts be made on different days at different times of day. Also consistent with the Medicare Part C Technical Specifications, we propose to require that, if the enrollee has not responded to these attempts, the SNP send a follow-up letter to conduct the initial or annual risk assessments. We also propose that, for any enrollees who are unable to be reached or decline to participate in the HRA, the SNP must document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate.

Fifth, in § 422.101(f)(1)(v), as discussed earlier in this proposed rulemaking in section III.E.b. of this proposed rule, we propose to require D–SNPs that are AIPs conduct a comprehensive HRA that meets all requirements at paragraphs (f)(1)(i) through (iv) of this section as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees complete a single integrated assessment for Medicare and Medicaid.

Sixth, we propose to relocate the requirement to ensure that the results from the comprehensive initial and annual HRA conducted for each individual enrolled in the plan are addressed in the enrollee's ICP to § 422.101(f)(1)(vi).

Seventh, we propose to add a new § 422.101(f)(1)(vii) that would require that SNPs within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later, develop and implement a comprehensive ICP that—

- Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and needs identified in the HRA;
- Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable), as feasible;
- Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided; and
- Is updated as warranted by changes in the health status or care transitions of enrollees.

While section 1859(f)(5)(A) of the Act uses the term individual throughout, we have used the term enrollee to make it clear that the proposed requirements are for individuals who are enrolled in the SNP, consistent with how we have generally used the term enrollee in other recent rulemaking.

The Resources for Integrated Care (RIC) Tip Sheet on Using Person-Centered Language provides context for what we intend the proposed requirements for a person-centered ICP to mean and include.[314] It notes that person-centered language acknowledges the person first and foremost and places any diagnosis, condition, or disability in the context of the whole person and describes person-centered language as an essential component of a person-centered MOC (see The Medical Model versus Person-Centered Model callout box). As also described in the RIC tip sheet, the traditional medical model of health care focuses mainly on diagnosis and treatment of disease, and individuals receiving services under this model are typically expected to take a passive role. In a person-centered model, people are empowered to participate as active partners in discussions and decisions about their care. The person-centered model considers diagnosis, condition, and disability in the context of the whole person. This model focuses on supporting and communicating with people by emphasizing their strengths, capabilities, and opportunities to reach their chosen goals. We also note that an IT system-generated ICP that simply suggests understanding the importance of keeping appointments with providers or taking medications as prescribed is not what we intend to meet the proposed requirement. We believe that, for the ICP to be an effective tool in promoting health, the ICP should be tailored to the specific needs of the enrollee based on the enrollee's chosen goals.

We intend for ICPs to engage and motivate enrollees by including goals that are meaningful to each enrollee. These may include goals that are not specific to a medical diagnosis, such as attending a child's graduation, pursuing higher education, or being able to attend religious services each week. The ICP should outline steps for managing conditions, such as diabetes or high blood pressure, that may have been identified in the HRA and impact the enrollee's ability to meet their goals. The steps should also take account of the enrollee's preferences for delivery of any needed services or benefits. For example, an enrollee may have a goal of attending a child's graduation, but weight and mobility limitations are current barriers identified in the HRA. The care plan would include specific steps to help the enrollee lose weight and improve mobility, which would support the enrollee's efforts to attend the graduation. This personalized approach allows enrollees to take control of their health and work toward achieving meaningful life goals and aspirations.

As part of a person-centered care plan, we also remind SNPs that § 422.2267(a)(3) requires that ICPs be

[314] *https://www.resourcesforintegratedcare.com/wp-content/uploads/2020/04/Using_Person_Centered_Language_Tip_Sheet.pdf.*

provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (a)(4) of § 422.2267 or accessible format upon receiving a request for any required materials (including the ICP) or otherwise learning of the enrollee's primary language or need for an accessible format. The HHS website Think Cultural Health [315] has a suite of resources that SNPs can use to ensure their case managers/care coordinators are developing person-centered plans that consider the language access and disability access needs of enrollees. In particular, the Guide to Providing Effective Communication and Language Assistance Services [316] may be useful to SNP front-line employees working with enrollees as well as D–SNP management. Another resource that SNPs may find helpful to ensure the development of culturally and linguistically appropriate care plans is the CMS OMH Guide to Developing a Language Access Plan.[317]

Proposed § 422.101(f)(1)(vii)(D) would codify that SNPs must update ICPs as warranted when there are changes in an enrollee's health status or the enrollee has a care transition. While not a complete list, examples of the types of changes that would necessitate a review of the ICP could include hospitalization, being diagnosed with a new chronic condition such as diabetes, admission to a long-term care facility when such admission is likely to result in long-term institutionalization, or return home from a long-term care facility.

Finally, we propose to add § 422.101(f)(1)(viii) to require that, for any enrollees who are unable to be reached or decline to participate in the development or updates to the comprehensive ICP, the SNP must document the attempts to contact the enrollee or the enrollee's refusal to participate. While our goal is for SNPs to develop person-centered ICPs, if a SNP is unable to reach an enrollee (after the SNP has fulfilled its obligations as previously described to contact the enrollee for the HRA) or an enrollee declines to participate, then at a minimum the SNP should base the ICP on enrollee encounter data or other available data. We strongly encourage SNPs to continue to try to reach the enrollee even after satisfying the proposed regulatory requirement. We note that RIC has developed a brief on Locating and Engaging Members: Key Considerations for Plans Serving Members Dually Eligible for Medicare and Medicaid, which SNPs may find helpful in bolstering their efforts to engage enrollees.[318]

In addition, as a result of these updates, we propose to redesignate § 422.101(f)(1)(iii) as § 422.101(f)(1)(ix) and redesignate § 422.101(f)(1)(iv) as § 422.101(f)(1)(x) and change the term ''individual's'' to ''enrollee's''.

Collectively, our proposals would promote more timely and person-centered HRAs and ICPs for SNP enrollees. Our proposals at §§ 422.101(f)(1)(i) through (iv), 422.101(f)(1)(vi), and 422.101(f)(1)(viii) through (x) would codify elements of the CY 2024 Part C Reporting Requirements and Technical Specifications and restructure the current section for better flow. Our proposal at § 422.101(f)(1)(vii) would require that SNPs create and implement the ICP within 30 days of conducting an initial HRA or 30 days after the effective date of enrollment, whichever is later, although many SNPs already complete ICPs within such timeframes. We believe that the benefit gained by the ability for enrollees to quickly have an ICP in place which will assist with coordinating their care in a person-centered manner outweighs this burden. These enrollees often have limited financial resources and health care needs that are more wide-ranging and complex than the average Medicare enrollee.[319] We are considering whether to instead adopt alternative timelines for development and implementation of the ICP. We note that the three-way contracts for MMPs participating in several of the FAI States require that HRAs and ICPs be conducted within 90 days of enrollment. Alternatively, we are considering allowing additional time for the development of the ICP, such as within 60 or 90 days of completion of the HRA. We are also considering that the ICP not be required when the enrollee is unable to be reached or declines to participate. Some States participating in the FAI—including Illinois, Michigan, South Carolina, and Texas—do not require the ICP in these circumstances. We are considering whether text messaging could be useful for contacting enrollees to conduct HRAs in addition to phone calls and how follow-up to conduct the HRA would occur following the contact by text messages.

Finally, for § 422.101(f)(vii) where we use the term ''person-centered,'' we are considering whether to cross-reference the elements of the person-centered planning process at § 441.540(a) as written, a subset of those elements, or a different definition. Cross-referencing the person-centered planning process at § 441.540(a) would promote consistency in the language across Medicare and Medicaid, which is helpful for the purpose of integrated Medicare and Medicaid. However, we are not sure that all the components of the description at § 441.540(a) fully apply to SNP enrollees.

We solicit comments on these alternatives. We also seek feedback on potential challenges to our proposals and alternatives under consideration.

e. Assuring Enrollee Advisory Committee Input on MOC Updates

In the May 2022 final rule, we codified the requirement at § 422.107(f) that D–SNPs establish or maintain one or more enrollee advisory committees (EACs) that serve the D–SNPs offered by the MA organization in a State. We believe that it is important for enrollees to have a voice in the development of the D–SNPs' MOC, which includes details regarding how a D–SNP conducts HRAs and ICPs. Enrollee feedback on the MOC should improve how D–SNPs and other SNPs engage enrollees in conducting HRA and ICPs, the quality of information obtained from these enrollees, and the usefulness of the HRAs and ICPs as tools in supporting enrollees' health care. Therefore, we propose adding language to D–SNP EAC requirements at § 422.107(f) to include updates to MOCs as described at § 422.101(f) among the minimum required EAC discussion topics. While MA organizations can already include MOCs among their D–SNP EAC topics, adding these topics to the D–SNP EAC conversations would ensure MA organizations solicit feedback directly from enrollees to improve the care coordination process including HRAs and ICPs as described in the MOC.

We are not proposing to require that D–SNP EACs review or approve the MOC, *per se,* because they are often lengthy and technical documents. However, we believe the D–SNP EAC's perspectives should inform updates to the MOC over time. We do not anticipate additional burden from this proposal. We welcome comments on our proposal and underlying assumptions.

[315] *https://thinkculturalhealth.hhs.gov/.*

[316] *https://thinkculturalhealth.hhs.gov/education/communication-guide.*

[317] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.*

[318] *https://www.resourcesforintegratedcare.com/wp-content/uploads/2022/11/Locating-and-Engaging-Members-Key-Considerations-for-Plans-Serving-Members-Dually-Eligible-for-Medicare-and-Medicaid-Brief.pdf?csrt=17807429552740464906.*

[319] *https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-advantage-dual-eligible-special-needs-plans-d-snps/.*

f. Comment Solicitation—Making State Medicaid Agency Contracts Public

Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) amended section 1859(f) of the Act to require that a D–SNP contract with the State Medicaid agency in each State in which the D–SNP operates. We refer to such contracts as SMACs. As we have emphasized in rulemaking over the last several years, SMACs are important vehicles for integrating the delivery of Medicare and Medicaid services and improving experiences for dually eligible individuals. In many States, the provisions in the SMAC are of significant public policy interest, affecting the ways that many people experience the Medicare and Medicaid programs.

Some States, including Indiana, New Jersey, and Washington, have posted SMACs and any SMAC amendments—usually as a single model agreement, rather than the individual signed copies with each D–SNP—on their websites. We encourage all States to post the content of the SMACs online. However, we have never done so on a CMS website.

Posting SMACs would improve public transparency on the important requirements included in these agreements. This, in turn, would promote accountability in implementing the terms of the SMAC and make it easier for States, advocates, researchers, and others to identify promising practices or opportunities for improvement across States. However, while we review all SMACs for compliance with the requirements of § 422.107, CMS is not a signatory to the SMACs. And we have never systematically analyzed the extent to which SMACs may include confidential commercial or financial information that should not be shared publicly.

We solicit comments on whether and how CMS should post SMACs online.

B. Clarifying Highly Integrated Dual Eligible Special Needs Plan Definition Relative to Oregon's Coordinated Care Organization Structure (§ 422.2)

The definition of HIDE SNPs is codified at § 422.2. According to this definition, a HIDE SNP, in addition to meeting other requirements, is a D–SNP offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract between the State Medicaid agency and the MA organization itself, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization. CMS defined this term in the final rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' which appeared in the April 16, 2019, **Federal Register** (hereinafter referred to as the April 2019 final rule) (84 FR 15705), and further refined it in the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the May 9, 2022, **Federal Register** (hereinafter referred to as the May 2022 final rule) (87 FR 27755).

The May 2022 final rule revised the HIDE SNP definition to outline more clearly the services HIDE SNPs must cover in their contracts with State Medicaid agencies to include LTSS or behavioral health services to the extent Medicaid coverage of those benefits is available to individuals eligible to enroll in a HIDE SNP, and required the capitated contract with the State Medicaid agency to cover the entire service area of the D–SNP beginning in 2025. The revisions facilitate HIDE SNP enrollees having access to both Medicare and Medicaid benefits from a single parent organization.

However, the definition of HIDE SNP at § 422.2 does not explicitly account for certain ownership arrangements of Medicaid managed care organizations that operate Medicaid health plans affiliated with D–SNPs that we believe should meet the definition of and be treated as a HIDE SNP. In Oregon, the State Medicaid managed care program utilizes community-governed organizations called coordinated care organizations (CCOs) to provide comprehensive Medicaid benefits, including physical, behavioral, and dental services.[320] These nonprofit community-governed organizations are locally based (rather than national organizations), and may be single corporate structures or networks of providers with contractual relationships, per Oregon law.[321]

In the Portland metro area that includes Clackamas, Multnomah, and Washington counties, one of the CCOs delivering Medicaid benefits to eligible residents is Health Share, a nonprofit public benefit corporation with 11 founding members that include providers, health systems, and county governments. A subset of these founding members includes organizations with which Health Share contracts to provide covered Medicaid physical, behavioral, and dental health services to beneficiaries assigned to them on a fully capitated basis through agreements called Integrated Delivery System (IDS) Participation Contracts. These founding members with IDS Participation Contracts administer Medicaid benefits on Health Share's behalf and assume full risk for their assigned beneficiaries' services.

Three of these Health Share founding members are organizations that also operate a D–SNP with a service area that includes the three-county Portland metro area. Dually eligible individuals in that three-county service area who are enrolled in one of these D–SNPs can therefore receive their Medicaid benefits from the same organization from which they receive their Medicare benefits, through the organization's IDS Participation Contract with Health Share to provide Medicaid benefits. Oregon estimates that between 80 and 91 percent of the Health Share enrollees who receive Medicare benefits through a D–SNP are assigned to the same organization for their Medicaid benefits, depending on which of the three organizations in which they are enrolled. We believe this arrangement is functionally similar to and should be treated as meeting the HIDE SNP definition because dually eligible individuals are receiving their Medicare and Medicaid benefits from the same organization or the parent organization of the entities that operate the D–SNP and the Medicaid managed care plan. While that organization does not *directly* hold a contract with the State Medicaid agency for Medicaid managed care services, it is responsible for the full obligations of the CCO contract with the State Medicaid agency through its IDS Participation Contract with Health Share. Furthermore, the current HIDE SNP definition requires the capitated contract to be between the State Medicaid agency and either the MA organization itself, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization. While the founding members of Health Share do not meet the CMS definition

[320] *https://www.oregon.gov/oha/HPA/Pages/CCOs-Oregon.aspx.*

[321] *https://oregon.public.law/statutes/ors_414.572.*

of a parent organization,[322] founding members appoint representatives to Health Share's board of directors, vote on key leadership decisions, serve on standing committees of the board (including committees that oversee Health Share's contractual obligations), and financially support Health Share. We believe this is functionally an entity that is owned and controlled by the MA organization's parent organization as included in paragraph (1)(ii) of the HIDE SNP definition. For these reasons, we categorized these D–SNPs in the three-county Portland area as HIDE SNPs for CY 2025 as part of our review of Oregon's SMAC agreements with D–SNPs operating in the State. Nonetheless, given the foregoing ambiguity about the applicability of the existing HIDE SNP definition, we are proposing to modify the HIDE definition at § 422.2 to make clear that it applies to this type of arrangement, whether in Oregon or elsewhere.

Under our authority at section 1859(f)(8)(D) of the Act to require that all D–SNPs meet certain minimum criteria for Medicare and Medicaid integration, and under section 1856(b) to establish requirements by regulation, we are proposing to amend the definition of a HIDE SNP at § 422.2 to make minor edits to paragraph (1) and add a new paragraph (1)(iii) to the definition to explicitly describe a scenario in which there is a capitated contract between the State Medicaid agency and a local nonprofit public benefit corporation of which the MA organization is a founding member. The proposed change would clarify that D–SNPs with this ownership arrangement meet the HIDE SNP definition. (We are not proposing any changes to paragraphs (2) or (3) of the HIDE SNP definition.)

In developing this proposal, we considered other scenarios that have arisen related to the HIDE SNP definition. For example, in the April 2019 final rule (84 FR 15705) we discussed a scenario in which an entity with a managed care contract with the State Medicaid agency subsequently subcontracts certain aspects of the managed care contract to another entity under § 438.230. We noted that in such situations where that subcontractor also is a D–SNP, we recognized that there may be a level of integration for enrollees that is greater than that of a D–SNP that has no contract—directly or indirectly—with a State to provide LTSS, behavioral health services, or both. However, we stated we do not believe that the subcontractor in that situation should be treated as a HIDE SNP.

We believe that the situation we addressed in the April 2019 final rule is fundamentally different from the arrangement in Oregon, in which the founding members with IDS Participation Contracts with Health Share have an ownership and leadership role within Health Share, as noted previously, participating financially and in key decision-making. In other more common delegation scenarios, like the one described in the April 2019 final rule, the delegated organization does not have such a role in the organization that is delegating its responsibilities. We believe this is an essential difference that sets these two situations apart. With our proposal, we do not aim to allow scenarios where the delegated organization does not have a meaningful ownership role in the delegating organization to meet the HIDE SNP definition. We therefore include the term ''local nonprofit benefit corporation'' in our proposal to be specific to the structure of CCOs and to clarify that such an arrangement does not include certain delegation situations in which an MCO—including a for-profit MCO—capitates an unrelated organization with no ownership stake in the MCO to administer Medicaid benefits on the MCO's behalf, as is currently common in California. We also include the term ''founding member'' because we have experience with this ownership arrangement in Oregon. In contrast, we have not fully analyzed how the arrangement may differ if an organization newly became a member through acquisition or otherwise. We chose to include this language to keep this narrowly applicable to a scenario we understand and limit any possible gaming until we have more experience. However, we welcome comments on our proposed use of the term ''founding member.''

We welcome comment on our proposed clarifications to the HIDE SNP definition. We also welcome comment on whether the language we propose here is sufficiently narrow such that it does not unintentionally encompass additional delegation situations that are contrary to our goals of increasing the level of integration between D–SNPs and affiliated Medicaid managed care plans and facilitating D–SNP enrollees having access to Medicare and Medicaid benefits provided by the same parent organization. Additionally, we welcome comment on whether there are existing scenarios like Health Share we may want to consider as we revise the HIDE SNP definition.

We do not believe that this provision would add any additional burden to the three D–SNPs in Oregon with affiliated Medicaid CCOs, which we have already classified as HIDE SNPs in recent years. We do not believe that any additional work from the three D–SNPs would amount to burden above and beyond what is routine, and as such, this work has already been accounted for in other burden estimates under OMB control number 0938–1410 (CMS–10796).

C. Technical Changes

1. Technical Change to the Specific Rights to Which a PACE Participant Is Entitled (§ 460.112)

In the Medicare Program: Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (hereinafter referred to as the April 2024 final rule), we finalized changes to the regulations impacting the specific rights to which a participant is entitled (89 FR 30756). Specifically, we added a new paragraph (a) which was entitled ''right to treatment,'' and redesignated existing paragraphs § 460.112 (a) through (c) as (b) through (d). In the new paragraph (a), we finalized that each participant has the right to appropriate and timely treatment for their health conditions.

On May 6, 2024, we issued the Nondiscrimination in Health Programs and Activities final rule (hereinafter referred to as the Nondiscrimination 2024 final rule), with the intention of adding language to the respect and nondiscrimination paragraph regarding sexual orientation and gender identity. Because the respect and nondiscrimination paragraph had only been redesignated a few weeks prior to the issuance of the Nondiscrimination 2024 final rule, the updated language was added in error to paragraph (a) instead of the redesignated paragraph (b); thereby replacing the right to treatment language provision added to paragraph (a) through the April 2024 final rule. As a result of this error, the current regulation text has two identically titled subsections (§§ 460.112(a) and 460.112(b)). To avoid any further confusion and for the reasons explained in the April 2024 final rule at 89 FR 30756, we propose to make a technical change to reinstate

[322] CMS considers a parent organization to be the legal entity that owns a controlling interest in a contracting organization.

the language that each participant has the right to appropriate and timely treatment for their health conditions in § 460.112(b) instead of in § 460.112(a).

We also finalized two paragraphs under § 460.112(a) in the April 2024 final rule. Paragraph (a)(1) related to the right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being. Paragraph (a)(2) related to the participants' rights to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. Since the two paragraphs under § 460.112(a), (a)(1) and (a)(2), more appropriately align with the requirement in the ''right to treatment'' paragraph, we propose to redesignate § 460.112(a)(1) and (a)(2) as § 460.112(b)(1) and (b)(2). The subparagraphs under § 460.112(b) more appropriately align with the ''respect and nondiscrimination'' paragraph. Therefore, we propose to redesignate the paragraphs under § 460.112(b)(1) through (b)(8) as § 460.112(a)(1) through (a)(8).

Finally, we note that two courts, in *Tennessee* v. *Becerra,* No. 1:24–cv–161–LG–BWR (S.D. Miss.), and *Texas* v. *Becerra,* 6:24–cv–211–JDK (E.D. Tex.), have issued orders that, in relevant part, stay nationwide the effective date of, respectively, § 460.112 to the extent it ''extend[s] discrimination on the basis of sex to include discrimination on the basis of gender identity'' and § 460.112(a). Nothing in this technical change is intended to affect the scope of those stay orders or CMS's compliance with those orders as long as they remain in effect.[323]

This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

2. Technical Change to PACE Contracted Services (§ 460.70(e)(2))

In the April 2024 final rule, we finalized changes to the PACE service delivery requirements at § 460.98. Specifically, we removed paragraph (b)(4), added a new paragraph at § 460.98(c), and redesignated paragraphs (b)(5) and (c) through (e) as paragraphs (b)(4) and (d) through (f), respectively (89 FR 30845). As part of these changes, the paragraph titled ''Minimum services furnished at each PACE center'' was redesignated from § 460.98(c) to § 460.98(d). However, the April 2024 final rule did not include a correction to the cross-reference at § 460.70(e)(2) to reflect the redesignation of ''Minimum services furnished at each PACE center'' requirements from § 460.98(c) to § 460.98(d).

Therefore, we are proposing a technical change at § 460.70(e)(2) to update the cross-reference from § 460.98(c) to § 460.98(d), which would affirm the connection between § 460.70(e)(2) and the ''Minimum services furnished at each PACE center'' requirements at the redesignated § 460.98(d).

The proposed technical change would not impose any new requirements or burden on PACE organizations. Additionally, we expect no cost impact to the Medicare Trust Fund.

We solicit comment on the proposed technical change.

3. Technical Change to Notice of Availability of Language Assistance Services and Auxiliary Aids and Services (§ 423.2267(e)(33))

In the April 2024 final rule, we finalized changes at § 422.2267(e)(31) and (e)(33) to—(1) update multi-language insert (MLI) references to notice of availability of language assistance services and auxiliary aids and services (Notice of Availability); (2) allow plans to utilize the updated MLI during contract year 2025; and (3) require the Notice of Availability be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

When amending the regulation at § 423.2267(e)(33)(i), we neglected to denote that the MLI is a notice for Part D sponsors. Similarly, when we amended the regulation at § 423.2267(e)(33)(ii), we neglected to note the Notice of Availability is a notice for Part D sponsors.

Therefore, we are proposing technical changes in § 423.2267(e)(33)(i) and (ii) to denote the MLI and notice of availability are notices for Part D sponsors.

The proposed technical changes would not impose any new requirements or burden on Part D sponsors.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule (CMS–4208–F, RIN 0938–AV40).

A. Wage Data

1. Private Sector

To derive average (mean) costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2023/may/oes_nat.htm*), which, at the time of publication of this proposed rule, provides May 2023 wages. In this regard, table 16 presents BLS's mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

[323] For updated information about court orders impacting the Nondiscrimination in Health Programs and Activities 2024 Final Rule, please see *hhs.gov/1557*.

TABLE 16: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupational Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialists (All Others)	13-1199	42.85	42.85	85.70
Computer Programmer	15-1251	51.80	51.80	103.60
Computer System Analyst	15-1211	53.27	53.27	106.54
Database Administrators	15-1242	50.39	50.39	100.78
Medical and Health Service Managers	11-9111	64.64	64.64	129.28
Pharmacist	29-1051	64.81	64.81	129.62
Software and Web Developers, Programmers, Testers	15-1250	62.74	62.74	125.48
Software Developer	15-1252	66.40	66.40	132.80
Software Quality Assurance Analysts and Testers	15-1253	52.15	52.15	104.30
Web Developer	15-1254	45.95	45.95	91.90

Adjusting our employee hourly wage estimates by a factor of 100 percent is a rough adjustment that is being used since fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

For valuing time spent outside of work, there is logic to this approach but also to using a fully loaded wage. In the past we have used occupational code 00–0000, the average of all occupational codes, which currently is $29.76/hr. Thus, we propose a range for enrollees of $20.71/hr to $29.76/hr. Nevertheless, the upper limit is based on an average over all occupations while the lower limit reflects a detailed analysis by ASPE targeted at enrollees many of whom are over 65 and unemployed; consequently, in our primary estimates we will use the lower limit as we consider it more accurate. The effect of this range will be footnoted in table J5 and the summary table (table F11). Since the impact to beneficiaries is approximately $54,000, increasing the wage by 50 percent would result in a roughly $24,000 increase.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this proposed rule.

1. ICRs Regarding Medicare Prescription Payment Plan Calculation of the Maximum Monthly Cap on Cost-Sharing Payments (§ 423.137(c))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

This rule proposes to implement the requirements in section 1860D–2(b)(2)(E)(iv) of the Act related to the calculation of the monthly caps on OOP cost sharing payments. The burden related to these new requirements for Part D sponsors reflects the time and effort needed to correctly calculate the monthly caps based on the statutory formulas, determine the amount to be billed, and send monthly bills to program participants.

We estimate a one-time burden for Part D sponsors to update their payment systems to process data from their PBMs and contracted pharmacies, calculate monthly caps, and determine the amount to be billed. The average number of Part D contracts per year is 807 (based on 2021, 2022, and 2023 data). This average number of Part D contracts per year excludes contracts with Program of All-Inclusive Care for the Elderly (PACE) organizations and D–SNPs and Medicare-Medicaid Plans (MMP) that exclusively charge $0 cost sharing, which we do not expect to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in this proposed rule and in the proposed new regulation at § 423.137. On average, we expect each Part D contract to have a team that consists of one software developer at $132.80/hr, one web developer at $91.90/hr, and one business operations specialist at $85.70/hr who will each spend 125 hours to implement these system changes. This team will also include a software quality assurance analyst and tester who will spend 10 hours at $104.30/hr performing assurance and testing. Thus, a total of 385 hours is spent per contract with a weighted average wage of $103.49/hr (see table 17).

TABLE 17 – WEIGHTED TEAM WAGE

Occupation	Time (hr)	Percent	Wage ($/hr)	Weighted Wage ($/hr)
Software Developer	125	32.5	132.80	43.16
Web Developer	125	32.5	91.90	29.87
Business Operations Specialist	125	32.5	85.70	27.85
Software Quality Assurance Analyst and Tester	10	2.5	104.30	2.61
TOTAL	385	100	n/a	103.49

In aggregate, we estimate a one-time burden of 310,695 hours (385 hr/contract * 807 Part D contracts) at a cost of $32,153,826 (310,695 hr * $103.49/hr).

After an enrollee elects to participate in the Medicare Prescription Payment Plan, the Part D sponsor will pay the pharmacy for any amounts that would have been due as OOP costs, calculate the enrollee's monthly payment based on the statutory formula and any prior prescription drug expenditures, and send a separate bill to the enrollee for those amounts every month.

The burden associated with sending monthly bills to program participants is a function of the number of enrollees likely to enroll in the program. CMS conducted internal analyses of CY 2021 Prescription Drug Event (PDE) data to identify the number of enrollees likely to be identified as likely to benefit from the program and estimates that between 435,000 and 3,200,000 individuals will elect to participate in the Medicare Prescription Payment Plan. Because of the prior to plan year and during the plan year targeted outreach required for individuals identified as likely to benefit, we assume that the majority of enrollees who participate will pick up a high-cost prescription early in the year, for which they will be billed over all 12 months of the plan year. Assuming 3,200,000 enrollees participate, and they all incur drug costs in January for which they are billed over the course of 12 months, the projected number of bills sent per year is 38,400,000 (3,200,000 * 12). Billing statements may be provided via mail or electronically; consistent with existing estimates for other required Part D materials, we estimate that approximately one-third or 12,800,000 (⅓ * 38,400,000) will be sent electronically since we estimate that one third of enrollees will opt to receive billing statements electronically while the remaining two-thirds or 25,600,000 (⅔ * 38,400,000) will receive hard copy billing statements.

We assume the following costs include paper, toner, and postage (envelope weight is normally considered negligible when citing these rates and is not included), and envelope (supplies) for hard-copy mailings:

- *Paper:* $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Toner:* $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Postage:* The cost of first-class metered mail is $0.73 per letter up to 1 ounce. We estimate that a sheet of paper weighs 0.16 ounces, and do not anticipate additional postage for mailings in excess of 1 ounce.
- *Envelope:* Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope.

We estimate the aggregate cost per mailed billing statement is $0.802 ([$0.007 for paper * 2 pages] + [$0.007 for toner * 2 pages] + $0.73 for postage + $0.044 per envelope). We assume a maximum of 4 single sided pages will be needed for a billing statement, based on the required content for billing statements. Billing statements are assumed to be printed double-sided to save on printing costs, yielding 2 pages of double-sided print, generally weighing less than 1 ounce. Because preparing and generating a hard-copy billing statement is automated once the systems have been developed, we do not estimate any labor costs. Therefore, we estimate a total annual mailing cost by sponsors to enrollees of $20,531,200 (25,600,000 mailings * $0.802/mailing).

Part D sponsors will also need to process payments received from Medicare Prescription Payment Plan participants. This may require the development of new systems since Part D premium payment often occurs through automatic deduction from Social Security. On average, we expect that for each Part D contract a two-person team consisting of one web developer at $91.90/hr and one business operations specialist at $85.70/hr will each spend 50 hours to these system changes. To make the necessary systems changes, we estimate a total one-time burden of 80,700 hours (807 Part D contracts * 100 hr/contract) at a cost of $7,166,160 (807 contracts × [($91.90/hr × 50 hr) + ($85.70/hr × 50 hr)]).

We also estimate annual burden associated with maintenance of associated systems. On average, we expect that for each Part D contract, a two-person team consisting of one database administrator at $100.78/hr and one computer systems analyst at $106.54/hr will each spend 50 hours per year performing system maintenance. In aggregate, we estimate an annual burden of 80,700 hours (807 Part D contracts * 100 hr/contract) at a cost of $8,365,362 (807 contracts × [($100.78/hr × 50 hr) + ($106.54/hr × 50 hr)]).

Therefore, the total burden for all Part D contracts associated with the aforementioned provisions is 472,095 hours at a first-year cost of $68,216,548 and an annual subsequent year cost of $28,896,562 (see table 18).

TABLE 18: BURDEN FOR CALCULATION PROVISIONS

Requirement	Total Time (hr)	Total Cost (Year 1)	Total Cost (Subsequent Years)	Labor (L) v non-Labor (NL)
Update Payment Systems	310,695	32,153,826	0	L
Mailing Billing Statements	0	20,531,200	20,531,200	NL
Development of New Systems	80,700	7,166,160	0	L
System Maintenance	80,700	8,365,362	8,365,362	L
TOTAL	472,095	68,216,548	28,896,562	n/a

2. ICRs Regarding Medicare Prescription Payment Plan Eligibility and Election Requirements (§ 423.137(d))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

This rule's proposed amendments to § 423.137(d) would require that Part D sponsors offer the Medicare Prescription Payment Program to all Part D enrollees. It also proposes requirements for how Part D sponsors must process program election requests, including timing and notice requirements and procedures for collecting missing information on election requests.

The proposed amendments to § 423.137(d) require Part D sponsors to have a process to effectuate retroactive election into the Medicare Prescription Payment Plan when an enrollee believes that a delay in filling a prescription would seriously jeopardize their life, health, or ability to regain maximum function and has paid the associated cost sharing before their participation was effective. Sponsors are also required to develop standardized procedures for determining and processing reimbursements for excess program payments made by participants who become LIS eligible. Finally, we propose to require Part D sponsors to send a notice alerting the Part D enrollee that their participation in the Medicare Prescription Payment Plan will continue into the next year unless they indicate that they choose to opt out. In developing these requirements, we referred to existing requirements and procedures for Part D plan enrollment, to minimize the updates and new systems necessary to implement and administer the Medicare Prescription Payment Plan.

We estimate a one-time burden for Part D sponsors to set up systems to process election requests and develop procedures to effectuate retroactive election into the program and process reimbursements for participants who become LIS eligible. We expect that for each Part D contract, a four-member team will be used consisting of one software developer at $132.80/hr, one web developer at $91.90/hr, and one business operations specialist at $85.70/hr will each work 40 hours while a software quality assurance analyst and tester will spend 10 hours at $104.30/hr to implement these system changes.

The total time spent per contract is 130 hours at a weighted average wage of $103.54/hr (see table 19).

TABLE 19 – WEIGHTED TEAM WAGE

Occupation	Time (hr)	Percent	Wage ($/hr)	Weighted Wage ($/hr)
Software Developer	40	30.8	132.80	40.90
Web Developer	40	30.8	91.90	28.31
Business Operations Specialist	40	30.8	85.70	26.40
Software Quality Assurance Analyst and Tester	10	7.6	104.30	7.93
TOTAL	130	100	n/a	103.54

In aggregate, we estimate a one-time burden of 104,910 hours (130 hr/plan * 807 Part D contracts) at a cost $10,862,381 (104,910 hr * $103.54/hr).

We estimate a one-time burden for Part D sponsors to develop a standard notice of request for additional information to provide to any enrollees who provide an incomplete election request form. On average, we expect that for each Part D contract, a team of one medical and health services manager who will spend 2 hours at $129.28/hr and one business operations specialist who will spend 10 hours at $85.70/hr will be needed to implement this proposal. In aggregate, we estimate a one-time burden of 9,684 hr (12 hr/contract * 807 Part D contracts) at a cost of $900,257 (807 contracts × [($129.28/hr × 2 hr) + ($85.70/hr × 10 hr)]).

We also estimate annual burden for Part D sponsors providing these requests for additional information to Part D enrollees. We estimate that 3,200,000 individuals will elect to participate in the Medicare Prescription Payment Plan, representing 3,200,000 election request forms. We estimate that approximately 10 percent of election request forms will be incomplete, requiring 320,000 requests for additional information. We assume that one-third or 106,667 (320,000 * ⅓) enrollees will receive this request electronically or via telephone; and the remaining two-thirds of enrollees or 213,333 (320,000 * ⅔) will receive hard copy notices.

We estimate the aggregate cost per mailed request for additional information to be $0.802 ([$0.007 for paper * 2 pages] + [$0.007 for toner * 2 pages] + $0.73 for postage + $0.044/envelope). We assume a maximum of 2

pages will be needed for this notice. Notices are assumed to be printed double-sided to save on paper costs, yielding 2 pages of double-sided print, generally weighing less than 1 ounce. Because preparing and generating hard copy notices is automated once the systems have been developed, we do not estimate associated labor costs. Therefore, we estimate total annual mailing costs to sponsors of $171,093 (213,333 hard copy notices * $0.802/notice).

To estimate the information collection burden for beneficiaries, we estimate that it would take approximately 15 minutes (0.25 hr) to complete the requests for additional information. We estimate the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. We estimate a total one-time burden of 80,000 hours (320,000 enrollees * 0.25 hr) at a cost of $1,656,800 ($20.71/hr * 80,000 hr) across 320,000 enrollees.

Finally, we estimate a one-time burden for Part D sponsors to develop a standard auto-renewal notice alerting the Part D enrollee that their participation in the Medicare Prescription Payment Plan will continue into the next year unless they indicate that they choose to optout. On average, we expect that for each Part D contract, a team of one medical and health services manager who will spend 2 hours at $129.28/hr and one business operations specialist who will spend 10 hours at $85.70/hr will be needed to implement this proposal. In aggregate, we estimate a one-time burden of 9,684 hours (12 hr/contract * 807 Part D contracts) at a cost of $900,257 (807 contracts × [($129.28/hr × 2 hr) + ($85.70/hr × 10 hr)]).

To estimate the information collection burden for beneficiaries, we estimate that approximately 160,000 enrollees will voluntarily terminate their participation in the program in CY2026. We estimate that 99,200 will opt out of the program electronically, and the remaining 60,800 will opt out via telephone. We estimate that it would take approximately 5 minutes (0.083 hr) to voluntarily terminate participation in the Medicare Prescription Payment Program. We estimate the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. We estimate a total one-time burden of 13,280 hours (160,000 enrollees * 0.083 hr) at a cost of $275,029 ($20.71/hr * 13,280 hr).

We estimate annual burden for Part D sponsors to provide these auto-renewal notices to all enrollees participating in the Medicare Prescription Payment Plan at the end of the plan year. Assuming 3,200,000 individuals participating in the Medicare Prescription Payment Plan, we estimate a total of 3,200,000 auto-renewal notices sent each year. We assume that one-third or 1,065,600 enrollees (3,200,000 * ⅓) will receive this notice electronically and the remaining two-thirds or 2,133,333 enrollees (3,200,000 * ⅔) will receive hard copy notices.

We estimate the aggregate cost per mailed request for additional information to be $0.802 ([$0.007 for paper * 2 pages] + [$0.007 for toner * 2 pages] + $0.73 for postage + $0.044/envelope). We assume a maximum of 2 pages will be needed for this notice. Notices are assumed to be printed double-sided to save on paper costs, yielding 2 pages of double-sided print, generally weighing less than 1 ounce. Because preparing and generating hard copy notices is automated once the systems have been developed, we do not estimate associated labor costs. Therefore, we estimate total annual mailing costs to sponsors of $1,710,933 (2,133,333 hard copy notices * $0.802/notice).

The total burden for all Part D contracts associated with the aforementioned requirements is 124,278 hours with one-time first year cost of $14,544,921 and subsequent year costs of $1,882,026 (see table 20). The total burden for Part D beneficiaries with the aforementioned requirements is 93,280 hours with an on-going annual cost of $1,931,829 (see table 20).

TABLE 20: BURDEN FOR ELECTION REQUIREMENTS

Requirement	Total Time (hr)	Total Cost (Year 1)	Total Cost (Subsequent Years)		Labor (L) vs Non-Labor (NL)
Part D Contracts					
Set Up Systems		104,910	10,862,381	0	L
Develop Standard Notice of Request for Additional Information		9,684	900,257	0	L
Mail Standard Notice of Request for Additional Information		0	171,093	171,093	NL
Develop Standard Auto-Renewal Notice		9,684	900,257	0	L
Mail Standard Auto-Renewal Notice		0	1,710,933	1,710,933	NL
Subtotal: Part D Contracts		124,278	14,544,921	1,882,026	N/A
Part D Beneficiaries					
Complete Requests for Additional Information		80,000	1,656,800	1,656,800	L
Complete Program Opt-Out Process		13,280	275,029	275,029	L
Subtotal: Part D Beneficiaries		93,280	1,931,829	1,931,829	N/A
Total		217,558	16,476,750	3,813,855	N/A

3. ICRs Regarding Medicare Prescription Payment Plan Part D Enrollee Targeted Outreach (§ 423.137(e))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

This rule proposes to require Part D sponsors to undertake targeted outreach to enrollees who are likely to benefit from making an election into the Medicare Prescription Payment Plan, including notifying a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program, and directly outreaching to enrollees likely to benefit prior to the plan year and on an ongoing basis during the plan year.

We estimate one-time burden for Part D sponsors to develop systems to identify ''likely to benefit'' enrollees prior to the plan year and during the plan year. On average, we expect that for each Part D contract, a three-person team consisting of one business operations specialist at $85.70/hr, one web developer at $91.90/hr, and one software developer at $132.80/hr who will each spend 20 hours to develop and program these systems. In aggregate, we estimate a one-time burden of 48,420 hours (807 Part D contracts * 60 hr/contract) at a cost of $5,009,856 (807 contracts x [($85.70/hr × 20 hr) + ($91.90/hr × 20 hr) + ($132.80/hr × 20 hr)]).

We estimate annual burden for Part D sponsors to review annual updates to the ''likely to benefit'' identification criteria and update their systems accordingly. On average, we expect that for each Part D contract, one business operations specialist will spend 2 hours at $85.70/hr (see table 16) to review annual updates and make corresponding systems changes. In aggregate, we estimate an annual burden of 1,614 hours (807 Part D contracts * 2 hr/contract) at a cost of $138,320 (1,614 hr * $85.70/hr).

The total burden for all Part D contracts associated with the aforementioned requirements is 50,034 hours with a first-year cost of $5,148,176 and a subsequent year cost of $138,320 (see table 21).

TABLE 21: BURDEN FOR PART D ENROLLEE TARGETED OUTREACH

Requirement	Total Time (hr)	Total Cost (Year 1)	Total Cost (Subsequent Years)	Labor (L) v Non-Labor (NL)
Develop Systems	48,420	5,009,856	0	L
Review/Update	1,614	138,320	138,320	L
TOTAL	50,034	5,148,176	138,320	n/a

4. ICRs Regarding Medicare Prescription Payment Plan Termination of Election, Reinstatement, and Preclusion (§ 423.137(f))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

This rule proposes to require Part D sponsors to have a process to allow a participant who has opted into the Medicare Prescription Payment Plan to opt out during the plan year. Part D sponsors are also required to terminate an individual's Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount.

We estimate a one-time burden for Part D sponsors to develop an opt-out process for enrollees who have elected into the program. On average, we expect that each Part D contract will build a 3-person team consisting of one business operations specialist at $85.70/hr, one web developer at $91.90/hr, and one software developer at $132.80/hr who will each spend 10 hours to develop and program these systems, for a per contract burden of 30 hours for the team. In aggregate, we estimate a one-time burden of 24,210 hours (807 Part D contracts * 30 hr) at a cost of $2,504,928 (807 contracts × [($85.70/hr × 10 hr) + ($91.90/hr × 10 hr) + ($132.80/hr × 10 hr)]).

We also estimate a one-time burden for Part D sponsors to develop processes to reinstate individual terminated for good cause. We note that because this provision mirrors existing requirements for reinstatements when an enrollee fails to pay their Part D premiums, this should be a minor systems change. On average, we expect that for each Part D contract a two-person team consisting of one business operations specialist at $85.70/hr and one software developer at $132.80/hr who will each spend 2 hours developing these processes and updating plan systems. In aggregate, we estimate a one-time burden of 3,228 hours (807 Part D contracts * 4 hr) at a cost of $352,659 (807 contracts × [($85.70/hr × 2 hr) + ($132.80/hr × 2 hr)]).

Finally, we estimate a one-time burden for Part D sponsors to develop systems to track individuals with outstanding balances who are precluded from program participation in subsequent plan years. On average, we expect that for each Part D contract a three-person team consisting of one business operations specialist at $85.70/hr, one web developer at $91.90/hr, and one software developer at $132.80/hr who will each spend 10 hours developing these processes and updating plan systems for a total of 30 hours per contract. In aggregate, we estimate a one-time burden of 24,210 hours (807 Part D contracts * 30 hr) at a cost of $2,504,928 (807 contracts × [($85.70/hr × 10 hr) + ($91.90/hr × 10 hr) + ($132.80/hr × 10 hr)]).

The total burden for all Part D contracts associated with the aforementioned requirements is 51,648 hours with a one-time first year cost of $5,362,515.

TABLE 22: BURDEN FOR TERMINATION OF ELECTION, REINSTATEMENT, AND PRECLUSION

Requirement	Total Time (hr)	Total Cost (Year 1)	Total Cost (Subsequent Years)	Labor (L) v non-Labor (NL)
Develop Opt-Out Process	24,210	2,504,928	0	L
Develop Reinstatement Process	3,228	352,659	0	L
Develop Tracking System	24,210	2,504,928	0	L
TOTAL	51,648	5,362,515	0	n/a

5. ICRs Regarding Medicare Prescription Payment Plan Pharmacy POS Notification Process (§ 423.137(i))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

This rule proposes to require Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. The provision also outlines the required claims processing methodology for applicable Medicare Prescription Payment Plan transactions.

The burden related to these new requirements for pharmacies reflects the time and effort needed to process the notifications provided by the Part D sponsor and include the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' with the enrollee's prescription collateral. We estimate a one-time burden for pharmacies to update their systems for this change, which will require 10 hours of time for each member of a two-person team consisting of one software developer at $132.80/hr and one web developer at $91.90/hr for a total of 20 hours per contract. Assuming approximately 73,397 pharmacies bill Part D based on monthly 2024 pharmacy network information, the total burden estimate across all pharmacies is 1,467,940 hours (73,397 pharmacies × 20 hr) at a cost of $164,923,059 (73,397 pharmacies × [($91.90/hr × 10 hr) + ($132.80/hr × 10 hr)]).

We do not estimate any additional burden for pharmacists to print and provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' because we expect this to be integrated into the other prescription collateral provided to the enrollee under existing practices, such as those approved by OMB under control number 0938–0975 (CMS–10147).

6. ICRs Regarding Medicare Prescription Payment Plan Pharmacy Claims Processing (§ 423.137(j))

The following proposed changes will be submitted to OMB for review under control number 0938–1475 (CMS–10882).

The electronic claims processing methodology outlined in this proposed rule is utilized today by Part D sponsors and pharmacies and therefore the addition of the BIN/PCN that is unique to the Medicare Prescription Payment Plan does not represent new burden that is not approved by OMB. However, CMS is requiring that Part D sponsors report their program-specific PCN starting with ''MPPP'' to CMS. We estimate that this will require 1 hour at $85.70/hr for a business operations specialist to report their identifier to CMS. In aggregate, we estimate a one-time burden of 807 hours (807 Part D contracts * 1 hr/response) at a cost of $69,160 (807 hr * $85.70/hr).

7. ICRs Regarding Part D Coverage of Anti-Obesity Medications (§ 423.100) and Application to the Medicaid Program

As indicated later in this section, we will submit proposed changes to OMB under control number 0938–0659 (CMS–R–153) regarding the modification of policies and criteria. We will also submit proposed changes to OMB under control number 0938–0193 (CMS–179) regarding the preparation and submission of State Plan Amendments.

We are proposing to reinterpret the phrase ''[a]gents when used for . . . weight loss'' in section 1927(d)(2) of the Act such that AOMs that are used for weight reduction or chronic weight management for the treatment of obesity and otherwise meet the definition of Part D drug at § 423.100 would no longer be excluded from Part D coverage pursuant to the exclusion in paragraph (2)(ii) of the definition, for drugs that may be excluded from Medicaid coverage under section 1927(d)(2) of the Act. Our proposed reinterpretation would also apply to Medicaid such that state Medicaid programs would no longer have the discretion to exclude these drugs pursuant to section 1927(d)(2) of the Act from Medicaid coverage when used for weight reduction or chronic weight management for the treatment of obesity. States that are not already covering AOMs for weight reduction or chronic weight management would be required to do so to treat obesity in Medicaid enrollees.

Except as indicated later in this section, there is no new or revised information collection burden for Part D plans associated with this proposal to allow for Part D coverage of AOMs. The Part D plan's activities related to the decision to include AOMs on their Part D formularies would be the same as for any new drug that comes on the market. This burden is currently approved by OMB under control number 0938–0964 (CMS–10141) under the requirement that the Pharmacy and Therapeutics committee documents its decisions regarding formulary development and revision.

The following proposed changes will be submitted to OMB for review under control number 0938–0659 (CMS–R–153) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

As Medicaid is an operationally different program from Medicare Part D, there will be a burden for the state Medicaid programs that do not already cover AOMs when used for weight reduction or chronic weight management for Medicaid enrollees with obesity to modify their existing coverage and reimbursement policies and criteria to remove such exclusion of AOMs. This burden may include the time and cost for administrative processes and requirements, including changes to utilization management criteria, claims processing to allow coverage of these products for this indication, review of stakeholder input, change to provider and beneficiary

documents to reflect this change in policy, and state internal operational implementation procedures. We believe that it will take a business operations specialist 40 hours at $85.70/hr to modify the state's policies and criteria. In aggregate, we estimate a one-time burden of 1,560 hours (39 states × 40 hr) at a cost of $133,692 (1,560 hr × $85.70/hr). Once the modifications are developed, there should be no additional burden.

The following proposed changes will be submitted for OMB review and approval under control number 0938–0193 (CMS–179) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

This new provision may also require the submission of a State Plan Amendment (SPA) for formal review and approval. In such instances, we estimate that it would take a Business Operations Specialist 20 hours at $85.70/hr. In aggregate, we estimate a one-time burden of 780 hours (39 states × 20 hr) at a cost of $66,846 (780 hr × $85.70/hr).

8. ICRs Regarding Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d))

The following proposed changes will be submitted to OMB for review under control number 0938–1154 (CMS–10396).

Based on comments we received from the December 2022 proposed rule (87 FR 79452), CMS proposes to revise § 423.153(d)(2)(iii)(A) identifying ''Alzheimer's disease'' as a core chronic disease to ''Alzheimer's disease and dementia,'' to include all other dementias in the core chronic diseases for targeting beneficiaries for MTM program eligibility. We are also revising our burden estimates to reflect updated data, including up-to-date postage rates and using 2023 data. We estimate that the proposed change to add dementia to the core chronic diseases will increase the number (and percentage) of Part D enrollees eligible for MTM services by 71,210 beneficiaries, from 7,882,987 (14.5 percent × 54,503,892 Part D enrollees based on internal data from 2023) to 7,954,197 (14.6 percent × 54,503,892 Part D enrollees based on internal data from 2023) among 866 Part D contracts with an approved MTM program in 2023.

Under § 423.153(d)(1)(vii)(B) and (C), all MTM enrollees must be offered a comprehensive medication review (CMR) at least annually and targeted medication reviews (TMRs) no less than quarterly. A CMR is an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth, that includes a review of the individual's medications and may result in the creation of a recommended medication action plan as required in § 423.153(d)(1)(vii)(B)(*1*). An individualized, written summary in CMS's Standardized Format must be provided following each CMR. For ongoing monitoring, sponsors are required to perform TMRs for all beneficiaries enrolled in the MTM program with follow-up interventions when necessary. The TMRs must occur at least quarterly beginning immediately upon enrollment in the MTM program and may address specific or potential medication-related problems. TMRs may be performed to assess medication use, to monitor whether any unresolved issues need attention, to determine if new drug therapy problems have arisen, or assess if the beneficiary has experienced a transition in care. Under § 423.153(d)(1)(vii)(E), plans are also required to provide all enrollees targeted for MTM services with information about safe disposal of prescription medications that are controlled substances. Plans may mail this information as part of the CMR summary, a TMR, or other MTM correspondence or service. The proposed changes do not impact the requirements for MTM services.

In this section, we estimate the additional burden on plan sponsors to conduct CMRs (labor cost) and mail the written CMR summaries (non-labor cost) to the additional beneficiaries that will be targeted for MTM enrollment based on our proposal to include dementia within the required core chronic diseases for identifying beneficiaries who have multiple chronic diseases. We also estimate the cost of sending safe disposal information to the beneficiaries who will be newly targeted under these revised criteria, but do not receive a CMR.

To obtain aggregate burden we separately estimate: (1) the burden for pharmacists to complete the CMR; (2) the mailing costs of the CMRs; and (3) the cost of mailing of safe disposal instructions to those targeted beneficiaries who do not accept the offer of a CMR.

- *The burden for pharmacists to complete the additional CMRs:* Based on plan-reported data, we found that 70.9 percent of MTM program enrollees accepted the offer of a CMR in 2023. To estimate the cost of conducting the additional CMRs, we multiply the expected number of additional MTM program enrollees (71,210) by 0.709 to obtain the number of additional CMRs we estimate will actually be conducted (50,488). We estimate a pharmacist would take 40 minutes (0.6667 hr) at $129.62/hr (see table 16) to complete a CMR. Thus, the total burden is 33,660 hours (0.6667 hr/CMR * 50,488 enrollees who accept the CMR offer) at a cost of $4,363,009 (33,660 hr * $129.62/hr).
- *Mailing Costs of CMRs:* To estimate the cost of sending the CMR summaries, we assume that the average length of a CMR is 7 pages double-sided (including 1 page for information regarding safe disposal). The cost of mailing one CMR summary is the cost of postage plus the cost of printing one CMR summary. First-class postage costs $0.64 per metered mailing. Paper costs are $0.007 per sheet ($3.50 per ream/500 sheets per ream), and toner costs $70.00 per cartridge and lasts for 10,000 sheets (at $0.007 per sheet = $70.00/10,000 sheets). Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope. Therefore, the cost of printing and mailing the average CMR summary is $1.022 ([$0.64 postage for the first ounce + $0.24 for the second ounce + $0.044/envelope] * [7 sheets * ($0.007 for paper + $0.007 for toner)]). And taken as a whole, the annual cost of mailing CMRs to the additional 50,488 beneficiaries expected to accept the CMR offer is $51,599 (50,488 enrollees × $1.022/mailing).
- *Mailing costs for Safe Disposal Information:* Out of the 71,210 additional beneficiaries expected to be targeted for MTM based on the revised criteria, we expect that 29.1 percent or 20,722 (71,210 * 0.291) beneficiaries will decline a CMR. These beneficiaries will still need to receive information regarding the safe disposal of prescription drugs that are controlled substances. For purposes of calculating the burden, we assume that any safe disposal information that is not included in a CMR is either (1) being mailed in a TMR, which may be as short as one page and may contain private health information; or (2) is mailed as a standalone document which does not contain any private health information. For purposes of impact, (1) if one additional page is included in the TMR, then there is no additional postage; and (2) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data with regard to what percentage of safe disposal information will be mailed as part of a TMR or other MTM correspondence or service, we are assuming that all safe disposal information not sent with a CMR will be

one page that is mailed separately using bulk postage in order to project the maximum cost of such mailing. If the letter does not contain private health information and thus bulk mailing (which include the envelope, typically a fold over paper) is used, the cost to mail one page of safe disposal information is $0.01495 per enrollee [(1 page * $0.007/sheet) + (1 page * $0.007 toner) + ($0.19/200 items for bulk postage).] Therefore, we estimate that the cost of mailing safe disposal information to those beneficiaries targeted for MTM who do not receive it in a CMR summary is $310 ($0.01495 * 20,722).

Therefore, the total burden associated with the proposed revisions to the MTM targeting criteria is 33,660 hours and $4,414,918 ($4,363,009 for a pharmacist to perform the CMRs for beneficiaries newly targeted for MTM under the revised criteria + $51,599 to mail the CMR written summary in the CMS Standardized Format with safe disposal information + $310 for mailing information regarding safe disposal to beneficiaries newly targeted for MTM who do not receive a CMR).

9. ICRs Regarding Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102(f)(4)(iii)(C))

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10915). At this time the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their clearance of this proposed collection of information request. CMS will include that number in the subsequent CMS–4208–F final rule. OMB will issue the control number's expiration date upon their approval of the final rule's collection of information request. The issuance of that date can be monitored at *www.Reginfo.gov.*

As explained in section III.H. of the proposed rule, for each SSBCI, the plan must list all the written policies and objective criteria on which the policies are based as noted in § 422.102(f)(4)(iii)(C) on a public facing website. For web developers and programmers to annually post the required information on the plan website we estimate it would take 2 hours at $125.48/hr (see table 16). We estimate 761 plans including local and regional CCPs, MSA, and PFFS and reflects the publicly available CMS counts of these plans as of July 2024 accessible at *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.* In aggregate we estimate an annual burden of 1,522 hours (761 plans * 2 hr/plan) at a cost of $190,981 (1,522 hr * $125.48/hr). Medicare Cost plans are excluded from the count since they are not permitted to offer SSBCI.

10. ICRs Regarding Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

As discussed in section III.M. of this proposed rule, we propose to amend the existing requirements at §§ 417.454 and 422.100(j) (that cost sharing for certain benefits not exceed cost sharing for the same benefits in Original Medicare) to add categories of mental health and substance use disorder services (collectively called ''behavioral health services''). The service categories include mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient services, inpatient hospital psychiatric services (all length of stay scenarios), outpatient substance use disorder services, and opioid treatment program services. This proposal requires Section 1876 Cost Plans (Cost Plans) and Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs)) in-network cost sharing for these behavioral health services to be no greater than that in Traditional Medicare, beginning in contract year 2026. Specifically, this proposal: (1) modifies the way that in-network service category cost-sharing limits for behavioral health services have been set by adopting a new cost-sharing standard and (2) updates current guidance governing organization bid requirements about how benefits must be provided by plans, which are currently approved by OMB under control number 0938–0763 (CMS–R–262).

Plans comply with our current practice because CMS annually reviews bids and organizations have submitted supporting documentation (for contract year 2024 and prior years) to demonstrate compliance with § 422.254(b)(5), (c)(5), and (c)(6), which require that MA organization bid submissions [324] must be prepared in accordance with CMS actuarial guidelines. Following these guidelines requires use of generally accepted actuarial principles, the actuarial bases of the bid, a description of cost sharing applicable under the plan,[325] and the actuarial value of the cost sharing. CMS relies on our oversight and monitoring authority and our longstanding bid review policy (and the compliance program, recordkeeping, audit and access requirements at §§ 422.503 and 422.504) to request any additional information and necessary documentation from organizations to investigate plan compliance with the program and benefit requirements.

Consequently, CMS asserts that that this proposal does not impose any new or revised collection of information requirements and/or burden and is not subject to the requirements of the PRA because: (1) this proposal does not change how CMS evaluates compliance with cost-sharing limits as part of bid review; (2) plans comply with our current practice; and (3) this proposal does not change any bid documentation requirements in the CMS issued, annual bid instructions.

11. ICRs Regarding Improving Equitable Access—Enhancing the Health Equity Analysis (§ 422.137(d))

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

Currently, under § 422.137(d), all MA organization utilization management committees must conduct an annual health equity analysis of the use of prior authorization at the plan-level, based on specified metrics, aggregated for all items and services. The MA organizations must make the results of the analysis publicly available on their plan's website in a manner that is easily accessible and without barriers. As explained in section III.N. of this proposed rule, CMS is proposing to amend the regulation to require that the metrics for the health equity analysis be reported for each covered item and service (in other words, the data in the analysis must be presented in a disaggregated form). The information relevant to this analysis and corresponding report is routinely collected in plan systems for each covered item and service, and therefore the data required for the analysis should be readily available for plans. Therefore, we do not believe there is a burden associated with this requirement. We estimate an annual burden for the requirement that the data must be

[324] Bid submissions from coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and MA private fee-for-service plans are subject to these actuarial guidelines.

[325] Cost Plans are not required to report information for all services in their plan benefit package.

compiled into a report and posted publicly. For web developers and programmers of any plan to annually post the required information on the plan website would require 8 hours at $125.48/hr) (see table 16). We estimate 767 plans including local and regional CCP, MSA, PFFS plans and Medicare Cost plans and is based on the publicly available CMS data on plan type counts accessible at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07. In* aggregate we estimate an annual burden of 6,136 hours (8 hr * 767 contracts) at a cost of $769,945 (6,136 hr * $125.48/hr) to fulfil the requirement that the plans publicly post the analysis to their website.

12. ICRs Regarding Formatting Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (§ 422.120(c))

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10906).

As indicated in section III.Q. of this proposed rule we propose adding new requirements at § 422.111(m) for MA organizations' provider directory formats. Under this proposal, MA organizations would be required to provide provider directory data that are formatted per CMS/HHS specifications to CMS/HHS and attest to the accuracy and consistency of their provider directory data. The purpose of this proposal is to allow for MA organizations' provider directory data to be populated into Medicare Plan Finder (MPF) so that current and prospective MA enrollees would have the ability to search for a provider or facility and determine whether the provider or facility has a contractual relationship with the MA plans displayed in MPF. We believe this would further CMS's objective to promote informed beneficiary choice, efficiency, and transparency through online resources while advancing health equity.

Since the production of provider directories are part of an automated process, the burden associated with this provision is a one-time burden for a computer programmer for each plan to create the proposed functionality within their system. We estimate that for each plan a computer programmer would spend 8 hours at $103.60/hr (see table 16). In aggregate, we estimate a one-time burden of 6,088 hours (761 plans * 8 hr/plan) at a cost of $630,717 (6,088 hr * $103.60/hr). The 761 plans include local and regional CCP, MSA, and PFFS plans and is based on the publicly available CMS data on plan type counts accessible at *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.* Medicare Cost plans have been excluded from the count since the ultimate goal of the provision is a display in Medicare Plan Founder, and Medicare Cost plans are not currently listed there.

13. ICRs Regarding Enhancing Review of Marketing and Communications (Part 422, Subpart V, and Part 423, Subpart V)

The following proposed changes will be submitted to OMB for review under control number 0938–1051 (CMS–10260).

As discussed in section III.R. of this proposed rule, in the April 2018 final rule, we narrowed the definition of ''marketing materials'' under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. As noted in section III.R. of this proposed rule, these definitions were further updated in the January 2021 final rule, with the net result of narrowing the types of materials CMS required to be submitted, to those materials that CMS considered, at the time of the January 2021 final rule, to be the most likely to influence a beneficiary's decision to enroll in a plan. However, as indicated in this proposed rule, since the time these rules were finalized, CMS has observed a shifting landscape of misleading marketing practices in MA and Part D, including television and mail ads that, despite not meeting the definition of marketing, seemingly draw a beneficiary's attention to a plan or influence a beneficiary's enrollment decision. Moreover, CMS has seen a steady increase in marketing misrepresentation complaints beginning after the issuance of the April 2018 final rule. Therefore, we believe many communications materials excluded from the current regulatory definition of marketing and, consequently, from the submission and review requirements for marketing materials in §§ 422.2261(b) and 423.2261(b), should in fact be collected, as they are likely influencing a beneficiary's enrollment decision even when they do not meet the content standards of the current regulatory definition of marketing.

The burden of this provision is the time and money incurred by plans and TPMOs submitting more materials. To estimate this burden, we refer to table 16 of April 2018 final rule (83 FR 16696 and 16697). This table is based on a year of marketing data, from July 2015—June 2016. We illustrate the effects of the current proposal by reviewing what was then called (in the April 2018 final rule), category 4000 material, which dealt with advertisements. Table 16 indicates that in 2015–2016, we received roughly 44,000 advertisements of which 11,000 (44,000 * 25%) would no longer be submitted once the April 2018 final rule was finalized as they did not meet the updated definition of marketing, so that we would continue to receive 33,000 (44,000 * 75%) advertisements that were still to be considered marketing. We assume these proportions are stable. If so, in each year from 2019–2025, 25 percent of MA and Part D plan advertisements were no longer submitted while 75% of advertisements are still considered marketing and continue to be submitted to CMS. If the rule is finalized, then effective 2026, besides the 75 percent of materials that would have been collected, we will also collect the 25 percent of materials that were not required to be submitted from 2019 through 2025. Thus, relative to what was submitted in 2019 through 2025, that is, relative to 75 percent of the advertisements that are potential marketing materials, we are adding 25 percent more advertisements that were not collected in 2019–2025. That means we are increasing the current 75 percent by 33.3 percent resulting in the 25 percent of the materials (33.3% * 75% = 25%) being added. A similar analysis applies to all categories of marketing affected by this proposal.

However, we now use a different classification system, rather than the classification system based on the categories mentioned in the April 2018 final rule. Since we currently only collect marketing materials, unless directly specified in our regulations, we classify most materials by material type and whether the material is marketing or CMS required material. To illustrate this, we point out, that we duplicated the sampling of data from July 2015 to June 2016 by reviewing marketing materials collected from July 2023 to June 2024. With this background we can illustrate some subtleties associated with the comparison of the 2015 to 2016 and the 2023 to 2024 data.

To properly compare the two samples, we must identify the categories of materials in each of them at the time, category 1100 (relevant to the 2015 and 2016 data) included the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. After the April 2018 final rule, the EOC was no longer considered a marketing material and was no longer required to be submitted to CMS. However, as of today, the EOC has been updated to be

required for submission to CMS, as per §§ 422.2261(c)(1) and 423.2261(c)(1), even though it was defined as a communications material. The ANOC is still a marketing material and continues to be collected, and therefore neither category will be affected by the update to the marketing definition, even though one material is marketing and one material is communications. Due to the differing classification system from the April 2018 final rule, and since there will be no burden impacts associated with the submission of the ANOC or EOC, the 1100 category is not relevant to the differences between the 2016 to 2017 data and the 2023 to 2024 data. Similarly, category 3000 (from the categories of the 2015–2016 data) refers to grievance forms, but for the 2023 to 2024 data, we no longer collect grievances forms as they are not considered marketing and therefore are not included in the data. Additionally, under the current proposal, grievance forms would not meet the definition of marketing and therefore does not have any associated burden. Table 23 contains all categories from the 2015 to 2016 sample and indicates which ones are still relevant to the current proposal.

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TABLE 23: WHICH MARKETING CATEGORIES USED IN THE 2015-2016 DATA ARE PRESENT IN THE 2023-2024 DATA

Category ID (2015-2016)	Brief Description	Does the Current Provision Affect This Category
1000	Enrollment and related documents	Yes, materials excluded in the April 2018 final rule are being added back in.
1100	ANOCs/EOCs/LIS Rider	Not affected by current proposal: ANOCs and EOCs are both currently required to be submitted to CMS and will continue to be submitted under this proposal.
2000	Disenrollment	Not affected by current proposal since disenrollment forms are not considered marketing and will not be considered marketing under this proposal.
3000	Grievances	Not affected by current proposal since grievance forms are not considered marketing and will not be considered marketing under this proposal
4000	Advertisements	Yes, materials excluded in the April 2018 final rule are being added back in.
5000	Formulary drug	Not affected by current proposal since formularies are not considered marketing and will not be considered marketing under this proposal.
6000	Presentations/Scripts/Surveys	Yes, materials excluded in the April 2018 final rule are being added back in.
8000	Creditable Coverage/LEP	Not affected by current proposal since these will not be considered marketing and will not be considered marketing under this proposal.

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The sample of marketing data from July 2023–June 2024 had 76,170 items. These 76,170 items include items corresponding to the 2015–2016 categories with category IDs listed in table 23 of 1000 (enrollment and related documents), 4000 (advertisements), and 6000 (Presentations/Scripts/Surveys). Table 16 of the April 2018 final rule (83 FR 16697) indicates the total number of marketing items in these categories as well as how many were not required to be submitted for 2019–2025. This allows us to accurately calculate how much the 76,170 materials from 2023–2024 data should be increased. Table 24 summarizes the numerical details.

We now make two observations. First, the 76,170 items in the 2023–2024 collection correspond to categories 1000, 4000, and 6000. Based on the April 2018 final rule, only 35,124 materials would have been collected in 2015–2016 had the provisions of the April 2018 final rule been in effect. Additionally, 28,172 items would not have been collected. Thus, 80.21% of the 35,124 materials (28,172) were not collected in 2019–2025; if the current proposal is finalized, we would be increasing marketing materials by 80.21%.

Secondly, the 35,124 materials that would have been collected in the 2015–2016 sample had the April 2018 final rule applied to them correspond to the categories of item in the 2023–2024 data which had 76,170 items. This indicates an annual trend in growth of marketing materials of 10.15% (that is, $35{,}124 * 1.1015^{8} = 76{,}170$). We expect this trend to continue in the near future.

Based on these observations, we can calculate the burden of this provision if finalized in 2026. The results are presented in table 25.

TABLE 24: COUNT OF ITEMS BY CATEGORY IN 2015-2016 DATA AND THE 2018 RULE EFFECT ON THEM

Category IDs of marketing material from the 2015-2016 data	Brief Description	Total Items in this category in the 2015-2016 data	Total items in this category that would not have been collected in 2015-2016 had the April 2018 final rule been in effect	Total items in this category that were excluded from collection in 2019-2025 but will be added back in effective 2026.
1000	Enrollment and related documents	16,495	981	15,514
4000	Advertisements	43,965	32,974	10,991
6000	Presentations /Scripts/Surveys	2,836	1,169	1,667
	Total	**63,296**	**35,124**	**28,172**

To clarify the meaning of table 25, we illustrate the calculation for 2026. For 2023–2024, we had 76,170 marketing materials. That number must be trended by a compound increase of 10.15 percent annually resulting in 101,797.6 ($76,170 * 1.1015^3$) marketing materials expected in 2026 if the provision is not finalized. If the provision is finalized, we must increase this by 81,652 materials (80.21% * 101,797.6) to a total of 183,449.5. The burden of processing the first 101,797.6 materials is included in the current burden, while the proposed provision would add the burden of processing an additional 81,651.9 materials. We estimate 767 plans will be impacted by these changes, including local and regional CCP, MSA, PFFS plans and Medicare Cost plans and is based on the publicly available CMS data on plan type counts accessible at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.we.*

To calculate the burden, as in the April 2018 final rule, we assume it would take an average of 30 minutes (0.5 hr) to process each material resulting in a burden of 40,826 hours (81,651.9 additional materials * 0.5 hr) in the first year. We also estimate a cost of $3,498,788 (40,826 hr * $85.70/hr for a business operations specialist) in the first year.

CMS received 76,170 materials in the base year of 2023, and that the applied trend increase of 10.15 percent would have applied in each year between 2023 and the proposed implementation date for this provision in 2026.

TABLE 25: CALCULATION BY YEAR OF BURDEN

Year	Base Year 2023	Annual Trend Increase of 10.15%/Year	Increase of 80.21% Due to Adding Back Items Excluded in April 2018 final Rule	Time to Process (0.5 hr per item)	Cost to Process at $85.70/hr
2026	76,170	101,797.6	81,652	40,826	$3,498,788
2027	76,170	112,130	89,940	44,970	$ 3,853,929
2028	76,170	123,511.2	99,068	49,534	$4,245,063
Total	n/a	n/a	270,660	135,330	$11,597,780
Annual	n/a	n/a	90,220 (270,660/3 years)	45,110 (135,330/3 years)	$3,865,927 ($11,597,780/3 years)

Given the annual increase, we have annualized our burden estimates over 3 years. In this regard, we estimate an annual burden of 45,110 hours at a cost of $3,865,927. We are also soliciting specific comment on the potential or alternative financial impacts of this proposal.

14. ICRs Related To Require Clinical or Quality Improvement Standards for Provider Incentive and Bonus Arrangements To Be Included in the MA MLR Numerator (§ 422.2420(b)(2))

The following proposed changes will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

We propose to amend § 422.2420(b)(2) to clarify that only provider incentives and bonuses tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards may be included in incurred claims for MA MLR reporting and remittance calculation purposes. We anticipate that implementing this provision would require minor changes to the MLR Annual Reporting Form Instructions and would not significantly increase the associated reporting burden of 61.1 hours per response.

We estimate that approximately 700 MA organizations contracts must comply with the updated reporting requirements based on 2021 reported MLR data (the most recent data available). We further estimate that it would take each MA organization a one-time effort of 1 hour at $85.70/hr (see table 16) for a business operations specialist to update the financial data needed for MLR calculations. In aggregate, we estimate a one-time burden of 700 hours (700 MA organization contracts * 1 hr/response) at a cost of $59,990 (700 hr * $85.70/hr).[326]

[326] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

15. ICRs Related to Proposal To Add Provider Payment Arrangement Reporting in the Medicare MLR Report Regulations (§§ 422.2460 and 422.2490)

The following proposed changes will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

We propose to amend §§ 422.2460 and 422.2490 to require MA organizations to submit data on provider payment arrangements through the MLR Reporting Tool. This additional reporting will not be made public unless the data is deidentified and reported as aggregate totals. We anticipate that implementing this provision would require minor changes to the MLR Annual Reporting Form and Instructions and would not significantly increase the associated reporting burden of 61.1 hours per response.

We estimate that approximately 700 MA organizations contracts must comply with the updated reporting requirements based on CY 2021 reported MLR data (the most recent data available). We further estimate that it would take each MA organization an annual effort of 3 hours at $85.70/hr (see table 16) for a business operations specialist to update the financial data needed for MLR calculations given that CMS is proposing to use a widely agreed upon HCPLAN APM framework. In aggregate, we estimate an annual burden of 2,100 hours (700 MA organizations contracts * 3 hr/response) at a cost of $179,970 (2,100 hr * $85.70/hr).[327]

16. ICRs Related To Prohibit Administrative Costs From Being Included in Quality Improving Activities in the MA and Part D MLR Numerator (§§ 422.2430(a) and 423.2430(a))

The following proposed changes will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

We propose to amend §§ 422.2430(a) and 423.2430(a) to specify that only expenditures directly related to activities that improve health care quality may be included as quality improving activity expenses for MLR reporting. We anticipate that implementing these provisions would require minor changes to the MLR Annual Reporting Form Instructions and would not significantly increase the associated reporting burden of 61.1 hours per response. We estimate that approximately 764 MA organizations and Part D sponsors contracts must comply with the updated reporting requirements based on 2021 reported MLR data (the most recent data available). We further estimate that it would take a business operations specialist at each MA organization and Part D sponsor a one-time effort of 1 hour at $85.70/hr (see table 16) to update the financial data needed for MLR calculations. In aggregate, we estimate a one-time burden of 764 hours (764 plans * 1 hr/response) at a cost of $65,475 (764 hr * $85.70/hr).[328]

17. ICRs Related to Establish Standards for MA and Part D MLR Audit Examinations (§§ 422.2480(d), 423.2480(d), 422.2401, 423.2401, 422.2450, 423.2450, 422.2452, 423.2452, 422.2454, and 423.2454)

The following proposed changes will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

Our proposed amendments would establish a process for MLR audit examinations and a collection and appeals process for MLR audit remittances based on MLR audit findings. We expect MA organizations and Part D sponsors would have to retain detailed MLR information for auditing purposes. We anticipate that implementing this provision would require minor changes to the MLR Annual Reporting Form Instructions and would not significantly increase the associated reporting burden of 61.1 hours per response.

MA organizations' and Part D sponsors' current record retention practices should already support future audits, however, there may be some burden associated with confirming compliance with record retention requirements. We estimate that approximately 764 MA organizations and Part D sponsors contracts must confirm compliance with the record retention requirements. We further estimate that it would take 1 hour at $85.70/hr (see table 16) for a business operations specialist to confirm the data needed for potential MLR auditing has been retained on an annual basis. Therefore, we expect approximately 764 hours (764 plans * 1 hr/year) at a cost of $65,475 ($764 hr * $85.70/hr).[329]

In addition, CMS may conduct up to 9 MLR audit examinations annually, and the compliance actions that result from the audits and provisions in this rule would take effect in 2026. The annual burden would be higher for audited contracts, although MA organizations and Part D sponsors should have all of the materials requested by auditors consistent with current record retention practices. We estimate the burden to be 80 hours for the contracts selected for audit. Therefore, if 9 audits are conducted in a given year we expect the burden to be approximately 720 hours (9 contracts * 80 hr/year) at a cost of $61,704 (720 hr * $85.70/hr).[330]

18. ICRs Regarding Improving Access—Enhancing Rules on Internal Coverage Criteria (§ 422.101(b)(6))

The following proposed changes will be submitted to OMB for review under control number (0938–0753) (CMS–R–267).

This rule proposes that by January 1, 2026, MA organizations must publicly display on the organization's website a list of all Medicare items and services where the MA organization uses internal coverage criteria when making medical necessity decisions. The list of items and services on the website must include the information in § 422.101(b)(6)(ii)(A) through (C) (or connect directly to that information through a hyperlink) and include the vendor's name when using a third-party vendor's criteria.

The MA organization's internal coverage criteria web page must be displayed in a prominent manner and clearly identified in the footer of the website. The web page must be easily available to the public, without barriers, including but not limited to ensuring the information is available free of charge, without having to establish a user account or password, without having to submit personal identifying information, in a machine-readable format with the data contained within that file being digitally searchable and downloadable, and include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

In § 422.101(b)(6)(ii)(A), which requires posting the internal coverage criteria in use, we are adding that any internal coverage criterion used by the MA organization in making medical necessity decisions on Part A and Part B benefits must be clearly identified and marked as internal coverage criteria of the MA plan within their coverage policies. In paragraph (B), we are proposing to add that the evidence supporting the internal coverage criteria must be connected with a corresponding footnote. In paragraph (C), we are

[327] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

[328] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

[329] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

[330] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

changing ''criteria'' to ''criterion'' to make it clear that we require an explanation of the rationale that supports adoption of each individual internal coverage criterion in use.

We believe that for a business operations specialist to make the public posting of the new information described previously would require on average 1.5 hours a month at $85.70/hr (see table 16). In aggregate, we estimate an annual burden of 13,806 hr (767 plans * 1.5 hr/month * 12 months) at a cost of $1,183,174 (13,806 hr * $85.70/hr). The 767 plans include local and regional CCP, MSA, PFFS plans and Medicare Cost plans and is based on the publicly available CMS data on plan type counts accessible at *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.*

19. ICRs Regarding Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, and 422.616)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

The proposal to clarify the definition of an organization determination is intended to enhance enrollee protections in inpatient settings. This would be accomplished by proposing to clarify that an MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization is an organization determination subject to part 422, subpart M.

When making an organization determination, the plan must issue a coverage determination notice. The proposed clarification to the definition of an organization determination would mean that when an MA organization downgrades an enrollee from receiving inpatient to outpatient services or when an MA organization denies payment for services after such services were rendered but before a request for payment is submitted, the MA organization would be required to provide proper notice of the decision to the enrollee. The proposal also includes strengthening requirements related to notifying providers. The existing notice requirements for standard organization determinations at § 422.568 specify that MA organizations must provide the enrollee with notice of its decisions. Under existing rules, MA organizations are required to use an OMB-approved standardized denial notice (CMS Form 10003–NDMCP/OMB 0938–0829) to notify enrollees of adverse decisions. We propose to amend requirements related to notice of a standard organization determination at § 422.568(b)(1) to notify an enrollee's physician or provider, as appropriate, as well. As stated in section III.V.3. of this proposed rule, we do not believe the proposal to strengthen notice requirements will have a substantial impact on the practices of MA organizations as we are codifying longstanding requirements and guidance that we believe the majority of plans already implement based on the few complaints we receive on this issue from providers and enrollees. In addition, we also understand that due to the contractual relationship MA organizations have with their providers, most contracted providers should already receive notice of relevant organization determinations, including those that the provider submitted on behalf of the enrollee.

However, while we acknowledge that some plans are complying with the existing rules in a manner that is consistent with our proposed clarification, we do not have the data on the number of plans that are complying with this requirement. We estimate that annually 60,000 inpatient approvals are downgraded to observation status. We are estimating that of those 60,000 cases, approximately 10 percent of those cases are being handled appropriately (that is, plans are complying with the existing regulations). We do not have definitive data sources that indicate the number of plans that may not be in compliance and, therefore, invite stakeholder comment on our assumptions.

The burden associated with the proposed provisions are due to: (1) additional notices to enrollees and providers not currently receiving them; and (2) an increase in the number of appeals received. Due to lack of data, we cannot fully quantify all burden; however, we can quantify some and perform qualitative estimates. We discuss each burden source separately.

a. Additional Notices

Under our proposal, there would be an increase in the number of notices to providers and enrollees regarding downgrading inpatient stays to observation status. The associated burden with this proposal would be the increase in costs related to the issuance of these notices. Because the issuance of these notices is typically automated, there could be a one-time first year cost to update systems in addition to a potential annual mailing cost. We estimate that, per plan, it may take a programmer 4 to 8 hours to update systems. In aggregate we estimate a one-time, first year burden of 5,816 hours (8 hr/plan * 727 plans) at a cost of $602,538 (5,816 hr * $103.60/hr).

We are basing our estimate for the cost of notices on the projected cost of postage (the major cost) and the number of notices. By examining risk-adjustment data for MA plan use of Condition Code 44, the code used in Traditional Medicare for a downgrade of an inpatient stay to observation, we estimate there are 60,000 downgrades annually. This approach has some assumptions, for example, that MA plans are using Condition Code 44 to indicate downgrades, and that most downgrades are being captured. Since the information in the notice is confidential, they must be mailed via first class at a postage rate of $0.73/notice. In addition, we believe that the majority of plans are currently not complying with our requirements and are estimating that there will be a new burden for approximately 90% of plans. This assumption is based on complaints, correspondence with plans, and other anecdotal evidence, but we acknowledge that it is speculative since we do not collect related data. Based on our assumptions, the cost of mailing notices would be a non-labor cost of $39,420 annually (60,000 downgrades * 90 percent that are not currently complying * $0.73/notice).

We note that besides the other assumptions detailed previously, this estimate is an over-estimate since some enrollees will receive their Integrated Denial Notice (IDN) in the hospital and hence incur no mailing costs. Because it is an over-estimate, we focused on the main drivers of cost and did not include the cost of paper, toner, and envelopes. Had we included toner and paper costs, the estimate would increase by a maximum of $756 (60,000 maximum notices * 90 percent * (0.007 cost of paper + 0.007 cost of toner). The inclusion of bulk envelopes could raise the cost by a maximum of $2,160 (60,000 maximum notices * 90 percent * $0.04 bulk envelope cost).

b. Increased Appeals

While we expect an increase in the number of organization determinations reported, as well as the number of appeals received, we do not have data to confirm this assumption. Appeals data available to CMS is not currently broken out by the type of service; therefore, we do not know how many

MA organizations fail to provide proper notification and how many inpatient approvals being downgraded to outpatient are appealed. There are no current appeals going to the Independent Review Entity (IRE) level. We are unable to estimate (1) how many cases of the 60,000 will now receive notices (2) how many appeals would arise, (3) how many are overturned, and (4) how many will go to the IRE. Thus, we cannot quantify this, but we can qualitatively identify this as a cost.

We also note that our proposal to amend the reopening rules at § 422.616 will not add to existing plan processes or requirements, so we believe any overall burden associated with processing a reopening of an organization determination related to inpatient hospital admissions will remain unchanged or will possibly be reduced (given that we are proposing to eliminate the discretion of an MA organization to reopen an approved authorization for an inpatient hospital admission based on new and material evidence). The decision to reopen an organization determination is at the discretion of an MA organization. Our proposal to curtail an MA organization's authority to reopen and modify an approved authorization for an inpatient hospital admission on the basis of good cause for new and material evidence does not impose any new burden in the decision-making process related to prior authorization for inpatient hospital admissions. Consequently, this provision will not have added impact. We do not believe the proposed changes will adversely impact enrollees or MA organizations. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

Likewise, our proposed clarification to § 422.562(c)(2) will not add to existing plan processes or requirements, so we believe the overall estimated burden on MA organizations associated with processing organization determinations and appeals will be unchanged and this provision will not have added impact. We do not believe the proposed change will adversely impact enrollees or MA organizations and, further, believe that most MA organizations are properly excluding provider payment appeals from the subpart M administrative appeals process when a dispute no longer involves enrollee financial liability for furnished services. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Funds.

We invite stakeholder comment on our approaches to determine the potential burden and our estimates.

20. ICRs Regarding Promoting Person-Centeredness in SNP ICPs and Timeliness of HRAs and ICPs (§§ 422.101(f) and 422.107(e))

In section V.A. of this proposed rule, we propose amendments to § 422.101(f)(1) to codify timeliness standards, improve the organization of the various HRA and ICP requirements, and strengthen these requirements. These proposals would require that—

- SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. This would better align with the Medicaid requirement at § 438.208(b)(3) and conform to the standard currently described for reporting HRA completion in the Part C reporting requirements.
- SNPs make at least three non-automated phone call attempts, unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day. We also propose that for any enrollees that are unable to be reached or decline to participate in the HRA, the SNP must document the attempts to contact the enrollee or the enrollee's choice not to participate. These updates would better conform to the standard currently described for reporting HRA completion in the Part C reporting requirements.
- Within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later, SNPs to develop and implement a comprehensive ICP that—

++ Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and needs identified in the HRA;

++ Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable) as feasible;

++ Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided; and

++ Is updated as warranted by changes in the health status or care transitions of enrollees.

Since SNPs are already required to conduct HRAs and ICPs, we do not anticipate that the proposed changes to § 422.101(f) would impose any new burden on MA organizations offering SNPs. However, we would need to revise language on timeframes and related narrative in the Model of Care Matrix that is currently approved by OMB under control number 0938–1296 (CMS–10565).

In section V.A. of this proposed rule, we also propose to add language to the D–SNP EAC requirements at § 422.107(f) to include updates to MOCs as described at § 422.101(f) among required EAC discussion topics. While MA organizations can already include MOCs among their D–SNP EAC topics, adding these topics to the D–SNP EAC conversations would ensure MA organizations solicit feedback directly from enrollees to improve the care coordination process including HRAs and ICPs as described in the MOC.

We do not anticipate new or additional burden from this proposal since MA organizations are already convening EACs per the existing requirements at § 422.107(f) and can solicit feedback on MOCs as part of their existing convenings. Thus, we would not need to revise any of the currently approved requirements and/or burden under OMB control number 0938–1422 (CMS–10799).

We welcome comments on our assumptions.

21. ICRs Regarding Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D–SNPs (§§ 422.2267(e)(30) and 423.2267(e)(32))

Our May 2022 final rule noted that the Member Identification Card burden is exempt from the requirements of the PRA since the issuance of Medicare Identification Cards is a normal and customary practice throughout the insurance industry, citing the fact that health plans, whether commercial, through Medicare or Medicaid, or Original Fee-for-Service issue cards that inform providers of the enrollee's insurance. The MA requirements were previously described in the May 2022 final rule, and we are simply combining these requirements with Medicaid requirements for one ID card. Sections 422.2267(e)(30) and 423.2267(e)(32) require D–SNPs to provide member ID cards to enrollees. Medicaid managed care plans also send member ID cards to enrollees. However, when a dually eligible individual is enrolled in both an MA plan and a Medicaid managed care plan, the plans may issue the enrollee separate member ID cards—one for their MA plan and one for their Medicaid managed care plan—to access services for each program. Our proposal would require that applicable integrated plans (AIPs), as defined in § 422.561, provide one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled. Given that issuance of member

ID cards is a normal and customary practice throughout the insurance industry and most States with AIPs currently require integrated member ID cards in their SMACs, we do not estimate any PRA-related burden for the proposed requirement. We welcome comments on our assumptions.

22. ICRs Regarding Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D–SNPs (§ 422.101(f)(1)(v))

The following proposed changes will be submitted to OMB for review under control number 0938–1446 (CMS–10825).

Medicare requirements at § 422.101(f)(1) require D–SNPs to conduct a comprehensive HRA for each enrollee, both at the time of enrollment and annually thereafter. Separately, Medicaid managed care regulations at § 438.208(b)(3) require Medicaid managed care plans to make a best effort to conduct an initial screening of enrollee needs within 90 days of their effective enrollment date, and State requirements may include additional assessments such as long-term services and supports (LTSS) and home and community-based services eligibility screenings. While some States have implemented their own requirements, through SMACs, to reduce burden and duplication, not all States have done so. In this rule, we propose to require D–SNPs that are AIPs to conduct a comprehensive HRA that meets all Medicare and Medicaid requirements, rather than two separate HRAs.

If this provision is finalized, AIPs in seven states (DC, FL, ID, NJ, PR, VA, and WI) that do not currently combine their HRAs would be required to adhere to this new provision. We believe that in plan year 2026, a business operation specialist associated with each contract that has an AIP in these seven states would spend an average of 2 hours to determine whether the HRA tool currently in use meets State requirements and make any necessary system updates in preparation for implementation in plan year 2027. With 26 unique contracts in the seven States that would be required to meet this provision, we estimate that half of the contracts or 13 contracts (26 contracts * ½) will only need to make minor administrative changes to comply with this provision. This would be a one-time burden of 26 hours (13 contracts * 2 hr) at a cost of $2,228 (26 hr * $85.70/hr (see table 26). We estimate that the other half of the contracts (13 contracts) would require more extensive updating and merging of two separate HRAs (at 40 hr/response) to comply with this provision. We estimate such MA organizations would need to merge two separate HRAs and implement systems updates to operationalize the integrated HRA. We estimate that these activities would take 40 hours per contract. This would be a one-time burden of 520 hours (13 contracts * 40 hr) at a cost of $44,564 (520 hr * $85.70/hr).

After initial implementation, this proposed requirement would reduce burden for AIPs in the seven states listed earlier with HRAs that are not already integrated, as plans would be conducting one integrated HRA instead of two. As discussed in the prior paragraph, we estimate that half of the contracts that would be affected by our proposal currently administer some form of a consolidated HRA. Conversely, we estimate that the other half of the contracts are currently conducting two HRAs. Based on this assumption, we are estimating that half of the contracts that would be required to adhere to this provision if it is finalized would see a reduction of burden by half. We expect some long-term burden reduction from the 13 contracts that currently administer two HRAs for their enrollees but would only administer one HRA under this proposal. We welcome comments on our assumptions.

C. Summary of Proposed Information Collection Requirements and Associated Burden

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TABLE 26: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
423.137(c)	Medicare Prescription Payment Plan: Calculations: System updates	0938-1475 (CMS-10882)	807	807	385	310,695	103.49	32,153,826	N/A
423.137(c)	Medicare Prescription Payment Plan: Calculations: Mailing bills	0938-1475 (CMS-10882)	25,600,000	N/A	N/A	N/A	N/A	20,531,200	20,531,200
423.137(c)	Medicare Prescription Payment Plan: Calculations: Payment system updates	0938-1475 (CMS-10882)	807	807	100	80,700	varies	7,166,160	N/A
423.137(c)	Medicare Prescription Payment Plan: Calculations: Maintenance	0938-1475 (CMS-10882)	807	807	100	80,700	varies	8,365,362	8,365,362
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: System updates	0938-1475 (CMS-10882)	807	807	130	104,910	103.54	10,862,381	N/A
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Standard notice for additional information	0938-1475 (CMS-10882)	807	807	12	9,684	varies	900,257	N/A
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Additional information mailings	0938-1475 (CMS-10882)	807	213,333	NA	NA	NA	171,093	171,093
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Auto renewal	0938-1475 (CMS-10882)	807	807	12	9,684	varies	900,257	N/A
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Auto renewal mailings	0938-1475 (CMS-10882)	807	2,133,333	NA	NA	NA	1,710,933	1,710,933
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Beneficiary: Additional information	0938-1475 (CMS-10882)	320,000	320,000	0.25	80,000	20.71	1,656,800	1,656,800
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Beneficiary: Opt out	0938-1475 (CMS-10882)	160,000	160,000	0.083	13,280	20.71	275,029	275,029

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
423.137(e)	Medicare Prescription Payment Plan: Part D Enrollee Targeted Outreach: System development	0938-1475 (CMS-10882)	807	807	60	48,420	varies	5,009,856	N/A
423.137(e)	Medicare Prescription Payment Plan: Part D Enrollee Targeted Outreach: System updates	0938-1475 (CMS-10882)	807	807	2	1,614	85.70	138,320	138,320
423.137(f)	Medicare Prescription Payment Plan: Termination of Election: Opt out	0938-1475 (CMS-10882)	807	807	30	24,210	varies	2,504,928	N/A
423.137(f)	Medicare Prescription Payment Plan: Termination of Election: Reinstatement	0938-1475 (CMS-10882)	807	807	4	3,228	varies	352,659	N/A
423.137(f)	Medicare Prescription Payment Plan: Termination of Election: Preclusion	0938-1475 (CMS-10882)	807	807	30	24,210	varies	2,504,928	N/A
423.137(i)	Medicare Prescription Payment Plan: POS Notification Process	0938-1475 (CMS-10882)	807	73,397	20	1,467,940	varies	164,923,059	N/A
423.137(j)	Medicare Prescription Payment Plan: Pharmacy Claims Processing	0938-1475 (CMS-10882)	807	807	1	807	85.70	69,160	N/A
N/A (section 1927(d)(2) of the Act)	AOMs: State Medicaid program coverage and reimbursement policies	0938-0659 (CMS-R-153)	39	39	40	1,560	85.70	133,692	N/A
N/A (section 1927(d)(2) of the Act)	AOMs: State Medicaid program State Plan Amendment	0938-0193 (CMS-179)	39	39	20	780	85.70	66,846	N/A
423.153(d)	MTM: Pharmacists	0938-1154 (CMS-10396)	866	50,488	0.6667	33,660	129.62	4,363,009	4,363,009
423.153(d)	MTM: Mailing CMR	0938-1154 (CMS-10396)	866	50,488	N/A	N/A	N/A	51,599	51,599
423.153(d)	MTM: Mailing Safe Disposal	0938-1154 (CMS-10396)	866	20,722	N/A	N/A	N/A	310	310
422.102(f)(4)(iii)(C)	SSBCI	0938-TBD (CMS-R-267).	761	761	2	1,522	125.48	190,981	190,981
422.137	Equitable Access – UM Committee	0938-0964 (CMS-10141)	767	767	8	6,136	125.48	769,945	769,945
422.120(c)	Provider directory - Plan finder	0938-TBD (CMS-10906)	761	761	8	6,088	103.60	630,717	N/A
422.2260 and 423.2260	Marketing Materials	0938-1051 (CMS-10260)	767	90,220	.5	45,110	85.70	3,865,927	3,865,927
422.2420(b)(2)	MLR: Quality Improvement Standards	0938-1232 (CMS-10476)	700	700	1	700	85.70	59,990	59,990
422.2460 and 422.2490	MLR: Provider Payment Arrangement Reporting	0938-1232 (CMS-10476)	700	700	3	2,100	85.70	179,970	179,970
422.2430(a) and 423.2430(a)	MLR: No Admin Costs in Quality Improvement	0938-1232 (CMS-10476)	764	764	1	764	85.70	65,475	65,475
422.2480 and 423.2480	MLR: Adherence to Standards for Audit Examinations	0938-1232 (CMS-10476)	764	764	1	764	85.70	65,475	65,475

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
422.2450, 423.2450, 422.2452, 423.2452, 422.2454, and 423.2454	MLR: Audit Examination Requirements	0938-1232 (CMS-10476	Less than or equal to 9	Less than or equal to 9	80	720	85.70	61,704	-
422.101(b)(6)	Internal Coverage Criteria	(0938-0753) (CMS-R-267)	767	767	18	13,806	85.70	1,183,174	1,183,174
422.138, 422.562, 422.566, 422.568, and 422.616	Enhance Enrollee Protections in Inpatient Settings: System Update	0938-0753 (CMS-R-267)	727	727	8	5,816	103.60	602,538	
422.138, 422.562, 422.566, 422.568, and 422.616	Enhance Enrollee Protections in Inpatient Settings: Mailings	0938-0753 (CMS-R-267)	727	60,000	N/A	N/A	N/A	39,420	39,420
422.101(f)(1)(v)	D-SNPs: Integrated HRAs (minimal work)	0938-1446 (CMS-10825)	13	13	2	26	85.70	2,228	N/A
422.101(f)(1)(v)	D-SNPs: Integrated HRAs (Work to integrate HRAs)	0938-1446 (CMS-10825)	13	13	40	520	85.70	44,564	N/A
TOTAL			26,102,257	3,187,725	Varies	2,379,390	Varies	272,508,297	43,618,537

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D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–4208–P), the ICR's CFR citation, and the OMB control number.

VII. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). It is necessary to codify our implementation of policies laid out in acts of Congress and to improve access, transparency, and equity for beneficiaries enrolled in MA and Part D plans. The rule includes a number of new policies from the Bipartisan Budget Act of 2018 (BBA) and the IRA, as well as policies instituted by those acts that have operated under program instruction to this point. Further explanation of the purpose, methods, and expected outcomes of those provisions believed to have an economic impact on beneficiaries, plans, providers, or other entities is provided in the Anticipated Effects section of this RIA.

Rulemaking is required for CMS to amend its longstanding interpretation of the reference in section 1927(d)(2) of the Act to ''[a]gents when used for . . . weight loss'' under which coverage for anti-obesity medications (AOMs) has been excluded from Part D, and is subject to state discretion under Medicaid, even for treating individuals with obesity.

We believe it would be more consistent with current medical views of obesity as a disease to propose to reinterpret the phrase ''[a]gents when used for . . . weight loss'' to exclude AOMs when used for weight loss or chronic weight management for the treatment of obesity.

B. Overall Impact Analysis

We have examined the impacts of this proposed 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), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1). Based on our estimates of the combined impact of the provisions in this proposed rule, OIRA has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of the rulemaking to the best of our ability. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, OMB has reviewed this proposed regulation, and the Department has provided the following assessment of its impact.

Section 202 of 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. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $183 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. There are currently fewer than 1,000 contracts (which includes MA, MA–PD, and PDP contracts) and 500 Medicaid MCOs, prepaid inpatient health plans (PIHP), and prepaid ambulatory health plans (PAHPs), as well as 55 State Medicaid Agencies. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $106.42 per hour, including fringe benefits, overhead, and other indirect costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 19 hours for each person to review this proposed rule. For each entity that reviews the rule, the

estimated cost is therefore $2,022 (19 hours × $106.42). Therefore, we estimate that the maximum total cost of reviewing this proposed rule is $4.04 million ($2,022 × 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $0.4 million.

Note that this analysis assumes one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts would reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this proposed rule.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We proposed a wide range of policies in the proposed rule. These policies would codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations such as HMOs, local and regional PPOs, MSAs, PFFS and Part D sponsors, PACE plans, and Stand-Alone Part D plans (PDP) (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 456110, have a $37.5 million threshold for ''small size'' with 88 percent of pharmacies, those with under 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a $47 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business. Several Medicare Advantage plans (about 30 to -40 percent) are not-for-profit resulting in a ''small entity'' status.
- Ambulatory Health Care Services, NAICS 621, including about 2 dozen subspecialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICS 621492, have a $47 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees typically exceed $34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals (NAICS 622110), Psychiatric and Substance Abuse Hospitals (NAICS 622210), and Specialty Hospitals (NAICS 622310) have a $47 million threshold for small size, with half of the hospitals (those with between 20–500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a $34 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this rule will not have a significant economic impact on a substantial number of small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be 3 to 5 percent or more of the affected entities' costs or revenues. To explain our position, we explain certain operational aspects of the Medicare program.

Each year, MA organizations, submit a bid for each plan for furnishing Part A and B (and sometimes D) benefits and the entire bid amount is paid by the government through the Medicare Trust Fund to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay a basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified in this section of this rule). Part D sponsors also submit a bid for each plan, and the payments made to stand-alone Part D plans (PDPs) are covered by the Supplementary Medical Insurance Medicare Trust Fund. PACE organizations are paid a capitation amount that is funded by both the Medicare Trust Funds (the Hospital Insurance and Supplementary Medical Insurance trust funds) as well as the State Medicaid programs they negotiate with.

MA plans can also offer enhanced benefits, that is, benefits not covered under Traditional Medicare. These enhanced benefits are paid for through enrollee premiums, rebates or a combination. Under the statutory payment formula, if the plan bid submitted by an MA organization for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Traditional Medicare) and/or to lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

Part D sponsors submit bids and plans are paid through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans, and PACE plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this proposed rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any proposed rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling

on bid payments annually calculated from Traditional Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. Since the HHS criterion for a ''substantial'' number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this proposed rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA. Besides the direct costs, discussed above, are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA–PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used to provide supplemental and/or lower beneficiary Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans. If the provisions of this proposed rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, and/or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of this proposed rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits. Notwithstanding the foregoing, we have requested comment on the assessment of this outcome in association with this proposed rule.

We next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for: (1) Pharmacies and Drug Stores, NAICS 446110; (2) Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) SNFs, NAICS 623110.

If these providers are contracted with the plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments.

The rules for non-contracted providers servicing plan enrollees depends on the plan type involved. Non-contracted providers in both MA and MA PD plans are not expected to incur burden from a final rule because the regulations (42 CFR 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act) require they be paid at least the FFS Rate. PACE must provide only contracted providers to its participants (42 CFR 460.70(a)). Similarly non-contracted pharmacies are a sporadic issue in stand-alone drug plans which are encouraged to limit out of network access to those situations when it is required (42 CFR 423.124). PACE plan participants must obtain services from the PACE organization or its contracted providers (42 CFR 460.70(a)). Consequently, non-contracted providers have no additional cost burden above the already existing burden in Traditional Medicare.

D. Anticipated Effects

Many provisions of this proposed rule have negligible impact either because they are technical provisions, clarifications, or provisions that codify existing guidance. Other provisions have an impact that cannot be quantified.[331] Throughout the preamble we have noted when we estimated that provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions' effects are estimated in section VI. of this proposed rule and in this RIA. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section VI. of this proposed rule in order to arrive at the total impact. The following table 27 provides a summary of the estimated transfers and costs associated with the various provisions in this proposed rule over a 10-year period. Further detail is provided in later in this RIA.

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[331] We request comment—especially data or other quantitative evidence—on costs, benefits and transfers attributable to the provisions of this proposed rule.

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TABLE 27: SUMMARY OF THE TRANSFERS AND COSTS OF THE PROPOSED RULE BY PROVISION AND YEAR (In $ Millions)

Category of Provisions	Year(s)										
TRANSFERS (AOM)	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**	**Year 10**	**Years 1-10**
AOMs: Federal Medicare Costs	$1,400	$1,500	$1,800	$2,100	$2,300	$2,500	$2,800	$3,200	$3,400	$3,800	$24,800
AOMs: Medicare Premium Offsets	-	-	-	-	-	$100	$100	$100	$200	$200	$700
AOMs: Federal Medicaid Costs	$400	$900	$1,000	$1,000	$1,100	$1,200	$1,200	$1,300	$1,400	$1,500	$11,000
AOMs: State Medicaid Costs	$100	$300	$300	$400	$400	$400	$400	$500	$500	$500	$3,800
TRANSFERS	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2026-2035
Cost Sharing for Insulin Products: Federal Spending	$110	$120	$120	$130	$140	$110	$110	$120	$120	$130	$1,210
Cost Sharing for Insulin Products: Premium Offsets	-	-	-	-	-	$30	$30	$30	$40	$40	$170
MLR: No admin costs in Quality Improvement	-$101	-$101	-$101	-$101	-$101	-$101	-$101	-$101	-$101	-$101	-$1,010
MLR: Audit Requirements	-$32	-$32	-$32	-$32	-$32	-$32	-$32	-$32	-$32	-$32	-$320
COSTS*	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2026-2035
Medicare Prescription Payment Plan Provisions (ICR)	$260	$33	$33	$33	$33	$33	$33	$33	$33	$33	$556
MTM Provisions	$4	$4	$4	$4	$4	$4	$4	$4	$4	$4	$44
Marketing Materials (ICR)	$3	$4	$4	$5	$5	$6	$6	$7	$8	$8	$56
Internal Coverage Criteria	$1	$1	$1	$1	$1	$1	$1	$1	$1	$1	$12
TOTAL COSTS**	$274	$45	$46	$46	$47	$47	$48	$49	$49	$50	$703

*Figures in the Costs section of table G1have been rounded to the nearest million. For that reason, numbers in the 2026-2035 column may not equal the sum of columns 2026 through 2035.

**The Total Costs row includes the annually recurring estimated impacts for the following provisions: Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) ($190,981), Improving Equitable Access—Enhancing the Health Equity Analysis ($769,945), the Information Collection Requirements for several MLR provisions ($370,910), and Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings ($641,958 for the first year and $39,420 per year thereafter); as well as first-year impacts for provisions on Formatting Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder ($630,717), Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D-SNPs ($46,792), and the information collection requirements for AOMs ($200,538). Lastly, there is an additional annually recurring estimated Federal cost for provisions to Enhance Review of Marketing and Communications Materials ($261,531 in 2026 and increasing by 10.15% per year thereafter) and to Establish Standards for MA and Part D MLR Audit Examinations ($1,500,000).

1. Effects of Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D (§§ 423.100 and 423.120)

This proposal would implement section 11401 of the IRA which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost-sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.

The cost-sharing limits for ACIP-recommended adult vaccines outlined in this proposed rule have been in place since CMS implemented the limits in 2023 through program instruction authority. We have annually reviewed cost-sharing in plan benefit package submissions and believe our proposed codification of these requirements should have minimal impact on Part D sponsors and beneficiaries. All Part D enrollees have had zero cost sharing for ACIP-recommended adult vaccines since 2023.

Shortly after the IRA was enacted, CBO scored the $0 cost-sharing requirement for ACIP-recommended adult vaccines as a Federal cost of $4.4 billion from FY 2022 to FY 2031 and, therefore, the estimates are not a result of this rule.[332]

2. Effects of Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D (§§ 423.100 and 423.120)

This proposal would implement section 11406 of the IRA, which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a 1-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. The applicable copayment amount for 2023, 2024, and 2025 was $35. For 2026 and each subsequent year, in accordance with the statute, we are proposing that, with respect to a covered insulin product covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold, the ''covered insulin product applicable cost-sharing amount'' is the lesser of—

- $35;
- An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of subchapter XI; or
- An amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the PDP or MA–PD plan.

The requirement to provide enrollees with an applicable copayment amount equal to the lesser of $35, 25 percent of the MFP, or 25 percent of the negotiated price, has not yet been implemented. As described in Part E of subchapter XI of the Act, the Secretary must establish a Drug Price Negotiation Program and negotiate MFPs for selected drugs that will go into effect beginning in initial price applicability year (IPAY) 2026. The selected drug list for IPAY 2026 includes insulin products that will be subject to the cost-sharing requirements outlined in this proposal.[333] The selected drug list under the Drug Price Negotiation Program in future years may also include additional insulin products. As defined in § 423.100, the negotiated price is the price for a covered Part D drug that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug. A negotiated price must meet all of the following: (1) includes all price concessions from network pharmacies or other network providers; (2) includes any dispensing fees; and (3) excludes additional contingent amounts, such as incentive fees, if these amounts increase prices. Finally, a negotiated price is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

Beginning in 2026, the applicable copayment amount for a 1-month supply of a covered insulin product will depend on which of the following is the lowest amount: $35, an amount equal to 25 percent of the insulin product's MFP (if the insulin product is a selected drug), or an amount equal to 25 percent of the negotiated price of the insulin product. If 25 percent of the MFP or 25 percent of the negotiated price is not less than $35, the impact on Part D sponsors will be minimal as this $35 applicable copayment amount has been in place since 2023. However, if either 25 percent of the MFP or 25 percent of the negotiated price is less than $35, the impact on Part D sponsors will depend on (1) the magnitude of difference between 25 percent of the MFP or 25 percent of the negotiated price and $35 and (2) the number of beneficiaries affected. In other words, the greater the difference in 25 percent of the MFP or 25 percent of the negotiated price and $35, the greater the impact on Part D sponsors.

We estimated the impact of the change in Part D insulin coverage for years 2026 through 2035 using a claim-level simulation model under the defined standard benefit before and after the application of the change. As the beneficiary cost-sharing is reduced, the net effect is an increase in benefit costs. Additionally, because of the premium stabilization provisions of the IRA, beneficiary premiums are not impacted until 2031. In 2031 and subsequent years, we expect beneficiaries will see small increase in premiums to account for the richer benefit structure. Overall, we expect Federal costs to increase by approximately $1.2 billion from 2026 to 2035.

[332] *https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf*

[333] *https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.*

TABLE 28. FINANCIAL IMPACT OF APPROPRIATE COST-SHARING FOR COVERED INSULIN PRODUCTS UNDER MEDICARE PART D

CY incurred: millions	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Net Medicare	$110	$120	$120	$130	$140	$110	$110	$120	$120	$130
Premium Offset	$0	$0	$0	$0	$0	$30	$30	$30	$40	$40
Gross Impact	$110	$120	$120	$130	$140	$140	$140	$150	$160	$170

3. Effects of Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program

We are proposing to reinterpret the reference to ''[a]gents when used for . . . weight loss'' in section 1927(d)(2)(A) of the Act to not include drugs used for weight loss or chronic weight management for the treatment of obesity to reflect changes in the prevailing medical consensus towards recognizing obesity as a disease. As a result of this proposed reinterpretation, AOMs used for weight loss or chronic weight management for the treatment of obesity would not be excluded from the definition of Part D drug at § 423.100, and state Medicaid programs would likewise not be permitted to exclude AOMs used for weight loss or chronic weight management for the treatment of obesity from Medicaid coverage pursuant to section 1927(d)(2)(A) of the Act.

As we stated in section III.A.1. of this proposed rule, while we refer to AOMs generally throughout our proposal and have included discussion on specific classes of AOMs, this proposal is not limited to particular drugs or drug classes. Older AOMs are significantly less costly than newer AOMs in the glucagon-like peptide-1 (GLP–1) and glucose-dependent insulinotropic polypeptide (GIP)/GLP–1 receptor agonist classes. AOMs in the GLP–1 and GIP/GLP–1 receptor agonist classes have emerged as preferred therapies over older AOMs and are therefore likely to be the driver of overall costs related to this proposal.

The impact of our proposed reinterpretation must be considered in the context of newly approved indications for AOMs that are medically accepted indications (MAIs) that are coverable under current policy, which will increase their coverage under Part D regardless of our proposal. Additionally, there is a robust pipeline for these drugs, which may impact pricing and utilization in the future.

It is also possible that the changes in Part D and Medicaid coverage of AOMs as a result of our proposal could prompt changes in private health plan coverage outside of Medicare and Medicaid. This could impact premiums for those plans, including Affordable Care Act marketplace plans, but these impacts are not quantifiable without data on changes for the private health insurance market in response to this proposal. We request comment on the potential impact of our proposal on the private employer insurance market and the ACA marketplace.

Furthermore, for the purposes of this impact analysis, when we refer to AOMs and their respective FDA-approved indications, we are generally referring to a drug's active ingredient(s) and not particular formulations or brands. Therefore, for the purposes of our estimates, if a beneficiary with obesity has type 2 diabetes, we assume that under current policy the beneficiary could obtain coverage for an AOM that is FDA-approved for glycemic control in type 2 diabetes, but not an AOM that is FDA-approved only for weight loss or chronic weight management. If the two drugs have the same active ingredient, then the beneficiary with obesity and type 2 diabetes is able to obtain coverage for the AOM because under current policy they can obtain coverage for the drug that is approved for glycemic control in type 2 diabetes.

a. Medicare Impacts

Currently, Part D enrollees can obtain coverage for AOMs only when prescribed for an FDA-approved indication or for a use that is supported by CMS-approved compendia for a condition other than weight loss. For example, some AOMs are FDA-approved for use in type 2 diabetes and cardiovascular risk reduction in individuals with established cardiovascular disease and either obesity or overweight. Existing AOMs may potentially receive FDA approval for new indications in the future. At least one manufacturer has conducted a study on sleep apnea that was published and met its primary endpoint of reducing the severity of sleep apnea for the treatment of obesity and is seeking regulatory approval.[334] Therefore, for the purposes of these estimates, we consider AOMs to be already coverable under current Part D policy for individuals with obesity and type 2 diabetes, established cardiovascular disease, or sleep apnea. Our proposal would extend AOM coverage to Medicare beneficiaries with obesity who do not have a condition that is coverable by Part D under the current policy.

We used Medicare claims data from 2022 to identify Part D enrollees with obesity. This was narrowed from those with obesity to those with obesity but without other conditions (specifically, type 2 diabetes, cardiovascular disease, or sleep apnea) for which we considered AOMs to be coverable under current Part D policy for the purposes of these estimates. We estimate that approximately 7 percent of the Part D population would become newly able to obtain coverage for these drugs if this proposal is finalized. We assumed a 1 percent annual growth rate. As shown in table 29, the majority of Medicare beneficiaries with obesity have a comorbid condition that we consider coverable under current Part D policy for the purposes of our estimates.

[334] Lilly. Lilly's tirzepatide reduced obstructive sleep apnea (OSA) severity, with up to 51.5% of participants meeting the criteria for disease resolution. June 21, 2024. Available from: *https://investor.lilly.com/news-releases/news-release-details/lillys-tirzepatide-reduced-obstructive-sleep-apnea-osa-severity.*

TABLE 29. MEDICARE PART D ENROLLEES WITH OBESITY AND COMORBID CONDITIONS THAT ARE MAIs, 2022 DATA

Obesity and Comorbid Conditions	Number of Beneficiaries	Percent of Beneficiaries with Obesity	Percent of Part D Population (n= 51,089,090)
Medicare Part D Enrollees with Obesity	12,809,627	100%	25%
Medicare Part D Enrollees with Obesity and Type 2 Diabetes, Cardiovascular Disease, or Sleep Apnea	9,442,100	73%	18%
Medicare Beneficiaries with Obesity *without* Type 2 Diabetes, Cardiovascular Disease, or Sleep Apnea	3,367,527	26%	7%

Next, we estimated the proportion of this population expected to utilize AOMs annually. This included the effect of treatment discontinuation to refine the estimated duration of treatment per year. Taking into account published discontinuation rates of AOMs in the GLP–1 agonist class,[335] our estimates assume that 52.5 percent of those who start treatment with an AOM will discontinue treatment after 2 months. This was combined with an assumption that 10 percent of the population newly able to obtain AOM coverage would initiate treatment with an AOM, growing by 0.3 percent each year, to determine the total amount of Part D utilization per year. We assumed a 10 percent rate of initiation of therapy in the population newly able to obtain AOM coverage since this was an approximate mean of the range used in a published modeling study.[336]

The cost per utilization was based on 2024 prescription drug event (PDE) data for the drugs in question. These costs were trended forward to each projection year and adjusted for estimated manufacturer rebates. To account for changes in the AOM drug development pipeline, the estimates assumed that there would be a gradual shift from older to newer products.

The resulting estimated utilization cost was used to modify the model for projecting Part D benefit costs to determine net Federal costs per year. As shown in table 30., we estimate an increase of $24.8 billion in trust fund expenditures over a 10-year period. As discussed in section III.A.4. of this proposed rule we are soliciting comment on an appropriate applicability date of the new interpretation should our proposal be finalized. Therefore, for the purposes of this analysis, we report annual costs with a placeholder for each year starting with the first year the reinterpretation is applicable in Medicare Part D. This analysis would be updated in any final rule for this policy to reflect the determined effective date of a final rule and the applicability date for Part D plans. There is no expected premium impact until 2031 due to the premium stabilization provisions in section 11201 of the IRA, so the premium offsets shown in table 30. reflect the earliest such offsets would be factored into the analysis (assuming 2026 notionally as year 1 of implementation). The estimates do not include medical cost savings for this proposal, as the magnitude and timing of any potential savings is highly uncertain. While we expect that there could be offsetting medical savings due to treatment of obesity, those savings will be much slower to emerge, such that in the near-term, the costs will have a larger impact on the overall picture of the estimated financial impact of this proposal. These estimates also assume that beneficiaries for whom these drugs are prescribed for a coverable indication under current Part D policy will continue to have access regardless of whether this provision is finalized as proposed; therefore, the costs associated with such use are not included in our estimates for this proposal. Our financial estimates include the population dually eligible for Medicare and Medicaid. As discussed in section III.A.3. of this proposed rule, should the proposal be finalized, AOM costs for these individuals would be borne by Medicare when the reinterpretation of section 1927(d)(2) to no longer exclude AOMs from the definition of Part D drug when used for weight loss or chronic weight management for the treatment of obesity becomes applicable under Part D. For dually eligible individuals, Medicaid provides drug coverage for covered outpatient drugs that are Part D excluded drugs. As such, state Medicaid programs would bear the costs of AOMs for dually eligible individuals if the applicable date of coverage under the Medicaid program is earlier than the applicable date of coverage under the Medicare program.

TABLE 30. FINANCIAL IMPACT OF MEDICARE COVERAGE OF AOMs FOR TREATMENT OF OBESITY (Ten-Year Assessment In $ Millions)

Costs (Millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total Years 1-10
Federal Benefit Cost	$1,400	$1,500	$1,800	$2,100	$2,300	$2,600	$2,900	$3,300	$3,600	$4,000	$25,500
Premium Offset	$0.0	$0.0	$0.0	$0.0	$0.0	$100	$100	$100	$200	$200	$700
Total Federal Cost	$1,400	$1,500	$1,800	$2,100	$2,300	$2,500	$2,800	$3,200	$3,400	$3,800	$24,800

It is possible that our estimates significantly underestimate the impact of our proposal. These estimates are sensitive to the utilization rate, which has a high degree of uncertainty. We factored in an estimated discontinuation

[335] Rodriguez PJ, Goodwin Cartwright BM, Gratzl S, et al. Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity. *JAMA Intern Med.* 2024;184(9):1056–1064. doi:10.1001/jamainternmed.2024.2525.

[336] Ippolito B, Levy JF. Expanding Medicare Coverage Of Anti-Obesity Medicines Could Increase Annual Spending By $3.1 Billion To $6.1 Billion. Health Aff (Millwood). 2024 Sep;43(9):1254–1262. doi: 10.1377/hlthaff.2024.00356.

rate based on published literature, but discontinuation rates and duration of therapy before treatment is discontinued vary in the literature.[337] Our assumption may not fully reflect patients who discontinue but subsequently resume treatment with AOMs. Discontinuation rates vary across studies and are influenced by a variety of factors including cost, adverse effects, or successful weight loss.[338] [339] Some factors contributing to discontinuation may be mitigated, for example, if AOMs approved in the future have more favorable tolerability profiles. Our estimates rely on available claims data and therefore a limitation in our estimates is whether a diagnosis of obesity was reliably reported. Available National Health and Nutrition Examination Survey (NHANES) data from 2017 to March 2020 indicates that the prevalence of obesity in the U.S. population age 60 and older was 41.5 percent,[340] which is much higher than the 25 percent prevalence observed in Medicare claims data. Additionally, the definition of cardiovascular disease that we applied to perform the analysis was based on CMS's pre-determined chronic condition algorithms for Ischemic Heart Disease, Stroke/Transient Ischemic Attack, and Peripheral Vascular Disease (PVD).[341] This definition is broader than the definition of cardiovascular disease in a recent clinical trial investigating major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight, in which established cardiovascular disease was defined as prior myocardial infarction, prior stroke, or peripheral arterial disease.[342] Therefore, our calculation may overestimate the proportion of beneficiaries with cardiovascular disease for whom AOMs are already coverable under current policy and, correspondingly, underestimates the number of beneficiaries who will be newly able to obtain AOM coverage under the proposed policy. Finally, for the purposes of our financial estimates, we included sleep apnea as a coverable indication under current policy since this new indication for an approved AOM has been submitted to FDA for approval. This assumption increases the number of Part D enrollees who we considered to already have a coverable indication under current policy. Part D enrollees with obesity and sleep apnea only (that is, enrollees with sleep apnea who do not have type 2 diabetes or cardiovascular disease as a coverable indication) would be considered part of the population newly able to obtain AOM coverage until sleep apnea meets the definition of an MAI coverable under current Part D policy.

We analyzed the population of Part D enrollees with obesity to determine if there were disparities between the population with comorbid conditions that are coverable MAIs under the current Part D policy and the population without such comorbid conditions for whom AOMs would become coverable under Part D if our proposal is finalized. We examined beneficiary characteristics to determine if our proposal would disproportionately affect underserved racial and ethnic minority groups, rural communities, individuals with lower incomes, or other disadvantaged groups. The population of Medicare beneficiaries with obesity but without type 2 diabetes, cardiovascular disease, or sleep apnea was more likely to be female (68 percent vs. 57 percent, respectively) or have a disability (22 percent vs. 18 percent, respectively) than the population of Medicare beneficiaries with obesity who had one or more of those conditions.

b. Medicaid Impacts

Currently, state Medicaid programs have discretion to cover the drugs or classes of drugs listed in section 1927(d)(2) of the Act, including ''agents used for . . . weight loss . . .'' As discussed in section III.A.3. of this proposed rule, should our proposal be finalized as proposed, state Medicaid programs providing coverage of drugs [343] would be required to provide coverage of AOMs under Medicaid when used for weight loss or chronic weight management for treatment of obesity. That is, state Medicaid programs would no longer be permitted to consider AOMs to be excludable agents under section 1927(d)(2)(A) of the Act when they are used for weight loss or chronic weight management for treatment of obesity. States do have the discretion to utilize preferred drug lists and implement prior authorization processes to establish certain limitations on the coverage of these drugs as long as such practices are consistent with the requirements of section 1927(d) of the Act to ensure appropriate utilization. We estimate financial impact to the Federal Government and state Medicaid programs if this proposal is finalized.

For Medicaid, estimates were developed first by determining the current amount of spending and claims on AOMs, including GLP–1 and GIP/GLP–1 agonists used for the treatment of other indications (for example, type 2 diabetes or cardiovascular disease). Gross spending on these drugs in Medicaid was $7.5 billion in 2023 based on analysis of Transformed Medicaid Statistical Information System (T–MSIS) data. According to Medicaid Drug Rebate Program data, net spending was significantly less, $2.5 billion in 2023, due to the significant rebates Medicaid collects on these drugs.[344]

There is limited data on the number of Medicaid enrollees with obesity. One study found that 44 percent of adult Medicaid enrollees in Rhode Island, for example, had obesity in 2017 to 2018.[345] According to data from the NHANES, 42.4 percent of all adults in the United States had obesity in 2017 to 2018.[346] For the purposes of our financial

[337] Gleason PP, Urick BY, Marshall LZ, Friedlander N, Qiu Y, Leslie RS. Real-world persistence and adherence to glucagon-like peptide-1 receptor agonists among obese commercially insured adults without diabetes. J Manag Care Spec Pharm. 2024 Aug;30(8):860–867. doi: 10.18553/jmcp.2024.23332.

[338] Cohen, JP. Study Shows 85% Of Patients Discontinue GLP-1s For Weight loss After 2 Years. Forbes. July 11, 2024. Available from: *https://www.forbes.com/sites/joshuacohen/2024/07/11/study-shows-85-of-patients-discontinue-glp-1s-for-weight-loss-after-2-years/*.

[339] Do D, Lee T, Peasah SK, Good CB, Inneh A, Patel U. GLP-1 Receptor Agonist Discontinuation Among Patients With Obesity and/or Type 2 Diabetes. JAMA Netw Open. 2024 May 1;7(5):e2413172. doi: 10.1001/jamanetworkopen.2024.13172.

[340] Stierman, B., et al. National Health and Nutrition Examination Survey 2017—March 2020 Prepandemic Data Files—Development of Files and Prevalence Estimates for Selected Health Outcomes. 2021. Available from *https://stacks.cdc.gov/view/cdc/106273*.

[341] *https://www2.ccwdata.org/web/guest/condition-categories-chronic* and *https://www2.ccwdata.org/web/guest/condition-categories-other*.

[342] Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med. 2023 Dec 14;389(24):2221–2232. doi: 10.1056/NEJMoa2307563.

[343] Under the Medicaid program, section 1902(a)(54) of the Act provides states with the option of providing coverage of prescribed drugs as described in section 1902(a)(12) of the Act. All states have elected to do so.

[344] Section 1927 of the Act governs the Medicaid Drug Rebate Program and payment for covered outpatient drugs. In general, for payment to be made available for covered outpatient drugs, manufacturers must enter into a national drug rebate agreement as set forth in Section 1927(a) of the Act. Pursuant to that agreement, manufacturers must pay rebates to states which are determined according to a formula set forth in section 1927(c) of the Act. In addition, states may have authority to enter into supplemental rebate agreements with the manufacturers through which states may obtain additional rebates.

[345] Mylona EK, Benitez G, Shehadeh F, Fleury E, Mylonakis SC, Kalligeros M, Mylonakis E. The association of obesity with health insurance coverage and demographic characteristics: a statewide cross-sectional study. Medicine (Baltimore). 2020 Jul 2;99(27):e21016. doi: 10.1097/MD.0000000000021016.

[346] *https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity*.

estimates, we assumed that 45 percent of adult Medicaid enrollees have obesity. We also assumed the Medicaid population with obesity had the same proportion of other conditions which, for the purposes of our estimates, we considered AOMs to be already coverable (type 2 diabetes, cardiovascular disease, or sleep apnea), as the Medicare population. Therefore, should our proposal be finalized, approximately 12 percent of the adult Medicaid population would be newly able to obtain coverage for AOMs. Twelve percent was derived by taking 26 percent (Medicaid enrollees with obesity and at least one coverable condition) of 45 percent (proportion of Medicaid enrollees with obesity).

To estimate the financial impact of our proposal, we developed assumptions on how much expanding coverage of these drugs would increase usage and spending. Fifteen states already cover AOMs for weight loss (in addition to other indications). We compared the number of AOM claims per enrollee in states covering AOMs for weight loss to the number in states that do not and found that the number of AOM claims per enrollee was 18 percent higher in states that cover AOMs for weight loss. Since some AOMs are FDA-approved for use in pediatric populations, these claims include current pediatric use. We also assumed that expanding AOM coverage to the 12 percent of Medicaid enrollees with obesity and no other conditions would also expand coverage to the 33 percent of Medicaid enrollees with obesity and at least one other condition (45 percent of Medicaid enrollees with obesity minus 12 percent of Medicaid enrollees with obesity and no coverable conditions) due to general increased awareness of AOM coverage in the Medicaid program. That is, we anticipated that there could be an increase in prescribing of these drugs for weight loss in Medicaid enrollees with obesity and other coverable conditions when a prescriber may not have otherwise prescribed the drugs for these individuals, despite coverage already being available. We assumed that use of these drugs would increase 30 percent because of the proposal—this could also include expanded access among Medicaid enrollees in states already covering these drugs for weight loss.

Medicaid costs are typically split between the Federal Government and the states. The Federal Medical Assistance Percentage (FMAP) can vary by state, by enrollment group, and by service. We arrived at an estimated the Federal share of 72 percent based on the average Federal share for prescription drugs and rebates. This Federal share is higher than the regular average FMAP in large part because this includes adults enrolled in Medicaid due to the Medicaid expansion under the Affordable Care Act, for whom the Federal share is 90 percent. As shown in table 31, we estimate that spending net of rebates on these drugs would increase by $14.8 billion over 10 years, with the Federal Government paying $11.0 billion and states paying $3.8 billion. As discussed in section III.A.4. of this proposed rule we are soliciting comment on an appropriate applicability date of the new interpretation should our proposal be finalized. Therefore, for the purposes of this analysis, we report annual costs with a placeholder for each year starting with the first year the new interpretation is applicable in Medicaid. This analysis would be updated in any final rule for this policy to reflect the determined effective date of a final rule and the applicability date for state Medicaid programs.

TABLE 31. FINANCIAL IMPACT OF MEDICAID COVERAGE OF AOMs FOR TREATMENT OF OBESITY (Ten-Year Assessment In $ Millions)

Costs (Millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total Years 1-10
Federal Cost	$400	$900	$1,000	$1,000	$1,100	$1,200	$1,200	$1,300	$1,400	$1,500	$11,000
State Cost	$100	$300	$300	$400	$400	$400	$400	$500	$500	$500	$3,800
Total Cost	$500	$1,200	$1,300	$1,400	$1,500	$1,600	$1,600	$1,800	$1,900	$2,000	$14,800

Costs may be significantly higher or lower than projected. Our estimates relied on assumptions about rates of obesity and other conditions in the Medicaid population since T–MSIS does not contain complete diagnosis-level data. It is possible that a larger proportion of the Medicaid population has obesity without other conditions since the Medicaid population is younger than the Medicare population and therefore may not yet have developed other conditions that are coverable under the current policy. The AOM utilization in states already covering AOMs for weight loss may include some utilization by Medicaid enrollees with overweight with weight-related comorbidities, if states permit such coverage. We were unable to determine if a claim was used for weight loss for treatment of obesity or in individuals with overweight with weight-related comorbidities. Using AOM utilization data from states that have not expanded AOM coverage approximates the baseline level of AOM coverage for conditions other than obesity. There is some additional uncertainty in the baseline costs under current policy given the limited data on the current state-by-state coverage rules and utilization of AOMs for other conditions. Spending on AOMs is already increasing significantly due to use for treatment of other conditions, and it is difficult to predict how many people may use these drugs in the future. States may take steps to limit use of these drugs even if they are covered by imposing utilization management restrictions or seek to lower the net price of these drugs by negotiating supplemental rebates by using preferred drug lists. We have not considered the impact of the use of AOMs on other medical costs.

4. Part D Medication Therapy Management (MTM) Program Targeting Requirements (§ 423.153)

We propose modifying the regulatory text at § 423.153(d)(2)(iii)(A) identifying ''Alzheimer's disease'' as a core chronic disease to ''Alzheimer's disease and dementia,'' which would expand the targeting criteria to include Alzheimer's disease and all other causes of dementias. We anticipate that this change would allow beneficiaries with other causes of dementia who could potentially benefit from MTM services to be targeted for MTM enrollment.

We estimate that this proposal would increase the number and percentage of Part D enrollees eligible for MTM services from 7.9 million (14.5 percent) to 8 million (14.6 percent). Although the increase in MTM program enrollment is

estimated to cost $4,414,918 for the provision of required MTM services to beneficiaries with dementia who become eligible for MTM enrollment under this proposal, there is uncertainty in the estimates of effects of this proposal because there may be other administrative costs attributable to MTM, and MTM program costs are not a specific line item that can be easily extracted from the bid. Additionally, published studies have found that MTM services may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions. CMS is unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables. The burden associated with these proposed changes is addressed in section VI. of this proposed rule (in the ICR section for MTM targeting criteria.

5. Effects of Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost-Sharing Limits (§§ 417.454 and 422.100)

Traditional Medicare benefits under Parts A and B include a wide range of mental health and substance use disorder services (collectively called ''behavioral health services'').[347] Per section 1876(c)(2)(A) of the Act and §§ 422.100 and 422.101, respectively, section 1876 Cost Plans (Cost Plans) and Medicare Advantage (MA) plans must cover the same set of services, subject to limited exclusions.[348] As discussed in section III.M. of this proposed rule, CMS believes the affordability of behavioral health services is especially crucial for MA enrollees as they (1) represent a significant proportion of Medicare-eligible beneficiaries and (2) pay between $7 and $47 more on average in in-network cost sharing per visit for one or more professional behavioral health service categories in comparison to beneficiaries in Traditional Medicare (as shown in table 32). In addition, while enrollment in Cost Plans represents a small proportion of all Medicare-eligible beneficiaries (approximately 169,000 as of July 2024) [349] we believe extending this proposal to Cost Plan enrollees is appropriate because: (1) CMS wants to improve equitable access to behavioral health services across all Medicare program choices and (2) enrollees in these plans pay between $5 and $13 more on average in in-network cost sharing per visit for one or more professional behavioral health service categories in comparison to beneficiaries in Traditional Medicare (as shown in table 32).[350] To this end, CMS is proposing behavioral health cost-sharing standards in MA and Cost Plans that strike a balance between: (1) improving the affordability of behavioral health services for enrollees in a timely manner and (2) minimizing disruption to enrollees' access to care and coverage options.

As part of CMS's behavioral health strategy and to improve the affordability of behavioral health services, we propose to require—beginning in contract year 2026—that in-network cost sharing for behavioral health service categories be no greater than that in Traditional Medicare for Cost Plans and MA plans (including employer group waiver plans (EGWPs)). The behavioral health service categories subject to this proposal include mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient program services, inpatient hospital psychiatric services (all length of stay scenarios), outpatient substance use disorder services, and opioid treatment program services. We also propose some clarifying amendments at §§ 417.454 and 422.100, including the applicability of the 50% coinsurance (or actuarially equivalent copayment) standard for Cost Plans. These proposed amendments primarily continue current policy with minor updates (such as, to annually update copayment limits CMS sets for Cost Plans based on the most recent Medicare FFS data projections).

If this proposal is finalized, CMS would not experience additional burden as we could, as needs arise, adjust the plan benefit package as part of normal business operations. In addition, CMS expects this proposal would prompt some—

- Organizations to adjust their plan benefit designs,[351] primarily to come into compliance with this proposal, if: (1) any of their contract year 2025 plan benefits are not compliant with the proposed behavioral health cost-sharing standard for contract year 2026 and (2) they submit a bid to continue that plan offering for contract year 2026; and
- Enrollees who remain in those continuing plans to experience changes in cost that will change over time based on their health status and service utilization (such as, behavioral health services or other service categories).

These potential impacts to organizations and enrollees are discussed in greater detail in the following section. In brief, CMS expects that this proposal to make in-network cost sharing for behavioral health services no greater than that in Traditional Medicare will increase utilization of these services and thus reduce: (1) enrollee disparities in health outcomes and health care costs formerly arising because of affordability issues related to behavioral health care; and (2) program costs due to better behavioral health disease management, health outcomes, and fewer high-cost services (such as, emergency room visits for life-threatening behavioral health condition complications).

a. Potential Impacts From Behavioral Health Cost-Sharing Limits No Greater Than Traditional Medicare to Organizations and Enrollees

From an aggregate perspective, CMS assumes that this proposal will not result in: (1) additional out of pocket costs for MA enrollees compared to beneficiaries in Traditional Medicare; or (2) significant losses for MA organizations. This is because there is a statutory requirement for MA organizations to submit bids that are at least actuarially equivalent to coverage in Traditional Medicare. This statutory requirement is operationalized through an actuarial equivalence test based on a projection of MA cost sharing under each plan. At the time that the actuarially equivalent cost sharing amounts are calculated, the expectation is that there will be no costs or savings for the policy year in question. As a result, the plan will cover—and MA enrollees would receive—the same level of total benefits on average in each contract year prior to and after implementation. However, CMS also expects lower behavioral health cost-sharing limits will pose varying

[347] McGinty, Beth. ''Medicare's Mental Health Coverage: What's Included, What's Changed, and What Gaps Remain,'' Commonwealth Fund, Mar. 2, 2023. Retrieved from: *https://www.commonwealthfund.org/publications/explainer/2023/mar/medicare-mental-health-coverage-included-changed-gaps-remain.*

[348] For example, MA plans are not required to provide hospice services—a service covered in Traditional Medicare.

[349] CMS. Contract Summary 2024. Data as of July 2024. Retrieved from: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.*

[350] We note that enrollees in Cost Plans can access basic benefits out-of-network at cost sharing in Traditional Medicare.

[351] Cost Plans may not have to adjust their benefit designs for all behavioral health service categories as these plans are not required to report information for all services in the plan benefit package, including for inpatient hospital psychiatric services.

individual impacts to MA organizations and enrollees that change over time.

Cost Plans are not required to submit a bid that is at least actuarially equivalent to coverage in traditional Medicare. As a result, if this proposal is finalized enrollees in these plans could receive a different level of total benefits on average after its implementation. However, CMS expects this proposal will not result in significant additional out of pocket costs for Cost Plan enrollees because our analysis of cost sharing for the applicable professional behavioral health service categories demonstrates that: (1) most of these plans already established cost sharing for these services that is equal to or less than cost sharing in Traditional Medicare (as shown in table 32; and (2) plans with cost sharing greater than cost sharing in Traditional Medicare should not have to vastly change their cost sharing designs to come into compliance (as shown in table 33). For example, as shown in table 33, only 5 percent of Cost Plans have cost sharing greater than Traditional Medicare for the ''outpatient substance abuse services'' service category. Of those plans, as shown in table 34, the average in-network cost sharing is $40, or $10 more than cost sharing in Traditional Medicare. Finally, we also note that Cost Plan enrollees may continue to receive basic benefits at cost sharing in Traditional Medicare by going out-of-network. As such, beneficiary choice will continue to act as an incentive for Cost Plan organizations to offer favorable benefit designs. As a result, we believe Cost Plans should not be incentivized to either drastically increase overall costs for their enrollees or leave the market as a direct result of this proposal.

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TABLE 32: PERCENT OF CONTRACT YEAR 2024 COST PLANS AND ENROLLEES WITH COST SHARING GREATER THAN THE PROPOSED COST-SHARING STANDARD BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Percent of Plans	Percent of Enrollees
Mental Health Specialty Services	8.3%	3.1%
Psychiatric services	13.3%	13.2%
Partial hospitalization	0%	0%
Outpatient substance use disorder services	5.0%	0.7%
Opioid treatment program services	50.0%	60.6%

TABLE 33: ILLUSTRATIVE COMPARISON OF PROPOSED COST-SHARING STANDARDS FOR MA PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH COST SHARING ABOVE PROPOSED COST-SHARING STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Proposed Standards and Illustrative Cost-Sharing Limits (All MOOP Types)[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing (Plans with Cost Sharing Above Values in Column B)	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$3,284.00	N/A[2]	N/A
Inpatient Hospital Psychiatric – 15 Days	$2,204.00	$2,322.62[3]	($118.62) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$2,036.00	$2,143.22[3]	($107.22) for 8 days
Mental Health Specialty Services	20.0% / $35.00	24.6% / $41.92[4]	($6.92) or (4.6%) per visit
Psychiatric Services	20.0% / $35.00	25.4% / $41.91[4]	($6.91) or (5.4%) per visit
Partial Hospitalization	20.0% / $60.00	26.5% / $80.86[4]	($20.86) or (6.5%) per visit
Outpatient Substance Use Disorder Services	20.0% / $30.00	41.1% / $60.38[4]	($30.38) or (21.1%) per day
Opioid Treatment Program Services	0.0% / $0.00	15.3% / $47.32[4]	($47.32) or (15.3%) per visit

[1]Proposed cost-sharing standards include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in this section and section VII.E.3.d.(3). of this proposed rule; and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]No contract year 2024 plans established cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario greater than the proposed illustrative dollar limit for that service category.

[3]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario; and (2) only plans with dollar cost sharing amounts that are greater than the illustrative proposed standard for that length of stay scenario. In addition, these dollar amounts exclude the few plans with coinsurance percentages for inpatient hospital psychiatric services.

[4]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the proposed standard for that service category; (2) the plan maximum cost sharing for the service category; and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 34: ILLUSTRATIVE COMPARISON OF PROPOSED COST-SHARING STANDARDS FOR COST PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF COST PLANS WITH COST SHARING ABOVE ALTERNATIVE 3 COST-SHARING STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY[1]

Column A: Service Category	Column B: Proposed Standards and Illustrative Cost-Sharing Limits[2]	Column C: Contract Year 2024 Weighted Average Cost Sharing (Plans with Cost Sharing Above Values in Column B)	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Mental Health Specialty Services	20.0% / $35.00	23.5% / $40.00[3]	($5.00) or (3.5%) per visit
Psychiatric Services	20.0% / $35.00	29.8% / $47.66[3]	($12.66) or (8.9%) per visit
Partial Hospitalization	20.0% / $60.00	N/A[4]	N/A
Outpatient Substance Use Disorder Services	20.0% / $30.00	27.2% / $40.00[3]	($10.00) or (7.2%) per day
Opioid Treatment Program Services	0.0% / $0.00	6.3% / $19.57[3]	($19.57) or (6.3%) per visit

[1]Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.
[2]Proposed cost-sharing standards include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in this section and section VII.E.3.d.(3). of this proposed rule and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).
[3]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the proposed standard for that service category, (2) the plan maximum cost sharing for the service category, and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with cost sharing above the proposed cost sharing limits rather than plans with solely copayments or coinsurance.
[4] No contract year 2024 plans established cost sharing for the partial hospitalization service category greater than the proposed cost sharing limit for that service category.

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CMS expects in the first applicable contract year when lower behavioral health cost-sharing limits would apply (contract year 2026), MA and Cost Plan organizations may or may not have increased costs to provide behavioral health services. This is because, as discussed in section III.M. of this proposed rule, plans incorporate varying cost sharing arrangements for behavioral health services—with amounts less than, greater than, or equal to cost sharing in Traditional Medicare for these services. As a result, continuing plans that previously established cost sharing for behavioral health services at amounts that are equal to or less than Traditional Medicare may not have any cost impacts as a direct result of this proposal. In contrast, for organizations that do reduce plan cost sharing for one or more behavioral health service categories in response to this proposal, CMS expects they will initially have increased costs to provide those behavioral health services. However, plan bids must: (1) remain at least actuarially equivalent to Traditional Medicare if it is an MA plan; and (2) satisfy Traditional Medicare coverage requirements for both MA and Cost Plans. As a result, CMS expects that the reduction in cost sharing for behavioral health services in contract year 2026 will lead organizations to—

- Predict the impacts that lower cost sharing will have on their cost to provide behavioral health benefits and profit margins (primarily based on plan-level total financial liability to provide behavioral health services and actuarial expectations of changes in enrollee utilization of behavioral health services based on the population served) and;
- Potentially adjust aspects of their bid design and allocation of rebate dollars (such as changes to cost sharing amounts for other service categories, premiums, deductibles, or supplemental benefits).

In contract year 2027 and subsequent years, organizations may become better aware of the cost impact of this proposal as potential cost savings from improved enrollee behavioral health outcomes become more apparent. As a result, as part of normal business operations, organizations may make additional adjustments based on their initial experience of actual changes to their cost of providing behavioral health benefits and profit margins. For example, each year organizations may adjust case management strategies and behavioral health provider contracting (and thus their total plan financial liability for behavioral health services). MA plans have significant plan design flexibility and multiple levers they can use to inform how they make these adjustments and develop bids that continue to remain actuarially equivalent to Traditional Medicare in contract year 2026 and subsequent years. CMS expects these types of adjustments and implementation timeframe would vary between organizations and influence how an organization chooses to design their plan bid(s) in subsequent contract years.

The specific adjustments organizations make in response to this proposal would in turn determine the varying short- and long-term individual financial impacts enrollees would experience. Specifically, CMS expects enrollees would experience different out-of-pocket impacts that change annually based on: (1) how organizations evolve their plan benefit designs; (2) their health conditions and utilization of services; and (3) enrollment switching patterns, if applicable. As an illustrative example, in response to this proposal, a continuing MA plan for contract year 2026 may have: (1) reduced cost sharing for behavioral health services; and (2) increased cost sharing for a few non-behavioral health benefits. In this scenario, enrollees that continue enrollment in this plan and utilize (to the same extent) the following:

- Behavioral health services—may experience cost savings.

• Non-behavioral health services that have increased cost sharing—may experience an increase in costs.
• Behavioral and non-behavioral health services with and without changes in cost sharing—may experience cost savings, increases, or neutral effects depending on how they allocate their utilization of these services.

However, the extent to which organizations may shift costs to services utilized by certain groups of enrollees is limited to ensure that beneficiaries—regardless of their health condition—can access needed health services. Consistent with statutory requirements, CMS would do the following:
• Not approve a plan bid if its proposed benefit design substantially discourages enrollment in that plan for certain Medicare-eligible individuals.
• Continue evaluations and enforcement of its current authority prohibiting plans from misleading beneficiaries in their marketing and communication materials and continue efforts to improve plan offerings and plan comparison tools and resources (for example, Medicare & You and 1–800–MEDICARE).

Over time, as plans continue to evolve their plan benefit designs and the long-term effects of lower behavioral health cost sharing begin to show, the out-of-pocket impacts individual enrollees experience may change. For example, potential long-term impacts for enrollees with behavioral health conditions may include the following:
• Improved aggregate health outcomes and health care costs from increased utilization of high-value behavioral health services (such as, regular check-ins with a behavioral health provider).
• Decreased utilization of high-cost services related to poor behavioral health management (such as, emergency psychiatric admissions).

Given the breadth of potential impacts to enrollees from changes organizations may make to their plan benefit designs in response to this proposal, changing the behavioral health cost-sharing standards could create savings or losses for certain organizations or groups of enrollees at different times after its implementation. For this reason, there is a possibility that this proposal may be of substantial magnitude. A discussion of possible quantification of these potential effects follows.

b. Impact Analysis: Behavioral Health Cost-Sharing Limits No Greater Than Traditional Medicare

Ideally, we would justify this proposal quantitatively but lack sufficient data. To accurately quantify this proposal's potential impacts to similarly situated organizations (such as those that lower behavioral health service category cost sharing amounts by a substantive or nominal amount as a direct result of this proposal) or by certain groups of enrollees (such as those with or without behavioral health conditions) the Office of the Actuary (OACT) would need sufficient data for the following:
• Contract year 2026—MA and Cost Plan organization and enrollee cost impacts based on: (1) expected decrease in behavioral health service category cost sharing amounts; (2) estimates of potential cost impacts to other non-behavioral health benefits to meet actuarial equivalence requirements for MA plans; (3) estimates of plans' total financial liability to provide services with a change in cost directly related to this proposal; and (4) the expected change in frequency of enrollee utilization of the impacted benefits (behavioral health services and non-behavioral health service categories or benefits).
• Contract year 2027 and subsequent years—annual MA and Cost Plan organization and enrollee cost impacts based on: (1) estimate of changes to plans' total financial liabilities to provide impacted behavioral health and non-behavioral health benefits; (2) revised estimates of potential cost impacts to other non-behavioral health benefits to continue meeting actuarial equivalence requirements for MA plans; (3) expected change in frequency of enrollee utilization of impacted benefits; (4) estimate of cost savings per enrollee from better behavioral health outcomes; and (5) enrollee migration patterns between plans.

OACT lacks sufficient data on these topics and as a result, cannot quantitatively project the financial impacts for certain organizations or groups of enrollees if this proposal is finalized. As noted previously, the aggregate, short term impact to MA organizations should be minimal due to the statutory requirement that plans remain actuarially equivalent to Traditional Medicare. While there are possible impacts due to the redistribution of cost sharing to compensate for the proposed limits on behavioral health cost sharing, these impacts would depend on which other services had corresponding changes in cost sharing. The affected service categories are unknown until bid submission, so the impacts are not currently quantifiable.

While there is uncertainty in the impact analysis of this proposal to lower behavioral health cost-sharing standards is not currently possible, existing studies clarify potential implications from this proposal for organizations and enrollees with and without a need for behavioral health services. For example, a study [352] comparing the rate of beneficiary follow-up within 30 days after a psychiatric hospitalization between plans with equivalent mental and physical health cost sharing amounts and plans with mental health cost sharing amounts that were greater than their primary and specialty care cost sharing found that beneficiaries in plans with equivalent cost sharing—
• Were significantly more likely to have follow-up visits after a psychiatric hospitalization; and
• This important service primarily benefited affected enrollees with lower education and in rural areas.

Another study [353] assessed the impact of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (which lowered beneficiaries' coinsurance from 50 percent to 20 percent for mental health visits) on changes to specialty and primary care outpatient mental care visits and psychotropic medication fills. They found that Medicare beneficiaries' use of psychotropic medication increased after the implementation of cost-sharing parity, without a detected change in visits. The greater use of psychotropic medications was primarily among people with probable serious mental illness and among Medicare beneficiaries who did not report having supplemental coverage. The article concluded that—
• Increased psychotropic medication fills could signal improvements in mental health care access among Medicare beneficiaries, especially among the subgroups most likely to benefit from the policy change; and
• A lack of changes to mental care visits may suggest other, nonfinancial barriers are impacting beneficiaries from receiving mental health treatment (for example, barriers related to transportation, the availability of

[352] Trivedi AN, Swaminathan S, Mor V. Insurance parity and the use of outpatient mental health care following a psychiatric hospitalization. JAMA. 2008 Dec 24;300(24):2879–85. doi: 10.1001/jama.2008.888. PMID: 19109116; PMCID: PMC4757896.

[353] Cook, Benjamin & Flores, Michael & Zuvekas, Samuel & Newhouse, Joseph & Hsu, John & Sonik, Rajan & Lee, Esther & Fung, Vicki. (2020). The Impact Of Medicare's Mental Health Cost-Sharing Parity On Use Of Mental Health Care Services: An assessment of whether Medicare cost-sharing reductions for outpatient mental health services was associated with changes in mental care visits to physicians and psychotropic medication fills. Health Affairs. 39. 819–827. 10.1377/hlthaff.2019.01008.

providers, or community- or person-level stigma).

As a result, CMS believes this proposal (which would also reduce the coinsurance limit for several professional behavioral health standards from 50 to 20 percent coinsurance) in conjunction with other provisions focused on addressing nonfinancial barriers for enrollees to receive behavioral health services described in section III.M. of this proposed rule would work together to improve access to, and utilization of, behavioral health services in MA and Cost Plans.

Another intended consequence of this proposal is a higher level of integration for medical and behavioral health services. Integrating medical and behavioral healthcare is one method some payers use to improve enrollee health outcomes while reducing the growth rate of healthcare claim expenditures. As lower behavioral health cost sharing limits may increase utilization of these services, we expect this proposal may provide additional financial incentive for MA plans to integrate these services. Specifically, there should be incentive through capitated payments to the MA organization to ensure beneficiaries receive efficient and effective care despite changes in cost sharing and utilization patterns. Medical and behavioral healthcare integration has been studied both qualitatively and quantitatively in several contexts. One such study [354] reviewed relevant literature, conducted interviews, and held a workshop to develop a human-centered vision for the mental health ecosystem, reinforced by the experiences of those with mental illness, behavioral health providers, and efforts already underway by state, local, and Federal health leaders. This vision hinges upon five major shifts for better mental health care access, with one major shift being reform of payment systems. This study cites numerous attempts to improve mental health both in the U.S. and in the United Kingdom. Several of the attempts cited had significant reductions in hospitalizations, emergency room visits, and overall costs. Milliman,[355] in a 2018 update to a report originally made to the American Psychiatric Association in 2014 on the efficiencies of integrating behavioral and medical health, estimated savings to Medicare of $6 to $12 billion, for calendar year 2017, if behavioral health services were integrated into lower cost medical services.

Based on these existing studies we believe that lowering cost sharing for behavioral health services could lead to significant savings for MA and Cost Plan organizations, enrollees, and Medicare over time.

c. Comment Solicitation: Behavioral Health Cost-Sharing Limits No Greater Than Traditional Medicare

CMS also considered how the proposed cost-sharing standard may impact the flexibility MA organizations have in preparing a plan bid that meets the existing actuarial equivalence requirements at § 422.100(j)(1) and (2).[356] To assess this, the Office of the Actuary (OACT) first estimated what percentage of total 2023 Medicare FFS cost sharing is represented by the MA service categories currently subject to cost sharing no greater than Traditional Medicare (2023 was the most recently available data at the time of developing this proposal). The OACT then estimated the percentage representing the additional behavioral health MA service categories subject to this proposal. We note that this approach is from the perspective of an MA plan having to meet the Traditional Medicare cost-sharing standards for all the service categories listed in paragraph (j)(1) even though only a subset MA plans with certain MOOP types are subject to that standard for certain service categories. This approach is intended to assess the minimum level of flexibility MA organizations would have to structure cost sharing differently from Traditional Medicare, regardless of their MOOP type (that is, most plans would have more flexibility). The OACT's analysis found that—

- Existing MA cost-sharing standards with limits above cost sharing in Traditional Medicare represent about 51 percent of total 2023 Medicare FFS cost sharing; and
- The proposed addition of behavioral health service categories to the list of services for which cost sharing must be no greater than Traditional Medicare would nominally increase the percentage of total 2023 Medicare FFS cost sharing that MA cost-sharing standards represent from 49 to 51 percent.

In assessing the results of this analysis, there are several limitations. First, these percentages are only estimates based on how Traditional Medicare pays by service and not differently by provider. Second, the OACT does not have a statistical method to determine how high a percent threshold would result in insufficient flexibility for MA organizations to design cost sharing that is different from Traditional Medicare while fulfilling the actuarial equivalence requirements in § 422.100(j)(1) and (2). However, the OACT generally expects an approximate 2 percent decrease to the proportion of total cost sharing that can be raised above what Traditional Medicare requires (from 51 to 49 percent) is not likely to result in insufficient flexibility for MA organizations when designing their plan benefits. As a result, we believe that this proposal, if finalized, will not require MA organizations to make disruptive changes to their plan benefit designs so their plans meet the existing actuarial equivalence requirements to Traditional Medicare while complying with the proposed behavioral health cost-sharing limits. Nevertheless, we solicit comment on this supposition.

In summary, we expect this proposal to make in-network behavioral health service category cost-sharing limits no greater than Traditional Medicare will result in both increased savings and higher quality of health care in the MA and Cost Plan program over time. A detailed analysis of these effects would require additional data that are not available at this time. We solicit public comment on the economic cost and benefits of this proposal, which may include comments on data sources and available analyses of behavioral health service utilization impacts on health care savings and costs that could offer additional insight into the likely impacts of this proposal.

6. Proposal To Enhance Review of Marketing and Communications (§§ 422.2260 and 423.2260)

CMS is proposing to expand the definition of marketing under §§ 422.2260 and 423.2260 to broaden CMS oversight of certain categories of MA and Part D communications materials and activities in order to strengthen beneficiary protections. The updated definition would ensure all communications materials and activities that intend to draw a beneficiary's attention to an MA plan, Part D Plan or other plan, influence a beneficiary's decision-making process when making a MA or Part D plan selection or influence

[354] Egizi, Alison Muckle; Blasco, Gwen; Collins, Helen. A human-centered vision for improving the mental health care ecosystem. July 2022. Retrieved from: *https://www2.deloitte.com/us/en/insights/industry/public-sector/mental-health-equity-and-creating-an-accessible-system.html.*

[355] Milliman. Potential economic impact of integrated medical-behavioral healthcare: Updated projections for 2017. February 2018. Retrieved from: *https://www.milliman.com/en/insight/potential-economic-impact-of-integrated-medical-behavioral-healthcare-updated-projections.*

[356] These actuarial requirements do not apply to Cost Plans.

a beneficiary's decision to stay enrolled in a plan (as described in the current intent standard of the marketing definition in §§ 422.2260(1) and 423.2260(1)) are submitted to CMS and subject to review under the more comprehensive marketing material review requirements. While CMS does expect this proposed change will result in an increase in the volume of materials submitted to CMS, most of those materials are, and will continue to be, designated as File & Use per §§ 422.2261(b) and 423.2261(b) and therefore, only those materials which are prospectively reviewed will directly impact CMS time and cost burden.

Under this provision, CMS estimates that if this provision is finalized based on the trend estimates in the COI, CMS will receive 80.21 percent more marketing materials. Of those submitted marketing materials, CMS estimates that 10 percent of those materials will be prospectively reviewed by health insurance specialists. Therefore, we take the hour burden of a single review (0.5 hour) and multiply that by the number of materials that we expect to be reviewed (10 percent of submitted materials as estimated in table F10) and the hourly wage of a health insurance specialist ($64.06). For CY 2026, the estimated cost burden for CMS would be $261,531.36 (0.5*8165.20*64.06). For CY 2027, the estimated cost burden for CMS would be $288,077.82 (0.5*8994*64.06). For CY 2028, the estimated cost burden for CMS would be $317,314.80 (0.5*9906.80*64.06).

CMS notes that it has not collected the materials currently categorized as communications since prior to the April 2018 final rule, and therefore these estimates could vary depending on how the advertising landscape has changed and how frequently plans and TPMOs have been utilizing communications materials which are not currently required to be submitted for CMS review. In addition, it is possible that, based on concerns brought to CMS' attention through data such as complaints, surveillance activities, or retrospective reviews, CMS could increase the percentage of materials that are prospectively reviewed.

7. Proposal To Require Clinical or Quality Improvement Standards for Provider Incentive and Bonus Arrangements To Be Included in the MA MLR Numerator (§ 422.2420(b)(2))

We propose to amend § 422.2420(b)(2) to clarify that only provider incentives and bonuses tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards may be included in incurred claims for MA MLR reporting. Due to the proposed change, if MA organizations report fewer provider incentives and bonuses in the MLR numerator and their MLR percent decreases, remittances paid could increase. While we do not know exactly how many incentives and bonuses would be impacted by this change, using information from prior Marketplace and Medicaid Regulatory Impact Analyses,[357] [358] we estimate that with a 1 percent decrease in incurred medical incentive pools and bonuses in the Medicare MLR numerator based on the Medicare MLR data for contract year 2017 (when detailed incentive and bonus data were last reported), the proposed clarification would have almost no impact on remittances paid by MA organizations, an estimated approximately $4 million per year. To arrive at this estimate, we calculated updated Medicare MLR remittances based on the assumptions outlined previously, subtracted those amounts from the actual Medicare MLR remittances and estimate a 1.8 percent increase per year in remittances paid by MA organizations.

8. Proposal To Prohibit Administrative Costs From Being Included in Quality Improving Activities in the MA and Part D MLR Numerator (§§ 422.2430(a) and 423.2430(a))

We also propose to amend §§ 422.2430(a) and 423.2430(a) to specify that only expenses directly related to activities that improve health care quality may be included in quality improving activity expenses for MA and Part D MLR reporting. We expect this proposed change could result in an increase in remittances from MA organizations and Part D sponsors that currently include indirect expenses in quality improving activities. Although we do not know how many MA organizations and Part D sponsors include indirect expenses in quality improving activities, we estimate the impact of the proposed change by assuming that indirect expenses inflate quality improving activities by 41.5 percent (the midpoint of the 33 percent to 50 percent range we have observed during commercial and Medicaid MLR audit examinations) for half of the organizations that report quality improving activity expenses (sorted based on lowest to highest and highest to lowest MA organization and Part D sponsor revenue). To determine the amount in remittances that we expect based on the proposed change, we reviewed the MLR data for contract year 2017 (when detailed health care quality improvement expenses were last reported). Using the assumption that indirect expenses improve the quality improving activities by 41.5 percent, we multiplied the quality improving activity expenses for each plan contract by 41.5 percent and subtracted these expenses from the numerator. Next, we updated the MLR for each contract and determined the change in remittances for contracts that fell below the 85 percent threshold. Using these calculations and steps, we determined the proposed clarification would increase remittances paid by MA organizations and Part D sponsors by a range of approximately $13 million to $189 million per year (sorted lowest to highest). Extrapolating the estimated transfers to the Treasury General Fund over 10 years, we expect the policy change to transfer an average of approximately $101 million per year, and $1.01 billion between 2026 and 2035.

9. Proposal To Establish Standards for MA and Part D MLR Audit Examinations (§§ 422.2480(d), 423.2480(d), 422.2401, 423.2401, 422.2450, 423.2450, 422.2452, 423.2452, 422.2454, and 423.2454)

Our proposed amendments to the MA and Part D MLR regulations, including the addition of or modification to §§ 422.2401, 423.2401, 422.2450, 423.2450, 422.2452, 423.2452, 422.2454, and 423.2454, would increase the MLR reporting burden by requiring that MA organizations and Part D sponsors to provide auditors with detailed MLR data and any underlying records that can be used to substantiate amounts included in the calculation of each contract's MLR and any remittance determined to be owed. We anticipate the level of effort related to record retention, responding to record requests, and preparing and mailing MLR audit remittances would vary by MA organization and Part D sponsor and their potential audit findings and is therefore difficult to quantify.

The proposed update would primarily impose additional costs on the Federal government. To conduct MLR audit examinations in Medicare we would pay a contractor to perform the audits to identify suspected inaccuracies and communicate findings to the MA organizations and Part D sponsors. We anticipate that we would pay a contractor to perform audits approximately equal to the number we are currently paying them to perform

[357] *https://www.govinfo.gov/content/pkg/FR-2022-01-05/pdf/2021-28317.pdf,* page 133.

[358] *https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08961.pdf,* page 139.

pilot MLR audit examinations, which is consistent with commercial MLR audits previously conducted (approximately $1 million to $1.5 million per year).

MA organizations and Part D sponsor MLR audits are expected to lead to more MLR remittances to the Treasury General Fund. These additional payments are transfers since no goods or services are being created. The impact to the Medicare Trust Funds is $0. To estimate the potential total increase in MLR remittances because of MA and Part D MLR audit examinations, first we accessed the total remittances paid for the most recent contract years available. Based on Medicare Part C and D MLR data, the average of total remittances paid for CYs 2017–2021, excluding 2020, which was significantly impacted by the COVID–19 pandemic with unusually large remittances collected, was $194,032,540.30.[359]

Then we reviewed the results of eight commercial MLR audit examination reports, which approximates the annual number of MA and Part D MLR examinations CMS expects to conduct. The commercial MLR audit examination reports from CYs 2015 to 2019, the most recent publicly available reports, reported $11,691,450 in rebates were distributed back to policyholders.[360] To compare MLR remittance amounts we determined that the MA and Part D programs are 2.7 times larger than the enrollment size of the commercial Marketplace. As of January 2024, 21.3 million consumers signed up for coverage through the commercial Marketplaces.[361] As of August 2024, 57.2 million people were enrolled in Medicare Part C and D, excluding PACE organizations, which do not report MLR.[362] Therefore, we multiplied the $11,691,450 in commercial MLR audit rebates by 2.7 to estimate MA and Part D MLR audit remittances, which would total approximately $31,566,915. Extrapolating the estimated transfers to the Treasury General Fund over 10 years, we expect the MLR audit examinations to transfer an average of approximately $32 million per year, and $320 million between 2026 and 2035.

[359] *https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio.*

[360] *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/MLR_examinations_reports.*

[361] *https://www.cms.gov/data-research/statistics-trends-reports/marketplace-products/2024-marketplace-open-enrollment-period-public-use-files.*

[362] *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/monthly-contract-and-enrollment-summary-report.*

10. Proposal To Add Provider Payment Arrangement Reporting in the Medicare MLR Reporting Regulations (§§ 422.2460 and 422.2490)

Our proposal to require separate reporting amounts for provider payment arrangements would increase the Medicare MLR reporting burden by requiring MA organizations to compile additional information in the MLR Reporting Tool. We anticipate the level of effort to compile this information would vary based on the size of the MA organization, how they submit the existing Medicare Part C reporting requirements to report payments to providers, and whether they have ever responded to the HCPLAN APM measurement survey. The 2023 APM Measurement Methodology and Results report stated a total of 64 health plans, four FFS Medicaid states, and Traditional Medicare participated in the 2023 LAN Measurement Effort representing almost 264 million or 86.7% of people covered by an insurance plan in the Commercial, Medicare Advantage, Medicaid, or Traditional Medicare markets.[363] While the level of effort is difficult to quantify, in the COI we estimate an annual burden of 2,100 hours (700 MA organizations * 3 hr/response) at a cost of $179,970 (2,100 hours * $85.70/hr).

The proposed update would also impose additional costs on the Federal government related to analyzing the additional data. However, given that the additional reporting will not change the Medicare MLR calculation we do not expect the proposal to increase MLR remittances or create significant additional costs for the Federal government.

11. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, and 422.616)

We are proposing modifications to existing regulations at 42 CFR part 422, subpart M, to clarify and strengthen existing rules related to organization determinations. The intent of this proposal is to clarify the definition of an organization determination to enhance enrollee protection in inpatient settings. We want to ensure enrollees and providers acting on their behalf receive notice of an inpatient/outpatient downgrade and are aware of their appeal rights. The intent of this provision is also to increase awareness when inpatient stays are downgraded with the expectation that there would be more appeals and some overturns. Thus, qualitatively, we expect this proposal to generate increased costs to the MA organizations and ultimately to the Medicare Trust Fund since inpatient stays are more expensive than observations.

In section VI.B.18. of this proposed rule, we estimated that there are annually 60,000 downgrades of inpatient to observation. Although we can estimate 60,000 affected enrollees, we do not have any way to estimate the following: (1) what percent of the enrollees are already receiving required written notification and what percent of them will receive a notice due to change in the provision; (2) of those receiving the notice, what percent will appeal; (3) of those appealing the downgrade, what percent will be overturned by the plan; (4) of those appeals upheld by the plan what percent will be overturned by the Independent Review Entity (IRE) (given that 100 percent of upheld plan decisions are forwarded to IRE). If this data was available, we could obtain average costs of inpatient stays and observation days and estimate the cost to the trust fund. In the absence of this data, we are estimating this as a non-quantified cost to the plans that is passed on to the Trust Fund.

E. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this proposed rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health.

1. Proposal for Medicare Prescription Payment Plan (§§ 423.137(e), 423.137 (d), 423.137(f), 423.137(i), and 423.137(j))

a. Auto Renewal

As Medicare Prescription Payment Plan participation is tied to drug expenditures in a given plan year, CMS considered how to address year-over-year program participation.

- *Option #1:* Implement an automatic election renewal process that requires a Part D sponsor to automatically renew a Part D enrollee's participation in the Medicare Prescription Payment Plan, provided the participant remains in the same Plan Benefit Package (PBP) in the upcoming year, unless the program participant indicates otherwise. This option would minimize burden for Part D enrollees, who would not need to

[363] *https://hcp-lan.org/workproducts/apm-methodology-2023.pdf.*

complete additional paperwork to remain in the program, and Part D sponsors, which would not be required to process new election forms for active program participants or conduct ''likely to benefit'' analyses for the upcoming plan year for those participants. The primary impact of this approach is the burden and cost on Part D sponsors associated with annual notifications alerting participants that their participation in the program is continuing into the next year.

- *Option #2:* Require Part D enrollees to re-elect into the program each plan year. This option would allow Part D enrollees to actively choose to participate in the program each year but would place additional burden on both enrollees and Part D sponsors. In addition to requiring Part D sponsors to send annual notifications alerting participants that their participation in the program is ending and that participation renewal is required, this option would also require enrollees to complete a new election request form annually and require plan sponsors to review election requests from the same enrollee each year and send new notices of election approval following the renewal request.

As noted in the earlier in this rule, CMS proposed an automatic election renewal process requiring Part D sponsors to alert program participants no later than December 7 that their participation in the program will continue into the next year unless they indicate they would like to opt out. We believe this approach minimizes burden for both enrollees and plan sponsors.

b. Point-of-Sale Enrollment

Timely effectuation of election requests is important to prevent dispensing delays and potential prescription abandonment. For enrollees who trigger the likely to benefit threshold with a new high-cost prescription and receive the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' informing them about the Medicare Prescription Payment Plan at the point of sale, a real-time or point of sale election mechanism could allow them to pay $0 at the point of sale and still leave the pharmacy with their medication. We considered the following three options for point-of-sale enrollment:

- *Option #1:* Permit point of sale enrollment by establishing a new value in an existing NCPDP data field for the Medicare Prescription Payment Plan. If a Part D enrollee indicates to the pharmacist that they would like to opt into the program, the pharmacist would reverse the claim and resubmit it with a specific clarification code indicating that the individual has agreed to opt into the program. The PBM would then accept the clarification code value, add the individual to the relevant eligibility file, and return a message to the pharmacy providing the plan-specific BIN/PCN. The pharmacist would process the claim like a COB claim, bill any other applicable OHI, and bill the plan-specific BIN/PCN for the Medicare Prescription Payment Plan. The new program participant would be able to collect their prescription without paying any OOP cost sharing at the POS. The PBM would then communicate to the Part D sponsor that the individual has opted into the program.
- *Option #2:* Permit real-time enrollment by telephone or mobile or web-based application. If a Part D enrollee wanted to elect into the Medicare Prescription Payment Plan, they could call their plan's telephone number or submit a web-based application. The Part D sponsor would manually effectuate the individual's election into the program and communicate the election to the PBM in real time. The PBM would then add the individual to the relevant eligibility file. Once the individual's election is effectuated, the pharmacist would either reverse and resubmit the claim to receive the plan-specific Medicare Prescription Payment Plan BIN/PCN, or the new program participant would receive a verbal confirmation via the phone call with the Part D sponsor providing the plan-specific BIN/PCN.
- *Option #3:* Require Part D sponsors to process election requests within 24 hours. If a Part D enrollee wishes to elect into the Medicare Prescription Payment Plan, they may use any of the plan's election mechanisms. During the plan year, Part D sponsors must process the election request within 24 hours. The Part D sponsor would then communicate the effectuation to the enrollee and to the PBM.

As noted earlier in this rule, CMS proposed to codify the 24-hour timeframe for election requests made during the plan year, as required in 2025, and requested comment on real-time election. We believe that the 24-hour timeframe, paired with the required process to retroactively apply the program to those meeting criteria for a retroactive election, reduces the likelihood of dispensing delays and prescription abandonment while avoiding the operational burden that would be required for Part D sponsors, PBMs, and pharmacies to develop and implement mechanisms to support real-time or POS election. We are continuing to explore the operational feasibility of a real-time election mechanism for 2026 and subsequent years.

b. Pharmacy Processes

Section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act states that an individual's participation in the Medicare Prescription Payment Plan does not affect the amount paid (or the timing of such payments) to pharmacies. Accordingly, we proposed that the Part D sponsor must pay the pharmacy for the final amount the individual would have otherwise paid at the POS. Because an individual's OOP costs are net of any contributions made by supplemental payers to Part D to which the individual may be entitled and that reduce the OOP amount due, this requires the Medicare Prescription Payment Plan to be integrated into current COB transactions for program participants.

We proposed to require pharmacies and Part D sponsors to utilize an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants.

We also considered the use of a pre-funded card, which would keep the pharmacy whole and could allow for COB with other payers supplemental to Part D; however, we are concerned this approach does not provide the same level of Part D sponsor oversight to ensure that payments are only made for covered Part D drugs for the participant cardholder. Additionally, there are other concerns surrounding timeliness of issuing payment cards and participants needing to present a physical card at the POS, which could be forgotten, lost, or stolen, potentially causing delays in obtaining prescription drugs, elevated risk of fraud, additional costs to the Part D program, and potential card processing fees for pharmacies. We are also aware that not all organizations have the financial capabilities established to enable a prefunded payment card system. Moreover, interested parties have also expressed a desire to have a single, uniform method of adjudicating and managing the patient liability for the Medicare Prescription Payment Plan at the POS; we determined the use of unique BIN/PCNs for the final transaction to the Medicare Prescription Payment Plan best accomplishes that objective.

2. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program

In this section, we discuss the alternative considered when developing our proposal to reinterpret section 1927(d)(2)(A) of the Act such that drugs

used for weight loss or chronic weight management for treatment of obesity would no longer be excluded from the definition of Part D drug to reflect changes in the prevailing medical consensus towards recognizing obesity as a disease. FDA-approved indications for available AOMs generally include weight loss or chronic weight management in both individuals with obesity and individuals with overweight and at least one weight-related comorbid condition. We considered an alternative proposal to extend our reinterpretation of the statutory exclusion to no longer consider drugs used for weight loss or chronic weight management for individuals with overweight and at least one weight-related comorbidity as excluded from the definition of Part D drug. This alternative proposal would expand Part D coverage of AOMs to Medicare beneficiaries with overweight and a weight-related comorbidity other than type 2 diabetes or cardiovascular disease, since those conditions are already coverable MAIs under current policy. See section III.A.2. of this proposed rule for further discussion regarding our rationale not to extend our reinterpretation of the statutory exclusion such that individuals with overweight and at least one weight-related comorbidity could receive coverage of AOMs under Part D.

These estimates follow a similar methodology to the estimates of our proposal to permit AOM coverage for weight loss or chronic weight management for treatment of obesity as described in section VII.D.6. of this proposed rule. For Medicare, the estimates expanded the population newly able to obtain AOM coverage from 7 percent to approximately 9 percent of total Part D enrollees based on 2022 data, which includes the number of Part D enrollees with obesity (7 percent) and with overweight and weight-related comorbidities (2 percent). As shown in table 35, the alternative proposal would result in expenditures of $35 billion over a 10-year period for the Part D trust fund (increased from $24.8 billion for the proposal discussed in section VII.D.1.a. to provide coverage for obesity only). For the purposes of this alternative analysis, we report annual costs with a placeholder for each year starting with the first year the reinterpretation would be applicable in Medicare Part D. Premium offsets reflect the earliest such offsets would be factored into the analysis due to premium stabilization provisions in section 11201 of the IRA (assuming 2026 notionally as year 1 of implementation).

TABLE 35. FINANCIAL IMPACT OF MEDICARE COVERAGE OF AOMs FOR BENEFICIARIES WITH OBESITY OR OVERWEIGHT AND WEIGHT-RELATED COMORBID CONDITIONS

Cost (Millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total Years 1-10
Federal Benefit Cost	$1,900	$2,100	$2,500	$2,900	$3,200	$3,700	$4,100	$4,600	$5,100	$5,700	$35,900
Premium Offset	$0.0	$0.0	$0.0	$0.0	$0.0	$100	$100	$200	$200	$300	$1,000
Total Federal Cost	$1,900	$2,100	$2,500	$2,900	$3,200	$3,600	$4,000	$4,400	$4,900	$5,400	$34,900

It is possible that our estimates significantly underestimate the impact of our alternative proposal. Our estimates rely on available claims data and therefore a major limitation in our estimates is whether a diagnosis of overweight was reliably reported. Available NHANES data from 2017 to 2018 indicates that the prevalence of overweight in the U.S. adult population was 30.7 percent [364] which is more than triple the prevalence observed in Medicare claims data (8.1 percent). NHANES data did not report the proportion of overweight in adults age 60 and older, but the prevalence of obesity in the overall U.S. adult population is similar to the prevalence in adults age 60 and older; therefore, we think it is reasonable to assume that the proportion of overweight in the Medicare population should be similar to the proportion of overweight in the overall U.S. adult population.

We were unable to estimate the financial impact of the alternative proposal on the Medicaid program due to lack of available data on the proportion of Medicaid enrollees with overweight and weight-related comorbidities.

[364] *https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.*

3. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost-Sharing Limits (§§ 417.454 and 422.100)

In this section, CMS discusses alternatives we considered when developing our proposal to add behavioral health service categories to the list of services for which MA and Section 1876 Cost Plan (Cost Plan) in-network cost sharing must be no greater than that in Traditional Medicare, beginning in contract year 2026. We do not include alternatives for the proposal to clarify the applicability of the 50 percent coinsurance (or actuarially equivalent copayment) standard for Cost Plans and other proposals that primarily continue current policy with minor updates. For example, this includes our proposed revision to § 417.454(a)(1) which would allow for CMS to annually update copayment limits for basic benefits that apply to Cost Plans based on the most recent Medicare FFS data projections.

a. Cost Estimation

As noted in section VII.D.4. of this proposed rule, because of multiple factors affecting bids and our longstanding actuarially equivalent MA plan bid requirements, we have not estimated a cost for this proposal and acknowledge a possible combination of savings and costs for individual organizations and enrollees. Similarly, we would not be able to quantify potential impacts from these alternative behavioral health cost-sharing standards considered for MA and Cost Plans. However, potential impacts from the alternatives on average MA and Cost Plan cost-sharing amounts for these services are noted in section VII.E.3.d. of this proposed rule. In addition, as the actuarial equivalence tests are applied to MA plans for each alternative presented in this section, the implication is that—in aggregate—the expected enrollee cost-sharing expenses will remain the same for those enrollees in MA and for beneficiaries in Traditional Medicare. This actuarial requirement does not apply to Cost Plans; however, we do not expect major effects from this proposal on these plans, primarily because: (1) only a

small proportion of these plans (20% or fewer) have established cost sharing greater than the alternatives considered; (2) in most cases plans with cost sharing greater than the alternatives considered should not have to vastly change their cost sharing designs to come into compliance (less than $20.00 per service category in most cases); and (3) Cost Plans represent a small proportion of all Medicare-eligible beneficiaries (approximately 169,000 as of July 2024 [365]). In addition, we expect beneficiary choice will continue to act as an incentive for Cost Plan organizations to offer favorable benefit designs. Consequently, we expect no material changes to the Medicare Trust Fund expenditures since aggregate enrollee cost sharing remains unchanged or minimally affected under the proposed or alternative scenarios discussed in section VII.E.3.d. of this proposed rule.

b. Applicability Date

All alternatives in section VII.E.3.d. of this proposed rule consider specific behavioral health cost-sharing standards that would apply beginning in contract year 2026. If this proposal is finalized and issued within an expected timeframe, we believe changes to the behavioral health cost-sharing standards should be applicable beginning no earlier than contract year 2026 to provide sufficient time between the publication of the final rule and the behavioral health cost-sharing compliance date (operationally this would be the bid deadline for the first contract year in which the cost-sharing limits would apply). Specifically, sufficient time between these dates is necessary for: (1) CMS to implement the finalized policy (which may include creating validations in the PBP functionality and issuing subregulatory operational guidance for MA organizations); and (2) organizations to ensure their benefit designs align with the finalized behavioral health cost-sharing policies and any operational guidance issued by CMS. However, as discussed in section III.M. of this proposed rule, we solicit comments on aspects of our proposal including whether a transition period from the existing contract year 2026 behavioral health cost-sharing standards in current regulations to the proposed cost-sharing standard (alternative 3) is necessary and if so, how long the transition should be.

[365] CMS. Contract Summary 2024. Data as of July 2024. Retrieved from: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-07.*

c. Evaluation Approach of Alternatives Considered

In section VII.E.3.d. of this proposed rule, we evaluate which alternative may best strike a balance between: (1) improving the affordability of behavioral health services for enrollees in a timely manner; and (2) minimizing disruption to enrollees' access to care and coverage options. This evaluation is supported by narratives and tables that indicate how each alternative may impact future contract year: (1) behavioral health service category cost-sharing (copayment and coinsurance) limits set by CMS; and (2) behavioral health cost sharing amounts established by MA and Cost Plans. Specifically, we evaluate these potential consequences for the following behavioral health service categories that are subject to this proposal:

- Inpatient hospital psychiatric services [366]
- Mental health specialty services [367]
- Psychiatric services
- Partial hospitalization [368]
- Outpatient substance use disorder services
- Opioid treatment program services

Tables indicating potential consequences to the cost-sharing limits and plan cost-sharing amounts for these service categories are included in section VII.E.3.e. of this proposed rule. To develop the illustrative dollar values in these tables, we used: (1) analyses of the most recent and relevant data sources CMS had at the time of developing this proposal: contract year 2025 Medicare FFS data projections (based on 2019–2023 Medicare FFS data, respectively) and contract year 2024 MA and Cost Plan data [369] and (2) application of the existing rounding rules in current regulation (§ 422.100(f)(6)(ii)) that apply to MA copayment limits and are proposed to apply to Cost Plan copayment limits per § 417.454(e). Additional detail about the specific Traditional Medicare FFS data projections used in the calculations to develop these amounts are available in the footnotes of tables 3 and 4 in section III.L. of this proposed rule. For example, this includes the provider specialties that informed the projected total weighted average allowed amount per visit for mental health specialty services.

- The consequences discussed and shown in the tables in sections VII.E.3.d. and e. of this proposed rule are uncertain because:
- Final behavioral health copayment and dollar limits set in future contract years (under the existing cost-sharing standards in current regulations, the proposed cost-sharing standard, or the other alternative cost-sharing standards considered) would likely be different than the illustrative behavioral health copayment and dollar limits in this

[366] Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, from a Cost Plan perspective we are only able to evaluate potential impacts to inpatient hospital psychiatric services cost-sharing limits (for all length of stay scenarios) and not to plan cost sharing amounts. In contrast, for MA plans we are able to evaluate potential impacts to both cost-sharing limits and plan amounts for this service category.

[367] Beginning January 1, 2024, Medicare started allowing marriage, family, and mental health counselors to bill independently for their professional services and made changes to payment for certain mental health specialty services including services involving community health workers and outpatient psychotherapy for crisis services. At the time of drafting this proposed rule, the OACT did not have sufficient utilization data available for these services to incorporate their costs into the projected weighted average allowed amount that we use to calculate illustrative ''mental health specialty services'' service category copayment limits that could result from the alternatives discussed in this section. As a result, the illustrative ''mental health specialty services'' service category copayment limits in this section are based on a projected weighted average allowed amount calculated using the same provider specialties that were used to calculate the copayment limits for this service category for contract year 2025, including: clinical psychologist, licensed clinical social worker, and psychiatry. Regardless of whether this proposal is finalized or not, CMS plans to update the Medicare FFS data used to inform the calculation of copayment limits for the ''mental health specialty services'' service category for contract year 2026 and future years to include covered services from marriage, family, and mental health counselors and new payment rates for certain mental health specialty services. As a result, CMS expects actual ''mental health specialty services'' service category copayment limits that would result from each alternative discussed in this section would be different from the illustrative copayment limits provided in this section.

[368] Beginning January 1, 2024, Medicare started covering Intensive Outpatient Program services. This benefit provides the same services as the partial hospitalization program benefit but requires fewer hours of therapy per week (a minimum of 9 hours versus over 20 hours). At the time of drafting this proposed rule, the OACT did not have sufficient utilization data available for this service type to project an allowed amount for these Intensive Outpatient Program services that is separate from partial hospitalization program services. As a result, in evaluating the alternatives discussed in this section, CMS considered that the illustrative partial hospitalization copayment limits in this section would also apply to the Intensive Outpatient Program services. Regardless of whether this proposal is finalized or not, CMS plans to set cost-sharing limits specific to Intensive Outpatient Program services for contract year 2026 and future years that are separate from the cost-sharing limits applicable to partial hospitalization program services and establish separate data entry for this benefit in the PBP bid tool. As a result, CMS expects actual copayment limits that would result from each alternative discussed in this section for Intensive Outpatient Program services would be different from the illustrative partial hospitalization program services copayment limits provided in this section.

[369] Excludes employer, D–SNPs, and MSAs.

proposed rule based on using updated Traditional Medicare FFS data projections and coverage rules to calculate the limits.

- Plan behavioral health cost-sharing amounts established by organizations in future contract years cannot be precisely predicted because: (1) organizations may establish plan cost sharing amounts up to the applicable final limit set by CMS, regardless of any prior trend in establishing cost sharing for that service category; (2) organizations establish plan cost sharing amounts based on many variables that may change annually (including provider contracting arrangements, managed care practices, and scope of supplemental benefit offerings); (3) if CMS does not set a copayment limit for a behavioral health service category, the plan's copayment amount may be actuarially equivalent to, or less than, the applicable cost-sharing standard based on data specified in the regulation which may include their total financial liability for that benefit (which may be greater or less than the illustrative copayment limits in this section); and (4) Cost Plans are not required to report information for all services.

However, the consequences each alternative poses to the behavioral health coinsurance limits and percent of estimated Traditional Medicare FFS cost sharing (which determine dollar cost-sharing limits for inpatient hospital psychiatric services) are characterized by a relatively high degree of certainty because these values are not subject to the influencing factors discussed previously.

CMS considered both the consequences discussed in this section to guide our decision making among the alternative behavioral health cost-sharing standards considered. We believe the data used to develop the potential consequences to future year behavioral health copayment limits and plan cost sharing amounts is sufficiently accurate for this purpose. Tables 32 to 34 and 36 to 55 indicate these consequences of each alternative. Next, we provide an overview of tables 32 to 34 and 36 to 55 to avoid repetitive text in the discussion of specific alternatives.

Tables 36 to 40 specify contract year 2026 and future year MA behavioral health cost-sharing standards that would apply to specific service categories based on: (1) the current (or baseline) cost-sharing standard from § 422.100(f)(6) and (j)(1); (2) the cost-sharing standard posed by each alternative (percent coinsurance or percent of estimated Medicare FFS cost sharing); and (3) illustrative dollar limits that reflect actuarially equivalent values to the baseline and alternative cost-sharing standards, based on contract year 2025 Traditional Medicare FFS data projections and application of the regulatory rounding rules. These comparisons are completed for categories from each group of behavioral health services that have different cost-sharing standards in current regulations. Specifically, tables 36 to 40 present information for the following MA behavioral health service categories:

- Mental health specialty services (table 36) and partial hospitalization program services (table 37) currently subject to a range of cost-sharing limits for professional services in paragraph (f)(6)(iii)).
- Inpatient hospital psychiatric services for the 15-day length of stay scenario (table 38) currently subject to dollar limits based on specific percentages of Medicare FFS cost sharing in paragraph (f)(6)(iv).
- Opioid treatment program services (table 39) and outpatient substance use disorder services (table 40) currently subject to the 50 percent coinsurance (or actuarially equivalent copayment) cap on cost sharing in paragraph (f)(6)(i).

CMS uses the information in tables 36 to 40 to assess each alternative's potential impact to MA behavioral health cost-sharing limits on an overall and service category specific basis. Tables 41 to 45 use similar data for Cost Plans for this same purpose. Substantive differences in table 41 to 45 from tables 36 to 40 include the following:

- A lack of a range of cost-sharing limits considered under Alternative 1 for Cost Plans (as they are not subject to setting one of three MOOP types as MA plans are) instead, the lowest cost-sharing limit under Alternative 1 is considered for all Cost Plans (as shown in tables 41 and 42).
- The illustrative dollar limits only reflect actuarially equivalent values to the alternative cost-sharing standards, not the baseline standards. This is because the current (baseline) standards derive from § 417.454 and longstanding dollar limits applied to Cost Plans for behavioral health services (as shown in tables 41 to 45).

Tables 46 and 47 specify—by service category—the number and percent of contract year 2023 and 2024 MA plans that: (1) established cost sharing amount(s) exceeding the cost-sharing limit applied to plans with a mandatory MOOP type for that contract year and service category; and (2) switched to a lower or intermediate MOOP type from a mandatory MOOP type in the prior contract year. CMS developed these tables to assess how each alternative may impact the number of MA plans that offer lower MOOP amounts in future contract years. We make this assessment for each alternative based on our evaluation in the narratives of how and to what extent tables 41 and 42 suggest that differentiated behavioral health cost-sharing limits (beginning in contract year 2023 [370]) may have incentivized MA plans to adopt lower MOOP amounts for contract year 2023 and 2024. Corresponding tables for Cost Plans are not applicable under this proposal.

Tables 33, 48, 49, 52 A through C, and 53 (MA plans and enrollees) and tables 34, 50, 51, 54, and 55 (Cost Plans and enrollees) evaluate contract year 2024 plan and enrollee data [371] by behavioral health service category. Specifically—

- Tables 48 and 49 (MA) and tables 50 and 51 (Cost Plans) identify the percent of plans and enrollees with cost sharing amounts that are greater than the cost-sharing limits considered by each alternative.
- Tables 33, 52A through C, and 53 (MA) and tables 34, 54, and 55 (Cost Plans) specify: (1) the weighted average plan cost sharing amount for the plans identified with cost-sharing amounts that are greater than the cost-sharing limits considered by each alternative; and (2) the difference between those weighted average plan cost sharing amounts and the cost-sharing standards posed by each alternative.

In essence, tables 33, 47,48, 52A through C, and 53 (MA plans and

[370] As discussed in the April 2022 final rule, most professional cost-sharing standards were the same for all MOOP types before contract year 2023. The cost-sharing standards established by the April 2022 final rule created differentiated professional and inpatient hospital cost-sharing limits (including for some behavioral health service categories) by MOOP type beginning in contract year 2023 to encourage plans to adopt lower MOOP amounts.

[371] Contract year 2024 plan weighted average cost sharing values reflect maximum cost sharing for each behavioral health service category (including plans with copayment and coinsurance percentages). Specifically, plan coinsurance values were converted into equivalent copayment dollar amounts and vice versa to calculate a weighted average coinsurance and copayment value for each category that reflects all cost sharing designs. These plan cost sharing conversions were based on the OACT's contract year 2025 projected total Medicare FFS allowed amount for each professional service category. This approach allows for a consistent comparison between plan cost sharing amounts and the potential cost-sharing standard that could apply if a particular alternative was finalized. As a result, contract year 2024 plan weighted average cost sharing values consistently reflect dollar values that are normalized based on the same and most recent data available, contract year 2025 Medicare FFS projections. The OACT developed the contract year 2025 projected total Medicare FFS allowed amounts using 2022 Medicare FFS cost and utilization data and their projections of cost changes between 2022 to 2025. The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)).

enrollees) and tables 34, 50, 51, 54, and 55 (Cost Plans and enrollees) approximate the: (1) proportion of plans that may lower cost sharing; (2) proportion of enrollees that may be in those plans and experience that lower cost sharing; and (3) weighted average reduction in plan cost sharing that may occur for each behavioral health service category (as possible) and alternative. As a result, in the narratives in section VII.E.3.d. of this proposed rule, we consider the information in these tables to reflect an estimate of each alternative's potential impact on MA and Cost Plans and enrollees based on the most recent Medicare FFS and plan data available.

d. Alternatives Considered for Behavioral Health Service Category Cost-Sharing Limits

In this section CMS summarizes the MA and Cost Plan cost-sharing standards considered by each alternative, evaluates the potential and definitive consequences of each alternative in comparison to the other alternatives, and provides rationale for our decision to propose the behavioral health cost-sharing standards considered under Alternative 3.

(1) Alternative 1

In this alternative, CMS considered MA behavioral health service category cost-sharing standards for contract year 2026 and future years that would: (1) maintain or increase the amount of cost-sharing incentive MA plans have to offer lower MOOP types; and (2) result in lower behavioral health cost-sharing limits for all MOOP types in comparison to the limits that would apply based on the existing cost-sharing standards in current regulations. As discussed in the April 2022 final rule, CMS set a transition to a range of cost-sharing limits for professional services proportionate to each MOOP type by contract year 2026 to incentivize MA organizations to offer plans with lower MOOP amounts. This alternative takes a similar approach by applying behavioral health service category cost-sharing standards that are unique to each MOOP type, with the lower MOOP types retaining the most cost-sharing flexibilities. To apply this alternative to Cost Plans (which lack MOOP types), we considered applying the lowest cost-sharing standard that was considered for MA plans (those with a mandatory MOOP type).

(a) Specific Cost-Sharing Standards Considered

This alternative considers the following MA cost-sharing standards for the professional behavioral health service categories (mental health specialty services, psychiatric services, partial hospitalization, outpatient substance use disorder services, and opioid treatment program services):

- *Lower MOOP Type:* Cost sharing no greater than Traditional Medicare (which is 20 percent coinsurance or an actuarially equivalent copayment, except for the ''opioid treatment program services'' service category which has no cost sharing in Traditional Medicare).
- *Intermediate MOOP Type:* 15 percent coinsurance (or an actuarially equivalent copayment).
- *Mandatory MOOP Type:* 10 percent coinsurance (or an actuarially equivalent copayment).

The 10 percent coinsurance (or an actuarially equivalent copayment) would apply to all Cost Plans for the same professional behavioral health service categories under this alternative. In addition, this alternative considers setting the ''inpatient hospital psychiatric services'' service category dollar limits (all length of stay scenarios) for MA plans based on the following:

- *Lower MOOP Type:* Cost sharing no greater than Traditional Medicare (100 percent of estimated Medicare FFS cost sharing).
- *Intermediate MOOP Type:* the numeric midpoint between the cost-sharing limits set for the lower and mandatory MOOP types (continuing current policy [372]).
- *Mandatory MOOP Type:* 50% of estimated Medicare FFS cost sharing.

The 50 percent estimated Medicare FFS cost sharing amount for MA plans with a mandatory MOOP type would also apply to all Cost Plans for the same ''inpatient hospital psychiatric services'' service categories under this alternative.

As a result, this alternative results in: (1) proportionate cost-sharing limits for each MOOP type for MA plans; and (2) meaningful decreases to the existing behavioral health cost-sharing standards in current regulations for contract year 2026 and future years (which in some cases go up to 50 percent coinsurance or an actuarially equivalent copayment) for MA and Cost Plans. For example, the professional behavioral health MA cost-sharing standards consistently decrease by a coinsurance increment of 5 percent between MOOP types (with the mandatory MOOP type receiving the least cost-sharing flexibility) under this alternative.

(b) Evaluation

In comparison to the existing cost-sharing standards in current regulations and the other alternatives in this section, this alternative considers the lowest behavioral health cost-sharing limits for MA and Cost Plans (with one exception for the opioid treatment program service category where alternative 3 results in a lower, zero-dollar cost-sharing requirement as shown in tables 39 and G18). For example, as shown in table 36 for MA plans, this alternative results in a $25 copayment limit for the ''mental health specialty services'' service category. This is $10 to $45 less than the copayment limits that would result for that service category and MOOP type if the existing MA cost-sharing standards or other alternatives were used. As another example, as shown in table 38 for MA plans, this alternative decreases the dollar limit for the 15-day length of stay scenario of the ''inpatient hospital psychiatric services'' service category and intermediate MOOP type by $826 in comparison to the current regulatory MA cost-sharing standard. This is the most significant decrease because alternatives 2 and 3 reflect decreases from the current regulatory MA cost-sharing standard of only $55 and $275, respectively—for the same service category, length of stay, and MOOP type. Tables 37, 39, and 40 (MA plans) and tables 41 to 43, and 45 (Cost Plans) reflect similar findings for additional behavioral health service categories.

This alternative improves upon the existing cost-sharing incentives for MA plans to offer lower MOOP types because it considers—

- Adding two service categories that have differentiated cost-sharing limits by MOOP type (opioid treatment program services and outpatient hospital substance use disorder services),
- Increasing the value of each inpatient hospital psychiatric services cost-sharing incentive by: (1) lowering all the cost-sharing limits; and (2) increasing the cost-sharing limit differentiation between the MOOP types from a coinsurance increment of 25 to 50 percent; and
- Nominal reductions to the cost-sharing limit differentiation between the MOOP types for the professional service categories from a coinsurance increment of 10 to 5 percent.

[372] While this alternative continues current policy to set the ''inpatient hospital psychiatric services'' service category cost-sharing limits for the intermediate MOOP type, this approach effectively lowers the cost-sharing limits for this MOOP type because the numeric midpoint would reflect a lower value from the changes considered to the cost-sharing standards for the mandatory and lower MOOP types.

In contrast, the other alternatives consider cost-sharing standards that apply to all MOOP types equally and thus do not retain or improve the existing behavioral health cost-sharing incentives for MA plans to establish lower MOOP amounts.

Despite these improvements to the cost-sharing incentives, CMS believes this alternative would not result in substantially more MA plans choosing to establish lower MOOP amounts in future contract years in comparison to the effects that alternative 2 and 3 might pose. This is because, as supported by tables 41 and 42, the driving force for MA plans to switch to lower MOOP types in contract year 2023 and 2024 seems to be the ability to utilize cost-sharing flexibilities for emergency services. For example, as shown in table 41, of the MA plans that switched from a mandatory MOOP type to a lower or intermediate MOOP type in contract year 2024, the percent of plans that utilized [373] cost-sharing flexibilities was about—:

- *86 percent:* emergency services;
- *39 percent:* partial hospitalization;
- *20 percent:* skilled nursing facility—first 20 days;
- *19 percent:* inpatient hospital psychiatric—8-day length of stay scenario;
- *12 percent:* urgently needed services; and
- Less than percent for all other service categories.

CMS takes these percentages [374] of utilization as evidence that the cost-sharing flexibilities for emergency services and other non-behavioral health service categories may, by themselves, offer sufficient incentive for a similar proportion of MA plans to offer lower MOOP types in future years.

Based on tables 33, 48, 49, 52, and 53, CMS expects this alternative, in comparison to the potential effects from the other alternatives, would result in: (1) the most MA plans and enrollees experiencing lower behavioral health cost sharing than prior contract years; and (2) the greatest decreases in plan cost sharing for most behavioral health service categories. For example, based on contract year 2024 MA plan data and the cost-sharing standards posed by this alternative, we estimate that—for the ''psychiatric services'' service category—of MA plans that continue in contract year 2026 and maintain a mandatory MOOP type are as follows:

- About 48 percent of plans would have to reduce their cost sharing (as shown in table 48).
- About 45 percent of enrollees could experience this reduction in cost sharing (as shown in table 49).
- The enrollees in those plans could experience a reduction in cost sharing—on average—of about $19 per visit (as shown in table 52C, from about $34 to $15 per visit).

In comparison, as shown in tables 33, 48, 49, and 53, the cost-sharing limits considered in alternatives 2 and 3 for this service category may impact fewer MA plans and enrollees and require less significant cost sharing decreases based on contract year 2024 plan data. Specifically, for the ''psychiatric services'' service category, we estimate that in response to alternative 2 and 3 that of MA plans that continue in contract year 2026:

- Less than 1 percent and about 25 percent of plans would have to reduce their cost sharing, respectively (as shown in table 48).
- About 1 percent and 22 percent of enrollees could experience this reduction in cost sharing, respectively (as shown in table 49).
- The enrollees in those plans could experience a reduction in cost sharing—on average—of about $10 per visit for alternative 2 (as shown in table 53) or about $7 per visit for alternative 3 (as shown in table 33).

Based on tables 34, 50, 51, 54, and 55, CMS also expects this alternative, in comparison to the potential effects from the other alternatives, would result in the most Cost Plans and enrollees experiencing: (1) lower behavioral health cost sharing than prior contract years; and (2) greater decreases in plan cost sharing for most behavioral health service categories. For example, based on contract year 2024 Cost Plan data and the cost-sharing standards posed by this alternative, we estimate that—for the ''mental health specialty services'' service category—of Cost Plans that continue in contract year 2026:

- About 20 percent of plans would have to reduce their cost sharing (as shown in table 50).
- About 13 percent of enrollees could experience this reduction in cost sharing (as shown in table 51).
- The enrollees in those plans could experience a reduction in cost sharing—on average—of about $17 per visit (as shown in table 54, from about $32 to $15 per visit).

In comparison, as shown in tables 34, 50, 51, and 55, the cost-sharing limits considered in alternatives 2 and 3 for this service category may impact fewer Cost Plans and enrollees and require less significant cost sharing decreases based on contract year 2024 plan data. Specifically, for the ''mental health specialty services'' service category, we estimate that in response to alternative 2 and 3 that of Cost Plans that continue in contract year 2026:

- 0 percent and about 8 percent of plans would have to reduce their cost sharing, respectively (as shown in table 50).
- 0 percent and about 3 percent of enrollees could experience this reduction in cost sharing, respectively (as shown in table 51).
- The enrollees in those plans could experience a reduction in cost sharing—on average—of about $0 per visit for alternative 2 (as shown in table 55) or about $5 per visit for alternative 3 (as shown in table 34).

Given the information in tables 33, 48, 49, 52, and 53 (MA plans) and tables 34, 50, 51, 54, and 55 (Cost Plans), this alternative (in comparison to the other alternatives in this section) has the most potential to improve the affordability of behavioral health services for enrollees. However, CMS believes this potential could pose significant disruption to MA plans' bidding process. This is because, the contract year 2024 plan data findings in these tables suggest that most continuing plans would have to significantly change their benefit designs to come into compliance with the cost-sharing standards posed by this alternative. We are also concerned that setting behavioral health service category cost-sharing limits for multiple MOOP types at amounts that are less than the cost sharing in Traditional Medicare for those benefits would impact an MA plan's ability to meet all other cost-sharing requirements (including overall bid actuarial equivalence to Traditional Medicare, as discussed in section III.L. of this proposed rule). In combination, this alternative could result in a proportion of MA and Cost Plans leaving the market.

(c) CMS Decision

We reject this alternative because CMS has concerns about whether this alternative would pose disruption significant enough to possibly cause MA and Cost Plan exits to the detriment of the overall market.

(2) Alternative 2

In this alternative, CMS considered proposing behavioral health cost-

[373] As discussed in section VII.E.3.c. of this proposed rule, in this context utilizing a cost sharing flexibility means the plan established a cost sharing amount for a service category that is greater than the applicable cost-sharing limit set for the mandatory MOOP type.

[374] The number and percentage of plans that utilized each service category cost sharing flexibility do not total to 100% as most plans that switched utilized cost-sharing flexibilities from multiple service categories.

sharing standards that would: (1) be less likely to result in MA and Cost Plans exiting the market in comparison to alternative 1 (by considering limits greater than those considered by alternative 1); and (2) still represent a decrease in comparison to the existing contract year 2026 and future year behavioral health cost-sharing standards in current regulations.

(a) Specific Cost-Sharing Standards Considered

Specifically, CMS considered the following behavioral health service category cost sharing limits for all MA and Cost Plans under this alternative:

- 30 percent coinsurance or actuarially equivalent copayment for mental health specialty services, psychiatric services, partial hospitalization, opioid treatment program services, and outpatient hospital substance use disorder services.
- 110 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, to set the cost sharing dollar limits for each inpatient hospital psychiatric length of stay scenario.

These values (30 percent coinsurance and 110 percent of estimated Medicare FFS cost sharing) are lower than the existing contract year 2026 and future year behavioral health cost-sharing regulatory requirements for both MA plans (with lower and intermediate MOOP types) and Cost Plans.[375] However, for MA plans with a mandatory MOOP type compared to current regulations this alternative results in: (1) increases to the inpatient hospital psychiatric dollar limits (all length of stay scenarios); (2) a reduction in cost sharing from 50 percent coinsurance to 30 percent coinsurance for opioid treatment program services and outpatient hospital substance use disorder services; and (3) no change to the cost-sharing standards for the other three service categories.[376] This is because this alternative considers cost-sharing standards that are greater than alternative 1 (which went up to 100 percent of estimated Medicare FFS cost sharing to set the inpatient hospital psychiatric service category dollar limits and up to 20 percent for the other behavioral health service categories for the lower MOOP type).

(b) Evaluation

In most cases, this alternative considers the smallest decreases from the behavioral health service category cost-sharing limits that exist in the current regulations for MA and Cost Plans. For example, as shown in table 37 for MA plans, this alternative results in a $90 copayment limit for the partial hospitalization service category (all MOOP types) which is $0 to $60 less than the copayment limits that would result for that service category (depending on MOOP type) if the existing cost-sharing standards were used. In comparison, alternative 1 would result in copayment limits ranging from $30 to $60 depending on MOOP type and alternative 3 would result in a $60 copayment limit for the same service category (all MOOP types). Using another example from table 40 (for MA plans), the $45 copayment limit for the ''outpatient substance use disorder services'' service category posed by this alternative reflects a decrease of $30 from the current regulatory cost-sharing standard ($75, all MOOP types). In comparison, the copayment limits resulting from alternatives 1 and 3 ($15 to $30, depending on MOOP type and $30 all MOOP types, respectively) reflect more significant decreases from the current regulatory cost-sharing standard for the same service category (decreases between $60 to $45, depending on MOOP type and $45 all MOOP types, respectively). Tables 36 and 39 (MA plans) and tables 43 to 45 (Cost Plans) reflect similar findings for additional service categories.

In contrast, table 38 highlights a case where this alternative would result in an increase to the existing inpatient hospital psychiatric cost-sharing standards in current regulations for MA plans. For example, as shown in table 38, this alternative would increase the percent of estimated Medicare FFS cost sharing that determines the dollar limits for the 15-day length of stay scenario of the ''inpatient hospital psychiatric services'' service category for an MA plan that establishes a mandatory MOOP amount from 100 percent (or a $2,204 dollar limit based on the current regulations at § 422.100(f)(6)(iv)) to 110 percent or $2,424. As shown in table 38 for the same length of stay scenario and MOOP type, alternative 1 would lower the percent of estimated Medicare FFS cost sharing to 50 percent or $1,102 and alternative 3 would retain the current regulatory standard of 100 percent estimated Medicare FFS cost sharing or $2,204. As a result, tables 36 to 40 show that this alternative would create some decreases and increases to the behavioral health service category cost-sharing limits (depending on the MA plan's MOOP type) in comparison to the existing contract year 2026 and future year MA cost-sharing standards in current regulations.

While this alternative applies cost-sharing limits consistently across all MOOP types, we expect this alternative would not substantially impact the number of MA plans switching to lower MOOP types in future years for multiple reasons. First, as discussed in relation to alternative 1 in this section, tables 46 and 47 show that most MA plans that switched from a mandatory MOOP type to lower MOOP types in contract year 2023 and 2024 did not utilize the behavioral health cost-sharing flexibilities available to them. Second, the most utilized cost-sharing flexibility by the plans that switched to lower MOOP types in those contract years—emergency services—would not be impacted by this alternative and increasing flexibility in the dollar limits for this category in future years are memorialized in § 422.113(b)(2)(v). As a result, we expect the emergency services cost-sharing flexibility will continue to be a significant incentive for MA plans to consider switching to lower MOOP types. Thirdly, we believe other factors such as principles and incentives inherent in managed care, effective negotiations between MA organizations and providers, and competition are considered by MA organizations when making determinations for their plan's design, including MOOP type. As a result, we do not believe the potential concern about this alternative adversely impacting the number of plans offering lower MOOP amounts in future years is as significant as it might otherwise be.

Tables 48 and 49 show that less than 5 percent of MA plans and enrollees would have lower cost sharing for the majority of the behavioral health service categories if this alternative was selected based on the cost sharing amounts plans established for contract year 2024. For example, based on contract year 2024 MA plan data and the cost-sharing standards posed by this alternative, we estimate that—for the partial hospitalization service category—of MA plans that continue in contract year 2026:

[375] The existing contract year 2026 and future years inpatient hospital psychiatric cost-sharing limit for MA plans with an intermediate MOOP type in current regulations is based on the numeric midpoint of the dollar limits set for the lower and mandatory MOOP types for each length of stay scenario. In assessing the midpoint of the methodology to set the dollar limits for the lower and mandatory MOOP types we note this is approximately 112.5% of estimated Medicare FFS cost sharing and above the 110% value posed under this alternative.

[376] The existing contract year 2026 and future years inpatient hospital psychiatric cost-sharing limit for the mandatory MOOP type in current regulations is based on 100% of estimated Medicare FFS cost sharing while this alternative calculates dollar limits for all MOOP types using 110% of estimated Medicare FFS cost sharing.

• About 3 percent of plans would have to reduce their cost sharing (as shown in table 48).
• About 3 percent of enrollees could experience this reduction in cost sharing (as shown in table 49).
• The enrollees in those plans could experience a reduction in cost sharing—on average—of about $10 per day (as shown in table 53, from $100 to $90).

As shown in tables 33, 48, 49, and 52, the cost-sharing limits considered in alternatives 1 and 3 for this service category may impact substantially more MA plans and enrollees and require more substantive cost sharing decreases based on contract year 2024 MA plan data. Specifically, for the partial hospitalization service category, we estimate that in response to alternative 1 and 3 that of MA plans that continue in contract year 2026 are as follows:
• About 59 percent and 23 percent of plans would have to reduce their cost sharing, respectively (as shown in table 48).
• About 50 percent and 16 percent of enrollees could experience this reduction in cost sharing, respectively (as shown in table 49).
• The enrollees in those plans could experience a reduction in cost sharing—on average—between $17 and $35 (depending on their plan's MOOP type for alternative 1 as shown in tables 52A through 52C) or $21 for alternative 3 (as shown in table 33).

A similar comparison can be made for Cost Plans. Tables 41 and 42 show that 0 percent of Cost Plans and enrollees would have lower cost sharing for all of the behavioral health service categories if this alternative was selected based on the cost sharing amounts plans established for contract year 2024. In contrast, as shown in tables 34, 50, 51, and 54, the cost-sharing limits considered in alternatives 1 and 3 for this service category may impact substantially more Cost Plans and enrollees and require more substantive cost sharing decreases based on contract year 2024 Cost Plan data. For example, for the ''outpatient substance use disorder services'' service category, we estimate that in response to alternative 1 and 3 that of Cost Plans that continue in contract year 2026 are as follows:
• About 20 percent and 5 percent of plans would have to reduce their cost sharing, respectively (as shown in table 50).
• About 13 percent and 1 percent of enrollees could experience this reduction in cost sharing, respectively (as shown in table 51).
• The enrollees in those plans could experience a reduction in cost sharing—on average—of $15 (for alternative 1 as shown in table 54) or $10 for alternative 3 (as shown in table 34). Based on our evaluation of tables 33, 48, 49, 52, and 53 (MA plans) and tables 34, 50, –51, 54, and –55 (Cost Plans), CMS expects this alternative: (1) would result in nominal decreases to plan cost sharing for most behavioral health cost sharing services for a small proportion of plans and enrollees; and (2) has the least potential to improve the affordability of behavioral health services for enrollees in comparison to the other alternatives.

(c) CMS Decision

We reject this alternative to apply another approach that would better address the potential financial barriers enrollees may face to access equitable and high-quality behavioral health services while still minimizing the potential for MA plans' exits to the overall detriment of the market.

(3) Alternative 3 (Proposed)

In this alternative and proposed approach, CMS considered behavioral health cost-sharing standards that would—
• Be more likely to result in a greater proportion of enrollees experiencing lower behavioral health cost sharing than alternative 2 (based on contract year 2024 plan data); and
• Not be as significantly different as alternative 1 in comparison to: (1) the existing cost-sharing standards in current regulations for contract year 2026 and future years; and (2) plan cost sharing amounts based on the contract year 2024 weighted average plan cost sharing of plans with cost sharing amounts above the standards considered for the behavioral health service categories.

In essence, this proposed alternative aims to strike a better balance in comparison to alternative 1 and 2 between: (1) improving the affordability of behavioral health services for enrollees in a timely manner; and (2) minimizing disruption to MA and Cost Plan enrollees' access to care and coverage options.

(a) Specific Cost-Sharing Standards Considered

This alternative (proposal) considers adding categories of behavioral health services to the list of services at §§ 417.454(e) and § 422.100(j)(1) for which Cost Plans and MA plans (including EGWPs) in-network cost sharing must be no greater than that in Traditional Medicare. Specifically, the following Traditional Medicare cost sharing amounts would apply as a cost-sharing limit to all MA and Cost Plans under this alternative:
• 20 percent coinsurance or actuarially equivalent copayment for mental health specialty services, psychiatric services, partial hospitalization, opioid treatment program services, and outpatient hospital substance use disorder services.
• 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, to set the cost-sharing dollar limits for each inpatient hospital psychiatric length of stay scenario.
• Zero cost sharing for the ''opioid treatment program services'' service category.

This proposed alternative results in cost-sharing limits that are lower than the existing cost-sharing limits for contract year 2026 and future years in the current regulations for all service categories and MA MOOP types (with one exception). The exception is that continuing MA plans with a mandatory MOOP type would retain a cost-sharing limit equal to cost sharing under Traditional Medicare for inpatient hospital psychiatric services (all length of stay scenarios) and experience no changes if this proposed alternative is finalized. However, if this proposal is finalized and Traditional Medicare changes the cost sharing amount for one of the behavioral health service categories subject to § 417.454(e) or § 422.100(j)(1), the new Traditional Medicare cost sharing amount would apply as the limit for that category.

(b) Evaluation

This alternative considers—with a few exceptions—behavioral health cost-sharing limits that are: (1) less than the existing cost-sharing standards for contract year 2026 and future years and the standards considered by alternative 2; and (2) greater than the standards considered by alternative 1. Specifically, applying either this alternative or alternative 1 result in the same cost-sharing limits for MA plans with the lower MOOP type in the ''mental health specialty services'', partial hospitalization, ''inpatient hospital psychiatric services'', and ''outpatient substance use disorder services'' service categories. However, as shown in tables 27 to 31, the differences between this alternative and alternative 1 are substantive for MA plans with one of the other MOOP types. For example, as shown in table 36 (MA plans), this alternative results in a $35 copayment limit for the ''mental health specialty services'' service category—a decrease of $15 to $50 (depending on the MA plan's MOOP type) in comparison to the copayment limits that would result for that service

category if the existing cost-sharing standards were used ($85 to $50). In contrast, the copayment limits for this service category resulting from alternatives 1 and 2 are $35 to $15 (depending on the MA plan's MOOP type) and $50, respectively. As a result, this alternative results in a copayment limit for the ''mental health specialty services service category'' that is: (1) less than the existing cost-sharing standards in current regulations and the standards considered by alternative 2 for all MA MOOP types; and (2) greater than the standards considered by alternative 1—excluding the lower MOOP type (where the standards are equivalent). In addition, as shown in tables 41 to 45, this alternative results in cost-sharing standards for Cost Plans that are greater than the standards considered by alternative 1 for all behavioral health service categories—excluding opioid treatment program services.

As shown in tables 38 and 43, this alternative results in a dollar limit of $2,204 for the 15-day length of stay scenario of the ''inpatient hospital psychiatric services'' service category (for MA and Cost Plans). In comparison, the dollar limits that would result for this service category and length of stay scenario using the existing cost-sharing standards or alternative 1 or 2 are: $2,204 to $2,755 (depending on MOOP type or $2,204 for Cost Plans), $1,102 to $2,204 (depending on MOOP type or $1,102 for Cost Plans), and $2,424 (MA and Cost Plans), respectively. As a result, this alternative results in a dollar limit for the 15-day length of stay scenario of the ''inpatient hospital psychiatric services'' service category that is: (1) less than the existing MA cost-sharing standards in current regulations—excluding the mandatory MOOP type (where the standards are equivalent); (2) different from the longstanding 50 percent coinsurance (or actuarially equivalent copayment) standard applied to Cost Plans; (3) less than the standard considered by alternative 2 for MA and Cost Plans; and (4) greater than the standards considered by alternative 1—excluding the lower MOOP type (where the standards are equivalent).

Based on tables 36 through 38 and 40 (MA plans) and tables 41 through 43 and 45, this alternative does not pose as significant a decrease from the existing contract year 2026 and future year behavioral health cost-sharing regulatory requirements as alternative 1 (which considered, at the lowest, cost-sharing limits of 10 percent coinsurance for the professional behavioral health service categories and 50 percent of estimated Medicare FFS cost sharing for inpatient hospital psychiatric services for the mandatory MOOP type). The exception to this finding is for the ''opioid treatment program services'' service category. As shown in tables 39 and 44, this alternative presents the most substantial decrease from the existing cost-sharing standards for the ''opioid treatment program services'' service category cost-sharing limit in comparison to the other alternatives. Specifically, based on the current regulations for contract year 2026 and future years, this alternative would lower the ''opioid treatment program services'' service category cost-sharing limit from 50 percent coinsurance (or a $155 actuarially equivalent copayment limit for all MA plans) to zero cost sharing. In contrast, for the same service category, the other alternatives would result in the following:

- *MA plans:* alternative 1 would lower the cost-sharing limit to 20 percent coinsurance (or $60) to 10 percent coinsurance (or $30), depending on MOOP type, and alternative 2 would lower it to 30 percent coinsurance or $95.
- *Cost Plans:* alternative 1 would lower the cost-sharing limit to 10 percent coinsurance (or $30) and alternative 2 would lower it to 30% coinsurance or $95.

While this decrease is substantial in comparison to the other alternatives, research finds that patients with severe alcohol and other drug problems report completing only two serious recovery attempts (median) before remission.[377] In addition, a study shows that every dollar spent on substance use disorder treatment saves $4 in health care costs.[378] As a result, CMS believes that the cost liability to cover opioid treatment program services with zero cost sharing is not as much of a concern as it otherwise would be for a highly utilized service (such as physical therapy) and applying zero cost sharing could have a significant positive impact on enrollees' ability to access those services. We also note the illustrative dollar limits for the behavioral health service categories in tables 36 to 45 are similar to cost sharing for these services in qualified health plans (QHPs) in the marketplace. For example, QHPs are required to offer standardized options for 2024 with set copayments for mental health and substance use disorder outpatient office visits that range between $0 and $50 based on the plan level (for example, bronze or silver).[379]

Similar to alternative 2, this alternative does not retain or improve the existing cost-sharing incentives for MA plans to establish lower MOOP amounts because the proposed behavioral health cost-sharing standards would apply equally to all MOOP types. However, as discussed in detail in section VII.E.3.d.(2). of this proposed rule, we believe the cost-sharing standards considered by alternative 2 or this proposal will not significantly affect the number of plans choosing to offer lower MOOP amounts in future years. Our primary rationale for this belief is because, as supported by tables 46 and 47, the driving factor for contract year 2023 and 2024 plans to switch to lower MOOP types seems to focus on the ability to access cost-sharing flexibilities for emergency services more so than any other service category.

The percent of contract year 2024 MA plans and enrollees that have higher behavioral health service category cost sharing compared to this alternative is shown in tables 48 and 49. In summary, we note the following:

- Less than 5 percent of MA plans and enrollees have cost sharing that is greater than this proposal for the inpatient hospital psychiatric service category (including all length of stay scenarios).
- About a quarter of MA plans (23 to 25 percent), representing between 16 and 22 percent of enrollees, have cost sharing greater than this alternative for most of the professional health service categories (mental health specialty services, psychiatric services, partial hospitalization), depending on the specific service category.
- About half of MA plans and enrollees (42 and 41 percent, respectively), have cost sharing greater than this proposal for outpatient substance use disorder services.
- Most MA plans (71 percent), representing approximately 62 percent

[377] Kelly JF, Greene MC, Bergman BG, White WL, Hoeppner BB. How Many Recovery Attempts Does it Take to Successfully Resolve an Alcohol or Drug Problem? Estimates and Correlates From a National Study of Recovering U.S. Adults. Alcohol Clin Exp Res. 2019 Jul;43(7):1533–1544. doi: 10.1111/acer.14067. Epub 2019 May 15. PMID: 31090945; PMCID: PMC6602820.

[378] Substance Abuse and Mental Health Services Administration (US); Office of the Surgeon General (US). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health [internet]. Washington (DC): US Department of Health and Human Services; 2016 Nov. CHAPTER 7, VISION FOR THE FUTURE: A PUBLIC HEALTH APPROACH. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK424861/.*

[379] See table 9 and 10 on page 25850 and 25851 from, ''Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024'' final rule published April 27, 2023. Retrieved from: *https://www.federalregister.gov/documents/2023/04/27/2023-08368/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2024.*

of enrollees, have cost sharing that is greater than this alternative for the ''opioid treatment program services'' service category.

In comparison, as shown in tables 48 and 49—for most behavioral health service categories—over 40 percent of MA plans and enrollees have cost sharing amounts greater than alternative 1 and less than 5 percent of MA plans and enrollees have cost sharing amounts greater than alternative 2.

The percent of contract year 2024 Cost Plans and enrollees that have higher behavioral health service category cost sharing compared to this alternative (proposal) is shown in tables 50 and 51. In summary, we note the following:

- No Cost Plans have cost sharing greater than this alternative for partial hospitalization.
- Approximately 8 percent of plans, representing about 3 percent of enrollees, have cost sharing greater than this alternative for mental health specialty services.
- About 13 percent of plans and enrollees, have cost sharing greater than this proposal for psychiatric services.
- Fifty percent of plans, representing approximately 61percent of enrollees, have cost sharing that is greater than this alternative for the ''opioid treatment program services'' service category.

In comparison, as shown in tables 50 and 51—for most behavioral health service categories—over 12 percent of plans and enrollees have cost sharing amounts greater than alternative 1 and no plans or enrollees have cost sharing amounts greater than alternative 2.

Table 33 demonstrates that this alternative may require plans to reduce cost sharing by nominal and more substantive amounts based on the service category, with one exception. This exception is that CMS does not expect MA plans would have to reduce cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario because, as shown in table 39, no contract year 2024 plans established cost sharing for this category that is greater than this alternative's limit. For example, based on contract year 2024 MA plan data and the cost-sharing standards posed by this alternative, we estimate that—for the ''outpatient substance use disorder services'' service category—of MA plans that continue in contract year 2026:

- About 42 percent of plans would have to reduce their cost sharing (as shown in table 48).
- About 41 percent of enrollees could experience this reduction in cost sharing (as shown in table 49).
- The enrollees in those plans could experience a reduction in cost sharing—on average—of about $30 per day (as shown in table 33, from $60 to $30).

In comparison, as shown in tables 48, 49, 52A through 52C, and 53 for the same service category, we estimate that in response to alternative 1 and 2 that of MA plans that continue in contract year 2026:

- About 68 percent and 13 percent of plans would have to reduce their cost sharing, respectively (table 48).
- About 64 percent and 17 percent of enrollees could experience this reduction in cost sharing, respectively (table 49).
- The enrollees in those plans could experience a reduction in cost sharing—on average—between $22 and $38 per day (depending on their plan's MOOP type for alternative 1 as shown in tables 52A through 52C) or $44 per day for alternative 2 (as shown in table 53).

Based on our evaluation of tables 33 through 34 and tables 48 through 55, this alternative results in a more substantial proportion of MA and Cost Plan enrollees likely having lower behavioral health cost sharing in comparison to alternative 2 while not proposing such significant changes as to be more likely to disrupt coverage options in comparison to alternative 1. For example, CMS does not expect a majority of MA or Cost Plans would have to decrease their cost sharing amounts by a significant amount for most of the behavioral health service categories if this alternative/proposal is finalized. As a result, we expect these cost sharing changes would not directly result in a significant number of plans leaving the market and reducing coverage options for Medicare-eligible beneficiaries.

(c) CMS Decision

After considering alternatives 1 through 3, we chose to propose applying cost sharing no greater than Traditional Medicare for the behavioral health service categories (alternative 3) as the cost-sharing standard for MA and Cost Plans beginning in contract year 2026. CMS's goal, as indicated in the introduction of this section, is to propose a cost-sharing standard that strikes a balance between: (1) improving the affordability of behavioral health services for enrollees in a timely manner; and (2) minimizing disruption to MA enrollees access to care and coverage options. For the reasons discussed in this section and section III.L. of this proposed rule, we believe this alternative best strikes this balance.

e. Summary Tables

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TABLE 36: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 MA "MENTAL HEALTH SPECIALTY SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Lower	Intermediate	Mandatory
Baseline: Contract year 2026 and future year cost-sharing limits	50% / $85.00	40% / $70.00	30% / $50.00
Alternative I: Apply unique cost-sharing limits based on MOOP type	20% / $35.00	15% / $25.00	10% / $15.00
Alternative 2: Apply a 30% coinsurance limit to all MOOP types	30% / $50.00	30% / $50.00	30% / $50.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare for all MOOP types	20% / $35.00	20% / $35.00	20% / $35.00

[1]Baseline cost-sharing limits include: (1) existing regulatory coinsurance limits for contract year 2026 and future years in current § 422.100(f)(6)(iii)(F) and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to the coinsurance limits in current paragraph (f)(6)(iii)(F) based on contract year 2025 Medicare FFS data projections.

[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).

TABLE 37: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 MA PARTIAL HOSPITALIZATION SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Lower	Intermediate	Mandatory
Baseline: Contract year 2026 and future year cost-sharing limits	50% / $150.00	40% / $120.00	30% / $90.00
Alternative I: Apply unique cost-sharing limits based on MOOP type	20% / $60.00	15% / $45.00	10% / $30.00
Alternative 2: Apply a 30% coinsurance limit to all MOOP types	30% / $90.00	30% / $90.00	30% / $90.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare for all MOOP types	20% / $60.00	20% / $60.00	20% / $60.00

[1]Baseline cost-sharing limits include: (1) existing regulatory coinsurance limits for contract year 2026 and future years at § 422.100(f)(6)(iii)(F) and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to the coinsurance limits in paragraph (f)(6)(iii)(F) based on contract year 2025 Medicare FFS data projections.

[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3) of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).

TABLE 38: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 MA "INPATIENT HOSPITAL PSYCHIATRIC SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3] FOR THE 15-DAY LENGTH OF STAY SCENARIO

Description	Lower	Intermediate	Mandatory
Baseline: Contract year 2026 and future year cost-sharing limits (a range of actuarially equivalent dollar limits that are equivalent to 100% or up to 125% of estimated Medicare FFS cost sharing, or the numeric midpoint between those two amounts – based on MOOP type)	125%; $2,755.00	Numeric Midpoint[4]; $2,479.00	100%; $2,204.00
Alternative I: Apply a range of actuarially equivalent dollar limits (equivalent to 50% or up to 100% of estimated Medicare FFS cost sharing, or the numeric midpoint between those two amounts) based on MOOP type	100%; $2,204.00	Numeric Midpoint[4]; $1,653.00	50%; $1,102.00
Alternative 2: Apply a dollar limit that is actuarially equivalent to 110% of estimated Medicare FFS cost sharing for all MOOP types	110%; $2,424.00	110%; $2,424.00	110%; $2,424.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare for all MOOP types (an actuarially equivalent dollar limit to 100% of estimated Medicare FFS cost sharing)	100%; $2,204.00	100%; $2,204.00	100%; $2,204.00

[1]Baseline cost-sharing limits include: (1) percentages of estimated Medicare FFS cost sharing from existing regulatory cost-sharing standards for contract year 2023 and future years at § 422.100(f)(6)(iv) and (2) illustrative dollar limits that reflect actuarially equivalent dollar values to the percentages of estimated Medicare FFS cost sharing from paragraph (f)(6)(iv) based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[2]Alternative 1 - 3 cost-sharing limits include: (1) percentages of estimated Medicare FFS cost sharing described in each alternative in sections VII.E.3.d.(1). through (3) of this proposed rule and (2) illustrative dollar limits that reflect actuarially equivalent dollar values to those percentages of estimated Medicare FFS cost sharing based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[3]All MA plans are required to establish cost sharing that does not exceed the plan's MOOP limit or overall cost sharing for inpatient benefits in Traditional Medicare on a per member per month actuarially equivalent basis. In addition, the specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, the projected Part A deductible and Part B professional costs) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).

[4]The numeric midpoint is based on the cost-sharing limits (before rounding rules applied) of the mandatory and lower MOOP types for the same service category and length of stay.

TABLE 39: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 MA "OPIOID TREATMENT PROGRAM SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Lower	Intermediate	Mandatory
Baseline: Contract year 2026 and future year cost-sharing limits	50% / $155.00	50% / $155.00	50% / $155.00
Alternative I: Apply unique cost-sharing limits based on MOOP type	20% / $60.00	15% / $45.00	10% / $30.00
Alternative 2: Apply a 30% coinsurance limit for all MOOP types	30% / $95.00	30% / $95.00	30% / $95.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare for all MOOP types	0% / $0.00	0% / $0.00	0% / $0.00

[1]Baseline cost-sharing limits include: (1) the existing regulatory 50 percent coinsurance cap for contract year 2023 and future years at § 422.100(f)(6)(i) and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to 50 percent coinsurance from paragraph (f)(6)(i) based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).

ABLE 40: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 MA "OUTPATIENT SUBSTANCE USE DISORDER SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Lower	Intermediate	Mandatory
Baseline: Contract year 2026 and future year cost-sharing limits	50% / $75.00	50% / $75.00	50% / $75.00
Alternative I: Apply unique cost-sharing limits based on MOOP type	20% / $30.00	15% / $20.00	10% / $15.00
Alternative 2: Apply a 30% coinsurance limit for all MOOP types	30% / $45.00	30% / $45.00	30% / $45.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare for all MOOP types	20% / $30.00	20% / $30.00	20% / $30.00

[1]Baseline cost-sharing limits include: (1) the existing regulatory 50 percent coinsurance cap for contract year 2023 and future years at § 422.100(f)(6)(i) and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to 50 percent coinsurance from paragraph (f)(6)(i) based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).

[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).

TABLE 41: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 COST PLAN "MENTAL HEALTH SPECIALTY SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Standard for Cost Plans
Baseline: Contract year 2026 and future year cost-sharing limits[4]	50% / $40.00
Alternative I: Apply a 10% coinsurance limit and actuarially equivalent copayment limit	10% / $15.00
Alternative 2: Apply a 30% coinsurance limit and actuarially equivalent copayment limit	30% / $50.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare	20% / $35.00

[1]Baseline cost-sharing limits include longstanding 50% coinsurance standard and copayment validation.
[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule; and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).
[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative alternative copayment limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).
[4]The amounts in this row reflect longstanding cost sharing PBP data validations applied to Cost Plans. Cost Plans may have requested to establish cost sharing amounts above these values as part of the bid review process.

TABLE 42: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 COST PLAN PARTIAL HOSPITALIZATION SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Standard for Cost Plans
Baseline: Contract year 2026 and future year cost-sharing limits[4]	50% / $55.00
Alternative I: Apply a 10% coinsurance limit and actuarially equivalent copayment limit	10% / $30.00
Alternative 2: Apply a 30% coinsurance limit and actuarially equivalent copayment limit	30% / $90.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare	20% / $60.00

[1]Baseline cost-sharing limits include longstanding 50% coinsurance standard and copayment validation.
[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).
[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative alternative copayment limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).
[4]The amounts in this row reflect longstanding cost sharing PBP data validations applied to Cost Plans. Cost Plans may have requested to establish cost sharing amounts above these values as part of the bid review process.

TABLE 43: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 COST PLAN "INPATIENT HOSPITAL PSYCHIATRIC SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3] FOR THE 15 DAY LENGTH OF STAY SCENARIO

Description	Standard for Cost Plans
Baseline: Contract year 2026 and future year cost-sharing limits[4]	50% or $9,999.99
Alternative I: Apply an actuarially equivalent dollar limit to 50% of estimated Medicare FFS cost sharing	50% / $1,102.00
Alternative 2: Apply an actuarially equivalent dollar limit to 110% of estimated Medicare FFS cost sharing	110% / $2,424.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare (an actuarially equivalent dollar limit to 100% of estimated Medicare FFS cost sharing)	100% / $2,204.00

[1]Baseline cost-sharing limits include longstanding 50% coinsurance standard and dollar validation.
[2]Alternative 1 - 3 cost-sharing limits include: (1) percentages of estimated Medicare FFS cost sharing described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative dollar limits that reflect actuarially equivalent dollar values to those percentages of estimated Medicare FFS cost sharing based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).
[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative dollar limits in this table (such as, the projected Part A deductible and Part B professional costs) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).
[4]The amounts in this row reflect longstanding cost sharing PBP data validations applied to Cost Plans. Cost Plans may have requested to establish cost sharing amounts above these values as part of the bid review process.

TABLE 44: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 COST PLAN "OPIOID TREATMENT PROGRAM SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Standard for Cost Plans
Baseline: Contract year 2026 and future year cost-sharing limits[4]	50% or $9,999.99
Alternative I: Apply a 10% coinsurance limit and actuarially equivalent copayment limit	10% / $30.00
Alternative 2: Apply a 30% coinsurance limit and actuarially equivalent copayment limit	30% / $95.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare	0% / $0.00

[1]Baseline cost-sharing limits include longstanding 50% coinsurance standard and dollar validation.
[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).
[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative alternative copayment limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).
[4]The amounts in this row reflect longstanding cost sharing PBP data validations applied to Cost Plans. Cost Plans may have requested to establish cost sharing amounts above these values as part of the bid review process.

TABLE 45: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1 – 3[2] ILLUSTRATIVE CONTRACT YEAR 2026 COST PLAN "OUTPATIENT SUBSTANCE USE DISORDER SERVICES" SERVICE CATEGORY COST-SHARING LIMITS[3]

Description	Standard for Cost Plans
Baseline: Contract year 2026 and future year cost-sharing limits[4]	20% / $9,999.99
Alternative I: Apply a 10% coinsurance limit and actuarially equivalent copayment limit	10% / $15.00
Alternative 2: Apply a 30% coinsurance limit and actuarially equivalent copayment limit	30% / $45.00
Alternative 3 (Proposed): Apply cost sharing no greater than Traditional Medicare	20% / $30.00

[1]Baseline cost-sharing limits include longstanding coinsurance and dollar validations.
[2]Alternative 1 - 3 cost-sharing limits include: (1) coinsurance limits described in each alternative in sections VII.E.3.d.(1). through (3). of this proposed rule and (2) illustrative copayment limits that reflect actuarially equivalent dollar values to those coinsurance limits based on contract year 2025 Medicare FFS data projections and application of the rounding rules at § 422.100(f)(6)(ii).
[3]The specific contract year 2025 Medicare FFS data projection used to calculate the illustrative alternative copayment limits in this table (such as, weighted average per visit) is described in detail in table 3's footnotes. The OACT employed generally accepted actuarial principles and practices in calculating this projected amount (per § 422.100(f)(7)).
[4]The amounts in this row reflect longstanding cost sharing PBP data validations applied to Cost Plans. Cost Plans may have requested to establish cost sharing amounts above these values as part of the bid review process.

TABLE 46: MA PLANS THAT SWITCHED TO LOWER MOOP TYPES IN CONTRACT YEAR 2024[1] AND UTILIZED COST-SHARING FLEXIBILITIES BY SERVICE CATEGORY[2]

Service Category	Number of Plans that Switched MOOP Types and Utilized Cost-Sharing Flexibility	Percent of Plans that Utilized the Cost-Sharing Flexibility Out of the Total Number of Plans that Switched MOOP Types
Emergency Services	114	86.4%
Partial Hospitalization	52	39.4%
Skilled Nursing Facility - First 20 Days	26	19.7%
Inpatient Hospital Psychiatric - 8 days	25	18.9%
Urgently Needed Services	16	12.1%
Inpatient Hospital Psychiatric - 15 days	10	7.6%
Inpatient Hospital Acute - 10 days	8	6.1%
Chiropractic care	8	6.1%
Occupational therapy	6	4.5%
Inpatient Hospital Acute - 6 days	5	3.8%
Mental Health Specialty Services	5	3.8%
Psychiatric Services	5	3.8%
Intensive Cardiac Rehabilitation	2	1.5%
Cardiac Rehabilitation	1	0.8%
Physician Specialist	1	0.8%
All Other Service Categories	0	0%
Total Number of Plans that Switched MOOP Types	**132**	**N/A**

[1]Only includes continuing plans from contract year 2023 that had a mandatory MOOP type and switched to a lower or intermediate MOOP type in contract year 2024.
[2]Only includes plans that established cost sharing amounts above the contract year 2024 cost-sharing limit set for the mandatory MOOP type.

TABLE 47: MA PLANS THAT SWITCHED TO LOWER MOOP TYPES IN CONTRACT YEAR 2023[1] AND UTILIZED COST-SHARING FLEXIBILITIES BY SERVICE CATEGORY[2]

Service Category	Number of Plans that Switched MOOP Types and Utilized Cost-Sharing Flexibility	Percent of Plans that Switched MOOP Types and Utilized Cost-Sharing Flexibility
Emergency Services	720	95.2%
Partial Hospitalization	227	30.0%
Skilled Nursing Facility - First 20 Days	153	20.2%
Inpatient Hospital Psychiatric - 15 days	19	2.5%
Skilled Nursing Facility – Days 21 through 100	14	1.9%
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)	12	1.6%
Mental Health Specialty Services	10	1.3%
Psychiatric Services	10	1.3%
All other service categories	0	0%
Total Number of Plans that Switched MOOP Types	**756**	**N/A**

[1]Only includes continuing plans from contract year 2022 that had a mandatory MOOP type and switched to a lower or intermediate MOOP type in contract year 2023.

[2]Only includes plans that established cost sharing amounts above the contract year 2023 cost-sharing limit set for the mandatory MOOP type.

TABLE 48: PERCENT OF CONTRACT YEAR 2024 MA PLANS WITH COST SHARING AMOUNTS GREATER THAN ALTERNATIVE 1, 2 AND 3 COST-SHARING LIMITS BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 1*	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 2	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 3/Proposed
Mental Health Specialty Services	46.9%	0.3%	24.4%
Psychiatric Services	47.9%	0.2%	24.9%
Partial Hospitalization	58.7%	3.3%	23.1%
Outpatient Substance Use Disorder Services	68.2%	13.1%	41.7%
Opioid Treatment Program Services	24.0%	5.0%	70.7%
Inpatient Hospital Psychiatric – 60 Days	14.0%	0.0%	0.0%
Inpatient Hospital Psychiatric – 15 Days	44.8%	0.0%	0.5%
Inpatient Hospital Psychiatric – 8 Days	53.3%	0.2%	4.3%

*Percent shown considers the plan's MOOP type.

TABLE 49: PERCENT OF ENROLLEES IN CONTRACT YEAR 2024 MA PLANS WITH COST SHARING AMOUNTS GREATER THAN ALTERNATIVE 1, 2, AND 3 COST-SHARING LIMITS BY BEHAVIORAL HEALTH SERVICE CATEGORY

Service Category	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 1*	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 2	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 3/Proposed
Mental Health Specialty Services	43.9%	0.9%	21.4%
Psychiatric Services	44.6%	0.9%	21.6%
Partial Hospitalization	50.1%	3.2%	16.4%
Outpatient Substance Use Disorder Services	64.0%	17.3%	40.7%
Opioid Treatment Program Services	23.6%	9.4%	62.3%
Inpatient Hospital Psychiatric – 60 Days	11.8%	0.0%	0.0%
Inpatient Hospital Psychiatric – 15 Days	38.4%	0.0%	0.6%
Inpatient Hospital Psychiatric – 8 Days	48.0%	0.3%	4.5%

*Percent shown considers the plan's MOOP type.

TABLE 50: PERCENT OF CONTRACT YEAR 2024 COST PLANS WITH COST SHARING AMOUNTS GREATER THAN ALTERNATIVE 1, 2 AND 3 COST-SHARING LIMITS BY BEHAVIORAL HEALTH SERVICE CATEGORY*

Service Category	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 1	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 2	Percent of Contract Year 2024 Plans with Cost Sharing Greater Than Alternative 3/Proposed
Mental Health Specialty Services	20.0%	0%	8.3%
Psychiatric Services	20.0%	0%	13.3%
Partial Hospitalization	15.0%	0%	0%
Outpatient Substance Use Disorder Services	20.0%	0%	5.0%
Opioid Treatment Program Services	15.0%	0%	50.0%

*Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.

TABLE 51: PERCENT OF ENROLLEES IN CONTRACT YEAR 2024 COST PLANS WITH COST SHARING AMOUNTS GREATER THAN ALTERNATIVE 1, 2, AND 3 COST-SHARING LIMITS BY BEHAVIORAL HEALTH SERVICE CATEGORY*

Service Category	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 1	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 2	Percent of Contract Year 2024 Enrollees in Plans with Cost Sharing Greater Than Alternative 3/Proposed
Mental Health Specialty Services	13.4%	0%	3.1%
Psychiatric Services	13.4%	0%	13.2%
Partial Hospitalization	12.7%	0%	0%
Outpatient Substance Use Disorder Services	13.4%	0%	0.7%
Opioid Treatment Program Services	3.3%	0%	60.6%

*Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.

TABLE 52A: COMPARISON OF ALTERNATIVE 1 COST-SHARING STANDARDS FOR MA PLANS WITH A LOWER MOOP TYPE AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH A LOWER MOOP TYPE AND COST SHARING ABOVE ALTERNATIVE 1 STANDARDS FOR THAT MOOP TYPE) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Alternative 1 Cost-Sharing Standard for Lower MOOP Type[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with a Lower MOOP Type and Cost Sharing Above Values in Column B	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$3,284.00	N/A[2]	N/A
Inpatient Hospital Psychiatric – 15 Days	$2,204.00	$2,313.36[3]	($109.36) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$2,036.00	$2,160.11[3]	($124.11) for 8 days
Mental Health Specialty Services	20.0% / $35.00	26.8% or $45.55[4]	($10.55) or (6.8%) per visit
Psychiatric Services	20.0% / $35.00	27.4% or $45.20[4]	($10.20) or (7.4%) per visit
Partial Hospitalization	20.0% / $60.00	31.1% or $94.91[4]	($34.91) or (11.1%) per visit
Outpatient Substance Use Disorder Services	20.0% / $30.00	46.3% or $67.99[4]	($37.99) or (26.3%) per day
Opioid Treatment Program Services	20.0% / $60.00	32.6% or $100.66[4]	($40.66) or (12.6%) per visit

[1]Alternative 1 cost-sharing standards for the lower MOOP type include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in section VII.E.3.d.(1). of this proposed rule and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]No contract year 2024 plans with a lower MOOP type established cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario greater than the alternative 1's illustrative dollar limit for that service category.

[3]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario and (2) only plans with a lower MOOP type and dollar cost sharing amounts that are greater than the alternative 1 standard for that length of stay scenario and MOOP type (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

[4]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with a lower MOOP type and cost sharing amounts (coinsurance or copayment) that are greater than the alternative 1 standard for that service category and MOOP type, (2) the plan maximum cost sharing for the service category, and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with a lower MOOP type and cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 52B: COMPARISON OF ALTERNATIVE 1 COST-SHARING STANDARDS FOR MA PLANS WITH AN INTERMEDIATE MOOP TYPE AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH AN INTERMEDIATE MOOP TYPE AND COST SHARING ABOVE ALTERNATIVE 1 STANDARDS FOR THAT MOOP TYPE) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Alternative 1 Standards for the Intermediate MOOP Type[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with an Intermediate MOOP Type and Cost Sharing Above Values in Column B	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$2,463.00	N/A[2]	N/A
Inpatient Hospital Psychiatric – 15 Days	$1,653.00	$1,881.81[3]	($228.81) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$1,527.00	$1,788.27[3]	($261.27) for 8 days
Mental Health Specialty Services	15.0% / $25.00	21.2% / $36.15[4]	($11.15) or (6.2%) per visit
Psychiatric Services	15.0% / $25.00	21.9% / $36.07[4]	($11.07) or (6.9%) per visit
Partial Hospitalization	15.0% / $45.00	20.3% / $61.81[4]	($16.81) or (5.3%) per visit
Outpatient Substance Use Disorder Services	15.0% / $20.00	28.4% / $41.79[4]	($21.79) or (13.4%) per day
Opioid Treatment Program Services	15.0% / $45.00	26.3% / $81.41[4]	($36.41) or (11.3%) per visit

[1]Alternative 1 cost-sharing standards for the intermediate MOOP type include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in section VII.E.3.d.(1). of this proposed rule; and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]No contract year 2024 plans with an intermediate MOOP type established cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario greater than the alternative 1's illustrative dollar limit for that service category.

[3]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario; and (2) only plans with an intermediate MOOP type and dollar cost sharing amounts that are greater than the alternative 1 standard for that length of stay scenario and MOOP type (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

[4]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with an intermediate MOOP type and cost sharing amounts (coinsurance or copayment) that are greater than the alternative 1 standard for that service category and MOOP type; (2) the plan maximum cost sharing for the service category; and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with an intermediate MOOP type and cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 52C: COMPARISON OF ALTERNATIVE 1 COST-SHARING STANDARDS FOR MA PLANS WITH A MANDATORY MOOP TYPE AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH A MANDATORY MOOP TYPE AND COST SHARING ABOVE ALTERNATIVE 1 STANDARDS FOR THAT MOOP TYPE) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Alternative 1 Standards for the Mandatory MOOP Type[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with a Mandatory MOOP Type and Cost Sharing Above Values in Column B	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$1,642.00	$1,819.21[2]	($177.21) for 60 days
Inpatient Hospital Psychiatric – 15 Days	$1,102.00	$1,691.82[2]	($589.82) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$1,018.00	$1,687.02[2]	($669.02) for 8 days
Mental Health Specialty Services	10.0% / $15.00	19.8% / $33.78[3]	($18.78) or (9.9%) per visit
Psychiatric Services	10.0% / $15.00	20.4% / $33.70[3]	($18.70) or (10.4%) per visit
Partial Hospitalization	10.0% / $30.00	19.1% / $58.11[3]	($28.11) or (9.1%) per visit
Outpatient Substance Use Disorder Services	10.0% / $15.00	34.3% / $50.37[3]	($35.37) or (24.3%) per day
Opioid Treatment Program Services	10.0% / $30.00	21.3% / $65.73[3]	($35.73) or (11.3%) per visit

[1]Alternative 1 cost-sharing standards for the mandatory MOOP type include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in section VII.E.3.d.(1). of this proposed rule; and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario; and (2) only plans with a mandatory MOOP type and dollar cost sharing amounts that are greater than the alternative 1 standard for that length of stay scenario and MOOP type (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

[3]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with a mandatory MOOP type and cost sharing amounts (coinsurance or copayment) that are greater than the alternative 1 standard for that service category and MOOP type; (2) the plan maximum cost sharing for the service category; and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with a mandatory MOOP type and cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 53: COMPARISON OF ALTERNATIVE 2 COST-SHARING STANDARDS FOR MA PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF MA PLANS WITH COST SHARING ABOVE ALTERNATIVE 2 STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY

Column A: Service Category	Column B: Alternative 2 Standards (All MOOP Types)[1]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with Cost Sharing Above Values in Column B (Alternative 2 Standards)	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Inpatient Hospital Psychiatric – 60 Days	$3,612.00	N/A[2]	N/A
Inpatient Hospital Psychiatric – 15 Days	$2,424.00	$2,551.24[3]	($127.24) for 15 days
Inpatient Hospital Psychiatric – 8 Days	$2,240.00	$2,323.75[3]	($83.75) for 8 days
Mental Health Specialty Services	30.0% / $50.00	35.2% / $59.96[4]	($9.96) or (5.2%) per visit
Psychiatric Services	30.0% / $50.00	36.4% / $60.00[4]	($10.00) or (6.4%) per visit
Partial Hospitalization	30.0% / $90.00	32.8% / $100.00[4]	($10.00) or (2.8%) per visit
Outpatient Substance Use Disorder Services	30.0% / $45.00	60.4% / $88.80[4]	($43.80) or (30.4%) per day
Opioid Treatment Program Services	30.0% / $95.00	33.1% / $102.18[4]	($7.18) or (3.1%) per visit

[1]Alternative 2 cost-sharing standards include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in section VII.E.3.d.(2). of this proposed rule and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[2]No contract year 2024 plans established cost sharing for the inpatient hospital psychiatric 60-day length of stay scenario greater than the alternative 2's illustrative dollar limit for that service category.

[3]Contract year 2024 weighted average plan dollar amounts for inpatient hospital psychiatric services are based on: (1) maximum cost sharing for each inpatient hospital psychiatry length of stay scenario and (2) only plans with dollar cost sharing amounts that are greater than the alternative 2 standard for that length of stay scenario (excludes the few plans with coinsurance percentages for inpatient hospital psychiatric services).

[4]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the alternative 2 standard for that service category, (2) the plan maximum cost sharing for the service category, and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

TABLE 54: COMPARISON OF ALTERNATIVE 1 COST-SHARING STANDARDS FOR COST PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF COST PLANS WITH COST SHARING ABOVE ALTERNATIVE 1 STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY[1]

Column A: Service Category	Column B: Alternative 1 Standards[2]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with Cost Sharing Above Values in Column B (Alternative 1 Standards)[3]	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)
Mental Health Specialty Services	10.0% / $15.00	19.0% / $32.37	($17.37) or (9.0%) per visit
Psychiatric Services	10.0% / $15.00	28.7% / $47.40	($32.40) or (18.7%) per visit
Partial Hospitalization	10.0% / $30.00	14.5% / $44.08	($14.08) or (4.5%) per visit
Outpatient Substance Use Disorder Services	10.0% / $15.00	20.7% / $30.44	($15.44) or (10.7%) per day
Opioid Treatment Program Services	10.0% / $30.00	18.4% / $56.92	($26.92) or (8.4%) per visit

[1]Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.

[2]Alternative 1 cost-sharing standards for Cost Plans include: (1) coinsurance and estimated Medicare FFS cost sharing percentages described in section VII.E.3.d.(1). of this proposed rule and (2) illustrative actuarially equivalent copayment and dollar limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[3]Contract year 2024 weighted average plan cost sharing amounts shown reflect: (1) only plans with cost sharing amounts (coinsurance or copayment) that are greater than the alternative 1 standard for that service category, (2) the plan maximum cost sharing for the service category, and (3) normalizing the plan cost sharing amounts (coinsurance or copayment). Normalizing the plan cost sharing amounts is completed by calculating the coinsurance or copayment equivalent it represents using contract year 2025 Medicare FFS data projections for that service category. Each of the resulting figures – a weighted average coinsurance and copayment – reflects all plans with cost sharing above alternative 1 standards rather than plans with solely copayments or coinsurance.

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TABLE 55: COMPARISON OF ALTERNATIVE 2 COST-SHARING STANDARDS FOR COST PLANS AND CONTRACT YEAR 2024 WEIGHTED AVERAGE PLAN COST SHARING (OF COST PLANS WITH COST SHARING ABOVE ALTERNATIVE 2 STANDARDS) BY BEHAVIORAL HEALTH SERVICE CATEGORY[1]

Column A: Service Category	Column B: Alternative 2 Standards[2]	Column C: Contract Year 2024 Weighted Average Cost Sharing of Plans with Cost Sharing Above Values in Column B (Alternative 2 Standards)[3]	Column D: Dollar Amount or Coinsurance Increment Difference (Column B minus Column C)[3]
Mental Health Specialty Services	30.0% / $50.00	N/A	N/A
Psychiatric Services	30.0% / $50.00	N/A	N/A
Partial Hospitalization	30.0% / $90.00	N/A	N/A
Outpatient Substance Use Disorder Services	30.0% / $45.00	N/A	N/A
Opioid Treatment Program Services	30.0% / $95.00	N/A	N/A

[1]Cost Plans are not required to report information for all services, including Part A inpatient hospital psychiatric services. Due to this lack of data, inpatient hospital psychiatric services, all length of stay scenarios, are excluded from this table.

[2]Alternative 2 cost-sharing standards include: (1) coinsurance percentages described in section VII.E.3.d.(2). of this proposed rule and (2) illustrative actuarially equivalent copayment limits to those percentages based on contract year 2025 Medicare FFS data projections that are described in detail in table 3's footnotes (such as, weighted average per visit) and application of the rounding rules at § 422.100(f)(6)(ii).

[3]No contract year 2024 Cost Plans established cost sharing for these service categories greater than the alternative 2's standards for those service categories.

4. Proposal To Require Clinical or Quality Improvement Standards for Provider Incentive and Bonus Arrangements To Be Included in the MA MLR Numerator (§ 422.2420(b)(2))

For our proposal to require clinical or quality improvement standards for provider incentive and bonus arrangements to be included in the MA MLR numerator, we considered two alternatives.

First, we considered requiring MA organizations to submit documentation with their annual MLR Report demonstrating how bonuses and incentives included in the MLR numerator were tied directly to improved care quality. This approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to produce the documentation necessary to justify the bonuses and incentives included in the MLR numerator. We estimate that it would take double the number of hours to prepare and submit such documentation, which would result in $105,672 ($52,836 × 2) additional aggregate burden for MA organizations.

Second, we considered auditing bonuses and incentives included in the annual MLR Report for select MA organizations to confirm these expenses were tied directly to improved care quality. This approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to prepare for and undergo an audit for these expenses. We estimate that it would take four times the number of hours to prepare and submit such documentation and work with auditors to validate the information provided in the MLR Report, which would result in $211,344 ($52,836 × 4) additional aggregate burden for MA organizations. This approach would also involve hiring additional staff or securing a contractor to complete this work on an annual basis. We estimate that it would take approximately one tenth the audit budget for a single MA organization ($1,500,000 total budget/9 MA organizations budgeted = $166,666.67 for a single audit) to audit these specific expenses, which would result in $16,666.67 additional aggregate burden for CMS per MA organization per year.

We are not proposing the first alternative because we do not believe adding a requirement to our current MLR reporting process is beneficial. This additional step of preparing and submitting documentation on bonuses and incentives would create additional burden for MA organizations to generate and for CMS to review. MA organizations already attest to the accuracy of their MLR report, and the desk review process provides oversight of submissions on an annual basis that may or may not use this additional documentation depending on issues identified and addressed through the desk review process.

CMS has the authority to conduct audits of MA organizations' MLR reports. However, we are not proposing the second alternative because we believe conducting full audits of select MA organizations' MLR reports would provide more information than auditing specific data elements alone. Smaller, more focused audits of bonuses and incentives would create additional burden for MA organizations to generate and for CMS to conduct, and this additional burden could outweigh the potential significance of findings and impact to MLR calculations reported.

5. Proposal To Prohibit Administrative Costs From Being Included in Quality Improving Activities in the MA and Part D MLR Numerator (§§ 422.2430(a) and 423.2430(a))

For our proposal to prohibit administrative costs from being included in quality improving activities in the MA and Part D MLR numerator, we considered two alternatives.

First, we considered requiring MA organizations to submit documentation with their annual MLR Report describing all quality improving activity costs included in the MLR numerator. This approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to produce the documentation necessary to describe all costs spent on quality improving activities included in the MLR numerator. We estimate that it would take double the number of hours to prepare and submit such documentation, which would result in $105,672 ($52,836 × 2) additional aggregate burden for MA organizations and Part D sponsors.

Second, we considered auditing quality improving activity costs included in the annual MLR Report for select MA organizations and Part D sponsors to confirm these costs were not administrative in nature. This approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to prepare for and undergo an audit for these costs. We estimate that it would take four times the number of hours to prepare and submit such documentation and work with auditors to validate the information provided in the MLR Report, which would result in $211,344 ($52,836 × 4) additional aggregate burden for MA organizations and Part D sponsors. This approach would also involve hiring additional staff or securing a contractor to complete this work on an annual basis. We estimate that it would take approximately one tenth the audit budget for a single MA organization or Part D sponsor ($1,500,000 total budget/9 MA organizations and Part D sponsors budgeted = $166,666.67 for a single audit) to audit these specific costs, which would result in $16,666.67 additional aggregate burden for CMS per MA organization or Part D sponsor per year.

We are not proposing the first alternative because we do not believe adding a requirement to our current MLR reporting process is beneficial. This additional step of preparing and submitting documentation on quality improving activities would create additional burden for MA organizations and Part D sponsors to generate and for CMS to review. MA organizations and Part D sponsors already attest to the accuracy of their MLR report, and the desk review process provides oversight of submissions on an annual basis that may or may not use this additional documentation depending on issues identified and addressed through the desk review process.

CMS has the authority to audit MA organizations and Part D sponsor's MLR reports. However, we are not proposing the second alternative because we believe conducting full audits of select MA organizations and Part D sponsors' MLR reports would provide more information than auditing specific data elements alone. Smaller, more focused audits of quality improving activities would create additional burden for MA organizations to generate and for CMS to conduct, and this additional burden could outweigh the potential significance of findings and impact to MLR calculations reported.

6. Proposal To Establish Standards for MA and Part D MLR Audit Examinations (§§ 422.2480(d), 423.2480(d), 422.2401, 423.2401, 422.2450, 423.2450, 422.2452, 423.2452, 423.2454, and 423.2454)

For our proposal to establish standards for MA and Part D MLR audit examinations, we considered two alternatives.

First, we considered requiring MA organizations and Part D sponsors to submit with the MLR Report documentation that details how the MLR calculation and remittances owed were determined each year. This

approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to produce the documentation necessary to outline the entire MLR calculation. We estimate that it would take four times the number of hours to prepare and submit such documentation, which would result in $211,344 ($52,836 × 4) additional aggregate burden for MA organizations and Part D sponsors.

Second, we considered auditing all MLR Reports for MA organizations and Part D sponsors that owed remittances for the previous reporting year. This approach would result in at least as many additional hours as our proposal, using the assumptions previously discussed, to prepare for and undergo an MLR audit. We estimate that it would take four times the number of hours to prepare and submit such documentation and work with auditors to validate the information provided in the MLR Report, which would result in $211,344 ($52,836 × 4) additional aggregate burden for MA organizations and Part D sponsors. This approach would also involve hiring additional staff or securing a contractor to complete this work on an annual basis. We estimate that it would take approximately three to four times the full audit budget ($1,500,000 total budget) to audit all MA organizations and Part D sponsors that owed remittances for the previous reporting year, since 60 MA organizations and Part D sponsors owed remittances in contract year 2022 (about six times the number of MA organizations and Part D sponsors budgeted), which would result in $9,000,000 additional aggregate burden for CMS per year.

We are not proposing the first alternative because we do not believe adding a requirement to our current MLR reporting process is beneficial. This additional step of preparing and submitting documentation on all MLR data elements would create additional burden for MA organizations and Part D sponsors to generate and for CMS to review. MA organizations and Part D sponsors already attest to the accuracy of their MLR report, and the desk review process provides oversight of submissions on an annual basis that may or may not use this additional documentation depending on issues identified and addressed through the desk review process.

We are not proposing the second alternative because this approach would require significant funding and effort on behalf of MA organizations, Part D sponsors, and CMS. Our option to audit up to 9 MA organizations' and Part D sponsors' MLR reports contracts would take approximately 9 months to 1 year to complete. Auditing up to 60 MA organizations and Part D sponsors' MLR reports would take, given the estimates above, at least 6 years to complete for a single contract year's reporting. The number of MA organizations and Part D sponsors that ultimately owe remittances for failing to meet the 85 percent threshold also changes year to year, making the ability to plan and conduct audits difficult.

7. Proposal To Add Provider Payment Arrangement Reporting in the Medicare MLR Reporting Regulations (§§ 422.2460 and 422.2490)

For our proposal to require separate reporting amounts for provider payment arrangements, we considered three alternatives. First, we considered keeping the status quo in reporting so MA organizations do not have to submit any detail on their provider payment arrangements.

Second, we considered requiring MA organizations to submit documentation with their annual MLR Report describing each of their provider payment arrangements in detail. We estimate that it would take double the number of hours to prepare and submit such documentation, which would result in $359,940 ($179,970 * 2) additional aggregate burden for MA organizations.

Third, we considered asking what provider payment arrangement information MA organizations may be able to share through the vertical integration request for information. This approach would have provided CMS with more information before proposing a policy change. However, we obtained recommendations from several stakeholders through the MA data request for information that CMS collect similar data that is reported through the HCPLAN survey to support access to additional data on APM adoption.

We are not proposing the first alternative because CMS and stakeholders will benefit from increased transparency in provider payment arrangement types. Such reporting will help policymakers understand more about the prevalence of different provider payment arrangements and consider whether and how MLR reports might vary based on different patterns in provider payment arrangements.

In addition, we are not proposing the second alternative because we were concerned about the additional reporting burden associated with requiring MA organizations to submit documentation with their annual MLR Report describing each of their provider payment arrangements in detail. CMS is proposing provider payment arrangement reporting in aggregate dollar amounts and limited categories to enable MA organizations to operationalize additional provider payment arrangement reporting and to see if we obtain enough data to better understand the different types of APM arrangements in MA.

Finally, we are not proposing the third alternative to ask what kind of provider payment arrangement information we should collect from MA organizations because the HCPLAN survey has standardized definitions widely agreed upon by industry stakeholders. In addition, through the MA data request for information CMS has already received feedback from many stakeholders advocating for the collection of more APM information. CMS is also asking for feedback on proposed provider payment arrangement categories in the proposed policy, which enables stakeholders to propose alternative data collection methods.

F. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision. As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in table 56, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this proposed rule over a 10-year period or for contract years 2026 through 2035.

TABLE 56: ACCOUNTING STATEMENT -CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS ($ MILLIONS)

Category	Primary Estimate (2% Discount Rate)	Period Covered
TRANSFERS (AOM)		
Annualized monetized Federal budgetary transfers	$2,502	10-year period
Bearers of transfer gain? Medicare PDPs		
Annualized monetized Federal budgetary transfers	1,084	10-year period
Bearers of transfer gain? Medicaid MCOs/FFS		
Annualized monetized State budgetary transfers	$374	10-year period
Bearers of transfer gain? Medicaid MCOs/FFS		
TRANFERS		
Annualized monetized Federal budgetary transfers	$4	CYs 2026-2035
Bearers of transfer gain? Medicare PDPs		
COSTS		
Annualized monetized costs	$72	CYs 2026-2035

* The implementation of section 11401 of the IRA for the $0 cost-sharing requirement of ACIP-recommended adult vaccines was scored by CBO to reflect a Federal cost of $4.4 billion for FY2022 through FY2031 and, therefore, the estimates are not a result of this rule.

G. Conclusion

This proposed rule would result in net annualized costs of $72 million. These costs are primarily attributable to provisions pertaining to the information collection requirements of the Medicare Prescription payment plan. This provision implements requirements created by the IRA and is expected to increase costs in the first year by over $264. million, dropping to $36.7 million annually in subsequent years. The proposed rule would also result in significant outlays from the Medicare Trust Fund. There are anticipated savings to the Trust Fund, notably coming from proposed adjustments in MLR calculations and audits, which may result in transfers of $1010 and $320 million over a 10-year period. However, the rule also includes transfers from the Medicare Trust Fund and other entities to cover AOMs. Coverage of AOMs are anticipated to result in annualized monetized Federal transfers amounting to $2,502 million from the Medicare Trust Fund, $ $1,084 million in Federal Medicaid transfers, and $374 million in State Medicaid transfers.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 8, 2024.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs-health Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 2. Section 417.454 is amended by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 417.454 Charges to Medicare enrollees.

* * * * *

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* For each year beginning on or after January 1, 2026, in-network cost sharing established by an HMO or CMP for the basic benefits listed in this paragraph may not exceed the cost sharing required under original Medicare. When an HMO or CMP uses coinsurance, the coinsurance must not exceed the coinsurance charged in original Medicare. When an HMO or CMP uses copayments, the copayment must not exceed the actuarially equivalent value calculated for that

benefit using the Medicare Advantage rules at § 422.100(j)(1)(ii) of this chapter and Medicare FFS data projections as defined in § 422.100(f)(4)(i). The benefits listed in this paragraph are as follows:

(1) Chemotherapy administration services to include chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(4) A COVID–19 vaccine and its administration described in section 1861(s)(10)(A) of the Act.

(5) Behavioral health service categories including all of the following:

(i) Intensive outpatient services.

(ii) Mental health specialty services.

(iii) Opioid treatment program services.

(iv) Outpatient substance use disorder services.

(v) Partial hospitalization.

(vi) Psychiatric services.

(6) Inpatient hospital acute and psychiatric services cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for the following length-of-stay scenarios for a period for which cost sharing would apply under original Medicare:

(i) For acute services as follows:

(A) 3 days.

(B) 6 days.

(C) 10 days.

(D) 60 days.

(ii) For psychiatric services as follows:

(A) 8 days

(B) 15 days.

(C) 60 days.

(7) Home health services (as defined in section 1861(m) of the Act).

(8) The following specific service categories of durable medical equipment (DME):

(i) Equipment.

(ii) Prosthetics.

(iii) Medical supplies.

(iv) Diabetes monitoring supplies.

(v) Diabetic shoes or inserts.

(9) Other drugs covered under Part B of original Medicare (that is, Part B drugs not included in paragraph (e)(1) of this section).

(f) *Cost sharing for other Medicare Part A and B benefits.* For Medicare Part A and Part B services furnished in-network for which a cost sharing limit is not established by other regulation or statute, the HMO or CMP must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in § 422.100(f)(7) of this chapter or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total HMO or CMP plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year).

■ 3. Section 417.486 is amended by adding paragraph (a)(3) to read as follows:

§ 417.486 Disclosure of information and confidentiality.

(a) * * *

(3) Risk adjustment data as specified in section 422.310 of this chapter for the purposes of determining an individual's health status. In applying this provision, references to MA organizations in § 422.310 shall be read to mean HMOs and CMPs.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 4. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 5. Section 422.2 is amended by—

■ a. Adding in alphabetical order definitions for ''Automated system'', ''Community-based organizations'', and ''Direct furnishing entity'';

■ b. Revising the definition of ''Hierarchical condition categories (HCC)'' and paragraph (1) of the definition of ''Highly integrated dual eligible special needs plan'';

■ c. Adding in alphabetical order a definition for ''In-home or at-home supplemental benefit provider''; and

■ d. Revising the definition of ''Service area''.

The additions and revisions read as follows:

§ 422.2 Definitions.

* * * * *

Automated system means any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques, and exclude passive computing infrastructure. 'Passive computing infrastructure' is any intermediary technology that does not influence or determine the outcome of decision, make or aid in decisions, inform policy implementation, or collect data or observations, including web hosting, domain registration, networking, caching, data storage, or cybersecurity. As used in this part, automated systems that are considered in scope are only those that have the potential to meaningfully impact individuals' or communities' rights, opportunities, or access.

* * * * *

Community-based organizations (CBOs) mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community, to address the health and social needs of those populations.

* * * * *

Direct furnishing entity means any individual or entity that delivers or furnishes covered benefits to the enrollee. This includes Medicare Part A and B covered benefits, as well as supplemental benefits.

* * * * *

Hierarchical condition categories (HCC) mean diagnosis groupings that predict average healthcare spending. HCCs consist of International Classification of Diseases, Clinical Modification (ICD–CM) diagnosis codes and represent the disease component of the enrollee risk score that are applied to MA payments.

Highly integrated dual eligible special needs plan * * *

(1) The capitated contract is between the State Medicaid agency and one of the following:

(i) The MA organization.

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization.

(iii) A local nonprofit public benefit corporation of which the MA organization, MA organization's parent organization, or another entity that is owned and controlled by its parent organization is a founding member where the local nonprofit public benefit corporation is responsible for the delivery of physical, behavioral, and dental health services.

* * * * *

In-home or at-home supplemental benefit provider means any direct furnishing entity in which the direct furnishing entity or an employee of the direct furnishing entity is given an enrollee's physical address in order to provide supplemental benefits or special supplemental benefits for the

chronically ill (SSBCI) items or services to that enrollee. An in-home or at-home supplemental benefit provider may include direct furnishing entities who offer both in-office as well as in-home or at-home supplemental benefits.

* * * * *

Service area means a geographic area that for local MA plans is one or more counties, as defined in § 422.116 of this chapter, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

* * * * *

■ 6. Section 422.100 is amended by:
■ a. Removing the phrase ''services, partial hospitalization, and'' and adding in its place the phrase ''services, occupational therapy, and'' in paragraph (f)(6)(iii)(A);
■ b. Removing the phrase ''under paragraph (f)(6)(iv) of this section'' and adding in its place the phrase ''under paragraphs (f)(6)(iv) and (j)(1)(i)(H) of this section'' in paragraph (f)(6)(iv)(A);
■ c. Revising paragraphs (f)(6)(iv)(B) and (f)(6)(iv)(D) introductory text;
■ d. Removing the phrase ''January 1, 2023, in-network'' and adding in its place the phrase ''January 1, 2023, unless otherwise specified in this section, in-network'' in paragraph (j)(1)(i) introductory text;
■ e. Revising paragraph (j)(1)(i)(C);
■ f. Adding paragraphs (j)(1)(i)(G) and (H); and
■ g. Revising paragraph (o)(2).

The revisions and additions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(6) * * *

(iv) * * *

(B) Cost sharing limits for inpatient hospital acute service categories are calculated for the following length-of-stay scenarios for a period for which cost sharing would apply under original Medicare:

(*1*) 3 days.

(*2*) 6 days.

(*3*) 10 days.

(*4*) 60 days.

* * * * *

(D) Provided that the total cost sharing for the inpatient benefit does not exceed overall cost sharing for inpatient benefits in original Medicare on a per member per month actuarially equivalent basis, MA plan cost sharing applicable to inpatient hospital acute service categories is permitted up to the following limits (based on original Medicare cost sharing for a new benefit period):

* * * * *

(j) * * *

(1) * * *

(i) * * *

(C) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP type; when the MA plan establishes the lower MOOP type, the cost sharing must not be greater than $20 per day for the first 20 days of a SNF stay; when the MA plan establishes the intermediate MOOP type, the cost sharing must not be greater than $10 per day for the first 20 days of a SNF stay. For all MOOP types, the per-day cost sharing for days 21 through 100 must not be greater than one-eighth of the projected (or actual) Part A deductible amount for the year. Total cost sharing for the overall SNF benefit must not be greater than the per member per month actuarially equivalent cost sharing for the SNF benefit in original Medicare.

* * * * *

(G) Behavioral health service categories for contract year 2026 and subsequent contract years including all of the following:

(*1*) Intensive outpatient services.

(*2*) Mental health specialty services.

(*3*) Opioid treatment program services.

(*4*) Outpatient substance use disorder services.

(*5*) Partial hospitalization.

(*6*) Psychiatric services.

(H) Inpatient hospital psychiatric services cost sharing must not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for the following length-of-stay scenarios for a period for which cost sharing would apply under original Medicare for contract year 2026 and subsequent years:

(*1*) 8 days.

(*2*) 15 days.

(*3*) 60 days.

* * * * *

(o) * * *

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding the last sentence of paragraph (j)(1)(i)(C) and the last sentence of paragraph (j)(1)(i)(E) of this section.

■ 7. Section 422.101 is amended by revising paragraphs (b)(6) and (f)(1)(i) through (iv) and adding paragraphs (f)(1)(v) through (x) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(b) * * *

(6) MA organizations may create publicly available internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely used treatment guidelines are those developed by organizations representing clinical medical specialties and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

(i) *Coverage criteria not fully established.* Coverage criteria are not fully established if any of the following occur:

(A) Additional, unspecified criteria are needed to interpret or supplement the plain language of applicable Medicare coverage and benefit criteria in order to determine medical necessity consistently.

(B) NCDs or applicable LCDs include flexibility that explicitly allows for discretionary coverage in circumstances beyond the specific indications that are listed in an NCD or LCD.

(C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

(ii) *Publicly available.* For internal coverage criteria, the MA organization must provide in a publicly available way all of the following:

(A) Each internal coverage criterion in use and a summary of evidence that was considered during the development of each internal coverage criterion used to make medical necessity determinations. Any internal coverage criterion used by the MA organization must be clearly

identified and marked as internal coverage criteria in the coverage policies of the MA plan.

(B) A list of the sources of such evidence that are connected by footnote to the applicable coverage criterion.

(C) An explanation of the rationale that supports the adoption of each coverage criterion used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (b)(6)(i)(A) of this section, the MA organization must identify the plain language of applicable Medicare coverage and benefit criteria that are being supplemented or interpreted.

(D) By January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. The list of items and services on the website must include the information in paragraphs (b)(6)(ii)(A) through (C) of this section (explicitly or by connecting directly to that information through a hyperlink) and include the vendor's name when using a third-party vendor's criteria. Additionally, the web page that lists the items and services that contain internal coverage criteria must meet the following requirements:

(*1*) Displayed in a prominent manner and clearly identified in the footer of the website.

(*2*) Easily available to the public, without barriers, including but not limited to ensuring the information is available:

(*i*) Free of charge.

(*ii*) Without having to establish a user account or password.

(*iii*) Without having to submit personal identifying information.

(*iv*) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(*v*) Include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

(iii) *Internal coverage criteria defined.* Internal coverage criteria are any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable Medicare statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination at § 422.101(c)(1). This includes any coverage policies that restrict access to or payment for medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness.

(iv) *Prohibited.* Use of an internal coverage criterion is prohibited when either of the following occur:

(A) The criterion does not have any clinical benefit.

(B) The criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination as required at § 422.101(c)(1)(i).

* * * * *

(f) * * *

(1) * * *

(i) Within 90 days (before or after) of the effective date of enrollment for all new enrollees, conduct a comprehensive initial health risk assessment (HRA).

(ii) Conduct a comprehensive annual HRA.

(iii) Use a comprehensive risk assessment tool that CMS may review during oversight activities that meet both of the following:

(A) Assesses the enrollee's physical, psychosocial, and functional needs.

(B) Includes one or more questions from a list of screening instruments specified by CMS in subregulatory guidance on each of the following domains:

(*1*) Housing stability.

(*2*) Food security.

(*3*) Access to transportation.

(iv) Must do all of the following:

(A) Make at least three non-automated phone call attempts, unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day to reach the enrollee to schedule the comprehensive initial or annual HRA.

(B) If the enrollee has not responded, send a follow-up letter to conduct the initial or annual HRA.

(C) For any enrollees who are unable to be reached or decline to participate in the HRA, document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate.

(v) For D–SNPs that are applicable integrated plans (as defined in § 422.561), conduct a comprehensive HRA that meets all requirements at paragraphs (f)(1)(i) through (iv) of this section as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees complete a single integrated assessment for Medicare and Medicaid.

(vi) Ensure that the results from the comprehensive initial and annual HRA conducted for each enrollee are addressed in the enrollee's individualized care plan as required under paragraph (f)(1)(vii) of this section.

(vii) Within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later, develop a comprehensive individualized plan of care that meets all of the following:

(A) Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and their needs identified in the HRA.

(B) Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable), as feasible.

(C) Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided.

(D) Is updated as warranted by changes in the health status or care transitions of enrollees.

(viii) For any enrollees who are unable to be reached or decline to participate in the development or updates to the comprehensive individualized plan of care, document the attempts to contact the enrollee or the enrollee's refusal to participate.

(ix) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(x) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the enrollee's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

* * * * *

■ 8. Section § 422.102 is amended by—

■ a. Revising paragraphs (a)(6)(i) and (f)(1)(i)(A);

■ b. Adding paragraphs (f)(1)(i)(C) and (f)(1)(iii);

■ c. Revising paragraph (f)(4)(iii); and

■ d. Adding paragraph (g).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(6) * * *

(i) Reductions in cost sharing through the use of manual reimbursement or through a debit card for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) A chronically ill enrollee is an individual enrolled in the MA plan who meets all of the following:

(*1*) Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.

(*2*) Has a high risk of hospitalization or other adverse health outcomes.

(*3*) Requires intensive care coordination.

* * * * *

(C) An enrollee who has one or more comorbidities and medically complex chronic conditions alone is not sufficient to demonstrate that an enrollee meets all 3 criteria set forth in paragraph (f)(1)(i)(A) of this section. MA plans must, through health risk assessments, review of claims data, or other similar means, demonstrate that enrollees meet all 3 criteria set forth in paragraph (f)(1)(i)(A) of this section.

* * * * *

(iii) Examples of items or services that may not be offered as SSBCI include all of the following:

(A) Procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage (for example, cosmetic surgery, such as facelifts, or cosmetic treatments for facial lines, atrophy of collagen and fat, and bone loss due to aging).

(B) Hospital indemnity insurance.

(C) Funeral planning and expenses.

(D) Life insurance.

(E) Alcohol.

(F) Tobacco.

(G) Cannabis products.

(H) Broad membership programs inclusive of multiple unrelated services and discounts.

* * * * *

(4) * * *

(iii) Have objective criteria for SSBCI. Specifically, the plan must:

(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(C) For each SSBCI, the MA plan must list all the written policies and objective criteria on which the policies are based as noted in paragraph (f)(4)(i) of this section on their public facing website.

* * * * *

(g) *Administration of supplemental benefits*—(1) *General rule.* MA organizations must have processes for delivering supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to all covered items and services, in accordance with § 422.112(a).

(2) *Provision of benefits through debit card.* MA organizations that administer reductions in cost sharing or provide coverage of 100 percent of the cost of a mandatory supplemental benefit through use of a debit card must do all of the following:

(i) Provide debit cards that are electronically linked to plan covered items and services through a real-time identification mechanism to verify eligibility of plan covered benefits at the point of sale.

(ii) Provide instructions for debit card use and customer service support to enrollees.

(iii) Have an alternative process that allows for reimbursement of eligible expenses for plan covered benefits.

(iv) Ensure debit cards are limited to the specific plan year.

■ 9. Section 422.107 is amended by revising paragraph (f)(1) to read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

* * * * *

(f) * * *

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, updates to the model of care described in § 422.101(f), and health equity for underserved populations.

* * * * *

■ 10. Section 422.111 is amended by revising paragraphs (b)(3)(i) and (b)(6) and adding paragraph (m) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(3) * * *

(i) The number, mix, and distribution (addresses) of providers and direct furnishing entities from whom enrollees may reasonably be expected to obtain services, including all of the following:

(A) All direct furnishing entities, as defined in § 422.2, from whom enrollees may reasonably be expected to obtain services.

(B) Each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

(C) Easily identifiable notations, filters, or other distinguishing features to indicate providers and direct furnishing entities that are community-based organizations (CBOs) (as defined in § 422.2).

(D) Easily identifiable notations, filters, or other distinguishing features to indicate in-home or at-home supplemental benefit providers (as defined in § 422.2).

(E) Any out-of-network coverage; any point-of-service option, including the supplemental premium for that option.

(F) How the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

* * * * *

(6) *Supplemental benefits.* Any mandatory supplemental benefits (including reductions in cost sharing) or optional supplemental benefits, the premium for optional supplemental benefits, and the applicable conditions and limitations associated with receipt or use of supplemental benefits. This includes both of the following:

(i) Disclosure of eligible over-the-counter items.

(ii) If providing supplemental benefits through a debit card, specifying which benefits may be accessed using the debit card.

* * * * *

(m) *Increasing consumer transparency.* For plan years beginning on or after January 1, 2026, MA organizations must do all of the following:

(1) Make the information described in paragraph (b)(3)(i) of this section available to CMS/HHS for publication online in accordance with guidance from CMS/HHS.

(2) Submit, or otherwise make available, the information described in paragraph (b)(3)(i) of this section to CMS/HHS in a format and manner and at times determined by CMS/HHS.

(3) Update the information subject to this paragraph (m) within 30 days of the date an MA organization becomes aware of a change.

(4) Attest, in a format and manner and at times determined by CMS/HHS, that

all information submitted or otherwise made available to CMS/HHS under this paragraph (m) is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements at § 422.116(a)(1)(i).

■ 11. Section 422.112 is amended by revising paragraph (a)(8) to read as follows:

§ 422.112 Access to services.

(a) * * *

(8) *Ensuring equitable access to Medicare Advantage (MA) services.* Ensure that services are provided as follows:

(i) In a culturally competent manner by including all of the following:

(A) People with limited English proficiency or reading skills.

(B) People of ethnic, cultural, racial, or religious minorities.

(C) People with disabilities.

(D) People who identify as lesbian, gay, bisexual, or other diverse sexual orientations.

(E) People who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex.

(F) People living in rural areas and other areas with high levels of deprivation.

(G) People otherwise adversely affected by persistent poverty or inequality.

(ii) Equitably irrespective of delivery method or origin, whether from human or automated systems. Artificial intelligence or automated systems, if utilized, must be used in a manner that preserves equitable access to MA services.

* * * * *

■ 12. Section 422.116 is amended by—

■ a. Redesignating paragraphs (a)(1) through (4) as paragraphs (a)(2) through (5);

■ b. Adding a new paragraph (a)(1) and

■ c. Revising paragraph (f)(1)(i)(A).

The addition and revision read as follows:

§ 422.116 Network adequacy.

(a) * * *

(1) County, for purposes of this section, is defined as the primary political and administrative division of most States and includes functionally equivalent divisions called ''county equivalents'' as recognized by the United States Census Bureau (for economic census purposes).

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type based on substantial and credible evidence, in the form and manner requested by CMS, regarding the following valid rationales:

(*1*) Provider is no longer practicing (for example, deceased, retired).

(*2*) Provider does not provide services at the office or facility address listed in the Provider Supply file (§ 422.116(a)(4)(ii)).

(*3*) Provider does not provide services for the specialty type listed in the Provider Supply file (§ 422.116(a)(4)(ii)).

(*4*) Provider has opted out of Medicare (in compliance with § 422.204(b)(4)).

(*5*) Provider is a sanctioned provider on the List of Excluded Individuals and Entities (in compliance with § 422.204); or provider is on the CMS preclusion list (in compliance with § 422.222).

(*6*) Provider is at capacity and is not accepting new patients; and

* * * * *

■ 13. Section § 422.137 is amended by revising paragraphs (d)(6)(iii)(A) through (H) and adding paragraph (d)(7)(v) to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee.

* * * * *

(d) * * *

(6) * * *

(iii) * * *

(A) The percentage of standard prior authorization requests that were approved, reported by each covered item and service.

(B) The percentage of standard prior authorization requests that were denied, reported by each covered item and service.

(C) The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.

(D) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.

(E) The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.

(F) The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

(7) * * *

(v) Include an executive summary of the results of the analysis. The executive summary must provide additional context for the results of the analysis. The executive summary must provide clarifying information for the report, including an overview of the information produced by the analysis. Accompanying language must not be misleading or misrepresent the findings that result from the analysis.

■ 14. Section 422.138 is amended by revising paragraph (c) to read as follows:

§ 422.138 Prior authorization.

* * * * *

(c) *Effect of prior authorization, pre-service, or concurrent approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization pre-service determination of coverage or payment, or a concurrent determination made during the enrollee's receipt of inpatient or outpatient services, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at §§ 405.986 and 422.616 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in § 405.902 of this chapter apply to this provision.

■ 15. Section 422.162 is amended by revising paragraphs (b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(iv) * * *

(A) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. If a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification or the reliability is less than 0.6 for a CAHPS measure, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

(B) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. For all measures except HEDIS, CAHPS, HOS, and call center measures, if a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

* * * * *

■ 16. Section 422.166 is amended by:

■ a. Revising paragraph (f)(3)(iv) introductory text;

■ b. Adding paragraphs (f)(3)(iv)(C), (f)(3)(v)(A), and reserved paragraph (f)(3)(v)(B);

■ c. Revising paragraphs (f)(3)(vi) and (f)(3)(viii)(B);

■ d. Adding paragraph (f)(3)(viii)(C); and

■ e. Revising paragraphs (g)(1)(i) and (ii).

The revisions and additions read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(f) * * *

(3) * * *

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet all of the following criteria:

* * * * *

(C) Beginning with the 2027 Star Ratings, for contracts that are Institutional Special Needs Plan (I–SNP) only contracts in the ratings year, the measure must be required to be reported for I–SNP-only contracts.

(v) * * *

(A) Starting with the 2029 Star Ratings if a contract's HEDIS measure score across all enrollees for a HEDIS measure included in the HEI calculated from the patient-level data submitted by the contract does not match the summary-level score submitted by the contract to NCQA for either of the measurement years used to construct the HEI, the contract will receive –1 points for the HEDIS measure in the calculation of the HEI. If a contract does not submit HEDIS patient-level data for a measure for which it submitted contract-level data for either of the measurement years used to construct the HEI, the contract will receive –1 points for the HEDIS measure in the calculation of the HEI.

(B) [Reserved]

(vi) Starting with the 2027 Star Ratings, to have the HEI calculated, contracts that are I–SNP-only contracts in the ratings year must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section for the subset of measures that I–SNP-only contracts are required to report. To have the HEI calculated, all other contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

* * * * *

(viii) * * *

(B) Starting with the 2027 Star Ratings, for the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score is combined across the consumed and surviving contracts in the consolidation and used in calculating the HEI score. The enrollment used in assessing whether the surviving contract meets an enrollment threshold under paragraph (f)(3)(vii) of this section will be the combined enrollment from the consumed and surviving contracts from the most recent year of data used to calculate the HEI.

(C) Starting with the 2029 Star Ratings, in states where, consistent with § 422.107(e), one or more MA contracts that only include one or more dual eligible special needs plans (D–SNPs) with a service area limited to that state are required to be established and maintained, the original MA contract(s) from which the D–SNP plan benefit package or packages were moved (hereafter referred to as the ''legacy MA contract(s)'') into the MA contract established under § 422.107(e) will have the HEI reward calculated as follows every year after the D–SNP-only contract is required to be created until the Star Ratings year in which additional SRFs beyond receipt of LIS, dual-eligibility, and disability are added to the HEI:

(*1*) If the legacy MA contract, based on its own enrollment, meets an enrollment threshold under paragraph (f)(3)(vii) of this section, the methodology for calculating the HEI reward in paragraph (f)(3)(viii) of this section is followed.

(*2*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and either one of the legacy MA contract or the MA contract established under § 422.107(e) cannot have the HEI reliably calculated as described in paragraphs (f)(3)(iv) and (vi) of this section, then the legacy MA contract does not qualify for an HEI reward.

(*3*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and the legacy MA contract's performance on the HEI based on its own enrollment is less than—

(*i*) The minimum index score defined at paragraph (f)(3)(vii) of this section; or

(*ii*) The performance on the HEI of the MA contract established under § 422.107(e)

Then, the legacy MA contract does not qualify for an HEI reward.

(*4*)(*i*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and both the legacy MA contract and the MA contract established under § 422.107(e) can have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi) of this section, then the enrollment combined across the legacy MA contract and the MA contract established under § 422.107(e) for the most recent measurement year used in calculating the HEI is used in assessing the enrollment threshold in paragraph (f)(3)(vii) of this section.

(*ii*) If an enrollment threshold is met using the combined enrollment described in paragraph (f)(3)(viii)(C)(*4*)(*i*) of this section, the legacy MA contract's rating-specific HEI score meets the minimum index score of greater than zero defined at paragraph (f)(3)(vii) of this section, and the legacy MA contract's rating-specific HEI score is greater than or equal to the rating-specific HEI score of the MA contract established under § 422.107(e), then the HEI reward for the legacy MA contract is calculated following paragraph (f)(3)(viii) of this section based on the enrollment threshold using the combined enrollment from the legacy MA contract and the MA contract established under § 422.107(e), and using the HEI score for the MA contract established under § 422.107(e).

(*5*) When multiple legacy MA contracts move their D–SNP plan benefit package(s) to the same MA contract established under § 422.107(e) and any of the legacy MA contracts do not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this

section, and both the legacy MA contracts and the MA contract established under § 422.107(e) can have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi) of this section, then the combined enrollment from the legacy MA contracts and the MA contract established under § 422.107(e) for the most recent measurement year used in calculating the HEI is used in assessing the enrollment threshold in paragraph (f)(3)(vii) of this section for any of the legacy MA contracts that do not meet an enrollment threshold on their own. If an enrollment threshold is met using the combined enrollment in this paragraph, the steps in paragraph (f)(3)(viii)(C)(*4*)(*ii*) of this section are followed separately for each of the legacy MA contracts. If a legacy MA contract meets the enrollment thresholds on its own or if it cannot have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi) of this section, the legacy MA contract would not be included in the calculation of the combined enrollment.

* * * * *

(g) * * *

(1) * * *

(i) If the highest rating rounded to the half star before the addition of the HEI reward, if applicable, for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating rounded to the half star before the addition of the HEI reward, if applicable, is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

* * * * *

■ 17. Section 422.562 is amended by revising paragraph (c)(2) to read as follows:

§ 422.562 General provisions.

* * * * *

(c) * * *

(2) Based on an MA organization's determination on a request for payment, if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

* * * * *

■ 18. Section 422.566 is amended by revising paragraph (b)(3) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(3) The MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

* * * * *

■ 19. Section 422.568 is amended by revising paragraphs (b)(1) introductory text, (d) introductory text, and (f) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) * * *

(1) *Requests for service or item.* Except as provided in paragraph (b)(2) of this section, when a party has made a request for an item or service, the MA organization must notify the enrollee (and the physician or provider involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires but no later than either of the following:

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee and the physician or provider involved, as appropriate, a written notice if—

* * * * *

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee and the physician or provider involved, as appropriate, with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

* * * * *

■ 20. Section 422.572 is amended by revising paragraph (f) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee and the physician or prescriber involved, as appropriate, with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

■ 21. Section 422.616 is amended by revising paragraph (a) and adding paragraph (e) to read as follows:

§ 422.616 Reopening and revising determinations and decisions.

(a) Subject to paragraph (e) of this section and the rules at § 422.138(c) of this part, an organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or attorney adjudicator or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

* * * * *

(e) Limitation on reopening a determination related to an approved inpatient hospital admission: If the MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) and (3), any additional clinical information obtained after the initial organization determination cannot be used as new and material evidence to establish good cause for reopening the determination.

■ 22. Section 422.631 is amended by revising paragraphs (a) and (d)(1)(i) and (ii) to read as follows:

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(3), 422.570(d)(2), and 422.572(a)(2).

* * * * *

(d) * * *

(1) * * *

(i) The applicable integrated plan must send an enrollee a written notice (and notify the physician or provider involved, as appropriate) of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable

integrated plan must send a notice to the enrollee (and notify the physician or provider involved, as appropriate) on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

* * * * *

■ 23. Section 422.2260 is amended by revising the definitions of ''Advertisement (Ad)'' and ''Marketing'' to read as follows:

§ 422.2260 Definitions.

* * * * *

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention.

* * * * *

Marketing means communications materials and activities that are intended to draw a beneficiary's attention to a MA plan or plans, influence a beneficiary's decision-making process when making a MA plan selection, or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing), except those required materials specified in § 422.2267(e) of this chapter, which will maintain the material designation as provided by CMS. In evaluating the intent of an activity or material, CMS considers objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's stated intent.

* * * * *

■ 24. Section 422.2263 is amended by adding paragraph (b)(11) to read as follows:

§ 422.2263 General marketing requirements.

* * * * *

(b) * * *

(11) Market the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, such as use of a debit card by the enrollee to provide the plan's payment to the provider for the covered services.

* * * * *

■ 25. Section 422.2267 is amended:

■ a. In paragraph (e)(30)(vi) by removing the word ''and'';

■ b. In paragraph (e)(30)(vii) by removing the phrase ''of this section.'' and adding in its place the phrase ''of this section; and''; and

■ c. By adding paragraph (e)(30)(viii).

The addition reads as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(30) * * *

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in § 422.561, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

* * * * *

■ 26. Section 422.2274 is amended by revising paragraph (c)(12) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment, CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics to be discussed include all the following:

(i) Primary care providers and specialists (that is, whether or not the beneficiary's current providers are in the plan's network).

(ii) Pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network).

(iii) Prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered).

(iv) Low-income subsidy eligibility (that is, at a minimum, explaining the eligibility requirements as defined at § 423.773, and the effect on drug costs if eligible, and identifying resources where they can get more information on applying).

(v) Resources for state programs, including Medicare Savings Programs

(vi) For beneficiaries who are enrolling into a MA plan when first eligible for Medicare, or those who are dropping a Medigap plan to enroll into an MA plan for the first time.

(A) The agent must explain all of the following:

(*1*) That there is a 12-month period under Federal law in which they are permitted to disenroll from the MA plan and switch back to Traditional Medicare and purchase a Medigap plan with guaranteed issue rights.

(*2*) If the beneficiary enrolls into Traditional Medicare and decides to purchase a Medigap plan outside of the 12-month window, that they are not guaranteed the right under Federal law to purchase a Medigap plan in the future, and if they do, the insurance company selling the Medigap plan may not cover all preexisting health conditions and may charge more based on past or present health problems.

(B) The agent may do either of the following:

(*1*) Provide additional state-based guaranteed issue rights information.

(*2*) Supplement state-based guaranteed issue rights information with the information provided under 422.2274(c)(12)(vi)(A) of this section, when it offers additional protections or flexibility.

(vii) Costs of health care services.

(viii) Premiums.

(ix) Benefits.

(x) Specific health care needs.

(xi) Conclude by pausing to ask if the beneficiary has any questions about the topics discussed in paragraph (c)(12) of this section or others, including those related to enrollment.

* * * * *

■ 27. Section 422.2401 is amended by adding in alphabetical order definitions for ''MLR audit remittance'' and ''MLR audit remittance process'' to read as follows:

§ 422.2401 Definitions.

MLR audit remittance means the amount CMS calculates and an MA organization pays for an MA contract that has failed to meet the 85 percent minimum MLR requirement as the result of an MLR audit examination.

MLR audit remittance process means the process by which CMS calculates the MLR audit remittance for a contract that is determined to have failed to meet the 85 percent minimum MLR requirement as the result of an MLR audit examination and notify the MA organization about the remittance. The process includes all of the following:

(1) Collecting the MLR audit remittance indicated in the final audit report issued by CMS.

(2) Receiving responses from MA organizations requesting an appeal of the MLR audit remittance.

(3) Taking actions to adjudicate an appeal (if requested).

(4) Receiving MLR remittances from MA organizations.

* * * * *

■ 28. Section 422.2420 is amended by—

■ a. Revising paragraph (b)(2)(xi);

■ b. Adding paragraph (b)(4)(i)(D);

■ c. Revising paragraph (c)(2)(iv)(B);

■ d. Redesignating paragraphs (d)(2)(i) through (iii) as paragraphs (d)(2)(ii) through (iv); and

■ e. Adding new paragraph (d)(2)(i).

The additions and revisions read as follows:

§ 422.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(2) * * *

(xi) The amount of incentive and bonus payments made, or expected to be made, to providers that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

(3) * * *

(4) * * *

(i) * * *

(D) Unsettled balances from the Medicare Prescription Payment Plan

* * * * *

(c) * * *

(2) * * *

(iv) * * *

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the MA organization is licensed, multiplied by the MA organization's earned premium for the contract.

* * * * *

(d) * * *

(2) * * *

(i) The report required in § 422.2460 must include a detailed description of the methods used to allocate expenses, including incurred claims, expenditures on quality improving activities, licensing and regulatory fees, and State and Federal taxes and assessments. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

■ 29. Section 422.2430 is amended by redesignating paragraphs (a) and (b) as paragraphs (b) and (c) and adding a new paragraph (a) to read as follows:

§ 422.2430 Activities that improve health care quality.

(a) *General requirements.* The report required in § 422.2460 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

* * * * *

■ 30. Section 422.2450 is added to read as follows:

§ 422.2450 MLR audit process.

(a) *Notice of audit.* CMS provides at least 15 calendar days advance notice of its intent to conduct an audit of an MA organization.

(b) *Conferences.* All audits include an entrance conference during which the scope of the audit is presented and an exit conference during which the initial audit findings are discussed.

(c) *Audit documentation.* All requested audit documentation must be provided by the MA organization to CMS within 30 calendar days of the audit entrance conference. CMS may extend, at CMS's discretion, the time for an MA organization to provide the documentation requested.

(d) *Preliminary audit findings.* CMS shares its preliminary audit findings with the MA organization, which then has 30 calendar days to respond to such findings. CMS may extend, for good cause, the time for an MA organization to submit such a response.

(e) *Final audit findings.* If the MA organization does not dispute the preliminary findings within the 30-day timeframe per paragraph (d) of this section, then the audit report becomes final. Alternatively, if the MA organization disputes the preliminary findings, CMS reviews and considers such response before finalizing the audit findings.

(f) *Corrective actions.* CMS sends a copy of the final audit report to the MA organization as well as issues corrective actions that the MA organization must undertake as a result of the audit findings.

(g) *Order to pay remittances.* If CMS determines as the result of an audit that an MA organization has failed to pay remittances it is obligated to pay under § 422.2480, it may order the MA organization to pay those remittances consistent with § 422.2452.

■ 31. Section 422.2452 is added to read as follows:

§ 422.2452 MLR audit remittance and payment process.

(a) *Notice of MLR audit remittance.* After the calculation of the MLR audit remittance, CMS sends the MA organization the final audit report with the MLR audit remittance amount. The final audit report contains the following information:

(1) A MLR audit remittance for the contract that has failed to meet the 85 percent MLR minimum requirement based on audit findings, which may be one of the following:

(ii) An amount due from the MA organization.

(iii) $0 if nothing is due from the MA organization.

(2) Relevant banking and financial mailing instructions for MA organizations that owe a MLR audit remittance.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the MLR audit remittance calculation, in accordance with the requirements specified in § 422.2454.

(b) *Request for an appeal.* A MA organization that disagrees with the MLR audit remittance has 15 calendar days from the date of issuance of the final audit report, as described in paragraph (a) of this section, to request an appeal of the MLR audit remittance under the process described in § 422.2454.

(1) If an MA organization agrees with the MLR audit remittance, no response is required.

(2) If an MA organization disagrees with the MLR audit remittance, it must request an appeal within 15 calendar days from the date of issuance of the final audit report. CMS will not consider any requests for appeal after this 15-day period.

(c) *Actions if a MA organization does not request an appeal.* (1) The MA organization is required to remit payment to CMS within 120 calendar days from the date of issuance of the final audit report.

(2) If the MA organization fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following a request for appeal.* If an MA organization responds to the final audit report disagreeing with the MLR audit remittance and requesting appeal, CMS conducts a review process under the process described at § 422.2454.

■ 32. Section 422.2454 is added to read as follows:

§ 422.2454 MLR audit remittance appeals process.

(a) *Appeals process.* If an MA organization does not agree with the MLR audit remittance described in § 422.2452(a), it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the MLR audit remittance described in § 422.2452(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date of issuance of the final audit report to the MA organization.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the MA organization disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the MLR audit remittance is incorrect.

(C) Not include new data or data that was submitted to CMS after the final audit report was issued.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the MLR audit remittance and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS's reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with the CMS hearing officer within 15 calendar days from the date of issuance of the reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date.

(B) The CMS reconsideration official provides, within 10 calendar days of the hearing officer receiving an informal hearing request, a copy of the record that was before the reconsideration official.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS reconsideration official had when making the reconsideration decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides whether to uphold or overturn the reconsideration official's decision and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. The MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review.

(B) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS's calculation of the MLR audit remittance.

(2) The MA organization bears the burden of proof for providing evidence demonstrating that CMS's audit examination results for the MLR audit remittance require further review. The MA organization may not challenge the underlying methodology for the MLR audit remittance calculation.

(c) *Stay of financial transaction until appeals are exhausted.* If an MA organization requests review of the MLR audit remittance, the financial transaction associated with the payment of the MLR audit remittance is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the MA organization to complete the financial transaction associated with the payment of the MLR audit remittance.

(d) *Continued compliance with other law required.* Nothing in this section limits a MA organization's responsibility to comply with any other statute or regulation.

■ 33. Section 422.2460 is amended by revising paragraph (a) to read as follows:

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, provider payment arrangements, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

* * * * *

■ 34. Section 422.2480 is amended by revising paragraph (d) introductory text to read as follows:

§ 422.2480 MLR review and non-compliance.

* * * * *

(d) Data submitted under § 422.2460, calculations, or any other MLR submission required by this subpart which have not been reported in a timely and accurate manner or have been found to be materially incorrect or fraudulent—

* * * * *

■ 35. Section 422.2490 is amended by adding paragraphs (b)(6) and (7) to read as follows:

§ 422.2490 Release of Part C MLR data.

* * * * *

(b) * * *

(6) DIR information reported within the MLR data as part of incurred claims.

(7) Provider payment arrangement data that is not reported on a deidentified basis and provider payment arrangement data that is not reported on an aggregate total basis.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 36. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 37. Section 423.100 is amended by adding in alphabetical order definitions for ''ACIP-recommended adult vaccine,'' ''Covered insulin product,'' ''Covered insulin product applicable cost-sharing amount,'' and ''Effective date of the ACIP recommendation'' to read as follows:

§ 423.100 Definitions.

ACIP-recommended adult vaccine means a covered Part D drug, as defined at § 423.100, that is a vaccine licensed by the U.S. Food and Drug Administration (FDA) under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) as adopted by the CDC Director.

* * * * *

Covered insulin product means, for purposes of § 423.120(h), an insulin product, including a product that is a combination of more than one type of insulin or a product that is a combination of both insulin and a non-insulin drug or biological product, that—

(1) Is a covered Part D drug covered under a PDP or MA–PD plan—

(i) Is licensed under section 351 of the Public Health Service Act; and

(ii) Is marketed under the license described in paragraph (1)(i) of this definition.

(2) Is not a compounded drug product that contains insulin (as described in § 423.120(d)).

Covered insulin product applicable cost-sharing amount means, with respect to a covered insulin product, as defined in this section, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold during plan year 2026 and each subsequent plan year, the lesser of the following:

(1) $35.

(2) An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with part E of subchapter XI.

(3) An amount equal to 25 percent of the negotiated price (as defined in § 423.100) of the covered insulin product under the PDP or MA–PD plan.

* * * * *

Effective date of the ACIP recommendation means the date specified on the CDC website noting the date the CDC Director adopted the ACIP recommendation.

* * * * *

■ 38. Section 423.120 is amended by adding paragraphs (g) and (h) to read as follows:

§ 423.120 Access to covered Part D drugs

* * * * *

(g) *Coverage of ACIP-recommended adult vaccines.* With respect to an ACIP-recommended adult vaccine, a Part D sponsor must—

(1) Not apply any deductible nor charge any cost-sharing; and

(2) Once a new or revised recommendation is posted on the CDC website, provide coverage consistent with paragraph (g)(1) of this section for dates of service on or after the effective date of the ACIP recommendation, as defined at § 423.100.

(3) Apply the requirements in paragraphs (g)(1) and (2) of this section to ACIP-recommended adult vaccines obtained from either an in-network or out-of-network pharmacy or provider in accordance with § 423.124(a) and (c).

(h) *Appropriate cost-sharing for covered insulin products.* With respect to a covered insulin product, as defined at § 423.100, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold, a Part D sponsor must do all of the following:

(1) Not apply a deductible.

(2) Ensure any enrollee cost sharing for each prescription fill up to a one-month supply does not exceed the covered insulin product applicable cost-sharing amount defined at § 423.100.

(3) Ensure any enrollee cost sharing for each prescription fill greater than a 1-month supply does not exceed the cumulative covered insulin product applicable cost-sharing amount (as defined in § 423.100) that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary.

(4) Apply the requirements in paragraphs (h)(1) through (3) of this section to covered insulin products obtained from either an in-network or out-of-network pharmacy or provider.

■ 39. Section 423.137 is added to subpart C to read as follows:

§ 423.137 Medicare Prescription Payment Plan.

(a) *General.* For plan years beginning on or after January 1, 2026, or, in the case of a plan operating on a non-calendar year basis, for the portion of the plan year starting on January 1, 2026, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan must provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined at § 423.4), the option to elect with respect to a plan year to pay $0 cost sharing at the point of sale and pay cost sharing under the plan in monthly amounts that are capped in accordance with this section.

(b) *Definitions.* For the purposes of this section, the following definitions apply:

(1) *OOP costs for the Medicare Prescription Payment Plan* means the out-of-pocket cost sharing amount the Part D enrollee is directly responsible for paying.

(i) For the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, it includes those Part D cost sharing amounts that the enrollee is responsible for paying after taking into account amounts paid by third-party payers.

(ii) It does not include the covered plan pay amount or other costs defined under section 1860D–2(b)(4)(C) of the Act.

(2) *Remaining OOP costs owed by the participant* means the sum of out-of-pocket costs for the Medicare Prescription Payment Plan that have not yet billed to the program participant. For example, if a Medicare Prescription Payment Plan participant incurs $2,000 in January 2025 and is billed $166.67, the remaining OOP costs for the Medicare Prescription Payment Plan are $2,000 − $166.67 = $1,833.33.

(c) *Calculation of the maximum monthly cap on cost-sharing payments.* For each month in the plan year for which an enrollee in a PDP or an MA–PD plan has made an election to participate in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization must determine a maximum monthly cap (as defined in paragraph (c)(1) of this section) for such enrollee.

(1) *Enrollee monthly payments.* For each month an enrollee is participating in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(i) *First month maximum monthly cap calculation.* For the first month for which the enrollee has made an election to participate in the Medicare Prescription Payment Plan, the maximum monthly cap is an amount determined by calculating the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act minus the incurred costs of the enrollee as described in section 1860D–2(b)(4)(C) of the Act; divided by the number of months remaining in the plan year.

(A) When the out-of-pocket costs incurred in the first month of program participation are less than the maximum monthly cap defined in paragraph (c)(1)(i) of this section, the PDP sponsor or MA organization must bill the participant the lesser of the participant's actual out-of-pocket costs or the first month's maximum monthly cap.

(B) When an enrollee opts into the Medicare Prescription Payment Plan prior to the start of the plan year, the calculation described in (c)(1)(i) applies to their first month of active coverage within the plan year.

(ii) *Calculation of maximum monthly cap in subsequent months.* For subsequent months in the plan year, the maximum monthly cap is an amount determined by calculating the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by the number of months remaining in the plan year.

(2) *Eligible out-of-pocket costs.* The calculations described in paragraphs (c)(1)(i) and (ii) of this section apply only to covered Part D drugs, as defined at § 423.100.

(3) *Months remaining in the plan year.* For the calculations described in paragraphs (c)(1)(i) and (ii) of this section, the number of months remaining in the plan year includes the month for which the cap is being calculated.

(4) *Impact on true out-of-pocket cost accumulation.* Participation in the Medicare Prescription Payment Plan must have no impact on true out-of-pocket cost accumulation. Costs defined under section 1860D–2(b)(4)(C) of the Act incurred under the Medicare Prescription Payment Plan must still be treated as incurred based on the date each Part D claim is adjudicated.

(5) *Prescriptions for an extended day supply.* For participants who fill prescriptions for an extended day supply, their OOP costs for the Medicare Prescription Payment Plan for those prescriptions must be attributed to the month the prescription was filled and not be pro-rated over the months covered by the prescription.

(6) *Mid-year plan switching.* When an individual opts into the Medicare Prescription Payment Plan after switching plans midyear, the new Part D sponsor must calculate the individual's monthly cap for the first month of participation under the new plan using the formula for the calculation of the maximum monthly cap in the first month.

(d) *Eligibility and election.* An individual is eligible for the Medicare Prescription Payment Plan if they are enrolled in a Part D plan and have not been precluded from participation due to failure to pay, as described in paragraphs (f)(2)(ii) and (f)(5) of this section. LIS-eligible Part D enrollees are eligible to participate in the program.

(1) *Election.* A Part D sponsor must allow any Part D enrollee, including those who are LIS-eligible, to opt into the program prior to the beginning of the plan year or at any point during the plan year. A Part D enrollee must also be allowed to opt into the program in advance of a new plan enrollment effective date, including during any of the following:

(i) The annual election period for the subsequent plan year.

(ii) The Part D initial enrollment period.

(iii) Part D special election periods.

(2) *Format of election requests.* A Part D sponsor must allow any Part D enrollee or a Part D enrollee's authorized legal representative acting on behalf of the enrollee to opt into the program using a paper or electronic election request form or through a telephone call. Part D sponsors must process any election request regardless of format.

(i) *Paper election requests.* Paper election requests are considered received on the date and time:

(A) The Part D sponsor initially stamps a document received by regular mail (that is, U.S. Postal Service); or

(B) A delivery service that has the ability to track when a shipment is delivered (for example, U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

(ii) *Telephonic election requests.* Telephonic election requests are considered received on the date and time that either of the following occurs:

(A) The verbal request is made by telephone with a customer service representative.

(B) A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

(iii) *Electronic election requests.* An electronic election request is considered received on the date and time a request is received through the Part D sponsor's website. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request.

(3) *Completion of election request.* For an election request to be considered complete, the Part D sponsor must receive all of the following:

(i) The name of the Part D enrollee.

(ii) The Medicare ID number of the Part D enrollee.

(iii) The Part D enrollee's or their authorized legal representative's agreement to the Part D sponsor's terms and conditions for the program (signature or, in the case of telephonic requests, verbal attestation).

(4) *Processing an election request*—(i) *Prior to plan year.* Part D sponsors must process election requests received prior to the plan year within the following timeframes:

(A) Within 10 calendar days of receipt, process a complete election request as specified in § 423.137(d)(3).

(B) Within 10 calendar days of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request as specified in § 423.137(d)(3).

(C) If information necessary to consider the request complete, as required at § 423.137(d)(3), is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(ii) *During a plan year.* Part D sponsors must process election requests received during a plan year within the following timeframes:

(A) Within 24 hours of receipt, process a complete election request, as specified in § 423.137(d)(3).

(B) Within 24 hours of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request, as required in § 423.137(d)(3).

(C) If information necessary to consider the request complete, as required at § 423.137(d)(3), is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(D) In the event a Part D sponsor fails to process the request within 24 hours due to no fault of the Part D enrollee, the Part D sponsor must—

(*1*) Process a retroactive election effective on the date on which the enrollee should have been admitted into the program; and

(*2*) Reimburse the enrollee for any cost-sharing paid on or after that date within 45 calendar days and include those amounts, as appropriate, in the program calculations.

(5) *Inclusion of all covered Part D drugs once in the program.* Once a participant has opted into the program, cost sharing for all covered Part D drugs must be included in the program.

(6) *Retroactive election.* (i) A Part D sponsor must have in place a process to effectuate a retroactive election into the Medicare Prescription Payment Plan if both of the following conditions are met:

(A) The Part D enrollee believes that any delay in filling the prescription(s) due to the 24-hour timeframe required to process their request to opt in may seriously jeopardize their life, health, or ability to regain maximum function.

(B) The Part D enrollee requests retroactive election within 72 hours of the date and time the claim(s) were adjudicated.

(ii) The Part D sponsor must process the reimbursement for all cost sharing paid by the enrollee for the prescription and any covered Part D prescription filled between the date of adjudication of the claim and the date that the enrollee's election is effectuated within 45 calendar days of the election date.

(iii) If the Part D sponsor determines that an enrollee failed to request retroactive election within the required timeframe, it must promptly notify the individual of its determination and provide instructions on how the individual may file a grievance, as required under § 423.137(h)(2).

(7) *Retroactive LIS eligibility.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants who become LIS eligible and that meet requirements specified at §§ 423.800(c) and (e) and 423.466(a).

(8) *Mid-year plan switching.* When a Part D enrollee switches Part D plans, whether offered by the same or a different Part D sponsor, during the plan year or is reassigned by CMS, the Part D sponsor of the new Part D plan is not permitted to automatically sign up the individual for the Medicare Prescription Payment Plan under the new plan but must allow the individual to opt into the program. Part D plan has the definition established at § 423.4.

(i) The Part D sponsor of the prior Part D plan must offer the participant the option to repay the full outstanding amount in a lump sum. If the individual chooses to continue paying monthly, the Part D sponsor must continue to bill the participant monthly based on the participant's accrued OOP costs for the Medicare Prescription Payment Plan while in the program under that sponsor's Part D plan. The Part D sponsor cannot require full immediate repayment.

(ii) Part D enrollees may only be precluded from opting into the program under a new Part D plan if both of the following conditions are met:

(A) Both the former and new plans are offered by the same Part D sponsor.

(B) The enrollee was involuntarily terminated from the program under the former plan, as described in paragraph (f)(2)(ii) of this section, for failure to pay and still owes an overdue balance.

(9) *Automatic renewal.* A Part D sponsor is required to automatically renew a Part D enrollee's participation in the Medicare Prescription Payment Plan for subsequent plan years. The Part D sponsor must notify the enrollee of the renewal and remind enrollees that they may opt out of the program at any time, in accordance with paragraph (f)(2)(i) of this section.

(10) *Election communications*—(i) *Election request form.* A Part D sponsor must make available throughout the plan year and during the Part D plan enrollment periods described at paragraph (d)(4)(i)(A) of this section an election request form in the formats specified in paragraph (d)(2) of this section.

(A) *Timing.* A Part D sponsor must send a paper election request form within the same timeframe as the membership ID card mailing specified at § 423.2267(e)(32)(i). The election form may be sent in the membership ID card mailing itself or in a separate mailing.

(B) *Contents.* The election request form must include or provide all of the following:

(*1*) Fields for all of the following Part D enrollee information:

(*i*) First and last name.

(*ii*) Medicare Number.

(*iii*) Birth date.

(*iv*) Phone number.

(*v*) Permanent residence street address, and mailing address, if different from permanent residence street address.

(*vi*) Signature field, allowing the enrollee to attest that they understand that form is a request to participate in the Medicare Prescription Payment Plan and the Part D sponsor will contact them if more information is needed to complete the request; (their signature indicates they have read and understood the Part D sponsor's terms and conditions; and the Part D sponsor will inform the individual when their participation in the program is active, and, until the individual receives that notification, they are not a participant in the program.

(*2*) Instructions for how to submit the form to the Part D sponsor.

(*3*) Instructions for how the Part D enrollee can contact the Part D sponsor for questions or assistance.

(C) *Additional information.* Additional educational information about the Medicare Prescription Payment Plan must accompany the election request form when provided in hard copy or on the web. The additional information requirement may be fulfilled by including with the election request form the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(D) *Terms and conditions.* A Part D sponsor may include their program terms and conditions on the election request form or may include them on a separate attachment.

(ii) *Notice of election approval.* Upon accepting an election request, the Part D sponsor must send a notice of election approval.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of election approval must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of election approval must be sent within 24 hours of receipt of the election request.

(*3*) The initial notice must be delivered via telephone, to be followed by a written notice delivered to the participant within three calendar days of delivering the initial telephone notice.

(B) *Contents.* The notice of election approval must include all of the following:

(*1*) The effective date of the individual's participation.

(*2*) A description of how payments for covered Part D drugs under the program will work.

(*3*) An overview of how the monthly bill is calculated.

(*4*) Information about procedures for involuntary termination due to failure to pay and how to submit an inquiry or file a grievance.

(*5*) A statement that leaving the program will not affect the individual's Part D plan enrollment.

(*6*) A description of how individuals may still owe a program balance if they leave the program, and they can choose to pay their balance all at once or be billed monthly.

(*7*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs. These programs include all of the following:

(*i*) Extra Help.

(*ii*) The Medicare Savings Program.

(*iii*) The State Pharmaceutical Assistance Program.

(*iv*) A manufacturer's Pharmaceutical Assistance Program.

(C) *Additional information.* Additional educational information

about the Medicare Prescription Payment Plan must accompany the notice of election approval. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(iii) *Notification of denial.* Upon denial of an election request, the Part D sponsor must send a notice of denial.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of denial must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of denial must be sent within 24 hours of receipt of the election request.

(*3*) For incomplete election requests, within 10 calendar days of the expiration of the timeframe for submission of additional information.

(B) *Contents.* The notice of denial must explain the reason for denial and a description of the grievance process available to the individual.

(iv) *Renewal notice.* A Part D sponsor must send a notice alerting program participants that their participation in the program will automatically renew for the subsequent plan year.

(A) *Timing.* The notice must be sent no later than the end of the annual coordinated election period, as described at § 422.62(a)(2).

(B) *Contents.* The notice must include all of the following:

(*1*) Notification to the participant that their participation will automatically renew for the upcoming year.

(*2*) Reminder that the participant may opt out of the program at any time, including for the upcoming plan year.

(*3*) The Part D sponsor's program terms and conditions for the upcoming plan year.

(e) *Part D enrollee targeted outreach.* A Part D sponsor must undertake targeted outreach to enrollees who are likely to benefit from making an election into the Medicare Prescription Payment Plan.

(1) *Identification criteria.* An enrollee deemed to be ''likely to benefit'' from the Medicare Prescription Payment Plan is identified by the Part D sponsor based on the following criteria.

(i) For 2026 and subsequent years, the targeted outreach criteria are as follows:

(A) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurs $600 or more in out-of-pocket costs for a single covered Part D drug.

(B) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurred $2,000 in out-of-pocket costs for covered Part D drugs in the first nine months of the year prior to the upcoming plan year.

(ii) A Part D sponsor may develop supplemental strategies for identification of additional Part D enrollees likely to benefit. If supplemental strategies are implemented, then the Part D sponsor must apply any additional identification criteria to every enrollee of each plan equally.

(2) *Point of sale notification.* (i) A Part D sponsor must have a mechanism to notify a pharmacy when a Part D enrollee incurs out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program using the identification criteria set forth in paragraphs (e)(1)(i)(A) and (e)(1)(ii) of this section.

(ii) A Part D sponsor must ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that it is likely that the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

(3) *Part D sponsor notification.* A Part D sponsor must directly outreach to enrollees identified as likely to benefit from the program during either of the following timeframes:

(i) *Prior to the plan year.* Prior to the plan year, a Part D sponsor must notify current enrollees that they are likely to benefit from the program during the fourth quarter of the year, and no later than the end of the annual coordinated election period, as described at § 422.62(a)(2), using the identification criteria set forth in paragraphs (e)(1)(i)(B) and (e)(1)(ii) of this section.

(ii) *On an ongoing basis during the plan year.* Part D sponsors must put in place reasonable guidelines for ongoing identification and notification of enrollees that are likely to benefit from the program on an ongoing basis during the plan year.

(4) *Targeted outreach notification requirements.* When an enrollee is identified as likely to benefit from the program, using the identification criteria set forth in paragraphs (e)(1)(i) and (ii) of this section or based on Part D sponsor-developed guidelines set forth at paragraph (e)(3)(ii) of this section, the Part D sponsor must provide to the enrollee the standardized Medicare Prescription Payment Plan Likely to Benefit Notice consistent with the requirements at § 423.2267(b).

(i) When the enrollee is identified as likely to benefit directly by the Part D sponsor, either prior to or during the plan year, the notification may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods).

(A) The outreach must include a program election request form and additional information about the Medicare Prescription Payment Plan. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V.

(B) During the plan year, the initial notice may be provided via telephone, so long as the written ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' election request form, and additional information are sent within three calendar days of the telephone notification.

(ii) When the enrollee is identified as likely to benefit during the plan year at the pharmacy point of sale, the notice must be provided as described in paragraph (i)(2) of this section.

(5) *Targeted outreach exclusions.* A Part D sponsor does not have to notify enrollees that they are likely to benefit from the program under any of the following circumstances:

(i) For the current year during the final month of the plan year (December).

(ii) When the enrollee is currently participating in the program, including—

(A) For the current year; and

(B) For the upcoming year.

(iii) When the enrollee is precluded from opting into the program.

(iv) When the PDP is non-renewing its contract or individual plan benefit package. This exclusion only applies to the requirements at paragraph (e)(3)(i) of this section related to prior to plan year targeted outreach.

(f) *Termination of election, reinstatement, and preclusion*—(1) *General rule.* Except as provided in paragraph (f)(2) of this section, a Part D sponsor may not do any of the following:

(i) Terminate an individual from the Medicare Prescription Payment Plan.

(ii) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(2) *Basis for termination*—(i) *Voluntary terminations.* A Part D sponsor must have a process to allow participants who have opted into the Medicare Prescription Payment Plan to opt out during the plan year.

(A) When a participant opts out of the Medicare Prescription Payment Plan, a Part D sponsor must—

(*1*) Process the termination with an effective date within 24 hours of receipt of the request for termination.

(*2*) Provide the individual with a notice of termination after the individual notifies the Part D sponsor that they intend to opt out under the Part D sponsor's established process.

(*i*) *Timing.* The Part D sponsor must send the notice of termination within ten calendar days of receipt of the request for termination.

(*ii*) *Contents.* The notice of voluntary termination must include all of the following. The date on which the individual's participation in the program ends. An explanation of why the individual is receiving the notice. A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan. A statement clarifying that the individual will continue to be billed monthly or can choose to pay the amount owed all at once, and that the individual will not pay interest or fees on the amount owed. A statement clarifying that the individual can join the Medicare Prescription Payment Plan again and instructions for how to do so. An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(*3*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*4*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(*5*) Maintain appropriate records of the termination once the termination is processed.

(ii) *Involuntary termination.* If a participant fails to pay their monthly billed amount under the program, a Part D sponsor is required to terminate that individual's Medicare Prescription Payment Plan participation.

(A) A participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period as specified at paragraph (f)(4) of this section.

(B) When a Part D sponsor involuntarily terminates a participant, the sponsor must do all of the following:

(*1*) Provide the individual with a notice of termination consistent with the requirements of paragraphs (f)(C) and (f)(D) of this section.

(*2*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*3*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(C) *Notice of failure to pay.* If a Part D sponsor involuntarily terminates a participant under paragraph (f)(2)(ii) of this section, the Part D sponsor must send the individual an initial notice explaining that the individual has failed to pay the billed amount.

(*1*) *Timing.* The notice of failure to pay must be sent within 15 calendar days of the payment due date.

(*2*) *Contents.* The notice of failure to pay must include all of the following:

(*i*) Pertinent dates, including the date the missed monthly payment was due, the amount the individual must pay to remain in the program, and the date by when payment must be received, which is the date of the end of the grace period.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan.

(*iii*) Instructions for how to submit payment.

(*iv*) Information about procedures for involuntary termination due to failure to pay, including the date on which the participant would be removed if payment is not received, and how to submit an inquiry or file a grievance.

(*v*) A statement describing how individuals should pay their Part D plan premium first if they cannot afford both their premium and their program balance.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(D) *Involuntary termination notice.* If the individual has failed to pay the amount due by the end of the grace period described at paragraph (f)(4) of this section, the Part D sponsor must send the individual a termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan.

(*1*) *Timing.* The involuntary termination notice must be sent within 3 business days following the last day of the end of the grace period.

(*2*) *Contents.* The involuntary termination notice must include all of the following:

(*i*) Pertinent dates, including the date the individual was originally notified of the missed monthly payment and the due date for that payment, as well as the date on which the individual's participation in the program ends, which should be the same date as the notice.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted.

(*iii*) Instructions for how to submit payment and the amount owed.

(*iv*) Instructions for how to submit an inquiry or file a grievance.

(*v*) A statement clarifying that the individual can join the Medicare Prescription Payment Plan again if they pay the amount owed.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(E) If either notice is returned to the Part D sponsor as undeliverable, the Part D sponsor must immediately implement its existing procedure for researching a potential change of address.

(3) *Required grace period and reinstatement.* When a program participant fails to pay a program bill, the Part D sponsor must provide individuals with a grace period of at least 2 months upon notifying the individual of the initial missed payment.

(i) The grace period must begin on the first day of the month following the date

on which the initial notice described in paragraph (f)(3) of this section is sent.

(ii) A participant must be allowed to pay the overdue balance in full during the grace period to remain in the program.

(iii) If a participant fails to pay their monthly billed amount under the program with fewer than 2 full calendar months remaining in the calendar year, the grace period must carry over into the next calendar year.

(A) If the program participant is within their grace period from the prior year, the Part D sponsor must allow the participant to opt into the program for the next year.

(B) If that participant fails to pay the amount due from the prior year during the required grace period, the Part D sponsor may terminate the individual's participation in the program in the new year following the procedures outlined in paragraph (f)(2)(ii).

(iv) If an individual who has been terminated from the Medicare Prescription Payment Plan demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed, a Part D sponsor must reinstate that individual into the Medicare Prescription Payment Plan.

(A) A Part D sponsor is expected to reinstate an individual into the program within a reasonable timeframe after the individual has repaid their past due Medicare Prescription Payment Plan balance in full.

(B) To demonstrate good cause, the individual must establish by a credible statement that failure to pay the monthly amount billed within the grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(v) If an individual who has been terminated from the Medicare Prescription Payment Plan pays all overdue amounts billed in full, a Part D sponsor may also reinstate that individual, at the sponsor's discretion and within a reasonable timeframe, even if the individual does not demonstrate good cause.

(4) *Preclusion of election in a subsequent plan year.* If an individual fails to pay the amount billed for a month as required under the Medicare Prescription Payment Plan, a Part D sponsor may preclude that individual from opting into the Medicare Prescription Payment Plan in a subsequent year.

(i) A Part D sponsor may only preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that Part D sponsor.

(ii) If an individual enrolls in a Part D plan offered by a different Part D sponsor than the Part D sponsor to which the individual owes an overdue balance, that individual cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by that different Part D sponsor.

(iii) If a Part D enrollee remains in a plan offered by the same Part D sponsor and continues to owe an overdue balance, preclusion may extend beyond the immediately subsequent plan year.

(A) If an individual pays off the outstanding balance under the Medicare Prescription Payment Plan during a subsequent year, the Part D sponsor must promptly permit them to opt into the Medicare Prescription Payment Plan after the balance is paid.

(B) [Reserved]

(iv) A Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plans. However, the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan.

(5) *Prohibition on Part D enrollment penalties.* A Part D plan sponsor is prohibited from doing any of the following:

(i) Disenrolling a Part D enrollee from a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan.

(ii) Declining future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the Medicare Prescription Payment Plan.

(6) *Disenrollment.* (i) If a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions in § 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan.

(ii) If the participant enrolls in a different plan, they may opt into the Medicare Prescription Payment Plan under their new plan.

(7) *Billing for amounts owed.* Nothing in this section prohibits a Part D sponsor from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed.

(g) *Participant billing rights*—(1) *General rule.* For each billing period after an individual has opted into the program and incurred out-of-pocket costs, a Part D sponsor must calculate a monthly amount that takes into account the out-of-pocket costs in that month that were incurred on or after the date on which the individual opted into the program.

(i) A Part D sponsor must not bill a participant who is in the program but has not yet incurred any out-of-pocket costs during the plan year.

(ii) While past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap, the amount billed for the month for which the maximum monthly cap is being calculated cannot be higher than the cap for that month.

(iii) A Part D sponsor must not charge late fees, interest payments, or other fees, such as for different payment mechanisms.

(A) A Part D sponsor must ensure that—

(*1*) Any third party it contracts with complies with such requirements.

(*2*) Participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor.

(iv) A Part D sponsor must send a bill for the Medicare Prescription Payment Plan that is separate from the bill for collection of premiums, if applicable.

(2) *Billing period.* Each billing period will be a calendar month.

(i) The billing period begins on either of the following:

(A) The effective date of a Part D enrollee's participation in the Medicare Prescription Payment Plan (for the first month a participant elects into the program during the plan year).

(B) The first day of the month (for each subsequent month or for the first month of a participant who elects into the program prior to the start of the plan year).

(ii) The billing period ends on the last date of that month.

(3) *Billing statement.* Billing statements must include all of the following information:

(i) A statement that the bill is for the Medicare Prescription Payment Plan;

(ii) A brief description of the program; and

(iii) A reference to where additional information about the program can be found.

(iv) The effective date of program participation.

(v) The last payment received, showing the date, amount of the last payment, and the means of payment made by the participant.

(vi) Any balance carried over from the prior month, including any missed payments.

(vii) Itemized out-of-pocket costs by prescription for the month being billed.

(viii) The amount due from the participant for the month being billed (that is, the amount based on the application of the monthly cap calculation).

(ix) The remaining total out-of-pocket cost sharing balance.

(x) Information on the next steps if the participant fails to pay by the stated due date.

(xi) Information on how to voluntarily opt out of the program and balances due if participation is terminated.

(xii) Information on the dispute processes available if the individual disputes their bill.

(xiii) LIS program information, including:

(A) General information about how to enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs).

(B) A statement that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.

(xiv) Plan contact information for participant questions about the billing statement.

(4) *Treatment of unsettled balances.* Any unsettled balances with respect to amounts owed under the program will be treated as plan losses.

(i) The Secretary is not liable for any such balances outside of those assumed as losses estimated in a Part D sponsor's plan bid.

(ii) If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, that Part D sponsor cannot treat the amount as a loss and cannot include it in its bid.

(5) *Prioritization of premium payments.* If a Part D enrollee has opted into the program and makes payments directly to the Part D sponsor, and it is unclear whether a payment should go towards the participant's outstanding Part D plan premium or Medicare Prescription Payment Plan balance, then the payment must be applied to the Part D premium.

(6) *Financial reconciliation.* A Part D sponsor must have a financial reconciliation process in place to correct inaccuracies in billing or payments or both.

(i) *Participant payment.* (A) A participant may pay more than the maximum monthly cap, up to the annual out-of-pocket threshold.

(B) The participant cannot pay more than their total OOP costs for the Medicare Prescription Payment Plan.

(C) If a participant does pay more than their total OOP costs for the Medicare Prescription Payment Plan, then the Part D sponsor must reimburse the participant the amount that is paid above the balance owed.

(ii) *Reimbursements for excess participant payments.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants.

(iii) *Claims adjustments resulting in increased amounts owed.* When Part D claims adjustments result in increased amounts owed by the participant, and these amounts have not yet been billed to the participant, they must be included in the revised remaining OOP costs owed by the participant (as defined at § 423.137(b)(1)) and, thus, in the subsequent month maximum cap for the next billing period.

(h) *Participant disputes*—(1) *Coverage determination and appeals procedures.* A Part D sponsor must apply the Part D coverage determination and appeals procedures specified at § 423.566(a) to any disputes made by program participants concerning the cost sharing amount of a covered Part D drug.

(2) *Grievance procedures.* A Part D sponsor must apply the Part D grievance procedure specified at § 423.562 to any dispute made by a program participant related to any aspect of the Medicare Prescription Payment Plan.

(i) *Pharmacy point of sale notification process.* (1) When a Part D sponsor is notifying a pharmacy that a Part D enrollee has incurred out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program, as required at paragraph (e)(2) of this section, the Part D sponsor must use standard codes for notifying the pharmacy that an enrollee has been identified as likely to benefit, as outlined by the National Council for Prescription Drug Programs.

(2) *Point of sale notification requirements.* A Part D sponsor must ensure that the Medicare Prescription Payment Plan Likely to Benefit Notice is provided to enrollees identified as likely to benefit (or the person acting on their behalf) through the pharmacy point of sale notification process.

(i) In pharmacy settings in which there is direct contact with enrollees (for example, community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up.

(ii) For non-retail pharmacy settings without in-person encounters (such as mail order pharmacies), a Part D sponsor must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method.

(iii) If the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee.

(3) A Part D sponsor must ensure that any contract between the Part D sponsor and a pharmacy (or between a first tier, downstream, or related entity and a pharmacy on the Part D sponsor's behalf) for participation in one or more of the Part D sponsor's networks includes a provision requiring pharmacies to provide this notification to Part D enrollees.

(j) *Pharmacy claims processing*—(1) *Electronic claims processing methodology.* Part D sponsors must use, and must ensure pharmacies use, a bank identification number (BIN) or processor control number (PCN) electronic claims processing methodology for applicable Medicare Prescription Payment Plan transactions.

(i) Part D sponsors must utilize, and ensure pharmacies utilize, an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants.

(ii) A Part D sponsor must provide the unique Medicare Prescription Payment Plan BIN/PCN and any other pertinent billing information to the pharmacy on paid claim responses when the enrollee is also a Medicare Prescription Payment Plan participant.

(iii) A Part D sponsor must assign a program-specific PCN that starts with ''MPPP'' and report the new BIN/PCN to CMS.

(iv) The transaction processed through the Medicare Prescription Payment Plan BIN/PCN will be submitted after processing any applicable other payer transactions in order to capture the final patient responsibility amount after all other payers have paid.

(2) *Supplemental coverage that increases final patient pay amount.* When a Part D enrollee has supplemental coverage that modifies their final out-of-pocket responsibility for covered Part D drugs:

(i) When the final patient pay amount returned to the pharmacy by a

supplemental payer for a covered Part D drug is higher than the original Part D patient pay amount, the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant's original Part D cost sharing, as determined by their plan-specific benefit structure.

(3) *Prescription drug event reporting.* A Part D sponsor must ensure that the claims processing methodology described in paragraph (j)(1) of this section has no impact on prescription drug event (PDE) cost/payment field reporting, meaning PDE records must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply.

(4) *Real-time benefit tools.* A Part D sponsor must ensure that participation in the Medicare Prescription Payment Plan or the associated claims processing methodology described in paragraph (j)(1) of this section or both has no impact on the cost-sharing information displayed in real-time benefit tools.

(5) *Inclusion of retroactive claims.* A Part D sponsor is not required to retroactively include under this program claims submitted to the Part D sponsor by a Medicare Prescription Payment Plan participant (whether the request is made via paper form, telephonically, or electronically) except as provided in 423.137(d)(6).

(6) *Re-adjudication of prescription drug claims for new program participants.* (i) When a Part D enrollee receives the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription that triggered the notification.

(ii) When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess the high-cost claim that triggered the likely to benefit notification.

(A) Should a Part D enrollee have other unpaid claims at the same pharmacy for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification, they may also request that those claims be readjudicated.

(iii) When the Part D claim date of service is the same as the date of program effectuation), the Part D sponsor is not required to ensure the pharmacy reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

(7) *Obtaining and providing OOP costs for the Medicare Prescription Payment Plan.* Part D sponsors must ensure that pharmacies—

(i) Can easily access a Part D enrollee's OOP costs for the Medicare Prescription Payment Plan at the point of sale; and

(ii) Are prepared to provide OOP costs for the Medicare Prescription Payment Plan to a participant at the point of sale.

(k) *Pharmacy payment obligations.* (1) A Part D sponsor must ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments, consistent with § 423.520. A Part D sponsor must not do either of the following:

(i) Impose any fees or costs related to program implementation on pharmacies.

(ii) Hold pharmacies responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

(l) [Reserved].

(m) *General Part D sponsor outreach and education requirements*—(1) *Mailing.* A Part D sponsor must provide a Medicare Prescription Payment Plan election request form, described at paragraph (d)(10)(i) of this section, and additional educational information on the program in a hard copy mailing.

(i) The mailing must be sent by the later of—

(A) Within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan; or

(B) The last day of the month prior to the plan effective date.

(ii) The election request form and supplemental information may be sent—

(A) With the membership ID card mailing described at § 423.2267(e)(32); or

(B) In its own envelope.

(iii) The mailing may be sent only to a Part D enrollee who is receiving a new membership ID card or to all Part D enrollees.

(iv) The additional information requirement may be fulfilled by including in the mailing the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423 subpart V.

(2) *Websites.* In addition to meeting requirements described at §§ 423.128(d)(2) and 423.2265(b), a Part D sponsor is required to include all of the following on its website:

(i) An election request mechanism, as described at § 423.137(d)(2).

(ii) An overview of the Medicare Prescription Payment Plan.

(iii) Examples of the program calculation and explanations.

(iv) A description of Part D enrollees who may be likely to benefit from the program.

(v) The financial implications of participation.

(vi) The implications of not paying monthly bills.

(vii) Instructions for how to opt into and out of the program, including timing requirements around election effectuation.

(viii) A description of the standards for retroactive election in cases where an enrollee believes that a delay in filling a prescription may seriously jeopardize their life, health, or ability to regain maximum function.

(ix) A description of the dispute and grievance procedure, as required under § 423.137(h).

(x) Contact information Part D enrollees can use to obtain further information

(xi) General information about the LIS program, including an overview of how LIS enrollment, for those who qualify, is likely to be more advantageous than program participation.

■ 40. Section 423.153 is amended revising paragraph (d)(2)(iii)(A) to read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management (MTM) programs, drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(A) Alzheimer's disease and dementia.

* * * * *

■ 41. Section 423.182 is amended by revising paragraphs (b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, if

a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. If a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification or the reliability is less than 0.6 for a CAHPS measure, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

(B) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except CAHPS, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. For all measures except CAHPS and call center measures, if a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

* * * * *

■ 42. Section 423.186 is amended by:

■ a. Revising paragraph (f)(3)(iv) introductory text;

■ b. Adding paragraphs (f)(3)(iv)(C), (f)(3)(v)(A), and reserved paragraph (f)(3)(v)(B);

■ c. Revising paragraph (f)(3)(vi) and (f)(3)(viii)(B);

■ d. Adding paragraph (f)(3)(viii)(C); and

■ e. Revising paragraphs (g)(1)(i) and (ii).

The revisions and additions read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(f) * * *

(3) * * *

(iv) For a measure to be included in the calculation of a contract's HEI score, the measure must meet all of the following criteria:

* * * * *

(C) Beginning with the 2027 Star Ratings, for contracts that are Institutional Special Needs Plan (I–SNP) only contracts in the ratings year, the measure must be required to be reported for I–SNP-only contracts.

(v) * * *

(A) Starting with the 2029 Star Ratings if a contract's HEDIS measure score across all enrollees for a HEDIS measure included in the HEI calculated from the patient-level data submitted by the contract does not match the summary-level score submitted by the contract to NCQA for either of the measurement years used to construct the HEI, the contract will receive −1 points for the HEDIS measure in the calculation of the HEI. If a contract does not submit HEDIS patient-level data for a measure for which it submitted contract-level data for either of the measurement years used to construct the HEI, the contract will receive −1 points for the HEDIS measure in the calculation of the HEI.

(B) [Reserved]

(vi) Starting with the 2027 Star Ratings, to have the HEI calculated, contracts that are ISNP-only contracts in the ratings year must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section for the subset of measures that I–SNP-only contracts are required to report. To have the HEI calculated, all other contracts must have at least 500 enrollees in the most recent measurement year used in the HEI and have at least half of the measures included in the HEI meet the criteria specified under paragraph (f)(3)(iv) of this section.

* * * * *

(viii) * * *

(B) Starting with the 2027 Star Ratings, for the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score is combined across the consumed and surviving contracts in the consolidation and used in calculating the HEI score. The enrollment used in assessing whether the surviving contract meets an enrollment threshold under paragraph (f)(3)(vii) of this section will be the combined enrollment from the consumed and surviving contracts from the most recent year of data used to calculate the HEI.

(C) Starting with the 2029 Star Ratings, in states where, consistent with § 422.107(e), one or more MA contracts that only include one or more dual eligible special needs plans (D–SNPs) with a service area limited to that state are required to be established and maintained, the original MA contract(s) from which the D–SNP plan benefit package or packages were moved (hereafter referred to as the ''legacy MA contract(s)'') into the MA contract established under § 422.107(e) will have the HEI reward calculated as follows every year after the D–SNP-only contract is required to be created until the Star Ratings year in which additional SRFs beyond receipt of LIS, dual-eligibility, and disability are added to the HEI:

(*1*) If the legacy MA contract, based on its own enrollment, meets an enrollment threshold under paragraph (f)(3)(vii) of this section, the methodology for calculating the HEI reward in paragraph (f)(3)(viii) of this section is followed.

(*2*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and either one of the legacy MA contract or the MA contract established under § 422.107(e) cannot have the HEI reliably calculated as described in paragraphs (f)(3)(iv) and (vi) of this section, then the legacy MA contract does not qualify for an HEI reward.

(*3*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and the legacy MA contract's performance on the HEI based on its own enrollment is less than—

(*i*) The minimum index score defined at paragraph (f)(3)(vii) of this section; or

(*ii*) The performance on the HEI of the MA contract established under § 422.107(e) Then, the legacy MA contract does not qualify for an HEI reward.

(*4*)(*i*) If the legacy MA contract, based on its own enrollment, does not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and both the legacy MA contract and the MA contract established under § 422.107(e) can have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi) of this section, then the enrollment combined across the legacy MA contract and the MA contract established under § 422.107(e) for the most recent measurement year used in calculating the HEI is used in assessing the enrollment threshold in paragraph (f)(3)(vii) of this section.

(*ii*) If an enrollment threshold is met using the combined enrollment described in paragraph (4)(*i*) of this paragraph, the legacy MA contract's rating-specific HEI score meets the minimum index score of greater than zero defined at paragraph (f)(3)(vii) of this section, and the legacy MA contract's rating-specific HEI score is greater than or equal to the rating-specific HEI score of the MA contract established under § 422.107(e), then the HEI reward for the legacy MA contract is calculated following paragraph

(f)(3)(viii) of this section based on the enrollment threshold using the combined enrollment from the legacy MA contract and the MA contract established under § 422.107(e), and using the HEI score for the MA contract established under § 422.107(e).

(*5*) When multiple legacy MA contracts move their D–SNP plan benefit package(s) to the same MA contract established under § 422.107(e) and any of the legacy MA contracts do not meet an enrollment threshold as defined in paragraph (f)(3)(vii) of this section, and both the legacy MA contracts and the MA contract established under § 422.107(e) can have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi) of this section, then the combined enrollment from the legacy MA contracts and the MA contract established under § 422.107(e) for the most recent measurement year used in calculating the HEI is used in assessing the enrollment threshold in paragraph (f)(3)(vii) of this section for any of the legacy MA contracts that do not meet an enrollment threshold on their own. If an enrollment threshold is met using the combined enrollment in this paragraph, the steps in paragraph (f)(3)(viii)(C)(*4*)(*ii*) of this section are followed separately for each of the legacy MA contracts. If a legacy MA contract meets the enrollment thresholds on its own or if it cannot have the HEI score reliably calculated following paragraphs (f)(3)(iv) and (vi), the legacy MA contract would not be included in the calculation of the combined enrollment.

* * * * *

(g) * * *

(1) * * *

(i) If the highest rating rounded to the half star before the addition of the HEI reward, if applicable, for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating rounded to the half star before the addition of the HEI reward, if applicable, is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

* * * * *

■ 43. Section 423.325 is added to read as follows:

§ 423.325 PDE submission timeliness requirements.

(a) *General PDE submission timeliness requirements.* Unless paragraph (b) of this section applies, a Part D sponsor must submit PDE records to CMS as follows:

(1) Initial PDE records within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

(2) Adjustment or deletion PDE records within 90 calendar days of the Part D sponsor (or its contracted first tier, downstream, or related entity) discovering or receiving notification of an issue that requires a change to the previously submitted PDE record.

(3) Revised PDE records to resolve CMS rejected records within 90 calendar days of the rejection.

(b) *Selected Drugs PDE submission timeliness requirement.* A Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

■ 44. Section 423.505 is amended by adding paragraphs (i)(7) and (8) and (q) to read as follows.

§ 423.505 Contract provisions.

* * * * *

(i) * * *

(7) Any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must include a provision requiring the sponsor or the first tier, downstream, or related entity to provide the pharmacy a list of the Part D PBPs that the pharmacy participates in pursuant to the contract.

(i) For every Part D PBP that the pharmacy participates in pursuant to the contract, the list must include all of the following:

(A) The Part D contract number assigned by CMS.

(B) The plan ID assigned by CMS for the PBP.

(C) The marketing name of the PBP.

(ii) The contract must require the sponsor or the first tier, downstream, or related entity to provide this list to the pharmacy by October 1 of the year prior to the plan year and at the pharmacy's request thereafter.

(iii) The sponsor or the first tier, downstream, or related entity can meet its obligations under this paragraph by either of the following:

(A) Providing a hard copy of the list to the pharmacy.

(B) Providing the list electronically by—

(*1*) Sending an electronic file to the pharmacy; or

(*2*) Providing the pharmacy instructions on how to access the list electronically.

(8) Any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks that allows the sponsor or the first tier, downstream, or related entity to terminate the contract or the pharmacy's participation in a particular network without cause must allow the pharmacy to terminate the contract or its participation in a particular network without cause after providing the same notice that the contract requires the Part D sponsor or the first tier, downstream, or related entity to provide for a termination without cause.

* * * * *

(q) *Enrollment in the Medicare Transaction Facilitator Data Module for the Medicare Drug Price Negotiation Program.* For contract year 2026 and all subsequent years, any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM) (or any successor to the MTF DM) in a form and manner determined by CMS. Such provision must also require the pharmacy to maintain and certify up-to-date, complete, and accurate enrollment information with the MTF DM, pursuant to applicable terms and conditions of participation with the MTF DM, including but not limited to contact, third-party support entity or entities, and banking information, in a form and manner determined by CMS.

■ 45. Section 423.2265 is amended by adding paragraph (b)(16) to read as follows:

§ 423.2265 Websites.

* * * * *

(b) * * *

(16) Information about the Medicare Prescription Payment Plan as described in § 423.137(m)(2).

* * * * *

■ 46. Section 423.2260 is amended by revising the definitions of ''Advertisement'' and ''Marketing'' to read as follows:

§ 423.2260 Definitions.

* * * * *

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for, or call to attention.

* * * * *

Marketing means communications materials and activities that are intended to draw a beneficiary's attention to a Part D plan or plans, influence a beneficiary's decision-making process when making a Part D plan selection, or influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing), except those required materials specified in § 423.2267(e) of this chapter, which will maintain the material designation as provided by CMS. In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the Part D sponsor's stated intent.

* * * * *

■ 47. Section 423.2267 is amended by—

■ a. Removing the word ''and'' at the end of paragraph (e)(32)(vi);

■ b. Removing the period and adding in its place ''; and'' at the end of paragraph (e)(32)(vii);

■ c. Adding paragraphs (e)(32)(viii);

■ d. Revising paragraphs (e)(33)(i) introductory text and (e)(33)(ii) introductory text; and

■ e. Adding paragraphs (e)(45) through (51).

The revisions and additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(32) * * *

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in § 422.561, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

* * * * *

(33) * * *

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice for Part D sponsors is referred to as the Multi-language insert (MLI). This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

* * * * *

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice for Part D sponsors is referred to as the Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). This is a model communications material through which Part D sponsors must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge.

* * * * *

(45) *Election request form.* This is a model communications material that Part D sponsors must provide to allow enrollees to request to opt into the Medicare Prescription Payment Plan, as required under § 423.137(d)(10)(i).

(46) *Notice of election approval.* This is a model communications material that Part D sponsors must provide upon accepting a Medicare Prescription Payment Plan election request, as required under § 423.137(d)(10)(ii).

(47) *Medicare Prescription Payment Plan Likely to Benefit Notice.* This is a standardized communications material that Part D sponsors must provide to enrollees identified as being likely to benefit from opting into the Medicare Prescription Payment Plan, as required under § 423.137(e)(4).

(48) *Notice of failure to pay.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who fail to pay a program bill, as required under § 423.137(f)(2)(C).

(49) *Involuntary termination notice.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who are being involuntarily terminated from the program due to failure to pay, as required under § 423.137(f)(2)(D).

(50) *Voluntary termination notice.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who request to voluntarily leave the program, as required under § 423.137(f)(2)(i)(A)(*2*).

(51) *Renewal notice.* This is a model communications material that Part D sponsors must send to Medicare Prescription Payment Plan participants alerting them that their participation in the program will automatically renew for the subsequent plan year, as required under § 423.137(d)(10)(iv).

■ 48. Section 423.2274 is amended by revising paragraph (c)(12) to read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(12) Ensure that, prior to an enrollment CMS' required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. Topics to be discussed include all the following:

(i) Pharmacies (that is, whether or not the beneficiary's current pharmacy is in the plan's network).

(ii) Prescription drug coverage and costs (including whether or not the beneficiary's current prescriptions are covered).

(iii) Low-income subsidy eligibility (that is, at a minimum, explaining the eligibility requirements as defined at § 423.773 and the effect on drug costs if eligible, and identifying resources where they can get for more information on applying).

(iv) Resources for state programs, including Medicare Savings Programs

(v) Premiums

(vi) Other services or incentives

(vii) Conclude by pausing to ask if the beneficiary has any questions about the topics discussed in paragraph (c)(12) of this section or others, including those related to enrollment.

* * * * *

■ 49. Section 423.2401 is amended by adding in alphabetical order definitions for ''MLR audit remittance'' and ''MLR audit remittance process'' to read as follows:

§ 423.2401 Definitions.

MLR audit remittance means the amount CMS calculates and a Part D sponsor pays for a Part D contract that has failed to meet the 85 percent minimum MLR requirement as the result of an MLR audit examination.

MLR audit remittance process means the process by which CMS calculates the MLR audit remittance for a contract that is determined to have failed to meet the 85 percent minimum MLR requirement as the result of an MLR audit examination and notify the Part D sponsor about the remittance. The process includes all of the following:

(1) Collecting the MLR audit remittance indicated in the final audit report issued by CMS.

(2) Receiving responses from Part D sponsors requesting an appeal of the MLR audit remittance.

(3) Taking actions to adjudicate an appeal (if requested).

(4) Receiving MLR remittances from Part D sponsors.

* * * * *

■ 50. Section 423.2420 is amended by—

■ a. Adding paragraph (b)(4)(i)(D);

■ b. Redesignating paragraphs (d)(2)(i) through (iii) as paragraphs (d)(2)(ii) through (d)(2)(iv); and

■ c. Adding new paragraph (d)(2)(i).

The additions read as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(D) Unsettled balances from the Medicare Prescription Payment Plan.

* * * * *

(d) * * *

(2) * * *

(i) The report required in § 423.2460 must include a detailed description of the methods used to allocate expenses, including incurred claims, expenditures on quality improving activities, licensing and regulatory fees, and State and Federal taxes and assessments. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

* * * * *

■ 51. Section 423.2430 is amended by redesignating paragraphs (a) and (b) as paragraphs (b) and (c) and adding a new paragraph (a) to read as follows:

§ 423.2430 Activities that improve health care quality.

(a) *General requirements.* The report required in § 423.2460 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

* * * * *

■ 52. Section 423.2450 is added to read as follows:

§ 423.2450 MLR audit process.

(a) *Notice of audit.* CMS provides at least 15 days advance notice of its intent to conduct an audit of a Part D sponsor.

(b) *Conferences.* All audits include an entrance conference during which the scope of the audit is presented and an exit conference during which the initial audit findings are discussed.

(c) *Audit documentation.* All requested audit documentation must be provided by the Part D sponsor to CMS within 30 calendar days of the audit entrance conference. CMS may extend, at CMS's discretion, the time for a Part D sponsor to provide the documentation requested.

(d) *Preliminary audit findings.* CMS shares its preliminary audit findings with the Part D sponsor, which then has 30 calendar days to respond to such findings. CMS may extend, for good cause, the time for a Part D sponsor to submit such a response.

(e) *Final audit findings.* If the Part D sponsor does not dispute the preliminary findings within the 30-day timeframe per paragraph (d) of this section, then the audit report becomes final. Alternatively, if the Part D sponsor disputes the preliminary findings, CMS reviews and considers such response before finalizing the audit findings.

(f) *Corrective actions.* CMS sends a copy of the final audit report to the Part D sponsor as well as issues corrective actions that the Part D sponsor must undertake as a result of the audit findings.

(g) *Order to pay remittances.* If CMS determines as the result of an audit that a Part D sponsor has failed to pay remittances it is obligated to pay under § 423.2480, it may order the Part D sponsor to pay those remittances consistent with § 423.2452.

■ 53. Section 423.2452 is added to read as follows:

§ 423.2452 MLR audit remittance and payment process.

(a) *Notice of MLR audit remittance.* After the calculation of the MLR audit remittance, CMS sends the Part D sponsor the final audit report with the MLR audit remittance amount. The final audit report contains the following information:

(1) A MLR audit remittance for the contract that has failed to meet the 85 percent MLR minimum requirement based on audit findings, which may be one of the following:

(ii) An amount due from the Part D sponsor.

(iii) $0 if nothing is due from the Part D sponsor.

(2) Relevant banking and financial mailing instructions for Part D sponsors that owe a MLR audit remittance.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the MLR audit remittance calculation, in accordance with the requirements specified in § 423.2454.

(b) *Request for an appeal.* A Part D sponsor that disagrees with the MLR audit remittance has 15 calendar days from the date of issuance of the final audit report, as described in paragraph (a) of this section, to request an appeal of the MLR audit remittance under the process described in § 423.2454.

(1) If a Part D sponsor agrees with the MLR audit remittance, no response is required.

(2) If a Part D sponsor disagrees with the MLR audit remittance, it must request an appeal within 15 calendar days from the date of issuance of the final audit report. CMS will not consider any requests for appeal after this 15-day period.

(c) *Actions if a Part D sponsor does not request an appeal.* (1) The Part D sponsor is required to remit payment to CMS within 120 calendar days from the date of issuance of the final audit report.

(2) If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the final audit report disagreeing with the MLR audit remittance and requesting appeal, CMS conducts a review process under the process described at § 423.2454.

■ 54. Section 423.2454 is added to read as follows:

§ 423.2454 MLR audit remittance appeals process.

(a) *Appeals process.* If a Part D sponsor does not agree with the MLR audit remittance described in § 423.2452(a), it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the MLR audit remittance described in § 423.2452(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date of issuance of the final audit report to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the Part D sponsor disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the MLR audit remittance is incorrect.

(C) Not include new data or data that was submitted to CMS after the final audit report was issued.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the MLR audit remittance and any additional evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS's reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with the CMS hearing officer within 15 calendar days from the date of issuance of the reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date.

(B) The CMS reconsideration official provides, within 10 calendar days of the hearing officer receiving an informal hearing request, a copy of the record that was before the reconsideration official.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS reconsideration official had when making the reconsideration decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides whether to uphold or overturn the reconsideration official's decision and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review.

(B) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS's calculation of the MLR audit remittance.

(2) The Part D sponsor bears the burden of proof for providing evidence demonstrating that CMS's audit examination results for the MLR audit remittance require further review. The Part D sponsor may not challenge the underlying methodology for the MLR audit remittance calculation.

(c) *Stay of financial transaction until appeals are exhausted.* If a Part D sponsor requests review of the MLR audit remittance, the financial transaction associated with the payment of the MLR audit remittance is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the Part D sponsor fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the Part D sponsor to complete the financial transaction associated with the payment of the MLR audit remittance.

(d) *Continued compliance with other law required.* Nothing in this section limits a Part D sponsor's responsibility to comply with any other statute or regulation.

■ 55. Section 423.2480 is amended by revising paragraph (d) introductory text to read as follows:

§ 423.2480 MLR review and non-compliance.

* * * * *

(d) Data submitted under § 423.2460, calculations, or any other MLR submission required by this subpart which have not been reported in a timely and accurate manner or have been found to be materially incorrect or fraudulent—

* * * * *

■ 56. Section 423.2490 is amended by adding paragraph (b)(6) to read as follows:

§ 423.2490 Release of Part D MLR data.

* * * * *

(b) * * *

(6) DIR information reported within the MLR data as part of incurred claims.

* * * * *

■ 57. Section 423.2536 is amended by—

■ a. Redesignating paragraphs (c) through (k) as paragraphs (d) through (l);

■ b. Adding a new paragraph (c); and

■ c. Revising newly redesignated paragraphs (i)(1) and (4).

The addition and revisions to read as follows:

§ 423.2536 Waiver of Part D program requirements.

* * * * *

(c) *Medicare Prescription Payment Plan.* Section 423.137.

* * * * *

(i) * * *

(1) Section 423.2265(b)(4), (5), (11), (13), and (16);

* * * * *

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), (33), and (45) through (51); and

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 58. The authority for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

§ 460.70 [Amended]

■ 59. Section 460.70 is amended in paragraph (e)(2) by removing the reference ''§ 460.98(c)'' and adding in its place the reference ''§ 460.98(d)''.

■ 60. Section 460.112 is amended by revising paragraphs (a)(1) and (2), adding paragraphs (a)(3) through (8), and revising paragraph (b) to read as follows

§ 460.112 Specific rights to which a participant is entitled.

(a) * * *

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(b) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to both of the following:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

* * * * *

■ 61. Section 460.180 is amended by revising paragraph (b)(3) to read as follows:

§ 460.180 Medicare payment to PACE organizations.

* * * * *

(b) * * *

(3) CMS adjusts the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. The provisions of § 422.310 of this chapter apply to PACE organizations and risk adjustment data submitted by PACE organizations to CMS. In applying § 422.310 to PACE organizations and risk adjustment of payments to PACE organizations, references to MA organizations are read as references to PACE organizations. CMS ensures that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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