DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4212–P]

RIN 0938–AV63

Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program

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), and Medicare cost plan regulations to implement changes related to Star Ratings, marketing and communications, drug coverage, enrollment processes, special needs plans, and other programmatic areas.

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 26, 2026.

ADDRESSES: In commenting, please refer to file code CMS–4212–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–4212–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–4212–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:

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

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

Lucia Patrone, (410) 786–8621—Part D Issues.

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

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

Beckie Peyton, (410) 786–1572—Manufacturer Discount Program Issues.

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

CMMI_MAStrategy@cms.hhs.gov—RFI on Future Directions in Medicare Advantage.

CPI_PartC&D_RegIssues@cms.hhs.gov—Part D Program Integrity 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/.*

Deregulation Request for Information (RFI): On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 ''Unleashing Prosperity Through Deregulation,'' which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. We have made available an RFI at *https://www.cms.gov/medicare-regulatory-relief-rfi.* Please submit all comments in response to this request for information through the provided weblink. Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

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, and Medicare cost plan program. This proposed rule includes a number of changes that would improve these programs for contract year 2027 as well as codify existing sub-regulatory 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 2027 marketing and communications, beginning October 1, 2026.

B. Summary of the Key Provisions

1. Medicare Part D Redesign

This proposal would implement the changes made to the Part D benefit design and the payment obligations of enrollees, Part D plan sponsors, manufacturers, and CMS by section 11201 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169).

We are proposing to codify the statutory changes to the phases of the Part D benefit made by the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket threshold, and alternative prescription drug coverage options. In alignment with these changes to the Part

D benefit, we are also proposing to codify technical and conforming changes to our specialty tier regulations. This proposal would codify additional structural and operational statutory changes to the Part D benefit design, including making changes to the types of payments that count as True Out-Of-Pocket costs (TrOOP), establishing a policy for how an enrollee's costs for drugs not subject to the Part D defined standard deductible count towards becoming eligible for manufacturer discounts under the Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program), making updates to the methodology for reinsurance payments from us to Part D sponsors, and implementing the Selected Drug Subsidy, among others.

2. Coverage Gap Discount Program

We propose to codify the sunsetting of the Coverage Gap Discount Program and termination of all Coverage Gap Discount Program agreements as of January 1, 2025, in alignment with subsection (h) of section 1860D–14A of the Social Security Act (the Act), as added by section 11201 of the IRA. Specifically, we propose to revise § 423.2300 by adding paragraph (b) to establish applicability dates for the Coverage Gap Discount Program, revise § 423.2345 by adding paragraph (f) to terminate all Coverage Gap Discount Program agreements, as well as make conforming changes for clarity.

3. Manufacturer Discount Program

We propose regulatory changes to codify the Manufacturer Discount Program, established in section 1860D–14C of the Act, as added by section 11201 of the IRA. Under the Manufacturer Discount Program, which replaces the Coverage Gap Discount Program and began on January 1, 2025, manufacturers that enter into a Manufacturer Discount Program agreement are required to provide discounts on applicable drugs in both the initial and catastrophic coverage phases of the Part D benefit. Specifically, we propose to add new subpart AA to part 423 to codify the Manufacturer Discount Program requirements and make several conforming changes throughout part 423 to reflect the new program.

4. Updates to Star Ratings

We have continued to identify enhancements to the Star Ratings program over time to increase the health and wellbeing of enrollees. In this proposed rule, we are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set. We also propose to not move forward with the implementation of the Health Equity Index (also called Excellent Health Outcomes for All) reward at §§ 422.166(f)(3) and 423.186(f)(3) and to continue to include the historical reward factor in the Star Ratings methodology at §§ 422.166(f)(1) and 423.186(f)(1). We also solicit comments on ways to further simplify and modify the Star Ratings program to further drive improved quality of care and reduce regulatory burden.

5. Request for Information on Dually Eligible Individual Enrollment Growth in C–SNPs and I–SNPs

Chronic condition special needs plans (C–SNPs) and the number of dually eligible individuals enrolled in these plans have grown significantly between 2021 and 2025. Dually eligible enrollment in institutional special needs plans (I–SNPs) has remained more stable. While C–SNPs and I–SNPs can offer benefits specific to chronic disease and institutional level of care, respectively, they do not integrate Medicare and Medicaid benefits and may not be the best approach for meeting the needs of dually eligible individuals. The growth in C–SNP enrollment could be an intentional approach by MA organizations to circumvent Federal and State requirements for dual eligible special needs plans (D–SNPs), such as States determining which D–SNPs will be offered in a State through their State Medicaid agency contract authority and general coordination and integration requirements. This proposed rule includes a request for information (RFI) to share information with interested parties on these trends and solicit feedback on them as well as on potential policy solutions for future consideration.

6. Request for Information on Future Directions in Medicare Advantage (Risk Adjustment and Quality Bonus Payments)

This RFI will serve as a formal mechanism to solicit comprehensive public input from interested parties, including MA organizations, beneficiary advocates, healthcare providers, as well as technology and industry experts, regarding the future direction of the MA program. The goal of this RFI is to solicit comment on modernizing and improving the MA program that could be implemented through either programmatic changes or through a CMS Innovation Center (CMMI) model. This public comment process will enable us to gather critical feedback on risk adjustment enhancements and quality bonus payment changes. Through this RFI, we are working to ensure any resulting changes would effectively address interested parties' concerns while achieving objectives of data transparency for beneficiaries to facilitate optimal plan selection, improved quality, enhanced competition, taxpayer savings, and minimizing fraud, waste, and abuse in the MA program.

C. Summary of Costs and Benefits

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TABLE A1: SUMMARY OF PROVISIONS AND FINANCIAL IMPACTS

Provision	Description	Financial Impact
Medicare Part D Redesign	We are proposing to codify the changes made to the Part D benefit design by section 11201 of the IRA. This includes our proposal to codify the sunsetting of the Coverage Gap Discount Program as of January 1, 2025, under section 1860D-14A(h) of the Act and our proposal to codify policies for the Manufacturer Discount Program beginning January 1, 2025, under section 1860D-14C of the Act.	Relative to a pre-statute baseline, codifying the statutory changes to the Part D benefit design would increase costs. The costs and transfers attributable to the Part D redesign are attributable to the IRA and are not a result of this rule.
Updates to Star Ratings	We are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set and not moving forward with the implementation of the Health Equity Index reward and to continue to include the historical reward factor in the Star Ratings methodology.	The net impact of the Star Ratings updates to the Medicare Trust Fund is estimated to be $13.18 billion from 2027 through 2036 or 0.15 percent of Medicare payments to private health plans during this ten year period.
RFI on Dually Eligible Individual Enrollment Growth in C-SNPs and I-SNPs	We are outlining data on C-SNP and I-SNP enrollment trends for dually eligible individuals and solicit comments on potential policy considerations for future rulemaking.	None
RFI on Future Directions in Medicare Advantage	We are seeking public input on future directions for the MA program to address risk adjustment and quality bonus payment changes that could be implemented either through programmatic changes at large or through a CMS Innovation Center model.	None

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D. Supplemental Requests for Information

We are requesting comments on several specific areas beyond the various comment opportunities already presented throughout the proposed rule as part of our commitment to reducing regulatory burden while strengthening program integrity. First, we are considering ways to modernize our approach to marketing oversight and agent/broker regulation in the Medicare program while ensuring beneficiaries continue to receive accurate information about plan choices. This includes, but is not limited to, all of the following:

- Modifying the current definition of third-party marketing organization (TPMO) under §§ 422.2260 and 423.2260 to delineate the roles of and requirements applicable to the different kinds of TPMOs.
- Modifying the 5 percent translation requirement found in §§ 422.2267 and 423.2267.
- Removing the requirement for our approval of plan use of the Medicare Card image found in §§ 422.2262(a)(1)(xix) and 423.2262(a)(1)(xviii).
- Eliminating the Outbound Enrollment Verification found in §§ 422.2272(b) and 423.2272(b).
- Modifying testimonial requirements found under §§ 422.2262(b) and 423.2262(b).
- Eliminating mailing statement requirements found under §§ 422.2267(e)(36) and 422.2267(e)(37).

We are also looking specifically at regulatory changes that will assist the agency in taking appropriate action against TPMOs, including agents and brokers who fail to adhere to our requirements. Our goal is to address non-compliance, holding MA plans and Part D sponsors accountable for those TPMOs who provide inaccurate, misleading, and confusing information, or act in a manner contrary to our requirements. We have considered options such as further segmentation of the definition for TPMOs found under §§ 422.2260 and 423.2260 to account for size, scope, and role of various interested parties; however, we recognize the need for industry input before implementing any change. We, therefore, solicit comments on how to hold ''bad actors'' accountable, while not burdening those TPMOs and plans that adhere to our requirements. We also solicit comments on how to properly align incentives in the agent or broker space, how to identify and address when agents and brokers perform their jobs in good faith but does not adhere to requirements that apply to the MA plan. For example, we welcome comment on whether updates to the training and testing requirements are needed or new ways CMS or MA organizations and Part D sponsors can improve how beneficiaries interact with agents or brokers. We are also soliciting comments on how best to monitor and assess the actions of MA organizations, Part D sponsors, and their downstream entities such as TPMOs, using data driven strategies. We are interested in finding ways to better utilize data—whether it is CMS, plan, first tier, downstream or related entity (FDR), or TPMO data—to review and monitor the MA and Part D market, and to assist us in addressing MA organization and PDP sponsor compliance with our requirements. Likewise, the agency is also seeking interested parties feedback regarding how technology can be leveraged, including on the use of artificial intelligence, to enhance the decision support tools used by beneficiaries and their caregivers.

In addition to issues regarding marketing oversight and agent/broker regulation and consistent with the Administration's deregulation priorities, we are seeking comment on current reporting processes and data collections to identify specific areas where requirements can be simplified, consolidated, or eliminated while maintaining program integrity and beneficiary protections in the following areas:

- Network adequacy.
- Medical loss ratio (MLR) reporting.
- Benefit, including supplemental benefit, usage and utilization data reporting.
- Requirements related to the SNP model of care (MOC).

We are interested in ideas for streamlining data collection processes for the areas listed previously, including automated data sharing to reduce manual reporting and ideas related to alignment with existing reporting mechanisms. We are also interested in feedback regarding which data elements are the most burdensome to collect and report, as we seek to balance the level of detail required to maintain proper program oversight while promoting efficiency.

Regarding network adequacy, we seek comments on how to simplify the provider and facility network review process overall, including the submission process, the exception request process, and the timing and frequency of the reviews. An example of a way that we could simplify the exception request process is to create a separate pattern of care exception under § 422.116(f)(1), that could be used where the pattern of care in the area is unique and the organization believes their contracted network is consistent with or better than the Original Medicare pattern of care. An organization could use this exception in lieu of demonstrating the current requirements under § 422.116(f)(1)(i), that is: (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 ; and (B) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

We welcome comments on these topics.

E. 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).

II. Implementation of Certain Provisions of the Inflation Reduction Act of 2022 and the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018

A. Medicare Part D Redesign

1. Background

Section 11201 of the Inflation Reduction Act of 2022 (IRA) made significant changes to the Part D benefit design that affect the structure of the Part D benefit and the payment obligations of enrollees, Part D plan sponsors, manufacturers, and CMS. Several of the changes made by section 11201 of the IRA have taken effect already and other changes will go into effect in 2026, as described later.

Section 11201(f) of the IRA directed the Secretary to implement section

11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. On February 1, 2023, we released guidance outlining changes to the Part D benefit that were specific to Calendar Year (CY) 2024 in the CY 2024 Advance Notice and Rate Announcement.[1] In that guidance, we eliminated cost sharing for covered Part D drugs in the catastrophic phase of coverage, consistent with section 1860D–2(b)(4)(A)(i) of the Social Security Act (the Act), as amended by section 11201 of the IRA.[2]

On April 1, 2024, we released the Final CY 2025 Part D Redesign Program Instructions.[3] In these program instructions, we implemented changes to the structure of the Part D benefit for CY 2025 made by section 11201 of the IRA. Section 11201 of the IRA added section 1860D–2(b)(4)(B)(i)(VII) of the Act to reduce the annual out-of-pocket (OOP) threshold to $2,000 for CY 2025 (to be annually increased by the annual percentage increase, as described in section 1860D–2(b)(6) of the Act). The IRA also amended section 1860D–2(b) of the Act to eliminate the coverage gap phase and added subsection (h) to section 1860D–14A of the Act to sunset the Coverage Gap Discount Program. The IRA added section 1860D–14C of the Act to establish the Manufacturer Discount Program.

On April 7, 2025, we issued the Final CY 2026 Part D Redesign Program Instructions which described changes to the Part D benefit for CY 2026.[4] In these program instructions, we implemented further changes made by the IRA to the Part D benefit that go into effect in CY 2026, including certain changes to the Part D benefit that relate to the Medicare Drug Price Negotiation Program that also was established by the IRA. Beginning January 1, 2026, the maximum fair prices (MFPs) negotiated under the Medicare Drug Price Negotiation Program go into effect.[5] This program, as established in Part E of title XI of the Act, permits the Secretary to negotiate MFPs for certain high expenditure, single source drugs and biological products with participating manufacturers. When these prices go into effect, the IRA makes further changes to payment obligations in Part D related to selected drugs (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act).

As described in the Final CY 2026 Part D Redesign Program Instructions, the defined standard Part D benefit for CY 2026 will consist of the following phases and liabilities, with the CY 2026 changes reflected in bolded and italicized font:

- *Annual deductible.* The enrollee pays 100 percent of their gross covered prescription drug costs (GCPDC) until the deductible is met.
- *Initial coverage.* The enrollee pays 25 percent coinsurance for covered Part D drugs. The Part D plan sponsor typically pays 65 percent of the costs of applicable drugs and selected drugs[6] and 75 percent of the costs of all other covered Part D drugs. The manufacturer, through the Manufacturer Discount Program, typically covers 10 percent of the costs of applicable drugs. ***In the initial coverage phase, CMS will pay a 10 percent subsidy for selected drugs during a price applicability period.*** This phase ends when the enrollee has reached the annual OOP threshold of $2,100 for CY 2026.
- *Catastrophic.* The enrollee pays no cost sharing for Part D drugs. Part D plan sponsors typically pay 60 percent of the costs of all covered Part D drugs. The manufacturer pays a discount, typically equal to 20 percent, for applicable drugs. Medicare pays a reinsurance subsidy equal to 20 percent of the costs of applicable drugs, and equivalent to 40 percent of the costs of all other covered Part D drugs that are not applicable drugs. ***In the catastrophic phase, Medicare will provide 40 percent reinsurance for selected drugs during a price applicability period.***

As part of the overall restructuring of the Part D benefit, the IRA also made changes to the treatment of Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines and covered insulin products under Part D. Section 11401 of the IRA added section 1860D–2(b)(8) 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 coinsurance or cost sharing for, an adult vaccine recommended by ACIP that is a covered Part D drug. Further, section 11406 of the IRA added section 1860D–2(b)(9) 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 applicable cost-sharing amount for all enrollees. For CYs 2023, 2024, and 2025, this amount was $35.

Sections 11401(e) and 11406(d) of the IRA directed the Secretary to implement the vaccine and insulin cost sharing changes for CYs 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, we issued several memoranda via the Health Plan Management System (HPMS) that implemented sections 11401 and 11406 of the Act for CYs 2023, 2024, and 2025.[7] These provisions of the IRA were then codified in the ''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)'' final rule, which appeared in the **Federal Register** on April 15, 2025 (90 FR 15792) (CY 2026 final rule).[8]

In the CY 2026 final rule, consistent with section 1860D–2(b)(9)(B) of the Act, we finalized the requirement that, for CY 2026 and each subsequent year, the applicable cost-sharing amount for a covered insulin product is the lesser of: (1) $35, (2) an amount equal to 25 percent of the MFP established for the covered insulin product in accordance with Part E of title XI of the Act; or (3) an amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan.

2. Redesigned Part D Benefit (§§ 423.100 and 423.104)

In this rule, we are proposing to codify at §§ 423.100 and 423.104

[1] *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

[2] *https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf.*

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

[4] *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf.*

[5] For more information on the Medicare Drug Price Negotiation Program, please see: *https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program.*

[6] An applicable drug under the Manufacturer Discount Program is a Part D drug approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA), but does not include a selected drug (as defined in section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to that drug. Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

[7] See the following HPMS memoranda: Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin (and Revision); Final Contract Year (CY) 2024 Part D Bidding Instructions; and Final CY 2025 Part D Redesign Program Instructions.

[8] *https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.*

changes to the Part D benefit made by the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket (OOP) threshold, and alternative prescription drug coverage options.

a. Deductible (§ 423.104(d)(1))

The IRA Part D benefit redesign does not change how the annual deductible for standard prescription drug coverage is calculated. However, as discussed previously, sections 11401 and 11406 of the IRA provide that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to ACIP-recommended adult vaccines or covered insulin products under Part D. We codified these changes in the CY 2026 final rule.[9] Specifically, the vaccine changes codified at § 423.120(g)(1) and the insulin changes codified at § 423.120(h)(1) state, respectively, that the Part D deductible does not apply with respect to ACIP-recommended adult vaccines and covered insulin products.

In alignment with these changes, we are proposing to revise the regulatory text at § 423.104(d)(1) by adding language to state there, too, that the deductible does not apply to ACIP-recommended adult vaccines or covered insulin products, as defined in § 423.100.

b. Initial Coverage Limit (§§ 423.104(d)(2) and 423.104(d)(3))

Section 11201 of the IRA amended section 1860D–2(b)(3)(A) of the Act to specify that the initial coverage limit only applies for years preceding CY 2025. Prior to this statutory change, once an enrollee met their deductible, they would enter the initial coverage phase, which would extend until the enrollee's gross covered prescription drug costs, as defined in § 423.100, reached the initial coverage limit. At that point the enrollee would enter the coverage gap phase. The enrollee would remain in the coverage gap phase until the enrollee's incurred costs, as defined in § 423.100, met the OOP threshold, at which point the enrollee would enter the catastrophic phase.

By eliminating the initial coverage limit beginning in CY 2025, the IRA eliminated the coverage gap phase, resulting in a three-phase benefit for Part D prescription drug coverage which includes the deductible phase, the initial coverage phase, and the catastrophic phase. As such, as of CY 2025, there is no longer an initial coverage limit and the initial coverage phase extends to the annual OOP threshold, at which point the catastrophic phase begins. Once an enrollee enters the catastrophic phase, they pay no cost sharing for Part D drugs.

As a result of these changes, we are proposing to revise § 423.104(d)(2) and (d)(3) to reflect the elimination of the initial coverage limit beginning in CY 2025. Specifically, we are proposing to revise the section heading at § 423.104(d)(2) by removing ''the initial coverage limit'' and replacing it with ''prescription drug plans'' to accurately reflect the new benefit structure in which there is no initial coverage limit beginning in CY 2025 and to ensure consistency with the statutory changes made by the IRA. This proposed heading language change is intended to accurately encompass the regulations included in the paragraphs that are subordinate to § 423.104(d)(2), which include regulations related to tiered copayments and the specialty tier.

We are also proposing to revise § 423.104(d)(2)(i), which currently specifies that coinsurance for actual costs for covered Part D drugs above the annual deductible applies up to the initial coverage limit. To align our regulations with current statute and the redesigned Part D benefit structure where beneficiaries move directly from the initial coverage phase to the catastrophic phase once they reach the OOP threshold, we propose to revise this language to specify that for each year preceding 2025, this coinsurance applies up to the initial coverage limit and, for 2025 and each subsequent year, this coinsurance applies up to the annual OOP threshold specified in § 423.104(d)(5)(iii).

We also propose to revise § 423.104(d)(3), which specifies how the initial coverage limit is determined. We first propose to correct § 423.104(d)(3) by removing the references to paragraphs (d)(4) and (d)(5) of this section because these paragraphs refer to regulations related to cost sharing in the coverage gap and the out-of-pocket threshold, which do not affect how the initial coverage limit is determined. We propose to revise § 423.104(d)(3)(ii) to specify that the methodology for increasing the initial coverage limit was in effect from 2007 to 2024. We are also proposing to add a new paragraph at § 423.104(d)(3)(iii) to state that, for 2025 and each subsequent year, there is no initial coverage limit.

Finally, we are proposing two conforming changes at § 423.128(e), which refers to the explanation of benefits that a Part D sponsor must furnish directly to enrollees. First, we propose to revise § 423.128(e)(3)(ii) which states that Part D sponsors are required to include information on the cumulative, year-to-date total amount of benefits provided in relation to the initial coverage limit for the current year in the explanation of benefits provided to enrollees. In alignment with section 1860D–4(a)(4)(B)(i) of the Act, as amended by section 11201 of the IRA, we are proposing to revise § 423.128(e)(3)(ii) by adding language to specify that the requirement to include information about the initial coverage limit was only in effect for years preceding 2025. Second, we propose to revise § 423.128(e)(7) which states that the explanation of benefits must be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including the covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii). In alignment with the elimination of the initial coverage limit and coverage gap phase beginning in CY 2025, we are proposing to add language to specify that the covered Part D spending between the initial coverage limit and the out-of-pocket threshold requirement is only applicable for years preceding 2025.

Rather than striking the regulations that apply through CY 2024, we are proposing to maintain these regulations, with the described revisions, for historical purposes and for any reconciliation activities related to benefit years prior to 2025.

c. Coverage Gap (§§ 423.100 and 423.104(d)(4))

Section 11201 of the IRA eliminated the coverage gap phase of the Part D benefit by amending section 1860D–2(b) of the Act to eliminate the initial coverage limit beginning in CY 2025.

To align with these changes to the Part D benefit, we propose to revise § 423.104(d)(4) by adding language to reflect that the coverage gap phase was eliminated. The proposed revision would state that the methodology for determining cost sharing in the coverage gap that is described in this section applies only for years preceding 2025. This proposed change aligns with our proposed revision to the definition of ''coverage gap'' in § 423.100 to specify that the coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the OOP threshold during the years 2006 through 2024.

[9] *https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare.*

We are also proposing to revise § 423.104(d)(4)(iii), which describes the generic gap coinsurance percentage, by adding an end date to paragraph (C) of this section to state that the 25 percent generic gap coinsurance percentage only applied for years 2020 through 2024. This aligns with the IRA's elimination of the coverage gap phase in CY 2025.We also propose to revise § 423.104(d)(4)(iv), which describes the applicable gap coinsurance percentage, by revising paragraph (E) to specify that the applicable gap coinsurance percentage for 2019 was 75 (not 80 percent) and to add an end date indicating that the 75 percent applies for years 2019 through 2024, and removing paragraph (F), which incorrectly stated that the applicable gap coinsurance percentage for 2020 and subsequent years was 75 percent. These changes align with changes made by the Bipartisan Budget Act (BBA) of 2018 and the IRA. Section 53116 of the BBA amended section 1860D–2(b)(2)(D)(ii) of the Act to specify that the applicable gap percentage for 2019 is 75 percent, not 80 percent, thus accelerating by 1 year a reduction in enrollee cost sharing in the coverage gap phase. We note that this revision to paragraph (E) is, in part, a technical correction to align our regulations with the statutory change made by the BBA, which was implemented in 2019. This revision does not change how the applicable gap percentage was calculated in the past, as these amounts were properly determined consistent with the statutory requirement. We additionally propose to add a new paragraph at § 423.104(d)(4)(v) to specify that, for 2025 and each subsequent year, there is no coverage gap.

Finally, we are proposing conforming changes to §§ 422.2267(e)(5)(ii)(B)(1) and 423.2267(e)(5)(ii)(A)(2) which state that information on prescription drug expenses, including information on the deductible, the initial coverage phase, coverage gap, and catastrophic coverage, is required to be included in the Summary of Benefits provided to prospective enrollees. Due to the elimination of the coverage gap in CY 2025, we are proposing to revise §§ 422.2267(e)(5)(ii)(B)(1) and 423.2267(e)(5)(ii)(A)(2) by adding language to specify that the requirement to include information about the coverage gap was only in effect for years preceding 2025.

Even though the coverage gap phase was eliminated in CY 2025, we are proposing to maintain these regulations, with the described revisions, for historical purposes and for any reconciliation activities related to benefit years prior to 2025.

d. Annual Out-of-Pocket Threshold (§ 423.104(d)(5))

Section 11201 of the IRA amended section 1860D–2(b)(4)(B)(i) of the Act to limit the annual OOP threshold for CY 2025 and each subsequent year. As amended, section 1860D–2(b)(4)(B)(i)(VII) of the Act specifies that the annual OOP threshold is $2,000 for CY 2025. For subsequent years, section 1860D–2(b)(4)(B)(i)(VIII) of the Act specifies that the annual OOP threshold will be increased by the annual percentage increase described in section 1860D–2(b)(6). Accordingly, as specified in the CY 2026 Rate Announcement, the annual OOP threshold for CY 2026 was determined to be $2,100.[10] This amount was calculated, consistent with section 1860D–2(b)(4)(B) of the Act, by multiplying the CY 2025 OOP threshold amount of $2,000 by the 2026 annual percentage increase and rounding to the nearest multiple of $50. Once an enrollee's incurred costs, as defined at § 423.100, exceed the annual OOP threshold, an enrollee will enter the catastrophic phase where there is no cost sharing for Part D drugs.

As a result of these changes, we are proposing to revise § 423.104(d)(5) to state the specific years for which certain aspects of this section apply and describe the new methodology for determining the annual OOP threshold, consistent with section 1860D–2(b)(4)(B)(i) of the Act.

We are proposing to revise § 423.104(d)(5)(i) to specify that, once an enrollee's incurred costs, as defined at § 423.100, exceed the annual OOP threshold described in paragraph (d)(5)(iii) of this section, they would have $0 cost sharing for 2024 and each subsequent year and, for each year preceding 2024, the cost-sharing structure currently outlined at paragraphs (d)(5)(i)(A) and (d)(5)(i)(B) of this section would apply. We also propose to revise § 423.104(d)(5)(i)(A)(2) to specify that the methodology described in this section for determining an enrollee's copayment amount applies through 2023. These proposed changes reflect the elimination of enrollee cost sharing for Part D drugs in the catastrophic phase beginning in CY 2024, consistent with section 1860D–2(b)(4)(A)(i) of the Act, as amended by section 11201 of the IRA.

We propose to revise § 423.104(d)(5)(iii)(F) to add an end date to state that this paragraph describes how the annual OOP threshold was determined for years 2021 through 2024. We also propose to add new § 423.104(d)(5)(iii)(G) to establish that for 2025, the annual OOP threshold was set at $2,000, consistent with section 1860D–2(b)(4)(B)(i)(VII) of the Act. Additionally, we are proposing to add new § 423.104(d)(5)(iii)(H) to specify the methodology for determining the annual OOP threshold for 2026 and each subsequent year. Consistent with section 1860D–2(b)(4)(B)(i)(VIII) of the Act, we propose that the annual OOP threshold for 2026 and each subsequent year would be the amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

e. Alternative Prescription Drug Coverage (§ 423.104(e)(5)) and Enhanced Alternative Coverage (§ 423.104(f)(1))

Part D sponsors must provide their enrollees with qualified prescription drug coverage which, as defined at § 423.100, means coverage that consists of either: (1) standard prescription drug coverage or (2) alternative prescription drug coverage. Standard prescription drug coverage, as defined at § 423.100, means coverage of Part D drugs that meets the requirements of § 423.104(d) and includes two distinct types of coverage: (1) defined standard coverage and (2) actuarially equivalent (AE) standard coverage.

Prior to the implementation of the IRA, defined standard coverage consisted of coverage of covered Part D drugs subject to an annual deductible, 25 percent coinsurance for costs above the annual deductible but at or below an initial coverage limit, coinsurance that was equal to the costs of non-applicable and applicable drugs during the coverage gap multiplied by the gap coinsurance percentages, and catastrophic coverage with nominal cost sharing for the remainder of the coverage year once an enrollee's incurred costs, as defined in § 423.100, exceeded the annual OOP threshold. After the implementation of the IRA, defined standard coverage, as discussed in more detail in the introduction of this section of the proposed rule, now consists of an annual deductible, an initial coverage phase where the enrollee pays 25 percent coinsurance for covered Part D drugs until they reach the annual OOP threshold ($2,100 for CY 2026), and the catastrophic phase where the enrollee pays no cost sharing for Part D drugs. AE standard coverage, as defined at § 423.100, provides for cost sharing as described in

[10] *https://www.cms.gov/files/document/2026-announcement.pdf.*

§ 423.104(d)(2)(i)(B) or cost sharing as described in § 423.104(d)(5)(ii), or both. In other words, under an AE plan, Part D sponsors modify certain benefit parameters, such as cost-sharing structures, while maintaining the same actuarial value. The changes the IRA made to the defined standard benefit are discussed in detail in the preceding sections of this proposed rule.

The IRA also, through section 11201 which amended section 1860D–2(c) of the Act, made changes to the requirements for alternative prescription drug coverage. Alternative prescription drug coverage, as defined in § 423.100, means coverage of Part D drugs, other than standard prescription drug coverage, that meets the requirements of § 423.104(e). Alternative prescription drug coverage includes two types of coverage: (1) basic alternative coverage and (2) enhanced alternative coverage. Both basic alternative and enhanced alternative coverage must provide access to negotiated prices, coverage of Part D drugs, and meet the requirements described in § 423.104(e).

Basic alternative coverage is alternative coverage that is actuarially equivalent to defined standard coverage, as determined through the processes and methods established under § 423.265(d)(2). Prior to the implementation of the IRA, Part D sponsors offering basic alternative coverage could, within the parameters for alternative prescription drug coverage as described in § 423.104(e), combine certain features to maintain an actuarial value of coverage equal to defined standard prescription drug coverage, such as: (1) reducing the deductible, (2) making changes in cost sharing in an actuarially equivalent manner to the 25 percent cost sharing above the deductible and below the initial coverage limit under defined standard coverage and in an actuarially equivalent manner to the gap coverage coinsurance during the coverage gap, or (3) modifying the initial coverage limit. With the changes made to the Part D benefit by the IRA, including the elimination of the initial coverage limit and the coverage gap, certain features that could be offered by basic alternative plans are no longer available. Thus, we are proposing to revise our regulations at § 423.104(e) to align with these changes, as discussed in more detail later.

Enhanced alternative coverage is alternative coverage that includes both required basic prescription drug coverage and supplemental benefits, as described at § 423.104(f)(1)(ii). Prior to the implementation of the Part D benefit redesign provisions in the IRA, supplemental benefits included: the coverage of drugs that are specifically excluded from the definition of a Part D drug in § 423.100 under paragraph (2)(ii) and/or any one or more of the following changes that increase the actuarial value of benefits above the actuarial value of defined standard prescription drug coverage:

- Reduction (or elimination) of the defined standard deductible.
- Reduction of cost sharing in the initial coverage phase.
- Increase of the initial coverage limit threshold.
- Additional cost-sharing reduction in the coverage gap phase.
- Reduction (or elimination) of cost sharing in the catastrophic phase.

As noted in the Final CY 2025 Part D Redesign Program Instructions, section 1860D–2(a)(2)(A)(i) of the Act does not include a reduction in the annual OOP threshold in its list of permissible supplemental benefits, and we have never interpreted such provision to allow for a reduction in the annual OOP threshold. Because the IRA established a defined annual OOP threshold of $2,000 for CY 2025, and an amount equal to the previous year's OOP threshold increased by the annual percentage increase for 2026 and subsequent years, and did not modify the list of permissible supplemental benefits in section 1860D–2(a)(2)(A)(i) of the Act to include a reduction in the annual OOP threshold, Part D sponsors may not lower the annual OOP threshold below the specified amount. Additionally, the IRA eliminated cost sharing in the catastrophic phase beginning in CY 2024 and eliminated the coverage gap phase and replaced the Coverage Gap Discount Program with the Manufacturer Discount Program beginning in CY 2025. Thus, only the following supplemental benefits remain as possible enhancement features: coverage of drugs that are specifically excluded from the definition of a Part D drug, and/or:

- Reduction (or elimination) of the defined standard deductible.
- Reduction of cost sharing in the initial coverage phase.

Given these changes to alternative prescription drug coverage, we propose to revise § 423.104(e)(5) to align our requirements for alternative prescription drug coverage with the changes made by the IRA. We are also proposing to revise § 423.104(f)(1) to align our requirements for enhanced alternative drug coverage with the changes made by the IRA.

We first propose to revise § 423.104(e)(5) to establish a distinction between the requirements for alternative prescription drug coverage that are applicable for years preceding 2025 and requirements for 2025 and each subsequent year. Specifically, we are proposing to add language that, for years preceding 2025, alternative prescription drug coverage is required to provide coverage that is designed to provide payment for costs incurred for covered Part D drugs that is equal to the initial coverage limit. We also propose to add language stating that, for 2025 and each subsequent year, this coverage must be equal to the annual OOP threshold, consistent with section 1860D–2(c)(1)(C) of the Act. Similarly, we propose to revise § 423.104(e)(5)(i) to specify that when calculating the required payment amount for costs incurred for covered Part D drugs, the amount the initial coverage limit exceeds the deductible should be used for years preceding 2025, and the amount the annual OOP threshold exceeds the deductible should be used for 2025 and each subsequent year. We propose maintaining § 423.104(e)(5)(ii) without change; therefore, the amount calculated in § 423.104(e)(5)(i) would be multiplied by 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section to determine the required payment amount.

Finally, we propose to revise § 423.104(f)(1) to specify that an increase in the initial coverage limit could be considered a supplemental benefit only for years preceding 2025. This change reflects the elimination of the initial coverage limit beginning in CY 2025. All other requirements for enhanced alternative coverage that are described in § 423.104(f) remain applicable under the redesigned Part D benefit. Therefore, we are not proposing any additional changes to this section.

3. Specialty Tier (§ 423.104)

Section 1860D–2(b)(2) of the Act established the parameters of the Part D program's defined standard benefit and allows for alternative benefit designs that are actuarially equivalent to the defined standard benefit, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan design. A specialty tier, as defined in § 423.104(d)(2)(iv), is a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(2) of this section) that are greater than the specialty-tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section. Consistent with § 423.104(d)(2)(iv)(D), Part D sponsors may maintain up to two specialty tiers.

Use of one or two specialty tiers provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs. Our policies for the specialty tier aim to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority.

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'' (CY 2022 final rule) which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864),[11] We codified several important aspects of the specialty-tier policy that had previously been maintained through subregulatory guidance, including our methodology for setting and increasing the specialty-tier cost threshold and determining the maximum allowable cost sharing for specialty-tier drugs.

In the CY 2022 final rule, we codified our methodology for setting the specialty-tier cost threshold at § 423.104(d)(2)(iv)(A), as well as our methodology for increasing this cost threshold at § 423.104(d)(2)(iv)(B). These rules describe our processes for setting a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier as well as adjusting this threshold to maintain approximately one percent of Part D drugs as specialty-tier eligible. In the CY 2022 final rule, we also codified, at § 423.104(d)(2)(iv)(D)(1) through (3), the maximum allowable cost sharing for drugs on the specialty tier between 25 and 33 percent coinsurance. By codifying this rule, we aimed to prevent discriminatory formulary structures and protect Part D enrollees with certain disease states that are treated only by specialty-tier eligible drugs. This ''25/33 percent'' maximum allowable cost sharing means that we approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL.

The implementation of the IRA has made it necessary for us to make changes to our current specialty-tier regulations related to adjusting the specialty-tier cost threshold and determining the maximum allowable cost sharing to align with the redesigned Part D benefit. In this rule, we propose to codify technical and conforming changes to our specialty-tier regulations at § 423.104.

a. Technical Correction to the Specialty-Tier Cost Threshold Determination (§ 423.104(d)(2)(iv)(A)(4))

We are proposing a technical correction in § 423.104(d)(2)(iv)(A)(4), which describes how the specialty-tier cost threshold is determined for the plan year. The current regulation text incorrectly refers to paragraph (d)(2)(iii) for the cost threshold determination, but it should refer to the top one percent methodology for determining the specialty-tier cost threshold at paragraph (d)(2)(iv)(A)(3). We therefore propose to correct this inadvertent technical error in this proposed rule.

b. Limit on Specialty-Tier Cost Threshold Adjustment (§ 423.104(d)(2)(iv)(B))

We annually calculate a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier. This cost threshold is adjusted to maintain approximately 1 percent of Part D drugs as specialty-tier eligible. In the CY 2022 final rule, we codified at § 423.104(d)(2)(iv)(B) our methodology to increase the specialty-tier cost threshold as follows:

(*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

Our current regulation only contemplates increasing the specialty-tier cost threshold and does not consider decreasing the threshold when market conditions might warrant such a change. Given the many changes made to the Part D benefit by the IRA, we believe that it may be necessary in future years to decrease the specialty-tier cost threshold due to reductions in Part D drug costs. In general, shifting market dynamics, such as increased utilization of lower cost generic drugs, could potentially lead to reductions in Part D drug costs. The Medicare Drug Price Negotiation Program, as established in Part E of title XI of the Act, which permits the Secretary to negotiate MFPs for certain high expenditure, single source drugs and biological products with participating manufacturers, could also lead to a future need for a downward adjustment. The MFPs for the first 10 selected drugs are scheduled to go into effect on January 1, 2026, with new MFPs taking effect and new drugs being selected for negotiation each subsequent year. Therefore, it is possible that as a result of general market dynamics and more high expenditure drugs being selected for negotiation and their negotiated MFPs taking effect, the methodology for determining the specialty-tier cost threshold, as described in § 423.104(d)(2)(iv)(A), may yield an amount that is at least 10 percent below the previous plan year's specialty-tier cost threshold.

Thus, we propose to revise § 423.104(d)(2)(iv)(B)(1) and (2) by adding language to allow us to reduce the cost threshold under certain circumstances. Specifically, in paragraph (B)(1) of this section, we are proposing to replace ''increase'' with ''modifies'' and add ''or below'' following ''10 percent above.'' In paragraph (B)(2), we are proposing to replace ''increase'' with ''modification.''

c. Specialty Tier Maximum Allowable Cost Sharing (§ 423.104(d)(2)(iv)(D))

Each year, we set the maximum allowable cost sharing for the specialty tier based on the plan's deductible, in accordance with § 423.104(d)(2)(iv)(D). The intent of this policy is to ensure a plan's value is reflective of the defined standard benefit. The regulation limits a plan with the full defined standard deductible to a 25 percent coinsurance on its specialty tier but allows a plan that fully eliminates the deductible up to a 33 percent coinsurance on its specialty tier. Based on the pre-IRA benefit design, we determined that the 33 percent maximum coinsurance was mathematically equivalent to the effective coinsurance for a beneficiary who would have paid the defined standard deductible for any given year plus the 25 percent coinsurance in the initial coverage phase until their drug costs reached the initial coverage limit. In other words, prior to CY 2025, beneficiary OOP costs divided by total drug costs equaled a 33 percent effective

[11] *https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare.*

coinsurance for the beneficiary regardless of the plan deductible, represented by the following equation:

$$\frac{(Beneficiary\ OOP\ costs)}{(Total\ drug\ costs)} = Effective\ coinsurance$$

To operationalize the concept of maximum allowable cost sharing for the specialty tier based on the plan's deductible, CMS, in the CY 2022 final rule, codified the following calculation at § 423.104(d)(2)(iv)(D)(3) to determine the deductible range that corresponded to each specialty-tier coinsurance percentage point from 25 percent through 33 percent. Thus, under the pre-IRA Part D benefit design, we used this equation for the calculation:

$$\frac{Deductible + Coinsurance\ (ICL - Deductible)}{ICL} = 33\%$$

Consistent with the first equation, the numerator here represents beneficiary OOP costs while the denominator represents total drug costs, resulting in an effective coinsurance of 33 percent, to align with the defined standard benefit. This equation was then solved for the deductible, and each specialty-tier coinsurance percentage point was inserted, to calculate the maximum allowable deductible value corresponding to that coinsurance percentage.

However, in CY 2025, the ICL was eliminated and, as a result, the methodology codified at § 423.104(d)(2)(iv)(D)(3) was no longer valid. Therefore, in the Final CY 2025 Part D Redesign Program Instructions,[12] we established a new methodology to determine the specialty-tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the redesigned Part D benefit. In the Final CY 2026 Part D Redesign Program Instructions,[13] we continued to use the methodology outlined in the Final CY 2025 Part D Redesign Program Instructions.

In accordance with the Final CY 2025 Part D Redesign Program Instructions, we are now proposing to codify this methodology for determining the specialty-tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the Part D benefit. To ensure that a plan's value is reflective of the defined standard benefit, we are proposing to codify a methodology similar to the methodology used to calculate the cost-sharing requirements in § 423.104(d)(2)(iv)(D). For Part D plans with the full deductible provided under the defined standard benefit, the coinsurance is 25 percent, consistent with the defined standard benefit. Using the CY 2025 defined standard benefit parameters of a $590 deductible, a $2,000 annual OOP threshold, and a 25 percent coinsurance after the deductible is met and before the annual OOP threshold is reached, the total drug costs can be calculated at $6,230. This results in an effective coinsurance of 32.1 percent. To ensure that coinsurance for the specialty tier remains in alignment with cost sharing under the defined standard benefit, we are retaining the 33 percent maximum coinsurance currently effective at § 423.104(d)(2)(iv)(D)(2).

We are proposing to use, as in previous years, an effective coinsurance equation to calculate the deductible that corresponds to each specialty-tier coinsurance percentage point from 25 percent through 33 percent. Consistent with our decision to retain the 33 percent maximum coinsurance, we are also proposing to use 33 percent to calculate the deductible that corresponds to each specialty-tier coinsurance percentage point. This equation would continue to represent beneficiary OOP costs in the numerator divided by total drug costs in the denominator. The following equation illustrates how we would calculate the effective coinsurance for the Part D benefit for purposes of calculating specialty-tier cost-sharing percentages:

$$\frac{(OOP\ Threshold)}{\left(\frac{(OOP\ Threshold - Deductible)}{Maximum\ allowable\ specialty\ tier\ coinsurance}\right) + Deductible)} = 33\%$$

As with the previous methodology, the equation is solved for the deductible, and each maximum allowable specialty tier coinsurance value is inserted, to determine the maximum allowable deductible value corresponding to that coinsurance. For example, the results for CY 2026 are shown in Table 1.

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

[13] *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf.*

TABLE 1: CY 2026 SPECIALTY-TIER COINSURANCE THRESHOLDS

Deductible Range	Maximum Allowable Specialty-Tier Coinsurance
$601.98 to $615.00	25%
$523.05 to $601.97	26%
$441.93 to $523.04	27%
$358.52 to $441.92	28%
$272.74 to $358.51	29%
$184.46 to $272.73	30%
$93.59 to $184.45	31%
$0.01 to $93.58	32%
$0	33%

Consistent with the approach taken for both CY 2025 and CY 2026 as detailed in the Final CY 2025 Part D Redesign Program Instructions, we are proposing to codify this methodology for determining specialty-tier coinsurance/deductible ranges. Thus, we propose to revise § 423.104(d)(2)(iv)(D)(3)(i) to describe how the maximum coinsurance percentage was determined for years preceding 2025. We also propose to add new § 423.104 (d)(2)(iv)(D)(3)(ii) to describe the methodology for calculating the maximum coinsurance percentage for 2025 and each subsequent year.

4. Changes in True Out-of-Pocket (TrOOP) Costs (§§ 423.100 and 423.464)

A beneficiary's progression through the Part D benefit phases is determined by the total amount of costs incurred by the beneficiary for covered Part D drugs in the plan year. This amount is also referred to as the beneficiary's accumulated TrOOP spending. Incurred costs are defined at section 1860D–2(b)(4)(C) of the Act and the statutory definition has been revised several times since the beginning of the Part D program. Between 2005 and 2010, TrOOP expenditures represented costs actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified State Pharmaceutical Assistance Program (SPAP). The Act also expressly excluded certain costs from the definition of TrOOP, including costs ''reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement.''

In January 2005, we published the final rule titled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4194), in which we initially codified the rules applicable to incurred costs at § 423.100 (hereinafter referred to as the January 2005 Medicare Final Rule). In that rule, we established that the terms ''insurance or otherwise'' are separate terms with separate definitions. The term ''insurance'' refers to a health plan that provides or pays the cost of covered Part D drugs, including, but not limited to health insurance coverage, an MA plan, and a PACE organization. The term ''or otherwise'' refers to government-funded health programs, and accordingly, we defined the term ''government-funded health programs'' to mean any program established, maintained, or funded—in whole or in part—by the Federal government, the governments of States or political subdivisions of States, or any agency or instrumentality of these governments which uses public funds in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs at § 423.100.

Enacted into law on March 23, 2010, section 3314 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) added section 1860D–2(b)(4)(C)(iii) of the Act to specify that costs borne or paid for by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization, and costs borne or paid for by an AIDS Drug Assistance Program (ADAP) count as incurred costs and accumulate towards TrOOP. In the final rule titled, ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes,'' which appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we revised the definition of incurred cost at § 423.100 to reflect the amendments to section 1860D–2(b)(4)(C)(iii) of the Act made by the PPACA. Specifically, we revised the regulation to include payments by the IHS, an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an ADAP in the definition of incurred costs at § 423.100. We also amended § 423.464(f)(2) to state that expenditures made by IHS, an Indian tribe or tribal organization, or under an urban Indian organization or under an ADAP are not required to be excluded when determining whether a Part D enrollee has satisfied the out-of-pocket threshold.

Section 11201 of the IRA further amended section 1860D–2(b)(4)(C) of the Act to update the definition of incurred costs. Section 1860D–2(b)(4)(C)(iii)(II) of the Act, as added by the IRA, amended the definition of incurred costs to include, for CY 2025 and subsequent years, costs incurred that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program. In addition, the IRA provided that, for beneficiaries who have opted into the Medicare Prescription Payment Plan described in section 1860D–2(b)(2)(E) of the Act, election into such program will not impact how a beneficiary moves through the Part D benefit or what counts towards TrOOP. Under section 1860D–2(b)(4)(F) of the Act, a Medicare Prescription Payment Plan participant's TrOOP-eligible costs that are paid by their Part D plan under the Medicare Prescription Payment Plan shall be treated as incurred costs.

Section 11201(f) of the IRA directed the Secretary to implement section 11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. In the Final CY 2025 Part D Redesign Program Instructions, we released guidance to implement the IRA's additions to section 1860D–2(b)(4)(C) of the Act. Specifically, we stated that

supplemental Part D coverage provided by enhanced alternative Part D plans and other health insurance (OHI) will be counted as incurred costs and included in the calculation of TrOOP for CY 2025. This includes supplemental coverage provided by Employer Group Waiver Plans (EGWPs), plan reductions in cost sharing for enrolled beneficiaries, such as reductions by Medicare-Medicaid Plans and D-Special Needs Plans (SNPs), and Center for Medicare and Medicaid Innovation (CMMI) model benefits that reimburse costs for covered Part D drugs (unless stated otherwise in an applicable CMMI model's respective Request for Applications or model guidance). In response to comments received, we explained that including supplemental coverage provided by enhanced alternative Part D plans in addition to OHI is required by the plain language of the statute. Specifically, by excluding ''coverage provided by a prescription drug plan or an MA-PD plan that is basic prescription drug coverage'' from the definition of costs ''reimbursed through insurance,'' the text of section 1860D–2(b)(4)(C)(iii)(II) indicates that drug coverage provided by Part D plans other than basic prescription drug coverage is included in the definition of costs ''reimbursed through insurance.'' This would include enhanced alternative supplemental benefits. If the provision only included EGWP supplemental coverage in the definition of costs ''reimbursed through insurance,'' then the statute would have explicitly included EGWP supplemental coverage in the definition of ''costs reimbursed through insurance'' and expanded the exclusion clause to apply to both basic prescription drug coverage and enhanced alternative supplemental coverage.

We further stated in the Final CY 2025 Part D Redesign Program Instructions that under section 1860D–2(b)(4)(C)(iii)(II) of the Act, only amounts reimbursed by supplemental coverage will be newly included in the calculation of TrOOP. For enhanced alternative plans, plan liability is mapped to the defined standard benefit to distinguish between basic and supplemental benefits provided under the Part D sponsor. Because of this, if beneficiary cost sharing is greater than what it would have been under the defined standard benefit, a negative value is recorded on a Prescription Drug Event (PDE) record for the field representing the value of the supplemental coverage. Such negative values will be disregarded (that is, be treated as zero) when calculating TrOOP, because they do not represent reimbursement to the beneficiary. In response to comments received, we explained that, while excluding such negative values from TrOOP can overstate the net value of total supplemental benefits provided to beneficiaries over the course of the year, including negative values in TrOOP would inappropriately disregard any beneficiary cost sharing in excess of the defined standard cost sharing amount when calculating TrOOP. This would particularly disadvantage certain beneficiaries who have patterns of utilization that disproportionately include this situation. For example, if a beneficiary in an enhanced alternative plan has higher cost sharing than the defined standard benefit for a maintenance medication, including the negative values in TrOOP could significantly disadvantage that beneficiary as these negative values would continually offset part of the payments the beneficiary actually paid OOP. This would create some circumstances where certain beneficiaries have a net negative value for their supplemental benefits when they reach the $2,100 OOP threshold, which means they would have to pay more than $2,100 OOP to reach the catastrophic phase for CY 2026.

Additionally, we noted that section 1860D–2(b)(4)(C)(iii)(II) of the Act states that reimbursements through ''certain other third party payment arrangements'' are to be included in the calculation of TrOOP. We did not identify any third party payment arrangements in addition to those described in the preceding paragraphs that could be included in the calculation of TrOOP. For instance, primary payer amounts paid on Medicare as secondary payer (MSP) claims are a category of third party payments that we considered for TrOOP eligibility. We determined that these payments should remain excluded from TrOOP due to the requirements at section 1862(b) of the Act, which was not amended by the IRA. As such, for 2025, we did not count as incurred costs any other third party payments not considered TrOOP-eligible prior to 2025. In the Final CY 2025 Part D Redesign Program Instructions, we also solicited comment on whether interested parties are aware of other third party payments that could be included under section 1860D–2(b)(4)(C)(iii)(II) of the Act. No commenters identified additional third party payments that they believed should be included in TrOOP. We also did not receive any comments on the Final CY 2026 Part D Redesign Program Instructions recommending that we include any other third party payments towards TrOOP.

Further, we stated that, as required by section 1860D–2(b)(4)(C)(iii)(II) of the Act, any manufacturer payments made under the Manufacturer Discount Program, which was newly created under the IRA, do not count as incurred costs and are not included in the calculation of TrOOP in 2025.

Finally, we stated that for beneficiaries who have opted into the Medicare Prescription Payment Plan described in section 1860D–2(b)(2)(E) of the Act, as added by section 11202 of the IRA, election into such program will not impact how a beneficiary moves through the Part D benefit or what counts towards TrOOP. Under section 1860D–2(b)(4)(F) of the Act, as codified at § 423.137(c)(4), a Medicare Prescription Payment Plan participant's TrOOP-eligible costs that are paid by their Part D plan under the Medicare Prescription Payment Plan shall be treated as incurred costs.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to incurred costs, also applied in CY 2026.

In this proposed rule, we propose to codify at § 423.100 the policies we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and applied via the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with respect to the definition of incurred costs for 2025 and subsequent years, without modification. These policies are currently in effect for CY 2026. Specifically, we propose to add a new subparagraph (3) to the definition of incurred costs at § 423.100 defining incurred costs for 2025 and subsequent years to include costs that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a PDP or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program under section 1860D–14C of the Act. We also propose to amend § 423.464(f)(2)(i)(C) to remove the exclusion of expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage and replace it with an exclusion limited to expenditures for covered Part D drugs made by

government-funded health programs or the coverage provided by a PDP or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program.

5. Policy for Drugs Not Subject to Defined Standard Deductible (§ 423.104)

Under sections 1860D–2(b) and (c) of the Act, as amended by section 11201 of the IRA, the coverage gap phase was eliminated in CY 2025. Beginning in CY 2025, a beneficiary leaves the initial coverage phase and enters the catastrophic phase once they incur enough TrOOP-eligible costs to meet the annual OOP threshold. Accordingly, under section 1860D–14A(h) of the Act, as added by section 11201 of the IRA, the Coverage Gap Discount Program sunset effective January 1, 2025. Section 11201 of the IRA added section 1860D–14C of the Act, which created the Manufacturer Discount Program beginning January 1, 2025. Under section 1860D–14C(b)(1)(A) of the Act, manufacturers that enter into a Manufacturer Discount Program agreement will provide discounts on applicable drugs, typically amounting to 10 percent of the negotiated price for enrollees in the initial coverage phase and 20 percent of the negotiated price for enrollees in the catastrophic phase, in CY 2025 and subsequent years.

Manufacturer discounts are available under the Manufacturer Discount Program once a beneficiary becomes an ''applicable beneficiary.'' Section 1860D–14C(g)(1) of the Act defines an applicable beneficiary as an individual who, on the date of dispensing a covered Part D drug, is enrolled in a PDP or MA–PD plan, is not enrolled in a qualified retiree prescription drug plan, and has incurred TrOOP-eligible costs that exceed the defined standard deductible specified in section 1860D–2(b)(1) of the Act. TrOOP-eligible costs for drugs not subject to the defined standard deductible, specifically covered insulin products, as well as TrOOP-eligible costs for drugs not subject to a non-defined standard plan deductible or drugs subject to a reduced deductible under non-defined standard plans, all count towards a beneficiary's satisfaction of the defined standard deductible.

In the Final CY 2025 Part D Redesign Program Instructions, we established a policy for drugs not subject to the defined standard deductible to address situations where a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible. The policy also addresses situations where a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount. The component of the definition of an applicable beneficiary at section 1860D–14C(g)(1)(C) of the Act creates the possibility for a beneficiary to encounter these situations; therefore, this policy was necessary to ensure that such situations are treated similarly by all Part D plan sponsors.

We established that in CY 2025, if a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible, they will be both an applicable beneficiary under the Manufacturer Discount Program, as we propose to define at § 423.100, and be deemed to have satisfied their plan deductible.

Furthermore, we established that, if a plan offers a non-defined standard plan deductible—whether that be a lower deductible than the defined standard deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount, discounts under the Manufacturer Discount Program are not available. As such, the plan is responsible for covering the portion of costs that would be covered by the manufacturer discount if the beneficiary were an applicable beneficiary until the beneficiary's TrOOP exceeds the defined standard deductible and they become an applicable beneficiary. The same guidance applies when a beneficiary under any Part D plan is dispensed a covered insulin product or ACIP-recommended vaccine before they have incurred TrOOP-eligible costs at or above the defined standard deductible amount.

For example, an enhanced alternative plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20 percent coinsurance for drugs in that tier. A beneficiary's first fill of the year is for a $200 tier 1 drug, meaning they pay $40 out of pocket. The beneficiary has not incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible of $615 (and has $415 in remaining TrOOP-eligible costs before they satisfy the deductible) and does not meet the definition of an applicable beneficiary under the Manufacturer Discount Program. Therefore, the plan must cover the 10 percent of costs that would be covered by the manufacturer discount if the beneficiary were an applicable beneficiary.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to drugs not subject to the defined standard deductible, also applied in CY 2026. We also established that the policy for drugs not subject to the defined standard deductible also applies to selected drugs for CY 2026. Specifically, we stated that if a plan offers a non-defined standard plan deductible—whether that be a lower deductible than the defined standard deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the defined standard deductible amount, the selected drug subsidy is not available for selected drugs during a price applicability period. As such, for a selected drug during a price applicability period, the plan is responsible for covering the portion of costs that would be covered by the selected drug subsidy if the beneficiary were an applicable beneficiary until the beneficiary's TrOOP exceeds the defined standard deductible and they become an applicable beneficiary.

In this proposed rule, we propose to codify the policy for drugs not subject to the defined standard deductible that are in effect for 2025 and 2026 without modification. Specifically, we propose to codify the policy for drugs not subject to defined standard deductible at a new § 423.104(j).

6. Annual Indexing of Part D Benefit Parameters Using the Annual Percentage Increase in Drug Expenditures (API) and Consumer Price Index (CPI) (§§ 423.104, 423.782)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA) added sections 1860D–2(b) and 1860D–14(a) of the Act directing the Secretary to index certain Part D benefit parameters each year, which include, but are not limited to, the deductible limit and low-income cost-sharing amounts. The required annual adjustments ensure that the actuarial value of the drug benefit remains consistent with changes in Part D drug expenditures and general inflation. The MMA established two indices for adjusting Part D benefit parameters: (1) the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in

the U.S. for Part D eligible individuals under section 1860D–2(b)(6) of the Act (referred to as the API); and (2) the annual percentage increase in the Consumer Price Index based on all items per a U.S. city average under section 1860D–14(a)(4)(A) of the Act (referred to as the CPI).

In the January 2005 Medicare Final Rule (70 FR 4194), establishing the regulatory framework for the Medicare Part D prescription drug benefit program created by the MMA. This rule codified the statutory requirements for annual adjustments of the deductible under section 1860D–2(b)(6) of the Act and low-income cost-sharing amounts under section 1860D–14(a) of the Act, using the API and the CPI. The rule also established the regulatory basis for annual adjustments to additional Part D parameters, including the annual out-of-pocket threshold and retiree drug subsidy (RDS) cost thresholds, to maintain the actuarial integrity of the benefit structure as drug costs and economic conditions change over time.

In accordance with the statute and corresponding regulation, the following Part D standard benefit, low-income subsidy, and RDS program parameters are updated using the API:

- *Standard Benefit Deductible*—section 1860D–2(b)(1)(A)(ii) of the Act; § 423.104(d)(1)(ii).
- *Initial Coverage Limit*—section 1860D–2(b)(3)(A)(ii) of the Act; § 423.104(d)(3)(ii).
- *OOP Threshold*—section 1860D–2(b)(4)(B)(i)(VIII) of the Act.
- *Maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees* (income less than 150 percent, but greater than 100 percent of Federal Poverty Level (FPL), not including institutionalized individuals)—section 1860D–14(a)(1)(D)(iii) of the Act; § 423.782(a)(2)(i).
- *RDS Cost threshold*—section 1860D–22(a)(3)(B)(i)(I) of the Act; § 423.886(b)(3).
- *RDS Cost limit*—section 1860D–22(a)(3)(B)(i)(II) of the Act; § 423.886(b)(3).

The CPI is used to update the following Part D low-income subsidy and cost-sharing program benefit parameter:

- *Maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees* (income less than 100 percent of the FPL)—section 1860D–14(a)(1)(D)(ii) of the Act; § 423.782(a)(2)(iii)(A).

While sections 1860D–2(b)(6) and 1860D–14(a)(4)(A) describe the parameter adjustments as an ''increase'' when referring to API and CPI, we have historically applied them multidirectionally, including decreasing the parameter values in the event of a decrease in annual Part D expenditures or deflation, to ensure that the actuarial value of the drug benefit remains consistent each year.

The current regulations do not describe the specific methods used to calculate the annual percentage increases. Instead, the specific methods for calculating the annual percentage increases in drug expenditures and CPI that are applied to the Part D benefit parameters have been proposed for each CY in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Advance Notice) and finalized in the Announcement of Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Rate Announcement). In this proposed rule, we propose to codify these methodologies in regulation. We also propose making certain technical changes to current regulations related to indexing certain benefit parameters for low-income individuals. Although we are proposing to codify the calculation methodology for the API and CPI in this rule, we will continue to publish the annual percentage increases in drug expenditures and CPI and updated Part D benefit parameters for each CY through the Advance Notice and Rate Announcement. The projections and calculations used in the methodologies described at proposed §§ 423.104 and 423.782 are made using generally accepted actuarial principles and practices. In applying generally accepted actuarial principles and practices, actuarial judgment and discretion may be used, including taking into account information such as changes in legislation (such as changes in Medicare benefits), Medicare payment policy, trends over several years of data, and external variables (such as public health emergencies); selecting among different approaches (such as weighting for utilization and using average or median values); and in selecting data or data samples.

Calculation of the Annual Percentage Increase in Drug Expenditures

Section 1860D–2(b)(6) of the Act defines the API for each year as the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals, for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify. We calculate the aggregate expenditures for Part D drugs using the GCPDC instead of an alternative cost measure such as actual net drug costs, because gross drug costs reflect the prices available to beneficiaries and are the basis for calculating beneficiary cost sharing and for beneficiary progression through the Part D drug benefit. The GCPDC is reported to CMS on PDE records; consequently, PDE records are the data source used for this calculation. For contract years 2006 and 2007, the API calculations were based on National Health Expenditure (NHE) prescription drug per capita estimates due to insufficient Part D program data availability; however, we transitioned to using PDE records for CY 2008 and future years.

The API calculation, where API represents the annual percentage increase for Part D expenditures for a given year, is comprised of two factors we refer to as: (1) an annual percentage trend (APT), and (2) a multiplicative update (MU) factor for prior-year revisions.

Mathematically, the formula is expressed as follows:

$API = (APT) * (MU)$

For a given payment year, the APT is the ratio of total per capita Part D drug expenditures in the 12-month period (August through July) prior to the given payment year (numerator) to the total per capita Part D drug expenditures two years prior to the given payment year (denominator).

For example, the APT for CY 2027 is equal to:

$$\left(\frac{\substack{\text{Total per Capita Part D Drug Expenditures from August 2025 to July 2026} \\ \text{(Numerator for previous year)}}}{\substack{\text{Total per Capita Part D Drug Expenditures from August 2024 to July 2025} \\ \text{(Denominator for 2 years prior)}}}\right) - 1.0$$

The MU factor is used to incorporate updated data for prior years into the calculation. We update data for prior years for two reasons: First, at the time the CMS Office of the Actuary calculates the API, actual, reasonably complete PDE data is typically only available for dates of service during the first 5 months of the measurement period (August–December). For the remainder of the measurement period (typically 7 months (January–July)), the costs must be estimated using historical data and actuarial experience. For example, for payment year 2027, the average per capita cost for August 2024–July 2025 (2 years prior) is calculated from submitted PDE data, while the average for August 2025–July 2026 (the year prior) is based on actual data from August 2025–December 2025 and projections for January–July 2026. Second, PDE data may be resubmitted to make corrections or retroactive claim adjustments [14] for activities such as coordination of benefits or changes in eligibility status for Part D or the Low-Income Subsidy program. Historically, we have used a retrospective period, typically 5 years, to update calculations to account for the impact of resubmissions that occur as part of Part D operations such as the annual Part D payment reconciliation under § 423.343 or a reopening of a reconciliation under § 423.346. We have found few to no resubmissions occur beyond a typical retrospective 5-year window.

The MU factor for a given year is the ratio of the product of the APTs for all prior recorded years (since the first calculation in 2007), with the most recent 5 years revised and updated with the currently available data (numerator) to the product of APTs in prior recorded years as published in the previous year's Rate Announcement (denominator). As discussed in the preceding paragraphs, the MU factor has a 5-year retrospective window; however, we have historically included data since 2007 for informational purposes, as this historical data is the same in the numerator and the denominator and has no effect. To convert ratios to percentages, it is necessary to add 1.0 to each factor prior to entering them into the formula.

For example, the MU factor for CY 2027 is equal to:

$$\frac{[(1.00+APT_{2025})(1.00+APT_{2024})...(1.00+APT_{2007})]}{[(1.00+APT_{CY26RA2025})(1.00+APT_{CY26RA2024})...(1.00+APT_{CY26RA2007})]}$$

In this example, APT is the annual percentage trend, denoted with a subscript for the year of the data. The numerator is updated from CY 2020 through CY 2025, using the most recent data available when it is calculated in 2026, and the denominator uses data published in the CY 2026 Rate Announcement (published in April 2025).

Historically, the statutory parameters updated by the API have included the defined standard benefit deductible, initial coverage limit, annual OOP threshold, and the parameters for the LIS and RDS benefits. The IRA eliminated the coverage gap phase and beneficiary cost sharing above the annual OOP threshold; it also set the annual OOP threshold at $2,000 for CY 2025. Given these changes, for CY 2025, only the defined standard deductible and LIS benefit parameters were updated using the API. For CY 2025 and subsequent years, no updates to the parameters for the initial coverage limit, maximum or minimum beneficiary cost sharing in the coverage gap or above the annual OOP threshold were necessary as the coverage gap phase and beneficiary cost sharing above the annual OOP threshold were eliminated. In CY 2026, the defined standard deductible, the annual OOP threshold, and the maximum copayment below the annual OOP threshold for low-income, full-subsidy-eligible beneficiaries with incomes between 100 and 150 percent of the FPL were updated using the API.

We propose to revise § 423.104(d)(5)(iv) by adding three paragraphs describing (1) the overall calculation of the annual percentage increase, or the API, in per capita Part D drug expenditures, (2) the calculation of the annual percentage trend, or the APT, and (3) the calculation of the multiplicative update factor, or the MU. We will continue to publish updates to the Part D benefit parameters calculated through these methodologies through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act.

Calculation of the Annual Percentage Increase in CPI

Section 1860D–14(a)(4)(A) of the Act specifies that the annual percentage increase in CPI, a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services,[15] is the annual percentage increase in the CPI (all items; U.S. city average) as of September of such previous year. As noted previously, the annual percentage increase in the CPI applies to the copayments for the lowest income dually eligible individuals (with incomes not exceeding 100 percent of the FPL) under section 1860D–14(a)(1)(D)(ii) of the Act, and is reflected at § 423.782(a)(2)(iii). The CPI is based on economic assumptions of the Consumer Price Index for All Urban Consumers (CPI–U), which is published by the Bureau of Labor Statistics. The method for calculating the annual percentage increase in the CPI comprises two factors we refer to as: (1) an annual percentage trend; and (2) a multiplicative update factor for prior-year revisions.

While the other Part D benefit parameters are indexed using the API to track drug expenditure trends and maintain actuarial equivalence within the drug benefit structure, this parameter uses the CPI because it represents a fixed dollar copayment amount that needs to maintain its purchasing power relative to general inflation rather than specifically tracking drug cost inflation trends.

Mathematically, the formula is expressed as follows:

*Annual Percentage Increase in CPI = (APT) * (MU),* where APT is the annual percentage trend, and MU is the multiplicative update factor for prior year revisions.

The APT consists of a year-over-year comparison of the CPI in the United States for all items, ending in the month of September. For a given payment year, it is the ratio of the CPI in the year ending the previous September (numerator) to the CPI for the year ending the September two years prior (denominator). To ensure that plan sponsors and CMS have sufficient time to incorporate cost-sharing requirements into the development of the benefit, any marketing materials, and necessary systems, we include an estimate of the September CPI based on projections from the President's Budget in its

[14] Medicare Prescription Drug Benefit Manual, Pub. 100–18, Chapter 14: Coordination of Benefits.

[15] Consumer Price Index, *https://www.bls.gov/cpi/* (last visited Jun 17, 2025).

methodology to calculate the annual increase in the CPI for the 12-month period ending in September prior to the applicable payment year.

For example, the annual percentage trend in the September CPI for CY 2027 is calculated as follows:

$$APT = \frac{Projected\ September\ 2026\ CPI}{Actual\ September\ 2025\ CPI}$$

The MU factor revises APTs in the September CPI to reflect updates (provided by the BLS) from the previously estimated September CPI to the actual reported September CPI. The MU factor for a given year is the ratio of the product of the APTs for all prior recorded years (since the first calculation in 2007), with the most recent year updated with the currently available data (numerator) to the product of APTs in prior recorded years as published in the previous year's Rate Announcement (denominator). As mentioned in the preceding paragraphs, data since 2007 is included for informational purposes. To convert the ratios to percentages, it is necessary to add 1.0 to each factor prior to entering them into the formula.

For example, the MU factor for CY 2027 is equal to—

$$\frac{[(1.00 + APT_{2025})(1.00 + APT_{2024}) \ldots (1.00 + APT_{2007})]}{[(1.00 + APT_{CY26RA2025})(1.00 + APT_{CY26RA2024}) \ldots (1.00 + APT_{CY26RA2007})]}$$

In this example, the numerator is updated from CY 2025 through CY 2026, using recent economic assumptions, and the denominator uses data published in the CY 2026 Rate Announcement (published in April 2025).

To implement the CPI calculation described previously in our regulations, we are proposing to revise § 423.782(a)(2)(iii)(A) to include a reference to a new paragraph (d), which we propose to add at the end of § 423.782. The new section at § 423.782(d) would comprise the general language of the statute, as well as add three subparagraphs describing: (1) the overall calculation of the annual percentage increase in CPI and specify the period ending in ''September of such previous year,'' (2) the calculation of the annual percentage trend, and (3) the calculation of the multiplicative update factor. We will continue to publish updates to the Part D benefit parameters calculated through these methodologies through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act.

Technical Changes

We are proposing two technical changes to § 423.782(b). First, we propose to add a cross-reference to § 423.104(d)(5)(iv) to the provision at § 423.782(b)(1) to make clear that the annual percentage increase in average per capita aggregate expenditures that we use to calculate the deductible for certain low-income subsidy eligible individuals is calculated as provided in § 423.104(d)(5)(iv). Second, we propose to streamline the regulation text at § 423.782(b)(3) so that it directly cross references the updated maximum copayment amounts that apply for years subsequent to 2006. Section 1860D–2(b)(4)(A)(i)(I) is implemented in regulation at § 423.104(d)(5)(i)(A)(2). We propose to replace the description in § 423.782(b)(3) of the annual process for updating maximum copayments with a cross reference to § 423.104(d)(i)(A)(2).

7. Changes to GCPDC and Allowable Reinsurance Cost Definitions To Include Costs Paid by the MDP (§ 423.308)

Section 1860D–15(b)(3) of the Act defines ''gross covered prescription drug costs'' as, ''with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan . . . regardless of whether the coverage under the plan exceeds basic prescription drug coverage.'' Section 1860D–15(b)(2) of the Act defines allowable reinsurance costs as ''. . . such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan . . .'' GCPDC and allowable reinsurance costs are defined and used at section 1860D–15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount.

In the January 2005 Medicare Final Rule (70 FR 4194), we codified the definition of ''gross covered prescription drug costs'' at § 423.308. This regulatory definition referred to ''gross covered prescription drug costs'' as ''actually paid costs.'' In the final rule that appeared in the **Federal Register** on April 12, 2023(70 FR 22120), we revisited the regulatory definition of GCPDC by amending the definition at § 423.308 to remove the phrase ''actually paid.'' We made this change because the term ''actually paid'' has a specific meaning in Medicare Part D and is separately defined at § 423.308 to mean costs actually incurred by the plan that are net of direct and indirect remuneration (DIR), including discounts, rebates, or other price concessions typically received and applied after the point of sale (POS). However, unlike the statutory definitions of ''allowable reinsurance costs'' and ''allowable risk corridor costs'' at sections 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act, respectively, the statutory definition of ''gross covered prescription drug costs'' at section 1860D–15(b)(3) of the Act does not use the phrase ''actually paid'' or otherwise specify that such costs must be net of all DIR. As we explained in the December 2022 proposed rule (87 FR 79611), because the definition of ''gross covered prescription drug costs'' was codified in regulation for the sole purpose of describing the methodology for calculating the reinsurance payment amount, in using the phrase ''actually paid'' in the regulatory definition of ''gross covered prescription drug costs,'' We were incorporating a requirement from the statutory definition of ''allowable reinsurance costs'' to emphasize that DIR would be netted out

in the calculation of costs eligible for Part D reinsurance. As we explained in the proposed rule, the proposed revisions to the definition would not change the fact that Part D reinsurance is ultimately based on net drug costs or change the final reinsurance payment amount a Part D sponsor receives. Rather, allowable reinsurance costs would continue to be defined at § 423.308 as the subset of gross covered prescription drug costs actually paid.

Manufacturer discounts, among other costs, paid under the Coverage Gap Discount Program (as described in section 1860D–14A of the Act) were always included in the calculation of GCPDC. This policy was consistent with the statutory and regulatory definition of GCPDC, which generally requires the inclusion of all costs incurred under the plan, including those paid on behalf of the Part D beneficiary. The IRA sunset the Coverage Gap Discount Program as of January 1, 2025. As such, these costs are no longer included in the calculation of GCPDC. Section 11201(b)(3) of the IRA amended section 1860D–15(b)(3) of the Act in two places to also require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program in the calculation of GCPDC (first, by specifying that the definition of GCPDC is subject to paragraph (2)(B) of section 1860D–15(b) of the Act and second, by adding language specifying that, in the case of an applicable drug, as defined at § 423.100, GCPDC shall be determined whether the costs are paid by the individual, under the plan, or by a manufacturer). Moreover, section 11201(b)(2) of the IRA also amended section 1860D–15(b)(2) of the Act to require the inclusion of manufacturer discounts paid under the Manufacturer Discount Program under section 1860D–14C of the Act in the calculation of allowable reinsurance costs in 2025.

In the Final CY 2025 Part D Redesign Program Instructions, under the requirement in section 11201(f) of the IRA that we use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025 and to mirror the statutory language in sections 1860D–15(b)(2) and (3) of the Act, as amended by the IRA, we stated that the regulatory definition of ''gross covered prescription drug costs'' at § 423.308 would be considered to have been revised for CY 2025 to include ''all amounts paid by manufacturers under the Manufacturer Discount Program (as defined in section 1860D–14C of the Act).'' Additionally, we stated that the regulatory definition of ''allowable reinsurance costs'' at § 423.308 would be considered to have been revised for CY 2025 to include ''the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined in section 1860D–14C(g)(2) of the Act) paid by manufacturers under the Manufacturer Discount Program (as defined in section 1860D–14C of the Act).''

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the policy with respect to the definitions of GCPDC and allowable reinsurance costs, also applied in CY 2026.

We propose to codify the policy that we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and applied via the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with the limited modifications mentioned later in this section. Specifically, we propose that the regulatory definition of ''gross covered prescription drug costs'' at § 423.308 be revised to include ''all amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).'' We also propose to add the phrase ''for years prior to 2025'' before the phrase ''amounts between the initial coverage limit and the out-of-pocket threshold'' and the phrase ''because the enrollee is between the initial coverage limit and the out-of-pocket threshold'' to reflect that the coverage gap phase does not exist for 2025 and subsequent years. Additionally, we propose to revise the regulatory definition of ''allowable reinsurance costs'' at § 423.308 to include ''the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined at § 423.100) paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).''

8. Reinsurance Methodology (§ 423.329)

Section 1860D–15(b) of the Act, originally enacted into law by the MMA, sets forth rules for the calculation and payment of federal reinsurance subsidies for Part D plans. For years preceding CY 2025, the reinsurance amount for a Part D eligible individual was an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred after that individual reached the catastrophic phase of the benefit. In the January 2005 Medicare Final Rule, we codified this calculation at § 423.329(c)(1).

Under section 1860D–15(b)(2) of the Act, we make reinsurance payments to Part D plan sponsors based on the GCPDC that were actually paid during the coverage year. ''Actually paid,'' defined at § 423.308, means that the costs must be actually incurred by the Part D sponsor and must be net of any DIR. Each year, sponsors report their DIR to us as part of the annual DIR reporting process, and we use this information, along with cost data reported on PDE records, to allocate a portion of the DIR towards reducing allowable reinsurance costs. Historically, we allocated DIR to reduce allowable reinsurance costs and calculate final reinsurance subsidy payments in accordance with the methodology provided in the CY 2006 Advance Notice.

The IRA significantly modifies the reinsurance subsidy under the Part D benefit in CY 2025. Specifically, under section 1860D–15(b) of the Act, as amended by section 11201(b) of the IRA, in 2025, the reinsurance payment amount for a Part D beneficiary will decrease from 80 percent of the allowable reinsurance costs incurred after the beneficiary exceeds the annual OOP threshold to 20 percent for applicable drugs or 40 percent for drugs that are not applicable drugs.

Covered Part D drugs that are not applicable drugs and which are eligible for reinsurance payments amounts equal to 40 percent of the allowable reinsurance costs incurred include selected drugs (as defined in section 1192(c) of the Act and as we propose to define at § 423.100) during a price applicability period (as defined in section 1191(b)(2) of the Act and as we propose to define at § 423.100), as well as non-applicable drugs (as defined in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance and section II.C. of this proposed rule).

Therefore, a different calculation applies to applicable drugs versus non-applicable and selected drugs for the reinsurance payment amount, and the methodologies for calculating the reinsurance subsidy and allocating direct and indirect remuneration (DIR) towards reinsurance, must also be reconsidered.

In the Final CY 2025 Part D Redesign Program Instructions, we established a methodology to calculate the reinsurance subsidy separately for applicable and non-applicable drugs and allocate the share of DIR for applicable and non-applicable drugs based on their respective gross drug costs that fall in the catastrophic phase. The methodology otherwise aligns with

our historical approach for apportioning DIR.

Specifically, we stated that after the end of the coverage year, we would reconcile reinsurance subsidies for applicable drugs as follows:

- Identify incurred reinsurance costs for applicable drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for applicable drugs at the plan level.
- Allocate DIR for applicable drugs to incurred reinsurance costs for applicable drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as ''reinsurance DIR.'')
- Subtract reinsurance DIR for applicable drugs from incurred reinsurance costs for applicable drugs, then multiply the difference by 20 percent (the reinsurance payment amount percentage for applicable drugs).

Similarly, after the end of the coverage year, we stated that we would reconcile reinsurance subsidies for non-applicable drugs as follows:

- Identify incurred reinsurance costs for non-applicable drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for non-applicable drugs at the plan level.
- Allocate DIR for non-applicable drugs to incurred reinsurance costs for non-applicable drugs by applying the ratio of total DIR to total allowed costs.
- Subtract reinsurance DIR for non-applicable drugs from incurred reinsurance costs for non-applicable drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable drugs).

The sum of the adjusted reinsurance amounts for applicable and non-applicable drugs will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year.

In the Final CY 2026 Part D Redesign Program Instructions, we updated the methodology applied in CY 2025 to account for selected drugs, as the selected drug subsidy program begins in 2026. Specifically, we stated that, for CY 2026, we would calculate the reinsurance subsidy separately for applicable drugs. Because the percentage of allowable reinsurance costs to calculate the reinsurance payment amount for a Part D beneficiary is the same for non-applicable and selected drugs, the reinsurance subsidy for non-applicable and selected drugs would be calculated together. Additionally, we stated that, for CY 2026, we would allocate the share of DIR for applicable drugs and non-applicable and selected drugs based on their respective share of gross drug costs that fall in the catastrophic phase.

After the end of CY 2026, we stated that we would reconcile reinsurance subsidies for non-applicable and selected drugs as follows:

- Identify incurred reinsurance costs for non-applicable and selected drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for non-applicable and selected drugs at the plan level.
- Allocate DIR for non-applicable and selected drugs to incurred reinsurance costs for non-applicable and selected drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as ''reinsurance DIR.'')
- Subtract reinsurance DIR for non-applicable and selected drugs from incurred reinsurance costs for non-applicable and selected drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable and selected drugs).

The sum of the adjusted reinsurance amounts for applicable drugs and non-applicable and selected drugs for CY 2026 will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year. To determine the appropriate category (applicable, non-applicable, or selected) for drugs, we stated we would use the 11-digit NDC submitted on each PDE record and assign it with an applicable, non-applicable, or selected designation based on the marketing category listed for that NDC in the U.S. Food and Drug Administration (FDA)'s NSDE file used for PDE processing and the list of NDCs referenced in the Medicare Drug Price Negotiation Program guidance.

For CY 2026, the calculation formulas for applicable drugs are:

Reinsurance DIR for applicable drugs = (total DIR/total allowed costs) × incurred reinsurance costs for applicable drugs.

Adjusted reinsurance for applicable drugs = (incurred reinsurance costs for applicable drugs − reinsurance DIR for applicable drugs) × 0.20.

For CY 2026, the calculation formulas for non-applicable and selected drugs are:

Reinsurance DIR for non-applicable and selected drugs = (total DIR/total allowed costs) × incurred reinsurance costs for non-applicable and selected drugs.

Adjusted reinsurance for non-applicable and selected drugs = (incurred reinsurance costs for non-applicable and selected drugs − reinsurance DIR for non-applicable and selected drugs) × 0.40.

In this proposed rule, we propose to codify at § 423.329 the policies we established in the Final CY 2025 Part D Redesign Program Instructions for CY 2025 and the Final CY 2026 Part D Redesign Program Instructions for CY 2026 with respect to the reinsurance methodology without modification. Specifically, we propose to redesignate paragraph (c)(1) as paragraph (c)(1)(i) and revise the introductory language to state ''general rule for years preceding 2025'' and add a new paragraph (c)(1)(ii) to codify the rules described previously for 2026 and future years.

9. Selected Drug Subsidy (§§ 423.265, 423.315, 423.329, 423.343)

Section 11201 of the IRA added section 1860D–14D to the Act, creating a new selected drug subsidy program, which began in CY 2026. Under the selected drug subsidy program, the Secretary must, periodically and on a timely basis, provide Part D plan sponsors with a subsidy for selected drugs, as defined under section 1192(c) of the Act, equal to 10 percent of the drug's negotiated price. The selected drug subsidy applies to a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a selected drug under the Medicare Drug Price Negotiation Program during a price applicability period. The subsidy is paid on behalf of an applicable beneficiary who is enrolled in a PDP or an MA–PD plan, has not incurred costs that are equal to or exceed the annual OOP threshold, and is dispensed a selected drug.

Under the selected drug subsidy program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act (that is, the deductible under the defined standard benefit) the selected drug subsidy is available in the initial coverage phase of the benefit. The selected drug subsidy lowers Part D plan sponsor liability on the negotiated price of the drug.

Because of the intertwined structure and wording of the Manufacturer Discount Program and selected drug subsidy program provisions at sections 1860D–14C and 1860D–14D of the Act, we interpret the statute as establishing the selected drug subsidy as a substitute for the Manufacturer Discount Program discount for a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a

selected drug under the Medicare Drug Price Negotiation Program during a price applicability period. As such, we propose to treat claims that are subject to the selected drug subsidy as coterminous with claims that would qualify for applicable discounts under the Manufacturer Discount Program, but for the drug's status as a selected drug during a price applicability period. In other words, the selected drug subsidy will apply if the selected drug that otherwise would be an ''applicable drug'' would have received an applicable discount under the Manufacturer Discount Program for the particular claim at issue under the rules of the Manufacturer Discount Program. Conversely, the selected drug subsidy will not apply if the applicable discount under the Manufacturer Discount Program otherwise would not have applied to that particular claim. For example, as discussed in section II.C. of this proposed rule, certain claims involving an applicable drug, such as Medicare Secondary Payer claims, are not subject to discounts under the Manufacturer Discount Program; in these situations, the selected drug subsidy would also not apply.

Because certain actual expenses can only be fully known after all costs have been incurred for a payment year, we make final payment for these costs after a coverage year after obtaining all the information necessary to determine the amount of payment. We currently make monthly prospective payments of certain estimated costs submitted with bids, including reinsurance costs and low-income cost-sharing subsidy (LICS) costs, to mitigate cash-flow concerns that plans could experience if such payments were made wholly on a retrospective basis.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that similar concerns suggested that we should also make monthly prospective payments for the selected drug subsidy program. We accordingly established a process where Part D plan sponsors are required to submit estimates of selected drug subsidy amounts with their annual bids and we pay Part D plan sponsors prospective selected drug subsidy amounts equal to these estimated amounts. We use the actual selected drug subsidy amounts that Part D plan sponsors report on PDE data to determine actual costs incurred for selected drug subsidy payments.

After the deadline for PDE submissions for a year, we will calculate the difference between the prospective payments made by us to the Part D plan sponsor and the actual payments made by the Part D plan sponsor to determine a selected drug subsidy reconciliation amount. We will make a lump-sum adjustment to monthly payments based on the calculated reconciliation amount in the same manner as is done for other Part D reconciliation payments. Specifically, we will recover payments made for a coverage year if prospective selected drug subsidy payments exceed the selected drug subsidy costs actually incurred by the plan or if the Part D plan sponsor does not provide the data requested by us to verify the plan's actual selected drug subsidy amount; similarly, we will make a lump sum payment if the actually incurred subsidy amount exceeds the prospective selected drug subsidy payments.

In this proposed rule, we propose to codify the policies we established in the Final CY 2026 Part D Redesign Program Instructions with respect to the selected drug subsidy for 2026 and subsequent years without modification. Specifically, we propose to codify at new § 423.265(d)(2)(vi) a requirement that assumptions regarding selected drug subsidy amounts payable be included in Part D bids submitted to us. We also propose to codify at new § 423.315(h) that we would provide prospective selected drug subsidy payments on a monthly basis. We also propose to codify at new § 423.329(e) the determination of selected drug subsidy payments. Finally, we propose to codify at § 423.343(e) that we would make final payment for selected drug subsidy payments after a coverage year after obtaining all information necessary to determine the amount of payment.

10. Technical Correction—Retroactive Adjustments and Reconciliations (§§ 423.336 and 423.343)

In the course of this rulemaking, we noticed the need for a technical correction at § 423.343(d)(2). The final sentence of this paragraph states that in the event Part D sponsors do not provide adequate data to us for the calculation of risk corridor payments, we assume that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount. This sentence is incorrectly placed in § 423.343, which describes payments of low-income cost-sharing subsidies, and should instead be placed in § 423.336, which describes risk sharing arrangements. Thus, we propose to revise § 423.343 to remove this sentence and revise § 423.336(c) to add this sentence in its proper context.

11. Base Beneficiary Premium (§ 423.286)

Section 1860D–13(a)(2) of the Act, as established by the MMA, describes the statutory formula for calculating plan-specific basic Part D premiums under the Part D program. The national base beneficiary premium (BBP) is the starting point for calculating a plan-specific basic Part D premium. Prior to the enactment of the IRA, the BBP was calculated as the product of the beneficiary premium percentage and the national average monthly bid amount. The beneficiary premium percentage (''applicable percentage'') is a fraction, with a numerator of 25.5 percent and a denominator equal to 100 percent minus a percentage equal to (i) the total reinsurance payments that we estimate will be paid for the coverage year, divided by (ii) that amount plus the total payments that we estimate will be paid to Part D plans based on the standardized bid amount during the year, taking into account amounts paid by both CMS and plan enrollees. In the January 2005 Medicare Final Rule, we codified the statutory formula for calculating the BBP at § 423.286.

Section 11201 of the IRA amended section 1860D–13(a)(2) of the Act such that the statutory formula described in the preceding paragraph would apply subject to a newly added section 1860D–13(a)(8)(A) of the Act, which states that, for a prescription drug plan for a month in 2024 through 2029, the BBP shall be equal to the lesser of the BBP for the preceding year increased by 6 percent or the amount computed under the formula described at section 1860D–13(a)(2) of the Act. In the Advance Notice of Methodological Changes for CY 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (2024 Advance Notice) [16] and the July 31, 2023 HPMS memorandum titled, ''Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information'',[17] we stated that it would calculate the BBP as the lesser of the prior year's BBP increased by 6 percent, or the BBP as it would have been calculated if the IRA's premium stabilization provision had not been enacted, to determine the CY 2024 BBP. In the July 29, 2024, HPMS memorandum titled, ''Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information,'' we applied the revised formula described in this paragraph to determine the CY 2025 BBP.

In this proposed rule, we propose to codify the statutory amendments to section 1860D–13(a) of the Act.

[16] *https://www.cms.gov/files/document/2024-announcement-pdf.pdf.*

[17] *https://www.cms.gov/files/document/july-29-2024-parts-c-d-announcement.pdf.*

Specifically, we propose to redesignate § 423.286(b) as § 423.286(b)(1) and codify the BBP formula for 2024 through 2029 at new § 423.286(b)(2).

12. Low-Income Cost-Sharing Subsidy (§ 423.782)

The Part D low-income subsidy (LIS) helps individuals with Medicare who meet certain statutory income and resource criteria pay for prescription drugs and lowers the costs of prescription drug coverage. Prior to the enactment of the IRA, individuals who qualified for the full LIS received assistance to pay their full premiums and deductibles (in certain Part D plans) and have reduced cost sharing. Individuals who qualified for the partial LIS paid reduced premiums (on a sliding scale based on their income) and also had reduced deductibles and cost sharing. Section 11404 of the IRA amended section 1860D–14 of the Act to expand eligibility for the full LIS to individuals who are determined to have incomes below 150 percent of the FPL and who meet either the resource standard in paragraph (3)(D) or paragraph (3)(E) of section 1860D–14(a) of the Act, with respect to plan years beginning on or after January 1, 2024. Thus, beginning in CY 2024, individuals who previously would have qualified for the partial subsidy now receive the full LIS.

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 April 12, 2023 **Federal Register** (88 FR 22120), and therewithin, we codified the applicable rules under §§ 423.773 and 423.780 to expand eligibility for the LIS under Part D. In this rule, we propose to also amend the eligibility criteria for LIS cost sharing reductions at § 423.782 to align with the IRA's amendments to section 1860D–14(a)(1) of the Act and the changes to §§ 423.773 and 423.780. Specifically, we propose to update the FPL limit specified in § 423.782(a)(2)(i)(B) to 150 percent for plan years beginning on or after January 1, 2024.

In addition, we propose to amend paragraph (a)(2) of § 423.782 to state that for years preceding 2025, LIS cost sharing reductions applied to covered Part D drugs obtained after the initial coverage limit and below the OOP limit.

13. Retiree Drug Subsidy Parameters (§§ 423.882 and 423.884)

Section 1860D–22 of the Act provides for subsidy payments to sponsors of qualified retiree prescription drug plans, provided that the employment-based retiree health coverage is at least actuarially equivalent to the standard prescription drug coverage under Medicare Part D. In the January 2005 Medicare Final Rule, we established regulations at 42 CFR part 423 Subpart R to, in part, determine which group health plans may qualify as qualified retiree prescription drug plans and, therefore, be eligible to receive retiree drug subsidy payments for a qualifying covered retiree.

Per section 1860D–22(a)(2)(A) of the Act, qualified retiree prescription drug plans are required to annually attest that the actuarial value of prescription drug coverage under the plan (as described in section 1860D–11(c) of the Act) is at least equal to the actuarial value of standard prescription drug coverage, not taking into account the value of any discount provided under the Manufacturer Discount Program as established in section 1860D–14C of the Act, and disclose that coverage under the plan is creditable in accordance with section 1860D–13(b)(6)(B) of the Act.

In the Final CY 2025 Part D Redesign Program Instructions, we addressed the implications of the amendments to the parameters of the standard prescription drug coverage made by the IRA for the retiree drug subsidy parameters described at Subpart R and summarized the IRA policies in effect for 2025 that are considered in determining the actuarial value of the defined standard benefit. While the IRA amends the parameters of the standard prescription drug coverage and makes other changes to the Part D benefit, we stated that there are no changes to the requirements for qualified retiree prescription drug plans.

In the Final CY 2026 Part D Redesign Program Instructions, we stated that certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the guidance related to the retiree drug subsidy parameters, also applied in CY 2026.

The majority of the IRA policies in effect for CY 2027 and subsequent years do not require updates to Subpart R; however, there are certain conforming edits required to reflect the proposed revisions to the definitions of ''gross covered prescription drug costs'' and ''allowable reinsurance costs'' as well as revisions needed to reflect the sunsetting of the Coverage Gap Discount Program and the establishment of the Manufacturer Discount Program. Specifically, we propose to revise the definitions of ''gross covered retiree plan-related prescription drug costs'' and ''allowable retiree costs'' at § 423.882 to reflect the proposed revisions to the definitions of ''gross covered prescription drug costs'' and ''allowable reinsurance costs'' at § 423.308. We also propose to replace all references in § 423.884(d) to ''not taking into account the value of any discount or coverage provided during the coverage gap'' with the statement ''for years prior to 2025, not taking into account the value of any discount or coverage provided during the coverage gap and for 2025 and subsequent years, not taking into account the value of any discount provided under the Manufacturer Discount Program.''

14. Medical Loss Ratio (§ 423.2420)

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 final rule titled ''Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' which appeared in the May 23, 2013 **Federal Register** (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 Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. 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* §§ 423.2401; 423.2420(b)(4); 423.2430(b)).

The MLR regulations at § 423.2420(c) specify that the following Part D plan payments from the federal government are included in the MLR denominator: the direct subsidy, prospective Federal reinsurance subsidy, reconciliation adjustments to the Federal reinsurance subsidy, low-income premium subsidy (LIPS) amount, and risk corridor payments. In the May 2013 Medicare MLR final rule, we explained that we viewed LICS and Coverage Gap Discount Program payments as pass-through payments for which plans do not retain any liability, and that these amounts should therefore be excluded from the MLR calculation (78 FR 31290); accordingly, LICS and Coverage Gap Discount Program payments are excluded from both the MLR numerator and denominator.

The IRA introduced new categories of Part D plan payments from the Federal government. These include the Manufacturer Discount Program payment, the Inflation Reduction Act Subsidy Amount (IRASA), and the selected drug subsidy payment. The payment process for the Manufacturer Discount Program payments includes a cost-based reconciliation intended to make Part D sponsors whole for the manufacturer discount amounts they advance on behalf of the manufacturer. The IRASA is a Part D payment specific to CY 2023 that we provided to Part D plan sponsors. This temporary retrospective subsidy was paid to Part D plans for the reduction in cost sharing and elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products during the 2023 plan year (that is, to cover the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended adult vaccine, under the plan's 2023 benefit design, and the applicable statutory maximum cost sharing ($35 for a one month-supply of covered insulin products and $0 for vaccines)). Finally, under the selected drug subsidy program, the government provides a subsidy to Part D plan sponsors for selected drugs dispensed to enrollees in the initial coverage phase.

In the Final CY 2025 Part D Redesign Program Instructions, we stated that for CY 2025 and prior years, the new Part D plan payments for the Manufacturer Discount Program and IRASA are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. In the Final CY 2026 Part D Redesign Program Instructions, we stated that the new Part D plan payments for the selected drug subsidy are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. In the Final CY 2026 Part D Redesign Program instructions, we applied certain policies described in the Final CY 2025 Part D Redesign Program Instructions, including the treatment of the Manufacturer Discount Program payments, in CY 2026.

In this proposed rule, we propose to codify for CY 2027 and subsequent years the policies established in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions with respect to the treatment of the Manufacturer Discount Program payments, IRASA, and selected drug subsidy program payments for MLR purposes. These policies are currently in effect. Specifically, we propose to codify the exclusion of the Manufacturer Discount Program payments, IRASA, and selected drug subsidy program payments at § 423.2420(b)(4)(iii), (iv), and (v) respectively.

15. Severability

The Medicare Part D redesign 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.

B. Medicare Coverage Gap Discount Program

The Patient Protection and Affordable Care Act (Pub. L. 111–148) amended Title XVIII of the Act by adding sections 1860D–14A and 1860D–43, establishing the Medicare Coverage Gap Discount Program. The Coverage Gap Discount Program, which began on January 1, 2011, was initially implemented through program instruction, and program requirements were codified in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' final rule (77 FR 22072) under subpart W of 42 CFR part 423.

The Coverage Gap Discount Program made manufacturer discounts available at the point of sale (POS) to Part D enrollees who are not eligible for the low-income subsidy (LIS) under section 1860D–14 of the Act when receiving applicable drugs (as defined at § 423.100) while in the coverage gap phase of the Part D benefit. Under Coverage Gap Discount Program rules, pharmaceutical manufacturers were required to enter into a Coverage Gap Discount Program agreement with CMS in order for their applicable drugs to be covered under Part D. In general, the discount was 70 percent of the negotiated price (as defined at § 423.2305) of the applicable drug.

The Inflation Reduction Act of 2022 (Pub. L. 117–169) (IRA) made significant changes to the Part D benefit design, which are discussed in more detail in section II.A. of this proposed rule. These changes included eliminating the coverage gap phase of the Part D benefit after 2024 and adding section 1860D–14C to the Act, which established the Manufacturer Discount Program, under which manufacturers pay discounts for applicable drugs when dispensed to Part D enrollees during the initial and catastrophic coverage phases. Our proposal to codify the Manufacturer Discount Program is discussed in section II.C. of this proposed rule.

Consistent with the elimination of the coverage gap phase of the Part D benefit, section 11201 of the IRA added section (h) to section 1860D–14A of the Act, which sunset the Coverage Gap Discount Program and terminated all Coverage Gap Discount Program agreements, effective January 1, 2025. Section 1860D–14A(h)(2) of the Act further specifies that the provisions of section 1860D–14A of the Act, including all responsibilities and duties under such agreements continue to apply with respect to applicable drugs dispensed prior to January 1, 2025. Accordingly, we propose to amend § 423.2300 by adding a new paragraph to specify that the requirements of Subpart W apply before January 1, 2025 and, with respect to applicable drugs dispensed prior to that date, continue to apply on and after January 1, 2025. To make this change, we propose to redesignate the existing text of § 423.2300 as paragraph (a) and redesignate existing paragraphs (a) through (h) as § 423.2300(a)(1) through (8), respectively. We propose to add the new text at § 423.2300(b). We also propose to revise § 423.2315(c)(2) to reflect the sunset of the Coverage Gap Discount Program by limiting this provision specifying the effective date of a Coverage Gap Discount Program agreement to 2012 and subsequent years prior to 2025. Finally, in accordance with section 1860D–14A(h)(1) of the Act, we propose to amend § 423.2345 by adding a new paragraph (f) to specify

that, subject to § 423.2300(b), as redesignated, all Coverage Gap Discount Program agreements under this subpart are terminated as of January 1, 2025.

As discussed in more detail in section II.C. of this proposed rule, ''discounted price'' is defined at section 1860D–14A(g)(4) of the Act for purposes of the Coverage Gap Discount Program and at section 1860D–14C(g)(4) of the Act for purposes of the Manufacturer Discount Program. Because the percentage of the negotiated price that the manufacturer agrees to pay is different under the two programs, the statutory term ''discounted price'' as well as its corresponding regulatory term ''applicable discount'' have different meanings between the two programs. To address the programmatic difference, we propose to revise the regulation text at § 423.2305 to clarify that the definitions in this section apply only for purposes of the Coverage Gap Discount Program. Further, we propose to revise the definition of ''applicable discount'' at § 423.2305 to specify that it refers to 50 percent of the negotiated price with respect to a plan year before 2019 and 70 percent of the negotiated price with respect to plan year 2019 through plan year 2024. This clarification further distinguishes the definition of ''applicable discount'' at § 423.2305 under the Coverage Gap Discount Program from the definition of ''applicable discount'' (proposed at § 423.2712 as part of this proposed rule) under the Manufacturer Discount Program.

Lastly, for clarity and readability, we propose technical changes throughout Subpart W to replace the shorthand term ''Discount Program'' with ''Coverage Gap Discount Program,'' to better distinguish it from the Manufacturer Discount Program.

C. Medicare Part D Manufacturer Discount Program

1. Background

The Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program) was enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public Law 117–169 (IRA) and codified in sections 1860D–14C and 1860D–43 of the Act. Section 11201(f) of the IRA directed the Secretary to implement the Manufacturer Discount Program by program instruction or other forms of program guidance for 2025 and 2026. In accordance with the law, on November 17, 2023, CMS released the Medicare Part D Manufacturer Discount Program Final Guidance. On December 20, 2024, we released the Revised Medicare Part D Manufacturer Discount Program Final Guidance (Manufacturer Discount Program Final Guidance).[18]

The IRA made significant changes to the Part D benefit, which are discussed in detail in section II.A. of this proposed rule. The IRA eliminated the coverage gap phase of the Part D benefit after 2024 and added subsection (h) to section 1860D–14A of the Act, which sunset the Coverage Gap Discount Program and terminated all Coverage Gap Discount Program agreements effective January 1, 2025. Our proposal to update the Part D regulations to reflect the statutory sunsetting of the Coverage Gap Discount Program and termination of Coverage Gap Discount Program agreements is discussed in section II.B. of this proposed rule.

In this proposed rule, we would codify the Manufacturer Discount Program Final Guidance, with the refinements and changes discussed herein, to be effective beginning CY 2027. Under the Manufacturer Discount Program, for applicable drugs and selected drugs to be coverable under Part D, manufacturers of such drugs are required to enter into a Manufacturer Discount Program agreement with CMS and agree to provide discounts on their applicable drugs when dispensed to Part D enrollees who are in the initial and catastrophic coverage phases of the Part D benefit. Similar to the Coverage Gap Discount Program which the Manufacturer Discount Program replaces, the discounts under the Manufacturer Discount Program are advanced at the point of sale by the Part D plan sponsor, and manufacturers are invoiced quarterly based on the amounts submitted by plan sponsors on Prescription Drug Event (PDE) records. CMS provides prospective payments to plan sponsors to ensure they are able to advance the discounts and adjusts the payments through an annual reconciliation.

Unlike the Coverage Gap Discount Program, discounts under the Manufacturer Discount Program generally reduce the amount the Part D sponsor pays for the drug versus reducing the out-of-pocket amount for the enrollee, and discounts are paid for all Part D enrollees who have exceeded the annual Part D deductible specified in section 1860D–2(b)(1) of the Act. While the discounts are a lower percentage of the negotiated price of the applicable drug than under the Coverage Gap Discount Program (10 percent in the initial coverage phase and 20 percent in the catastrophic coverage phase), they continue through the end of the plan year once the enrollee exceeds the deductible. The discount percentages manufacturers are required to pay are phased in over the first several years of the program for manufacturers that meet statutory criteria for specified manufacturers and specified small manufacturers.

Many of the other policies currently in effect pursuant to the Manufacturer Discount Program Final Guidance, which we propose to codify in this rule, mirror longstanding policies under the Coverage Gap Discount Program, including use of a third party administrator (TPA) to facilitate program operations such as invoicing and payment, use of the Health Plan Management System (HPMS) to execute agreements and house data, and the manufacturer dispute resolution process. All of these policies are discussed in more detail later in this section.

2. Basis and Scope (§ 423.2700)

We propose to codify the requirements for the Manufacturer Discount Program under sections 1860D–14C and 1860D–43 of the Act as new subpart AA of part 423. Proposed § 423.2700(a) and (b) set forth the basis and scope, respectively.

We propose a conforming change at § 423.1 to incorporate section 1860D–14C of the Act into the scope of part 423.

3. Definitions (§§ 423.100, 423.1002, 423.2305, and 423.2704)

In this proposed rule, we propose to codify the definition of frequently used terms consistent with section 1860D–14C of the Act or established in the Manufacturer Discount Program Final Guidance, as well as new definitions based on the policies in this proposed rule.

Several of these terms are also used for purposes of the Coverage Gap Discount Program. In some cases, the same term has a different meaning for the Manufacturer Discount Program than for the Coverage Gap Discount Program because of differences in the programs reflected in sections 1860D–14C and 1860D–14A of the Act, respectively. Where possible under the statutory requirements, we propose to use the same terms, defined in the same way, for both programs. Because some of the terms are applicable to both subpart W and proposed subpart AA, we propose to revise certain definitions in existing §§ 423.100, 423.1002, and 423.2305, move certain definitions from § 423.2305 to § 423.100 with revisions

[18] Available at: *https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf.*

as necessary to comply with relevant statutory requirements, and add new definitions for purposes of the Manufacturer Discount Program at proposed § 423.2704.

At § 423.100, we propose to revise a number of existing definitions as discussed below.

• ''Applicable beneficiary'';

We propose to revise the definition of ''applicable beneficiary'' to reflect the statutory definition of such term under the Coverage Gap Discount Program and the Manufacturer Discount Program. Specifically, we propose adding that for the purposes of the Coverage Gap Discount Program, applicable beneficiary means an individual who on the date of dispensing a covered Part D drug is not entitled to an income-related subsidy under section 1860D–14(a) of the Act; has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year; has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and has a claim that is within the coverage gap or straddles or spans the coverage gap. We also propose adding to the definition that for the purposes of the Manufacturer Discount Program, applicable beneficiary means an individual who on the date of dispensing a covered Part D drug has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that exceed the annual deductible specified in section 1860D–2(b)(1) of the Act.

• ''Applicable drug'';

We propose to modify the existing definition of ''applicable drug'' to specify that compounded drug products (as described in § 423.120(d)) containing an applicable drug are excluded. This proposed change would codify both longstanding CMS policy under the Coverage Gap Discount Program that excluded compounds as well as the policy established in section 40.1 of the Manufacturer Discount Program Final Guidance. As stated in the guidance, while plans may cover compounds that include at least one Part D ingredient, and that ingredient would be an applicable drug if dispensed on its own, we believe that the applicable drug determination must be made with respect to the compound as a whole. Because the compound as a whole is not approved under a New Drug Application (NDA) or Biologic Licensing Application (BLA), a compound does not meet the definition of an applicable drug.

Further, for the purposes of the Manufacturer Discount Program, we propose to clarify that applicable drug also includes a Part D drug that is provided to a particular applicable beneficiary as a transition fill under § 423.120(b)(3) or as an emergency supply as may be required for an applicable beneficiary who is a long-term care resident. This clarification would codify our longstanding approach under the Coverage Gap Discount Program where, in practice, such fills have been treated as meeting the definition of ''applicable drug.''

Finally, in accordance with the statutory definition of ''applicable drug'' at section 1860D–14C(g)(2) of the Act and the Manufacturer Discount Program Final Guidance, we further propose to specify in the definition of ''applicable drug'' that, for the purposes of the Manufacturer Discount Program, an applicable drug is not a selected drug during a price applicability period with respect to such drug.

We propose to add definitions for the following terms at § 423.100:

• ''Applicable discount'';

At § 423.100, we propose to add a definition of ''applicable discount'' that identifies the separate programmatic definitions of such term for the Coverage Gap Discount Program and the Manufacturer Discount Program. Specifically, we propose to define ''applicable discount'' as, for purposes of the Coverage Gap Discount Program, having the meaning set forth at § 423.2305, and for purposes of the Manufacturer Discount Program, the meaning set forth at § 423.2712.

• ''Applicable number of calendar days'';

We propose to remove the definition of ''applicable number of calendar days'' from § 423.2305 and add it at § 423.100. This definition would apply to both the Coverage Gap Discount Program and the Manufacturer Discount Program.

• ''Date of dispensing'';

We propose to remove the existing definition of ''date of dispensing'' from § 423.2305 and add it, with revisions, at § 423.100. Specifically, we propose to add at the end of the definition, ''For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.'' This proposed revision is consistent with the definition of ''date of dispensing'' used in the Manufacturer Discount Program Final Guidance and with criteria established under § 423.2325(g) for the Coverage Gap Discount Program.

• ''Labeler code'';

We propose to remove the existing definition of ''labeler code'' from § 423.2305 and add it, with revisions, at § 423.100. Specifically, we propose to remove the phrase ''Food and Drug Administration'' for conciseness and accuracy.

• ''Manufacturer'';

We propose to remove the existing definition of ''manufacturer'' from § 423.2305 and add it at § 423.100 with a revision removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program and the Manufacturer Discount Program'' for accuracy.

• ''Manufacturer Discount Program'';

We propose to define ''Manufacturer Discount Program'' as the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

• ''Manufacturer Discount Program agreement'';

We propose to define ''Manufacturer Discount Program agreement'' as the agreement described at section 1860D–14C(b) of the Act.

• ''Medicare Coverage Gap Discount Program'';

We propose to remove the definition of ''Medicare Coverage Gap Discount Program'' from § 423.2305 and add it at § 423.100, with revisions to remove the phrase ''Program (or Discount Program)'' and add in its place the phrase ''Program (or Coverage Gap Discount Program)''.

• ''Medicare Coverage Gap Discount Program agreement'';

We propose to remove the definition of ''Medicare Coverage Gap Discount Program agreement'' from § 423.2305 and add it at § 423.100 with revisions to remove the phrase ''Program agreement (or Discount Program agreement)'' and add in its place the phrase ''Program agreement (or Coverage Gap Discount Program agreement)''.

• ''National Drug Code (NDC)''; and

We propose to remove the definition of ''National Drug Code'' from § 423.2305 and add it at § 423.100 with revisions to remove the phrase ''the product'' and add in its place the phrase ''the product's manufacturer, product''. This proposed revision aligns with the definition of NDC used in the Manufacturer Discount Program Final Guidance.

• ''Non-applicable drug'';

We propose to define ''non-applicable drug'' to mean any Part D drug that is not an applicable drug and not a selected drug during a price applicability period with respect to such drug.

• ''Price applicability period'';

We propose to define ''price applicability period'' as having the

meaning given such term in section 1191(b)(2) of the Act and any applicable regulations and guidance.

• ''Selected drug''; and

We propose to define ''selected drug'' as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance. Such definition aligns with the definition used in the Manufacturer Discount Program Final Guidance.

• ''Third Party Administrator (TPA)''.

We propose to add at § 423.100 the definition of ''Third Party Administrator'' that we propose to remove from § 423.2305, with revisions. Specifically, we propose to remove the phrase ''section 1860D–14A of the Act'' and add in its place the phrase ''sections 1860D–14A and 1860D–14C of the Act''.

At § 423.1002, we propose to revise the existing definition of ''affected party'' to account for the definition of ''manufacturer'' under the Coverage Gap Discount Program and the definition of ''agreement holder'' under the Manufacturer Discount Program. Specifically, we propose that affected party means any Part D sponsor or, for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100), or, for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704), impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

We propose to remove the following definitions from § 423.2305 because, as noted previously, we propose to add definitions for such terms at § 423.100, for purposes of incorporating the Manufacturer Discount Program:

• ''Applicable number of calendar days'';
• ''Date of dispensing'';
• ''Labeler code'';
• ''Manufacturer'';
• ''Medicare Coverage Gap Discount Program'';
• ''Medicare Coverage Gap Discount Program Agreement'';
• ''National Drug Code (NDC)''; and
• ''Third Party Administrator (TPA)''.

At § 423.2704, we propose to define the following terms for purposes of proposed subpart AA and the Manufacturer Discount Program:

• ''Agreement holder'';

We propose to define ''agreement holder'' as a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

• ''Applicable discount'';

We propose to define ''applicable discount'' as having the meaning set forth at § 423.2712.

• ''Applicable LIS percent'';

We propose to define ''applicable LIS percent'' as having the meaning set forth at § 423.2712(d)(1).

• ''Applicable small manufacturer percent'';

We propose to define ''applicable small manufacturer percent'' as having the meaning set forth at § 423.2712(d)(2).

• ''Covered Part D drug'';

We propose to define ''covered Part D drug'' as having the meaning set forth at § 423.100.

• ''Dispute submission deadline'';

We propose to define ''dispute submission deadline'' as the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the agreement holder's dispute.

• ''Negotiated price'';

We propose to define ''negotiated price'' as having the meaning set forth at § 423.100, and with respect to an applicable drug under the Manufacturer Discount Program, such negotiated price includes any dispensing fee and, if applicable, any vaccine administration fee and sales tax.

• ''Network pharmacy'';

We propose to define ''network pharmacy'' as having the meaning set forth at § 423.100.

• ''Part D drug'';

We propose to define ''Part D drug'' as having the meaning set forth at § 423.100.

• ''Primary manufacturer'';

We propose to define ''primary manufacturer'' as having the meaning given such term pursuant to applicable regulations and guidance for the Medicare Drug Price Negotiation Program.

• ''Specified drug'';

We propose to define ''specified drug'' as meaning, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified manufacturer.

• ''Specified small manufacturer drug''; and

We propose to define ''specified small manufacturer drug'' as meaning, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified small manufacturer.

• ''Total expenditures''.

We propose to define ''total expenditures'' as meaning, with respect to Part D, the total gross covered prescription drug costs, as defined in § 423.308; and as meaning, with respect to Part B, the total Medicare allowed amount (that is, total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.

4. Conditions for Coverage of Drugs Under Part D (§ 423.2708)

Section 1860D–43(a) of the Act, as amended by the IRA, specifies that, beginning January 1, 2025, in order for Part D coverage to be available for the covered Part D drugs of a manufacturer, the manufacturer must participate in the Manufacturer Discount Program and have entered into and have in effect a Manufacturer Discount Program agreement with CMS, as described in section 1860D–14C(b) of the Act. Operationally, coverage of a drug under a Manufacturer Discount Program agreement is determined by coverage of its labeler code (as defined at § 423.100) under such agreement. As discussed in section 40 of the Manufacturer Discount Program Final Guidance, CMS maintains a list of all labeler codes that are covered by a Manufacturer Discount Program agreement, which is updated monthly and posted on the CMS website to assist Part D sponsors in accurately adjudicating claims at the point of sale. As described in more detail in section II.C.12. of this preamble, manufacturers are required to provide CMS with a complete list of the labeler codes covered under their agreements.

Any Part D drug that is a selected drug during a price applicability period with respect to such drug, is excluded from the definition of applicable drug under section 1860D–14C(g)(2)(B) of the Act and, therefore, not subject to applicable discounts under the Manufacturer Discount Program when dispensed during a price applicability period. However, a selected drug would otherwise meet the definition of an applicable drug, but for it being in a price applicability period following its selection into the Medicare Drug Price Negotiation Program. Therefore, applying section 1860D–43(a) of the Act's coverage exclusion in the absence of a Manufacturer Discount Program agreement to both applicable drugs and selected drugs provides incentive for manufacturers of brand name drugs and biological products to participate in the Manufacturer Discount Program, while not undermining beneficiary access to generics. Moreover, this interpretation is consistent with the IRA's addition of

section 1860D–43(c)(2) of the Act, which prohibits the Secretary from authorizing coverage for a covered Part D drug of a manufacturer without a Manufacturer Discount Program agreement for any period described in section 5000D(c)(1) of the Internal Revenue Code under the exception for drugs determined to be essential to the health of Part D enrollees. This provision further demonstrates that the statute does not allow for a selected drug to be eligible for Part D coverage in the absence of a Manufacturer Discount Program agreement. As stated in section 40 of the Manufacturer Discount Program Final Guidance and consistent with the policy on applicable drugs, beginning January 1, 2025, Part D coverage for selected drugs during a price applicability period is available only for selected drugs for which the labeler code is covered by a Manufacturer Discount Program agreement with CMS, as described in section 1860D–14C(b) of the Act.

Accordingly, at § 423.2708(a), we propose to codify that, in order for coverage to be available under Part D for a Part D drug of a manufacturer that is an applicable drug or a selected drug during a price applicability period:

- The FDA-assigned labeler code of such drug must be covered under a Manufacturer Discount Program agreement that is in effect;
- The manufacturer must participate in the Manufacturer Discount Program; and
- The manufacturer must have entered into and have in effect a Manufacturer Discount Program agreement.

We expect each manufacturer choosing to participate in the Manufacturer Discount Program to enter into its own Manufacturer Discount Program agreement with CMS. However, we acknowledge a longstanding practice where CMS has permitted manufacturers to cover by their Manufacturer Discount Program agreement (and previously by their Coverage Gap Discount Program agreement) labeler code(s) assigned by the FDA to another manufacturer. CMS does not currently and is not proposing to prohibit this practice, provided all other requirements as discussed in this proposed rule are met. As such, we clarify that a manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement under proposed § 423.2708(a)—and thus, under section 1860D–43(a) of the Act—if such manufacturer executes and has in effect its own Manufacturer Discount Program agreement or participates by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement that is in effect. We propose to codify this requirement at § 423.2708(b).

We further clarify that, while a manufacturer that participates in the Manufacturer Discount Program in accordance with proposed § 423.2708(b)(2) is a participating manufacturer, as described in more detail in section II.C.12. of this preamble, only the entity that executes an agreement pursuant to proposed § 423.2708(b)(1) is an agreement holder (as defined at § 423.2704). Consistent with our longstanding practice, only the agreement holder is a party to the Manufacturer Discount Program agreement with CMS, and the agreement holder is the entity subject to the rights and obligations of the Manufacturer Discount Program agreement, including the obligation to pay all invoiced amounts under such agreement.

In accordance with section 1860D–43(c)(1)(A) of the Act, we propose to codify at § 423.2708(c) that an applicable drug of a manufacturer that does not participate in the Manufacturer Discount Program or has not entered into and does not have in effect a Manufacturer Discount Program agreement under section 1860D–14C(b) of the Act is not excluded from Part D coverage if CMS has made a determination that the availability of the applicable drug is essential to the health of Part D enrollees. In addition, we propose to codify that, as specified in section 1860D–43(c)(2) of the Act, this exception to the exclusion from Part D coverage does not apply to any applicable drug or selected drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to such manufacturer.

Consistent with our prior interpretation of section 1860D–43(a) of the Act under the Coverage Gap Discount Program, for purposes of the Manufacturer Discount Program, the exclusion from Part D coverage applies only to applicable drugs and selected drugs not covered by a Manufacturer Discount Program agreement that is fully executed and in effect. Coverage under Medicare Part D is available to non-applicable drugs of a manufacturer regardless of whether the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

With regard to the Coverage Gap Discount Program, we previously explained our interpretation that the conditions for coverage described in section 1860D–43(a) of the Act must be read together with section 1860D–14A of the Act's provision for Part D coverage of non-applicable drugs under certain circumstances in the absence of a Coverage Gap Discount Program agreement (77 FR 22082). The IRA adopted parallel language for the Manufacturer Discount Program, including section 1860D–14C(f) of the Act, which states that ''[n]othing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).'' For the same reasons described in the Manufacturer Discount Program Final Guidance and our prior rulemaking, we propose to adopt the same interpretation here with regard to the parallel provisions of section 1860D–14C of the Act. Accordingly, at § 423.2708(d), we propose that non-applicable drugs, as we propose to define the term in § 423.100, will continue to be coverable under Part D whether or not the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

5. Applicable Discounts (§ 423.2712)

Under the Manufacturer Discount Program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act, that is, the deductible under the defined standard benefit, manufacturer discounts are available in both the initial and catastrophic coverage phases of the benefit. The applicable discount lowers Part D sponsor liability on the negotiated price of the drug.

a. Defined

As described in section 50 of the Manufacturer Discount Program Final Guidance, for the purposes of the Manufacturer Discount Program, ''applicable discount'' means, subject to the phase-ins and the straddle claims policy described in this section, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary (as we propose to define in § 423.100) who has—

- Not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act for the year, 10 percent of the negotiated price of such drug; and

• Incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act for the year, 20 percent of the negotiated price of such drug.

We propose to codify this policy at § 423.2712(a). Consistent with the statutory requirements and the Manufacturer Discount Program Final Guidance, the applicable discount is not available until the enrollee has incurred costs exceeding the annual deductible specified in section 1860D–2(b)(1) of the Act, regardless of whether the enrollee has to pay a deductible (for example, through eligibility for an income-related subsidy or enrollment in an enhanced benefit plan with a reduced or no deductible, or for a drug that is not subject to the deductible, such as a covered insulin product or an Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccine). Because the applicable discount and enrollee cost sharing are both calculated based on the negotiated price of the drug, as described in section II.A. of this proposed rule, the applicable discount will not affect the application of the standard 25 percent coinsurance under section 1860D–2(b)(2)(A) of the Act or the application of the copayment amount under section 1860D–2(b)(4)(A) of the Act unless, after the discount is applied to the negotiated price of the drug, the enrollee cost sharing specified under the plan would exceed such negotiated price minus the applicable discount. In such a situation, the enrollee cost sharing will be the negotiated price minus the applicable discount. We propose to codify this at § 423.2712(g).

In accordance with section 1860D–14C(c)(1)(C) of the Act, we propose to codify at § 423.2712(b) our policy that the value of the discount is calculated before the application of supplemental benefits, and at § 423.2712(c) that the applicable discount must be calculated before any coverage or financial assistance under another health or prescription drug benefit plan or program that provides prescription drug coverage or financial assistance.

b. Application of Discount Phase-In for Specified Manufacturers and Specified Small Manufacturers

The IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022, during a multi-year phase-in period which concludes by 2031. Under section 1860D–14C(g)(4) of the Act, there are two such phase-ins: one for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for LIS under section 1860D–14(a) of the Act and one for certain applicable drugs of specified small manufacturers dispensed to all applicable beneficiaries.

The applicable discount paid by specified manufacturers for specified drugs dispensed to applicable beneficiaries who are eligible for LIS, referred to in the statute as the ''specified LIS percent,'' is defined in section 1860D–14C(g)(4)(B) of the Act. The discount paid by specified small manufacturers for specified drugs dispensed to all applicable beneficiaries, referred to in the statute as the ''specified small manufacturer percent,'' is defined in section 1860D–14C(g)(4)(C) of the Act. These provisions, which also set forth the criteria by which specified manufacturers and specified small manufacturers are defined, require such manufacturers to pay, when applicable, the phased-in discount.

(1) Applicable LIS Percent

Under section 1860D–14C(g)(4)(B) of the Act, for an applicable drug of a specified manufacturer (as described at proposed § 423.2716(a)) that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3) of the Act), the applicable discount is as follows:

• For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

++ For 2025, 1 percent;
++ For 2026, 2 percent;
++ For 2027, 5 percent;
++ For 2028, 8 percent; and
++ For 2029 and each subsequent year, 10 percent.

• For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

++ For 2025, 1 percent;
++ For 2026, 2 percent;
++ For 2027, 5 percent;
++ For 2028, 8 percent;
++ For 2029, 10 percent;
++ For 2030, 15 percent; and
++ For 2031 and each subsequent year, 20 percent.

We propose to codify the policy for the applicable LIS percent at § 423.2712(d)(1).

(2) Applicable Small Manufacturer Percent

Under section 1860D–14C(g)(4)(C) of the Act, for an applicable drug of a specified small manufacturer (as described at proposed § 423.2716(b)), that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary, the applicable discount is as follows:

• For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

++ For 2025, 1 percent;
++ For 2026, 2 percent;
++ For 2027, 5 percent;
++ For 2028, 8 percent; and
++ For 2029 and each subsequent year, 10 percent; and

• For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

++ For 2025, 1 percent;
++ For 2026, 2 percent;
++ For 2027, 5 percent;
++ For 2028, 8 percent;
++ For 2029, 10 percent;
++ For 2030, 15 percent; and
++ For 2031 and each subsequent year, 20 percent.

We propose to codify the policy for the applicable small manufacturer percent at § 423.2712(d)(2).

(3) Marketed as of the Date of Enactment

Sections 1860D–14C(g)(4)(B)(i) and 1860D–14C(g)(4)(C)(i) of the Act limit the application of the discount phase-ins for specified manufacturers and specified small manufacturers, respectively, to drugs of such manufacturers that are ''marketed as of the date of enactment'' (that is, August 16, 2022). CMS interprets the reference to a drug that is marketed as of August 16, 2022 to refer to a drug that was marketed by the manufacturer on one specific, backward-looking date, that is, the date of enactment of the IRA. Accordingly, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-ins, CMS will determine whether an applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

We propose to codify this requirement at § 423.2712(d)(3).

c. Straddle Claims

In the case of a claim for an applicable drug for an applicable beneficiary that ''straddles'' multiple phases of the benefit, section 1860D–14C(g)(4)(E) of the Act requires that for claims that do not fall entirely—

• Above the annual deductible specified in section 1860D–2(b)(1) of the

Act, the manufacturer provides the applicable discount on only the portion of the negotiated price that falls above the deductible; and

• Below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act, the manufacturer provides the applicable discount on each portion of the negotiated price in accordance with this section based on the benefit phase into which each portion of the negotiated price falls.

We propose to codify the policy for straddle claims at § 423.2712(e).

d. Claims Not Subject to Discount

Under the Coverage Gap Discount Program, certain coordination of benefits and other non-standard Part D claims for applicable drugs were not subject to manufacturer discounts. In response to the Manufacturer Discount Program Draft Guidance, released on May 12, 2023, we received public comments seeking clarification about how to calculate manufacturer discounts under the Manufacturer Discount Program in certain situations involving coordination of Part D with other benefits and non-standard format claims. In the Manufacturer Discount Program Final Guidance, CMS responded to those comments by clarifying that discounts are not paid on Medicare Secondary Payer (MSP) claims or Medicaid subrogation claims involving an applicable drug.

As described in section 60.1.4 of the Manufacturer Discount Program Final Guidance, discounts are not applied to MSP claims under the Manufacturer Discount Program because CMS is unable to ascertain from the PDE how much liability, if any, the Part D sponsor has on such claims. Discounts are not applied to Medicaid subrogation claims under the Manufacturer Discount Program because drug costs reported on such claims are accounted for during the payment reconciliation process as contributing entirely to Covered D Plan Paid Amounts (CPP). We propose to codify those policies at § 423.2712(f)(1) and (2), respectively.

The Manufacturer Discount Program Final Guidance also referred to Indian Health Service (IHS) ''subrogation'' claims as not being subject to discounts under the Manufacturer Discount Program. We clarify that, while the guidance specifically referred to IHS claims, our intent was to adopt the longstanding policy applied under the Coverage Gap Discount Program where coordination of benefits claims involving payer-to-payer reconciliation are not subject to manufacturer discounts. Using an example from Appendix E, Chapter 14, of the Medicare Prescription Drug Benefit Manual, if a tribal member newly enrolled in Part D is initially unable to access their Part D benefits through their Part D plan, the tribe may step in to pay for the individual's Part D drugs. In this scenario, the tribe is entitled to seek compensation from the Part D plan once enrollment is confirmed. Consistent with CMS coordination of benefits requirements at § 423.464, the Part D plan is required to reimburse the tribe when the tribe has paid primary. In accordance with these requirements, we propose at § 423.2712(f)(3) to specify that non-standard format coordination of benefits claims involving an applicable drug are not subject to discounts under the Manufacturer Discount Program. We further clarify that claims submitted by a pharmacy operated by IHS, tribes or tribal organizations, or Urban Indian organizations to a Part D plan as the primary payer for an applicable drug dispensed to an applicable beneficiary are subject to discounts under the Manufacturer Discount Program, consistent with our policy under the Coverage Gap Discount Program.

Lastly, at § 423.2712(f)(4) we propose to codify our longstanding policy that manual claims involving an applicable drug with a service provider identification qualifier of ''Other'' are not subject to discounts under the Manufacturer Discount Program. Because PDE records for such claims do not have a service provider identifier, there is no way to furnish the manufacturer with an invoice containing all of the required data elements necessary for manufacturer review to confirm or dispute the validity of the dispensing entity. Section II.C.13.a. of this preamble contains a more detailed discussion of the required data elements for manufacturer invoices.

As discussed in section II.C.3. of this preamble, compounded drug products are excluded from the definition of applicable drug that we propose to revise at § 423.100; as such, claims for Part D compounds are not subject to discounts under the Manufacturer Discount Program.

6. Phase-In of Applicable Discounts (§§ 423.2716 Through 423.2728)

As discussed in sections 50.1.1 and 50.1.2 of the Manufacturer Discount Program Final Guidance, the IRA establishes lower percentages for discounts on applicable drugs that are subject to phase-ins for specified manufacturers and specified small manufacturers. Since the discount reduces the plan liability for applicable drugs, Part D sponsors are responsible for covering the remaining amount of the negotiated price, less enrollee cost sharing, for applicable drugs subject to a phased-in discount percentage as discussed in this section. For example, the applicable discount for applicable drugs in the initial coverage phase is 10 percent. In 2025, the applicable LIS percent for a specified drug dispensed to an LIS enrollee during the initial coverage phase is 1 percent. In a defined standard plan, the plan liability in the initial coverage phase is 75 percent of the negotiated price before the discount. With a 10 percent applicable discount, the plan liability would be reduced to 65 percent of the negotiated price. With a 1 percent applicable LIS percent in 2025, the plan liability would be reduced to 74 percent of the negotiated price.

Section 1860D–14C(b)(1)(A) of the Act specifies that a Manufacturer Discount Program agreement shall require the agreement holder to provide discounted prices for applicable drugs covered by its agreement when dispensed to applicable beneficiaries. The IRA does not provide a mechanism by which CMS could permit specified manufacturers or specified small manufacturers to ''opt out'' of the phase-in discounts. At § 423.2716, we propose to codify, without modification, the criteria for phase-in eligibility for specified manufacturers and specified small manufacturers established in the Manufacturer Discount Program Final Guidance.

a. Specified Manufacturer

Pursuant to section 1860D–14C(g)(4)(B)(ii) of the Act, a specified manufacturer is a manufacturer of an applicable drug that, in 2021 had—

• A Coverage Gap Discount Program agreement in effect; [19]

• Total expenditures for all of its specified drugs (as proposed at § 423.2704) covered by a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 represented less than 1.0 percent of total expenditures for all Part D drugs in 2021; and

• Total expenditures for all of its specified drugs that are single source

[19] A manufacturer that participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) were listed on another manufacturer's Coverage Gap Discount Program agreement would be considered to have had an agreement in effect during 2021. See November 17, 2023 HPMS memorandum entitled, ''Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers'' for more information.

drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

Pursuant to the aggregation rule set forth in section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section. Our proposed definition of specified manufacturer is subject to the limitation with respect to manufacturer acquisitions proposed at § 423.2724 and discussed in section II.C.6.d. of this preamble.

The eligibility criteria for specified manufacturers are proposed at § 423.2716(a) and the aggregation rule is proposed at § 423.2716(c).

b. Specified Small Manufacturer

Pursuant to section 1860D–14C(g)(4)(C)(ii) of the Act, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021—

- Is a specified manufacturer as described at proposed § 423.2716(a); and
- The total expenditures under Part D for any one of its specified small manufacturer drugs (as defined in § 423.2704) covered under a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

Pursuant to the aggregation rule set forth in section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section. Our proposed definition of specified small manufacturer is subject to the limitation with respect to manufacturer acquisitions proposed at § 423.2724 and discussed in section II.C.6.d. of this preamble.

The eligibility criteria for specified small manufacturers are proposed at § 423.2716(b) and the aggregation rule is proposed at § 423.2716(c).

c. Determination of Phase-In Eligibility

As discussed in section 50.1 of the Manufacturer Discount Program Final Guidance, CMS identifies which manufacturers qualify for phase-ins by analyzing Medicare Part B claims data, Part D PDE data, and ownership information submitted by manufacturers. All manufacturers that sign a Manufacturer Discount Program agreement that takes effect prior to the end of the phase-in periods will be considered and do not need to submit a separate application. Our policy describing the methodology used to identify manufacturers eligible for phase-ins was provided in the November 17, 2023 HPMS memorandum titled ''Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers'' (Manufacturer Discount Program Methodology).

The phase-in determination is a one-time assessment that CMS performs with respect to each manufacturer when it executes a Manufacturer Discount Agreement or when a manufacturer's labeler code(s) is first added to another manufacturer's Manufacturer Discount Program agreement. As such, the phase-in statuses have already been determined for likely the vast majority of manufacturers that will participate in the Manufacturer Discount Program during the phase-in periods (that is, through 2030). Codifying the methodology described in the Manufacturer Discount Program Methodology for identifying specified manufacturers and specified small manufacturers ensures consistency across the program by applying the same methodology to future cases of new phase-in determinations to be made under the regulations proposed in this rule (for example, when a new manufacturer enters into a Manufacturer Discount Program agreement with respect to 2027 or thereafter) as the methodology that was applied to the manufacturers currently participating in the Manufacturer Discount Program. We are proposing to codify such methodology at § 423.2720.

Specifically, we propose to codify at § 423.2720 that for each manufacturer with one or more FDA-assigned labeler codes covered by a Manufacturer Discount Program agreement, CMS will determine whether the manufacturer is a specified manufacturer or a specified small manufacturer when the manufacturer executes a Manufacturer Discount Program agreement, or, in the case of a manufacturer whose FDA-assigned labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, when such labeler code(s) is first added to such agreement. In addition, we propose to codify that in applying the aggregation rule at § 423.2716(c), CMS will attribute expenditures for a drug to a manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

As discussed in detail later in this section, we propose at paragraph (a) of § 423.2720 the methodology for identifying ''specified manufacturers'', at paragraph (b) of § 423.2720 the methodology for identifying ''specified small manufacturers'', and at paragraph (c) the approach CMS will use to issue the phase-in determination notices once a phase-in determination is made.

For identification of a specified manufacturer, we propose to codify at § 423.2720(a)(1) that a manufacturer is considered to have had a Coverage Gap Discount Program agreement in 2021, as specified at § 423.2716(a)(1), if the manufacturer (i) had a Coverage Gap Discount Program agreement in effect during 2021, or (ii) participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) was covered by another manufacturer's Coverage Gap Discount Program agreement in effect during 2021.

As described in the Manufacturer Discount Program Methodology, CMS will calculate the three values needed for determining which manufacturers that had a Coverage Gap Discount Program agreement in 2021 are specified manufacturers and specified small manufacturers. The three values are:

- The manufacturer's percent share of Part D total expenditures,
- The manufacturer's percent share of Part B total expenditures, and
- Each drug's percent share of the specified manufacturer's Part D total expenditures.

The first value that needs to be determined is each manufacturer's share of Part D total expenditures, which will be used to determine if the manufacturer's total expenditures for all of its applicable drugs covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, represented less than 1.0 percent of total expenditures for all Part D drugs in 2021. CMS will identify manufacturers that meet this threshold for the specified manufacturer phase-in by first summing the 2021 Part D total expenditures for Part D drugs, then summing the 2021 Part D total expenditures for applicable drugs for each manufacturer, and finally, identifying each manufacturer for which 2021 Part D total expenditures for applicable drugs are less than 1.0

percent of all 2021 Part D total expenditures.

The first step is to calculate the Part D total expenditures for 2021. We will calculate the Part D total expenditures for 2021 reported on all final action,[20] non-delete Prescription Drug Event (PDE) records submitted as of June 30, 2022, which represents the annual PDE data submission deadline for Part D payment reconciliation, for all Part D drugs dispensed in benefit year 2021. This value represents the Part D total expenditures and will be used as the denominator when calculating the percent share of Part D total expenditures attributable to each manufacturer's applicable drugs in step 3 below.

The second step is to calculate each manufacturer's Part D total expenditures for applicable drugs for 2021. For purposes of calculating each manufacturer's Part D total expenditures for applicable drugs, CMS will identify the National Drug Codes (NDCs) attributable to the manufacturer that have a Marketing Category Code of 'NDA', 'BLA', or 'NDA AUTHORIZED GENERIC' on the NDC SPL Data Elements (NSDE) File maintained by the Food and Drug Administration (FDA). CMS will attribute an NDC as reported on the PDE record to the manufacturer using the labeler code extracted from the first 5 digits of each NDC. CMS will calculate the Part D total expenditures for each relevant NDC attributable to the manufacturer as reported on all final action, non-delete PDE records submitted as of June 30, 2022 for applicable drugs dispensed in benefit year 2021. CMS will then sum the Part D total expenditures for all relevant NDCs attributable to the manufacturer—that is, the Part D total expenditures for all applicable drugs of all manufacturers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, as identified by the ownership information submitted and attested to by the manufacturer (as described in the aggregation rule proposed at § 423.2716(c)).

The third step is to calculate each manufacturer's percent share of Part D total expenditures for 2021. CMS will divide the Part D total expenditures for applicable drugs of the manufacturer, determined in step 2 above, by the Part D total expenditures for all Part D drugs, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share. If a manufacturer's Part D total expenditures for its applicable drugs are less than 1.0 percent of the 2021 Part D total expenditures, CMS will consider the manufacturer to have satisfied the Part D total expenditure criterion for specified manufacturer phase-in eligibility.

We propose to codify this part of the methodology at § 423.2720(a)(2).

The next value that needs to be determined is each manufacturer's share of Part B total expenditures, which will be used to determine if the manufacturer's total expenditures for all of its specified drugs that are single source drugs or biological products represented less than 1.0 percent of the total expenditures for all drugs or biologicals under Part B in 2021, excluding expenditures for a drug or biological that are bundled or packaged into payment for another service. This calculation involves three steps: identifying 2021 Part B total expenditures for drugs and biological products, identifying the 2021 Part B total expenditures for single-source drugs and biological products for each manufacturer that had a Coverage Gap Discount Program agreement(s) in 2021, and identifying eligible manufacturers for which Part B total expenditures for single source drugs or biological products represent less than 1.0 percent of total expenditures for drug and biological products under Part B for 2021.

The first step is to calculate Part B total expenditures for all drugs and biological products for 2021. CMS will identify all Healthcare Common Procedure Coding System (HCPCS) codes for drugs and biological products. Then, CMS will calculate Part B Carrier, durable medical equipment (DME), and Outpatient Medicare Part B total expenditures for drug and biological products for Fee-for-Service claim line items with a drug- or biological product-related HCPCS code, submitted as of December 31, 2022, which represents the Medicare Fee-For-Service submission deadline for CY 2021.

The second step is to calculate each manufacturer's Part B total expenditures for applicable drugs that are single-source drugs and biological products for 2021. CMS will first map the HCPCS codes identified in step 1 above to NDCs using the NDC–HCPCS Crosswalk file provided as part of the CMS ASP Pricing File and the Pricing, Data Analysis and Coding (PDAC) HCPCS to NDC crosswalk file. Since the ASP NDC–HCPCS Crosswalk file is not a comprehensive list of all drugs/NDCs available in the United States, a Medi-Span Generic Product Identifier (GPI–14) expansion is used to help identify all NDCs associated with the HCPCS codes. We define a single source drug or biological following the definition in section 1847A(c)(6)(D) of the Act and we are identifying NDCs for single source drugs using Medi-Span and the FDA NSDE marketing category data, or biological products using the FDA Purple Book. A HCPCS code is considered to be indicative of a single source drug or biological product if each NDC associated with the HCPCS code is for a single source drug or biological product. The corresponding NDCs are used to determine the labeler codes for each applicable HCPCS code. CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer. Since a HCPCS code can be mapped to multiple NDCs and labeler codes, it can also be associated with multiple manufacturers. While Part B single source drugs or biological products can be mapped to a particular HCPCS code, mapping applicable Part B expenditures to a particular manufacturer when a particular HCPCS code may reflect drugs of multiple manufacturers can be challenging. For this reason, CMS will only count the payments associated with a HCPCS code toward a manufacturer's 2021 Part B total expenditures if the HCPCS code is only mapped to drugs of that same manufacturer, consistent with the aggregation rule proposed at § 423.2716(c).

The third step is to calculate each manufacturer's percent share of Part B total expenditures for 2021. CMS will divide the Part B total expenditures for the applicable drugs that are single source drugs and biological products of the manufacturer, determined in step 2 above, by the Part B total expenditures for all drugs and biological products, determined in step 1 above, and then multiply by 100 to get the manufacturer's percent share. If a manufacturer's Part B total expenditures are less than 1.0 percent of the 2021 Part B total expenditures, CMS will consider the manufacturer to have satisfied the Part B total expenditure criterion for the specified manufacturer phase-in eligibility.

We propose to codify this part of the methodology at § 423.2720(a)(3).

The last value that needs to be determined for each specified manufacturer is the total expenditures under Part D for any one of the manufacturer's specified drugs covered

[20] CMS uses the term ''final action'' to describe the most recently accepted original, adjustment, or delete PDE record representing a single dispensing event. See the 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, page 3–29, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FJUKANFCP1~Prescription%20Drug%20Program%20(Part%20D)~Training.*

under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021, which will be used to determine if the manufacturer's total expenditures for one specified drug are equal to or greater than 80 percent of the total expenditures for all of its specified drugs covered under Part D in 2021 such that the manufacturer is eligible for the specified small manufacturer phase-in.

The first step is to aggregate all NDCs for applicable drugs reported on PDEs for each specified manufacturer that have the same active moiety for drug products, or same active ingredient for biological products, and with the same holder of the NDA or BLA. To determine one drug's share of a manufacturer's Part D total expenditures, which we will use to identify specified small manufacturers, we first note that for drug products, one specified small manufacturer drug will include all dosage forms and strengths of a drug with the same active moiety and the same holder of the NDA,[21] inclusive of products that are marketed pursuant to different NDAs. For biological products, one specified small manufacturer drug will include all dosage forms and strengths of the biological product with the same active ingredient and the same holder of the BLA,[22] inclusive of products that are marketed pursuant to different BLAs. CMS will identify the holder of the NDA/BLA for a drug or biological product as reported in Drugs@FDA or FDA Purple Book. If a drug is a fixed combination drug[23] with two or more active moieties/active ingredients, the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for the purpose of identifying a specified small manufacturer drug. Therefore, all formulations of this distinct combination with the same NDA/BLA holder will be aggregated across all dosage forms and strengths of the fixed combination drug. A product containing only one (but not both) of the active moieties/active ingredients with the same NDA/BLA holder will not be aggregated with the formulations of the fixed combination drug and will be considered a separate specified small manufacturer drug. CMS will attribute Part D expenditures for a drug, including authorized generic drugs and repackaged and relabeled drugs, to a specified manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer. (See the aggregation rule proposed at § 423.2716(c)).

The second step is to calculate the Part D total expenditures for each aggregated drug for 2021. CMS will calculate the Part D total expenditures for each aggregated drug attributable to the manufacturer as identified in step 1 by summing the Part D total expenditures for all NDCs under each aggregated drug as reported on all final action, non-delete PDE records submitted as of June 30, 2022, for drugs dispensed in benefit year 2021.

The third step is to calculate each drug's percent share of the specified manufacturer's Part D total expenditures for applicable drugs for 2021. CMS will divide the Part D total expenditures for each aggregated drug, determined in step 2, by the Part D total expenditures for all applicable drugs of the specified manufacturer, and then multiply by 100 to get the percent share. Specified manufacturers that have 2021 Part D total expenditures for a single specified drug that are equal to or greater than 80 percent of the specified manufacturer's Part D total expenditures for all specified drugs are considered to have met the eligibility criteria for specified small manufacturers and are eligible for the specified small manufacturer phase-in.

We propose to codify this part of the methodology at § 423.2720(b).

Finally, at paragraph (c)(1) of § 423.2720, we propose to specify that CMS will issue a phase-in determination notice to each manufacturer that has executed and has in effect a Manufacturer Discount Program agreement when such determination is made, delivered by electronic mail, to the primary point of contact as identified by the manufacturer. At paragraph (c)(2) of § 423.2720, we propose to specify that in the case of a manufacturer that participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, CMS will issue a phase-in eligibility determination notice to the agreement holder.

For purposes of identifying manufacturers eligible for phase-ins, the aggregation rule at section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers requires that CMS treat as a single manufacturer all entities that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986. As noted previously, we propose to codify the aggregation rule at § 423.2716(c). The statute, at section 1860D–14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers, also requires that manufacturers provide and attest to necessary information as specified by CMS. Because CMS does not have information about which entities are treated as a single employer under the Internal Revenue Code of 1986, manufacturers that wish to participate in the Manufacturer Discount Program must submit and attest to information about the company and its products in order for CMS to make a determination about phase-in eligibility.

d. Effect of Manufacturer Acquisition on Phase-In Eligibility

Section 1860D–14C(g)(4)(B)(ii)(III) of the Act requires that when a specified manufacturer is acquired after 2021 by another manufacturer that is not a specified manufacturer, the acquired manufacturer is no longer a specified manufacturer effective at the beginning of the plan year immediately following the acquisition. For acquisitions before 2025, the change is effective January 1, 2025. Section 1860D–14C(g)(4)(C)(ii)(III) of the Act establishes a similar requirement for specified small manufacturers: when acquired after 2021 by a manufacturer that is not a specified small manufacturer, such manufacturer is no longer a specified small manufacturer effective at the beginning of the plan year immediately following the acquisition (or January 1, 2025, for acquisitions before 2025).

While the statute is explicit that an acquired specified manufacturer or specified small manufacturer loses that specific phase-in status upon acquisition by another manufacturer that is not a specified manufacturer or a specified small manufacturer, respectively, it does not expressly address whether such acquired manufacturers assume the phase-in eligibility of the acquiring manufacturer or lose all phase-in eligibility (for example, a specified manufacturer is acquired by a specified small manufacturer or a specified small manufacturer is acquired by a specified manufacturer). Similarly, the statute does not expressly address what happens if a specified manufacturer or a specified small manufacturer acquires a manufacturer that CMS determined was not eligible for either phase-in. Consistent with our approach to

[21] As described in section 505(c) of the FD&C Act.

[22] As described in section 351(a) of the PHS Act.

[23] As described in 21 CFR 300.50.

acquisitions under the Manufacturer Discount Program thus far, we propose at § 423.2724 to review phase-in status bidirectionally such that acquired manufacturers may gain or lose phase-in eligibility as the result of an acquisition. In other words, regardless of the phase-in status of the acquiring manufacturer or the acquired manufacturer at the time of the acquisition, when a manufacturer acquires another manufacturer (that is, the acquired manufacturer becomes part of such acquiring manufacturer under the aggregation rule at § 423.2716(c)), the acquired manufacturer will assume the phase-in status of the acquiring manufacturer, as of the effective date following the acquisition discussed later in this section. CMS believes this bidirectional policy best aligns with the statutory structure and purpose of the phase-ins. First, we believe this policy is most consistent with the directive in sections 1860D–14C(g)(4)(B)(ii)(II)(bb) and 1860D–14C(g)(4)(C)(ii)(II)(bb) of the Act to treat all entities, including corporations, partnerships, proprietorships, and other entities, treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as one manufacturer for the purposes of the phase-ins. Without applying the effect of acquisitions bidirectionally, manufacturers that are members of the same controlled group could have different phase-in eligibility statuses as a result of an acquisition. Additionally, while a specified small manufacturer that is acquired by a specified manufacturer will lose its specified small manufacturer status consistent with section 1860D–14C(g)(4)(C)(ii)(III) of the Act, such manufacturer becomes a specified manufacturer under this policy, rather than losing eligibility for phase-in altogether.

We propose that all changes to a manufacturer's phase-in status as a result of an acquisition will become effective on January 1 of the year following the acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. This aligns the effective date of changes to a manufacturer's phase-in status across all acquisitions with the requirements in sections 1860D–14C(g)(4)(B)(ii)(III) and 1860D–14C(g)(4)(C)(ii)(III) of the Act discussed previously and is consistent with our approach to date for acquisitions that have already occurred. Operationally, adopting a January 1 effective date minimizes burden on Part D sponsors who would otherwise need to regularly make additional claims processing changes to accommodate phase-in status changes throughout the year given the frequency of corporate ownership changes in the pharmaceutical industry. It also minimizes any need for Part D sponsors to make retrospective PDE adjustments if, for example, CMS does not become aware of the acquisition until after it occurs.

In sum, in alignment with the statutory requirements and the procedures already in place under the Manufacturer Discount Program, we propose at § 423.2724 to codify a regulatory policy for manufacturer acquisitions where, regardless of the manufacturer's phase-in eligibility status prior to the acquisition, once acquired, the acquired manufacturer is recognized as having the phase-in eligibility status of the acquiring manufacturer. Consistent with the statutory requirements related to the loss of phase-in eligibility, and to minimize any potential impact on Part D sponsors or manufacturers as a result of changes to manufacturer phase-in status in the middle of a plan year, we also propose at § 423.2724 that any change in phase-in eligibility status as a result of an acquisition, regardless of whether the acquired manufacturer gains or loses phase-in eligibility, would be effective on January 1 of the year following the acquisition.

e. Recalculation

We propose to codify the recalculation policy discussed in section 50.2.2 of the Manufacturer Discount Program Final Guidance, with certain modifications, at § 423.2728.

As discussed in the guidance, while the requirements to qualify as a specified manufacturer or specified small manufacturer are set forth in statute, we recognize that, while unlikely, a manufacturer may wish to raise concerns with the outcome of the application of those statutory requirements. As such, CMS established a mechanism for manufacturers that wish to request a recalculation of their phase-in eligibility determination. Such requests can only be filed by the manufacturer that received the determination. We propose to codify this requirement at § 423.2728(a).

Under the recalculation policy, a manufacturer that seeks a recalculation of their phase-in eligibility determination must file the request with CMS no later than 30 calendar days from the date the eligibility determination is electronically sent to the manufacturer. The request must clearly describe the issue(s) forming the basis of the request for recalculation, and include any relevant supporting information. We propose to codify these requirements at § 423.2728(b).

After consideration of the issues raised in a recalculation request, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer that will include CMS's decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination. The decision is final and binding, subject to the requirements of the Manufacturer Discount Program under section 1860D–14C of the Act and the Manufacturer Discount Program agreement. We propose to codify this policy at § 423.2728(c).

Finally, at § 423.2728(d), we propose to limit the recalculation process to requests that meet the requirements proposed in § 423.2728(a) and (b). The recalculation request process cannot be used to request or be granted an exception to the requirements set forth in statute that determine eligibility for the specified manufacturer or specified small manufacturer phase-in.

7. Use of a Third Party Administrator (§ 423.2732)

Unlike under the statute establishing the Coverage Gap Discount Program, section 1860D–14C of the Act does not require CMS to engage a third party administrator (TPA) under the Manufacturer Discount Program. However, section 1860D–14C(d)(2) of the Act prohibits CMS from receiving or distributing any funds of a manufacturer under the Manufacturer Discount Program. Because of this limitation, under our authority at section 1860D–14C(d)(1) of the Act, CMS has engaged a TPA to assist in the administration of the Manufacturer Discount Program, which includes, but is not limited to Manufacturer Discount Program invoicing, the receipt and distribution of funds of a manufacturer, and dispute resolution. We propose to codify the agency's engagement of a TPA at § 423.2732(a).

As proposed at § 423.2752(a)(6), the Manufacturer Discount Program agreement requires agreement holders to enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA. It further requires agreement holders to comply with the TPA's instructions, processes, and requirements. We believe these requirements are important because of the quantity of Part D sponsor and manufacturer data elements, and the sensitivity of such data elements, that is processed each quarter by the TPA. Accordingly, we are proposing to codify at § 423.2732(b)(1) that agreement

holders must enter into and have in effect an agreement with the TPA and that such TPA agreement will only terminate upon the termination of the agreement holder's Manufacturer Discount Program agreement.

We are also proposing at § 423.2732(b)(2) that agreement holders must establish and maintain electronic connectivity with the TPA for the purpose of timely transmission of data and funds. Because Part D sponsors, under § 423.505(b)(25), must agree to maintain administrative and management capabilities sufficient for financial, communication, and other activities related to the delivery of Part D services, we have not proposed a separate requirement in subpart AA regarding Part D sponsors' establishment and maintenance of an account on the TPA's electronic portal; we believe § 423.505(b)(25) already establishes this obligation.

8. Requirement for Point-of-Sale Discounts (§§ 423.505 and 423.2736)

a. Point-of-Sale Discounts

Under section 60.1 of the Manufacturer Discount Program Final Guidance, Part D sponsors must provide applicable discounts on applicable drugs at the point of sale on behalf of the manufacturer. This policy aligns with the process used under the Coverage Gap Discount Program since 2011, to which interested parties are accustomed, coupled with prospective payments to sponsors and the payment reconciliation process at proposed § 423.2744(a) and (c), respectively, minimizes burden on plan sponsors, manufacturers, pharmacies, and Part D enrollees. We propose to codify this policy at § 423.2736(a).

In order to provide point-of-sale discounts, plan sponsors must determine whether an enrollee is an applicable beneficiary (as defined at § 423.100), including where the enrollee falls in the phases of the Part D benefit based on their gross drug spend and incurred costs at the time an applicable drug is dispensed; whether a drug is an applicable drug (as defined at § 423.100); and the amount of the discount (in accordance with proposed § 423.2712).

Part D regulations at part 423 subpart K set forth the requirements for Part D contracts between Part D sponsors and CMS. We propose a conforming change to revise the text of § 423.505(b)(24) to specify that Part D sponsors must provide applicable discounts on applicable drugs when dispensed to applicable beneficiaries in accordance with the requirements in subpart W of part 423 for the Coverage Gap Discount Program and the requirements in subpart AA of part 423 for the Manufacturer Discount Program.

b. Direct Member Reimbursement

As established under section 60.1.1 of the Manufacturer Discount Program Final Guidance, Part D sponsors must provide applicable discounts on claims for applicable drugs submitted by applicable beneficiaries as direct member reimbursements (DMRs), including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. While the sponsor must account for the discount in adjudicating the DMR request and the associated PDE submitted to CMS, the point-of-sale requirement does not apply. We propose codifying this policy at § 423.2736(b). For purposes of discounting DMR claims for prescriptions filled at out-of-network pharmacies, the negotiated price means the plan allowance as set forth in § 423.124. CMS guidance related to DMR processing can be found in Chapter 14, section 50.4.3, of the Medicare Prescription Drug Benefit Manual.[24]

c. Pharmacy Prompt Payment

Pursuant to section 1860D–14C(c)(1)(B) of the Act, and consistent with section 60.3 of the Manufacturer Discount Program Final Guidance and CMS pharmacy prompt payment requirements at § 423.520, we propose at § 423.2736(c) that Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days (as defined in § 423.100) after the date of dispensing (as defined in § 423.100) of an applicable drug. As described in the definition of date of dispensing, for long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

d. Prescription Drug Event Requirements

We propose codifying at § 423.2736(d) PDE requirements established in section 60.2 of the Manufacturer Discount Program Final Guidance, specifically, that Part D sponsors must report the applicable discounts made available to their enrollees under the Manufacturer Discount Program on the PDE records associated with such discounts. This information will be used for the cost-based reconciliation of prospective Manufacturer Discount Program payments made to each sponsor (as proposed at § 423.2744(c)) and to invoice agreement holders for reimbursement of the amount advanced on their behalf by the Part D sponsor at the point of sale (as proposed at § 423.2756(a)).

e. Retroactive Adjustments

Under section 60.1.5 of the Manufacturer Discount Program Final Guidance, Part D sponsors must make retroactive adjustments to applicable discounts as necessary to reflect applicable changes, including changes to the claim, beneficiary eligibility, or benefit phase determined after the date of dispensing. We propose codifying this policy at § 423.2736(e).

9. Negative Invoice Payment Process for Part D Sponsors (§ 423.2740)

In certain instances in the quarterly Manufacturer Discount Program invoicing process (proposed at § 423.2756(a)) a Part D sponsor may receive a negative invoice amount. This can occur when a PDE, which had been previously invoiced, is either deleted or adjusted by the plan such that the reported discount amount is less than originally invoiced. A negative invoice amount can be thought of as the amount an agreement holder has overpaid a Part D sponsor in a prior quarter that is now due back to the agreement holder because of a PDE adjustment or deletion. Negative invoice amounts occurred under the Coverage Gap Discount Program, and CMS developed our proposed Manufacturer Discount Program negative invoice policy based on program instruction for the Coverage Gap Discount Program, including the July 12, 2013 HPMS memorandum titled ''Instructions for Resolving Coverage Gap Discount Program (CGDP) Negative Invoice Amounts.'' Accordingly, we propose that Part D sponsors must pay such negative invoices in the manner specified by CMS within 38 calendar days of receipt of the invoice, the same timeframe specified in the July 12, 2013 memorandum. A sponsor's failure to pay such a negative invoice within the 38-day deadline may result in CMS taking compliance action in accordance with § 423.505(n). We propose codifying this negative invoice policy at § 423.2740.

10. Prospective Payments to Part D Sponsors (§ 423.2744)

a. General Rule

We propose at § 423.2744(a) to provide monthly prospective

[24] Available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-14-Coordination-of-Benefits-v09-14-2018.pdf*.

Manufacturer Discount Program payments to Part D sponsors for sponsors to advance applicable discounts at the point of sale under proposed § 423.2736(a) and reimburse network pharmacies within the timeframe required under proposed § 423.2736(c).

Consistent with section 60.4 of the Manufacturer Discount Program Final Guidance, CMS calculates Manufacturer Discount Program prospective payments based on the projections in each plan's bid and current enrollment. Under this process, CMS estimates the per member per month cost of the manufacturer discounts for each plan based on a percentage of the cost assumptions submitted with plan bids under § 423.265 and negotiated and approved under § 423.272, adjusted as necessary to account for applicable drug costs for applicable beneficiaries. CMS then multiplies the plan's manufacturer discount estimate by the number of beneficiaries enrolled in the plan and distributes the prospective Manufacturer Discount Program payments to plans on the first of each month. The Manufacturer Discount Program payments are reflected as a separate line item on each plan's Monthly Membership Detail Reports and included in the Part D payments displayed on the Monthly Membership Summary Reports.

When manufacturers pay their quarterly Manufacturer Discount Program invoices, sponsors will appear to have a temporary duplicate payment from two sources, the manufacturer and CMS, for the same expense. After receiving payment from the manufacturer, the Part D sponsor no longer needs the cash flow advance from the prospective Manufacturer Discount Program payment. Therefore, CMS will offset the monthly prospective Manufacturer Discount Program payment, with the offset amount being equal to the total manufacturer discount amount received by the Part D sponsor from the manufacturer in the previous quarter.

b. Exception

As described in section 60.4 of the Manufacturer Discount Program Final Guidance, employer group waiver plans (EGWPs) do not submit Part D bids; therefore, CMS does not have the information necessary to estimate the cost of applicable discounts for these plans and will not provide prospective Manufacturer Discount Program payments to EGWPs. We propose to codify this exception to the Manufacturer Discount Program prospective payments at § 423.2744(b). However, because manufacturers are required to provide discounts for applicable drugs when dispensed to applicable beneficiaries who are enrolled in an EGWP, EGWPs are required to advance such discounts at the point of sale. The discounts will be invoiced to the manufacturer for reimbursement to the EGWP through the invoicing process at proposed § 423.2756(a).

c. Reconciliation

Because prospective discount payments are estimates, Part D sponsors may incur actual Manufacturer Discount Program costs that are greater or less than the prospective payments. To ensure that Part D sponsors are made whole for the manufacturer discount amounts they advanced on behalf of the manufacturer, we propose at § 423.2744(c) to codify cost-based reconciliation in accordance with subpart G of Part 423 and as implemented under section 60.5 of the Manufacturer Discount Program Final Guidance. Manufacturer Discount Program reconciliation occurs after Part D payment reconciliation. In general, CMS calculates the discount reconciliation amount by subtracting the prospective discount payments from manufacturer discount amounts as reported by Part D sponsors on PDE data and invoiced to manufacturers. If the difference is positive, CMS pays the difference to Part D sponsors. If the prospective discount payments exceed the invoiced manufacturer discount amounts, CMS recovers the difference from Part D sponsors. Manufacturer discount amounts reported on invoiced PDE data submitted by the PDE submission deadline for Part D payment reconciliation are included in the Manufacturer Discount Program reconciliation. Any manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for Part D payment reconciliation for a plan year are not subject to the Manufacturer Discount Program reconciliation process for that plan year.

d. Manufacturer Bankruptcy

In the event that an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of the bankruptcy, does not pay all invoiced amounts due under the requirements of proposed § 423.2756(a), we propose at § 423.2744(d) to adjust the Manufacturer Discount Program reconciliation amount for each affected Part D sponsor to account for the total unpaid quarterly invoiced amount owed to each Part D sponsor for the contract year being reconciled, as per proposed § 423.2744(c). We propose to reserve the government's right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

11. Requirement To Use the Health Plan Management System (§ 423.2748)

The Health Plan Management System (HPMS) is CMS's primary system of record for the collection, review, and storage of information that must be submitted by Part D manufacturers for CMS review. As announced in the April 17, 2023 HPMS memorandum, ''April 2023 Drug Manufacturer Module Enhancements,'' [25] CMS modified the Drug Manufacturer Contract Management module in the HPMS in support of the IRA, including changes to support the Manufacturer Discount Program. CMS relies on ownership and other identifying information that agreement holders provide and attest to in the HPMS and in accordance with proposed § 423.2752(a)(7) for determining manufacturers' discount phase-in eligibility status and for other program operations.

We propose to codify the HPMS instructions included in the Manufacturer Discount Program Final Guidance, for program continuity and to minimize burden. Specifically, under proposed § 423.2748, agreement holders are required to use the HPMS to—

- Provide and maintain required information, as specified by CMS;
- Attest to the completeness and accuracy of the data necessary for CMS to determine whether the manufacturer qualifies as a specified manufacturer or specified small manufacturer, as described at § 423.2716;
- Execute a Manufacturer Discount Program agreement and a TPA agreement; and
- As otherwise specified by CMS to administer the program.

More information about the use of the HPMS for the Manufacturer Discount Program is provided in the Part D Manufacturer Discount Program Information Collection Request (ICR) (CMS–10846, OMB control no. 0938–1451), which was approved by the Office of Management and Budget through September 30, 2025. The Part D Manufacturer Discount Program ICR, including the supporting statement, information collection instruments, a

[25] Available at *https://www.cms.gov/https/editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-3-april-17-21.*

summary of changes, and responses to comments received during the comment periods can be viewed at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003* (select ''all'' to see full details). The ICR renewal package was published on June 20, 2025, for a 60-day public comment period, and was published again on October 2, 2025, for a 30-day public comment period.[26] CMS received no comments during either comment period, and the ICR renewal package has submitted to OMB for approval.

To comply with the requirements under proposed § 423.2748, agreement holders must obtain and maintain access in the HPMS. The May 4, 2023 HPMS memorandum entitled ''Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)'' [27] describes the steps involved in obtaining and maintaining access. These steps include requesting a CMS user identification and HPMS access, establishing HPMS access and electronic signature access, and annually recertifying identification and password requirements.

Because Part D sponsors are already required to maintain administrative and management capabilities sufficient for financial, communication, and other activities related to the delivery of Part D services, under existing § 423.505(b)(25), we have not proposed separate requirements in subpart AA regarding Part D sponsors' use of HPMS.

12. Manufacturer Discount Program Agreement (§ 423.2752)

Section 1860D–14C(a) of the Act requires CMS to enter into Manufacturer Discount Program agreements with manufacturers in order for manufacturers to participate in the Manufacturer Discount Program. We propose to codify section 80.1 of the Manufacturer Discount Program Final Guidance at proposed § 423.2752.

CMS released the Manufacturer Discount Program agreement template on November 17, 2023. The burden associated with executing the agreement and related requirements is currently approved under OMB control number 0938–1451 (CMS–10846) and referenced in the COI section of this proposed rule.

a. Requirements of Agreement

As discussed in more detail in section II.C.4. of this preamble, a manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement, as required under section 1860D–43(a) of the Act, if such manufacturer executes and has in effect its own Manufacturer Discount Program agreement or participates by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement that is in effect. We propose to codify this requirement at § 423.2708(b). We further clarify that only a manufacturer that is an agreement holder (as defined in § 423.2708) is a party to such agreement with CMS, and the entity subject to the rights and obligations of such agreement. In accordance with this framework, the requirements we propose at § 423.2752 related to the Manufacturer Discount Program agreement apply only to manufacturers that are agreement holders. Pursuant to section 1860D–14C(b) of the Act, we propose that the Manufacturer Discount Program agreement require, at a minimum, each agreement holder to:

- Reimburse, within the required 38-day timeframe, all applicable discounts provided by Part D sponsors on behalf of the manufacturer for applicable drugs dispensed on or after January 1, 2025 that have an NDC with a labeler code that is covered by the manufacturer's Manufacturer Discount Program agreement and invoiced to the manufacturer. As proposed at § 423.2756(b)(2), when an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.
- Provide CMS with all labeler codes covered by its Manufacturer Discount Program agreement.
- Ensure that the labeler codes provided to CMS include, at a minimum, all labeler codes assigned by the FDA to the manufacturer that contain NDCs for any of the manufacturer's applicable drugs or selected drugs, and promptly update CMS with any labeler codes newly assigned to the manufacturer by the FDA that contain NDCs for any of the manufacturer's applicable drugs or selected drugs in accordance with the timing requirements discussed later in this section and proposed at § 423.2756(c)(3) for newly assigned labeler codes.
- Comply with the requirements established by CMS for purposes of administering the Manufacturer Discount Program and monitoring compliance with such program, including providing the manufacturer's Employer Identification Number (EIN) and other identifying information to CMS upon request.
- Comply with the requirements related to the provision and maintenance of data, including collecting, maintaining, and reporting appropriate data related to the labeler codes covered by its agreement and any other data CMS determines necessary to carry out the Manufacturer Discount Program and demonstrate compliance with its requirements.
- Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA and comply with such agreement and all TPA instructions, processes, and requirements.
- Provide and attest to information, as specified by CMS, necessary for CMS to determine eligibility for, and implement, the specified manufacturer and specified small manufacturer phase-in discounts.
- Agree that, no less than 30 days after the date CMS determines that a primary manufacturer of a selected drug has, in accordance with proposed § 423.2752(c)(1)(ii), provided notice to CMS of its decision not to enter into or continue its participation in the Medicare Drug Price Negotiation Program and to discontinue its applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, none of the drugs of such primary manufacturer will be covered by the manufacturer's Manufacturer Discount Program agreement.
- Comply with all other requirements of the Manufacturer Discount Program.

We propose to codify these requirements at § 423.2752(a).

b. Term and Renewal

Consistent with section 1860D–14C(b)(4)(A) of the Act, Manufacturer Discount Program agreements are valid for an initial term of not less than 12 months, and automatically renew for a period of 1 year on each subsequent January 1, except as described later in this section, unless terminated as described in section II.C.12.c. of this preamble. Under section 1860D–14C(b)(1)(C)(i) of the Act, a manufacturer must have entered into the agreement no later than March 1, 2024 to participate in the Manufacturer Discount Program in 2025. The initial

[26] Available at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreduction actof1995/pra-listing/cms-10846*.

[27] Available at *https://www.cms.gov/https/editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-1-may-1-5*.

12-month term began on January 1, 2025 and ends on December 31, 2025.

Consistent with the policies CMS established in the Manufacturer Discount Program Final Guidance, for subsequent years, we propose that a Manufacturer Discount Program agreement would become effective on the first day of a calendar quarter. We further propose that a manufacturer must enter into the agreement no later than the last day of the first month of a calendar quarter for the term to begin on the first day of the next calendar quarter. If a manufacturer enters into the agreement after the last day of the first month of a particular calendar quarter, the initial term would begin on the first day of the second calendar quarter after the calendar quarter in which the manufacturer entered into the agreement.

Under our proposal, an initial term that begins on January 1 would end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 would end on December 31 of the following calendar year. The following examples illustrate these proposed requirements:

- Manufacturer enters into agreement on October 31, 2027; agreement is effective on January 1, 2028 and the initial term ends on December 31, 2028.
- Manufacturer enters into agreement on November 1, 2027; agreement is effective on April 1, 2028 and the initial term ends on December 31, 2029.

We propose to codify the requirements related to the Manufacturer Discount Program agreement term and renewal at § 423.2752(b).

c. Termination of Agreement

(1) Termination by CMS

Under section 1860D–14C(b)(4)(B)(i) of the Act, CMS may terminate a Manufacturer Discount Program agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to a manufacturer's participation in the Manufacturer Discount Program. The statute also specifies that a termination by CMS will not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination. We propose to codify the policies for termination by CMS at § 423.2752(c)(1).

Consistent with applicable guidance for the Medicare Drug Price Negotiation Program,[28] a manufacturer that is a primary manufacturer, as we propose to define at § 423.2704, may submit a request for termination of a Manufacturer Discount Program agreement in connection with a notice of its decision that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program.

Specifically, a manufacturer that is the primary manufacturer of a selected drug may provide a notice to CMS stating the primary manufacturer's unwillingness to participate in, or its request to terminate an agreement under, the Medicare Drug Price Negotiation Program (herein referred to as a ''Request to Terminate''). In accordance with applicable regulations and guidance for the Medicare Drug Price Negotiation Program, such Request to Terminate must incorporate both: (1) a request for termination of the primary manufacturer's applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(A)(i); and (2) an attestation that provides in part that through the end of the price applicability period (as defined in section 1191(b)(2) of the Act) for the selected drug that the primary manufacturer (i) shall not seek to enter into any subsequent agreement with the Manufacturer Discount Program under section 1860D–14C of the Act; and (ii) shall not seek coverage for any of its drugs under the Manufacturer Discount Program under section 1860D–14C of the Act, consistent with the requirements set forth in 26 U.S.C. 5000D(c)(1)(B). If CMS determines the primary manufacturer's Request to Terminate complies with applicable requirements, the primary manufacturer's request will constitute good cause under section 1860D–14C(b)(4)(B)(i) of the Act to terminate the primary manufacturer's applicable agreements under the Manufacturer Discount Program in accordance with the proposed § 423.2752(c)(1)(ii) and the proposed § 423.2752(c)(1)(v)(A)(1), as applicable.[29] CMS also will terminate coverage for all of the drugs of the primary manufacturer under the Manufacturer Discount Program in accordance with proposed § 423.2752(c)(1)(v)(A)(2), as discussed in more detail later in this section.

Consistent with the requirement in section 1860D–14C(b)(4)(B)(i) of the Act and the termination policies established in section 80.1.3.1 of the Manufacturer Discount Program Final Guidance, CMS will provide, upon written request, a manufacturer a hearing concerning a termination by CMS. This hearing will take place prior to the effective date of the termination with sufficient time for the termination to be repealed prior to the effective date if CMS determines repeal would be appropriate. If a manufacturer or CMS receives an unfavorable decision from the hearing officer, the manufacturer or CMS may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding. A timely request for a hearing before a hearing officer or review by the CMS Administrator will stay termination until the parties have exhausted their appeal rights under the Manufacturer Discount Program, which means either the timeframes to pursue a hearing before a hearing officer or review by the CMS Administrator have passed or a final decision by the Administrator has been issued and there is no remaining opportunity to request further administrative review. We propose to codify these policies regarding hearings at § 423.2752(c)(1)(iv)(A) and (B).

In the case of a primary manufacturer of a selected drug under the Medicare Drug Price Negotiation Program that is unwilling to enter into a Medicare Drug Price Negotiation Program agreement or continue its participation in the Medicare Drug Price Negotiation Program and submits a Request to Terminate that complies with all

[28] See, for example, sections 40.1 and 40.6, as applicable, of the June 30, 2023 Medicare Drug Price Negotiation Program Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, available at *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf;* the October 2, 2024 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, available at *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf;* and the September 30, 2025 Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, available at *https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[29] 26 U.S.C. 5000D(c)(2), as enacted by section 11003 of the IRA, defines ''applicable agreement.'' In the context of the Manufacturer Discount Program, the primary manufacturer's applicable agreements include any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, as well as any arrangement in which FDA-assigned labeler code(s) of the primary manufacturer is/are covered under the Manufacturer Discount Program agreement of another manufacturer. If the primary manufacturer's Request to Terminate complies with applicable requirements, CMS will effectuate removal of only the previously described FDA-assigned labeler code(s) from the Manufacturer Discount Program agreement of another manufacturer.

applicable requirements, CMS shall, upon written request from such primary manufacturer, provide a hearing concerning the termination of the primary manufacturer's applicable agreements under the Manufacturer Discount Program, in accordance with section 1860D–14C(b)(4)(B)(i) of the Act. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be held solely on the papers. CMS' determination that there is good cause for termination depends solely on the primary manufacturer's request for termination to effectuate its decision not to participate in or to terminate its participation in the Medicare Drug Price Negotiation Program. Therefore, the only question to be decided in the hearing is whether the primary manufacturer has asked to rescind its Request to Terminate prior to the effective date of the termination. CMS will automatically grant such request from the primary manufacturer to rescind its Request to Terminate. We propose to codify these policies at § 423.2752(c)(1)(iv)(C).

If CMS determines that a primary manufacturer's Request to Terminate complies with all applicable requirements, we will effectuate the removal of the FDA-assigned labeler code(s) of the primary manufacturer from all Manufacturer Discount Program agreements for which the primary manufacturer is not the agreement holder no earlier than 30 days from the date we send the notice of termination to the manufacturer in accordance with proposed § 423.2752(c)(1)(iii).

We propose to codify this requirement at § 423.2752(c)(1)(v)(A)(*1*).

Similarly, CMS will effectuate the termination of coverage under any Manufacturer Discount Program agreement specific to NDCs of all applicable drugs and selected drugs for which the primary manufacturer is the holder of the new drug application or biologics license application. Such termination of coverage will apply to all applicable drug and selected drug NDCs of the primary manufacturer for which the labeler code is assigned to a manufacturer other than the primary manufacturer and for which the primary manufacturer is the new drug application or biologics license application holder for such drug. We propose to codify this requirement at § 423.2752(c)(1)(v)(A)(*2*).

At § 423.2752(c)(1)(v)(B), we propose to clarify that, consistent with the requirement at § 423.2752(c)(3) discussed below, the removal of labeler code(s) in accordance with § 423.2752(c)(1)(v)(A)(*1*) and the termination of coverage specific to NDCs in accordance with § 423.2752(c)(1)(v)(A)(*2*) do not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs with such labeler code(s) or such NDCs that were incurred under the agreement before the effective date of removal or termination.

(2) Termination by the Manufacturer

In accordance with section 1860D–14C(b)(4)(B)(ii) of the Act, an agreement holder may terminate its Manufacturer Discount Program agreement for any reason. Under the policies established in section 80.1.3.2 of the Manufacturer Discount Program Final Guidance, if the manufacturer provides notice of termination under section 1860D–14C(b)(4)(B)(ii) of the Act before January 31 of a calendar year, such termination will be effective as of January 1 of the succeeding calendar year. If the manufacturer provides such notice of termination on or after January 31 of a calendar year, the termination will be effective as of January 1 of the second succeeding calendar year. The following examples illustrate these requirements:

- If a manufacturer notifies CMS on January 20, 2027 that it wishes to terminate, the termination will be effective as of January 1, 2028.
- If the manufacturer notifies CMS on February 1, 2027 that it wishes to terminate, the termination will be effective as of January 1, 2029.

We propose to codify these existing policies without modification at § 423.2752(c)(2).

(3) Post-Termination Obligations

Consistent with section 1860D–14C(b)(4)(B)(iii) of the Act, the termination of a Manufacturer Discount Program agreement under either sections 1860D–14C(b)(4)(B)(i) or 1860D–14C(b)(4)(B)(ii) of the Act will not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with labeler code(s) covered by the manufacturer's agreement that were incurred under the agreement before the effective date of termination.

We propose to codify this requirement at § 423.2752(c)(3).

(4) Reinstatement

As described in section 80.1.4 of the Manufacturer Discount Program Final Guidance, reinstatement in the Manufacturer Discount Program subsequent to termination by CMS will be available to a manufacturer only upon payment of all outstanding applicable discounts and penalties incurred under any previous Manufacturer Discount Program agreement or Coverage Gap Discount Program agreement. The timing of any such reinstatement will be consistent with the requirements for entering into an agreement under proposed § 423.2752(b).

We propose to codify this policy at § 423.2752(c)(4).

(5) Automatic Assignment Upon Change of Ownership

At § 423.2752(d) we propose to codify the requirements of section 80.5.1 of the Manufacturer Discount Program Final Guidance and section (VIII)(b) of the Manufacturer Discount Program agreement, that in the event of a change in ownership of a manufacturer that is an agreement holder, the Manufacturer Discount Program agreement is automatically assigned to the new owner, and all terms and conditions of the agreement remain in effect as to the new owner unless terminated in accordance with requirements at § 423.2752(c). Further, we propose that the new agreement holder would agree to be bound by and to perform all the duties and responsibilities under the Manufacturer Discount Program, and assume all obligations and liabilities of, and all claims incurred against, the prior agreement holder under the Manufacturer Discount Program agreement whether arising before or after the effective date of the change of ownership.

13. Manufacturer Requirements (§ 423.2756)

We propose that manufacturers that are agreement holders, as defined at § 423.2704, must comply with all requirements at proposed § 423.2756.

a. Manufacturer Invoicing

CMS established its manufacturer invoicing policy in section 80.2 of the Manufacturer Discount Program Final Guidance. We propose to codify this policy at § 423.2756(a). Specifically, we propose that CMS will calculate, based on information reported by Part D sponsors, the amounts owed for applicable discounts for applicable drugs having NDCs with a labeler code covered by the agreement holder's Manufacturer Discount Program agreement. We also propose that CMS will invoice agreement holders quarterly through the TPA's portal, consistent with the published invoicing

calendar.[30] Such invoices will be itemized at the NDC level. In addition, we propose that CMS will invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

CMS considered feedback from interested parties received prior to issuing the Manufacturer Discount Program Draft Guidance regarding data elements to include in manufacturer invoices. Based on this feedback, and in an effort to provide transparency and minimize manufacturer disputes, CMS includes the following detail on Manufacturer Discount Program invoices:

- Date of service;
- Service provider identifier qualifier;
- Service provider identifier;
- Prescription/service reference number;
- Product/service identifier;
- Quantity dispensed;
- Days supply;
- Fill number;
- Reported discount;
- Low-income cost sharing amount;
- Total gross covered drug cost accumulator;
- True out-of-pocket accumulator;
- Gross drug cost below out-of-pocket threshold; and
- Gross drug cost above out-of-pocket threshold.

b. Requirement for Timely Payment

We propose at § 423.2756(b)(1) that agreement holders must pay each Part D sponsor the invoiced amounts through the TPA portal no later than 38 calendar days from receipt of the relevant invoice, in the manner specified by CMS, with limited exceptions in proposed paragraphs (b)(2) and (b)(3). At § 423.2756(b)(2), we propose that if an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

At § 423.2756(b)(3), we propose that agreement holders are not permitted to withhold payment for any disputed invoiced amount, including while a dispute is pending, except when the basis for the dispute is that the agreement holder has been invoiced amounts for applicable drugs that have NDCs that do not correspond to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. Under the proposed regulation, if payment is withheld in such an instance, the agreement holder must notify the TPA within 38 calendar days of the manufacturer's receipt of the applicable invoice that payment is being withheld for this reason.

This payment withholding rule is consistent with processes established in section 80.2.3 of the Manufacturer Discount Program Final Guidance, and we believe it continues to strike a reasonable balance between the needs of manufacturers and Part D sponsors. CMS performs extensive quality assurance with respect to PDE data submitted by sponsors and, based on our experience under the Coverage Gap Discount Program, we believe that prohibiting the withholding of disputed invoices minimizes the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer. The PDE data used to calculate quarterly invoices are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim as part of their process to reimburse pharmacies for the cost of the drug. In addition, CMS applies multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other erroneous entries for variables, such as discount amount, beneficiary eligibility for the discount, and NDCs.

c. Reporting Requirements

At paragraph (c)(1) of § 423.2756, we propose that, in general, agreement holders must collect, have available, and maintain appropriate data related to the labeler codes covered by their Manufacturer Discount Program agreement. This includes FDA drug approvals, FDA NDC Directory listings, NDC last-lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines necessary to carry out the Manufacturer Discount Program and demonstrate compliance with its requirements. We also propose that manufacturers maintain such data as described previously for a period of not less than 10 years from the date of payment of the corresponding invoice. This 10-year timeline is consistent with the Part D record retention requirement for Part D sponsors at § 423.505(d).

At § 423.2756(c)(2), we propose requirements related to providing information to CMS about manufacturer ownership. Specifically, at paragraph (c)(2)(i), we propose to require agreement holders to provide and attest to ownership and other data, in the form and manner specified by CMS, as necessary for CMS to determine eligibility for discount phase-ins for specified manufacturers and specified small manufacturers in accordance with statutory requirements, as we propose to codify at § 423.2716. Likewise, at paragraph (c)(2)(iii), we propose that if the agreement holder covers the FDA-assigned labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement, the agreement holder would also be required to provide ownership information about such other manufacturer.

Similarly, it is imperative that CMS be notified promptly of any ownership changes of a manufacturer participating in the Manufacturer Discount Program so that CMS can evaluate such changes as they relate to the application of discount phase-ins, including the acquisition policy under proposed § 423.2724. At § 423.2756(c)(2)(ii), we propose to codify our longstanding policy that agreement holders notify CMS of a change in their ownership no later than 30 calendar days after the agreement holder executes a legal obligation for such an arrangement and no later than 45 calendar days prior to the change in ownership taking effect. At § 423.2756(c)(2)(iii), we propose a corresponding requirement that, if an agreement holder covers the labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement, the agreement holder must notify CMS of a change in ownership of such other manufacturer.

If CMS is not notified of an ownership change, the original agreement holder will be invoiced and payment will have to be reconciled between the manufacturers involved in the transaction. CMS will not consider untimely notice of a change of ownership to be grounds for an agreement holder to dispute the invoiced amount.

At § 423.2756(c)(3), we propose requirements related to labeler codes. Consistent with the Manufacturer Discount Program Final Guidance, section 80.5.2, we propose at § 423.2756(c)(3)(i) that each agreement holder must cover by its agreement all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs. We also propose at § 423.2756(c)(3)(ii) that, consistent with § 423.2708(b)(2), an agreement holder may cover by its Manufacturer Discount Program agreement applicable drugs or selected drugs with labeler code(s) assigned by the FDA to another manufacturer, provided the other

[30] Available at *https://tpadministrator.com/internet/tpaw3_files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf.*

manufacturer has not executed and does not have in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

We propose that agreement holders must provide to CMS and maintain all required labeler code information as instructed by CMS. Specifically, we propose at § 423.2756(c)(3)(iii) to require agreement holders to provide to CMS the following labeler code information:

- All labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs; and
- All labeler codes assigned by the FDA to another manufacturer that the agreement holder covers by its agreement and for which the agreement holder agrees to pay discounts.

We also propose at § 423.2756(c)(3)(iv) that agreement holders must provide labeler codes newly assigned by the FDA to the agreement holder to CMS no later than 3 business days after receiving written notification of the newly assigned labeler code(s) from the FDA and in advance of providing any NDCs associated with such labeler codes to electronic database vendors.

As proposed at § 423.2756(c)(3)(v), agreement holders are responsible for maintaining the list of labeler codes covered by their agreement to ensure that it remains current on an ongoing basis. An agreement holder's failure to update labeler codes covered by its agreement does not change the agreement holder's responsibility to pay the amounts invoiced for applicable drugs. Specific instructions on how agreement holders are to submit information to CMS are available in the HPMS Drug Manufacturer Management User Manual.

As part of maintaining the list of labeler codes covered by their Manufacturer Discount Program agreement, agreement holders should submit a request in HPMS to terminate labeler codes where all of the NDCs are past the last lot expiration date. In order to submit the request, the agreement holder must attest in HPMS that the marketing end date on the FDA NDC SPL Data Elements file, defined by the FDA as the date of expiration of the last lot released to the marketplace, has passed for all applicable drugs and selected drugs associated with the labeler code. Termination of labeler codes where all of the NDCs are past the last lot expiration date differs from the process proposed at § 423.2752(c)(1)(v), which applies to the CMS termination of labeler codes and NDCs of a primary manufacturer and is described in section II.C.12.c. of this preamble.

At § 423.2756(c)(4), we propose requirements related to maintenance of FDA records and related records. CMS relies on data available through the FDA to identify applicable drugs in the Manufacturer Discount Program. Accordingly, we propose at § 423.2756(c)(4)(i)(A) that agreement holders must ensure that all labeler codes assigned by the FDA to the agreement holder that contain NDCs for any of its applicable drugs or selected drugs are properly listed on the FDA NDC Directory. We propose at § 423.2756(c)(4)(i)(B) that agreement holders must electronically list all NDCs of their applicable drugs or selected drugs with the FDA in advance of commercial distribution of the product(s) so that CMS and plans can accurately identify applicable drugs once they are provided to pharmacies for distribution. Further, CMS proposes at § 423.2756(c)(4)(i)(C) that agreement holders must maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory. As we discussed in section 80.5.3 of the Manufacturer Discount Program Final Guidance, accurate NDC listings enable CMS and Part D sponsors to accurately identify applicable drugs. For this reason, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases used for pharmacy claims processing.

In addition, we propose at § 423.2756(c)(4)(i)(D) that agreement holders must maintain up-to-date listings with the electronic database vendors to whom they provide their NDCs for pharmacy claims processing. Only manufacturers know the last-lot expiration dates for their NDCs and, therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market. A manufacturer's failure to provide appropriate advance notice to electronic database vendors may result in the agreement holder being responsible for discounts after the last-lot expiration date unless the manufacturer can document that it provided such appropriate advance notice to the database vendors, or the manufacturer has provided advance notice to the FDA of the marketing end date.

At § 423.2756(c)(4)(ii), we propose that if an agreement holder's Manufacturer Discount Program agreement covers labeler code(s) that are assigned by the FDA to another manufacturer that participates in the Manufacturer Discount Program in accordance with § 423.2708(b)(2), the agreement holder must ensure that the requirements of this section are met with respect to such labeler codes.

At § 423.2756(d), we propose to codify existing CMS policy that permits agreement holders to transfer labeler code(s) between Manufacturer Discount Program agreements so long as the transfer is consistent with requirements of the proposed subpart AA and the Manufacturer Discount Program agreement and is approved by CMS. Among other requirements, such a transfer must be consistent with proposed § 423.2756(c)(3)(i), which requires all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs to be covered by the agreement holder's Manufacturer Discount Program agreement. Specifically, consistent with section 80.5.2.2 of the Manufacturer Discount Program Final Guidance, agreement holders are permitted to transfer existing labeler code(s) from one Manufacturer Discount Program agreement to another Manufacturer Discount Program agreement provided that both agreement holders take part in the transfer process. As instructed by CMS in the HPMS Drug Manufacturer Management User Manual, the agreement holder that covers under its Manufacturer Discount Program agreement the labeler code(s) of another manufacturer must request that the labeler code(s) be transferred to the other agreement holder, and the agreement holder that intends to assume coverage by its agreement must request that the labeler code(s) be added to its Manufacturer Discount Program agreement. If both agreement holders are in agreement and all other Manufacturer Discount Program requirements are met, CMS will approve the labeler code transfer between agreements by approving both agreement holders' requests. Transfers of labeler codes from one Manufacturer Discount Program agreement to another are not considered complete until CMS has approved both requests. The agreement holder seeking to transfer the labeler code from its agreement remains liable for payment of all discounts related to such labeler code until the transfer is complete. An agreement holder is not permitted to transfer its own FDA-assigned labeler code(s) to the Discount Program agreement of another manufacturer.

Once the transfer is complete, the receiving agreement holder assumes responsibility for all Manufacturer

Discount Program requirements with respect to the transferred labeler code(s). Manufacturer Discount Program invoices to the receiving agreement holder will include the discount amounts by labeler code for the entire quarter. If an agreement holder assumes liability for a labeler code effective the second or third month of a quarter, that agreement holder will be invoiced and is responsible for all discount amounts of that labeler code for the entire quarter, including any claims from dates of service in prior quarters that are included on that quarter's invoice. For example:

- If a labeler code transfer request is approved by CMS in February and becomes effective on March 1st, the first quarter (Q1) invoice will be delivered to the receiving agreement holder that assumed responsibility for the labeler code.
- If a labeler code transfer request is approved by CMS in March and becomes effective April 1st, the Q1 invoice will be delivered to the prior (that is, transferring) agreement holder.

In the event that business needs do not coincide with the timing of the transfer, agreement holders are expected to reconcile any payments among themselves without CMS involvement.

The transfer of a labeler code between Manufacturer Discount Program agreements includes all NDCs associated with the transferred labeler code; CMS will not transfer individual NDCs.

14. Audits (§ 423.2760)

We propose, at § 423.2760, to codify the Manufacturer Discount Program audit processes established in section 90 of the Manufacturer Discount Program Final Guidance. Such processes conform with section 1860D–14C(c)(2) of the Act, which requires CMS to monitor a manufacturer's compliance with the terms of a Manufacturer Discount Program agreement, and with section 1860D–14C(b)(2) of the Act, which requires manufacturers to collect and have available appropriate data, as determined by CMS, to ensure they can demonstrate to CMS compliance with the requirements of the Manufacturer Discount Program. Though the Act does not specifically allow audits by agreement holders, CMS proposes codifying that under CMS's authority to provide for implementation of the Manufacturer Discount Program under section 1860D–14C(d)(1) of the Act, CMS will permit agreement holders to conduct periodic audits of the TPA data and information used to calculate the quarterly invoices described in § 423.2756(a). CMS believes that continuing to permit audits in the manner established under the Medicare Part D Manufacturer Discount Program Final Guidance promotes transparency as well as consistency in Part D program operations.

Specifically, we propose at § 423.2760(a)(1) that an agreement holder may conduct audits, directly or through third parties and no more often than annually, of TPA data and information used to determine discounts for applicable drugs covered under the agreement holder's Manufacturer Discount Program agreement. As proposed at § 423.2760(a)(2), the agreement holder must provide 60 calendar days' notice to the TPA of the reasonable basis for the audit and a description of the information required for the audit.

When developing audit processes for the Manufacturer Discount Program Final Guidance, CMS considered feedback from interested parties. In response to this feedback and in alignment with section 90.1.2 of the Manufacturer Discount Program Final Guidance, CMS provides the following data to agreement holders that are auditing TPA data, in addition to the data elements included on invoices:

- Contract number;
- Plan benefit package identifier;
- Ingredient cost paid;
- Dispensing fee paid;
- Total amount attributed to sales tax;
- Non-covered plan paid amount; and
- Vaccine administration fee or additional dispensing fee.

CMS proposes limits on audits of TPA data and information at § 423.2760(a)(3). To appropriately balance transparency and efficiency, and in alignment with generally accepted auditing standards, we propose at § 423.2760(a)(3)(i) that the data provided to the manufacturer conducting the audit be limited to a statistically significant random sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. Such data is sufficient for a manufacturer to reach statistically valid conclusions that could be used to support a dispute under proposed § 423.2764(a). We further propose at § 423.2760(a)(3)(ii) that manufacturers are not permitted to audit CMS records or the records of Part D sponsors beyond the data provided to the TPA, which includes claim-level information.

CMS is obligated to protect the privacy of beneficiary medical information. Accordingly, CMS proposes at § 423.2760(a)(3)(iii) that audits must occur on site at a location specified by the TPA, and with the exception of work papers, such data cannot be removed from the audit site. Additionally, CMS proposes at § 423.2760(a)(3)(iv) that the auditor may release only an opinion of the audit results and is prohibited from releasing any other information obtained from the audit, including work papers, to its client, employer, or any other party. CMS believes these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the discounts.

Regarding CMS audits of manufacturer data, we propose at § 423.2760(b)(1) that an agreement holder is subject to periodic audit by CMS no more often than annually, directly or through third parties. We propose at § 423.2760(b)(2) that CMS must provide agreement holders with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit. We further propose at § 423.2760(b)(3) that CMS has the right to audit appropriate data, including data related to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement and related NDC last-lot expiration dates, utilization, and pricing information relied on by the agreement holder to dispute quarterly invoices, and any other data CMS determines necessary to evaluate compliance with the requirements of the Manufacturer Discount Program.

15. Dispute Resolution (§ 423.2764)

Section 1860D–14C(c)(1)(D) of the Act requires CMS to provide a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, Part D sponsors, and the Secretary. For continuity and familiarity, CMS proposes codifying the dispute resolution processes established in section 100 of the Manufacturer Discount Program Final Guidance.

Specifically, at § 423.2764, we propose a 3-level dispute resolution framework through which agreement holders can dispute applicable discounts that they were invoiced via the invoicing process proposed at § 423.2756(a). Such invoices may contain applicable discounts that an agreement holder believes are incorrect and which the agreement holder wishes to contest.

We propose at § 423.2764(a) that an agreement holder may dispute applicable discounts invoiced to such agreement holder under § 423.2756(a) by filing an initial dispute. This is the

first level of the dispute resolution framework. Under proposed § 423.2764(a)(1), the initial dispute must be filed in the manner specified by CMS no later than the dispute submission deadline, which CMS proposes to define at § 423.2704 as the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the dispute. The disputing manufacturer must explain why it believes the invoiced discount amount is in error and must provide supporting evidence that is material, specific, and related to the dispute. We propose at § 423.2764(a)(2) that CMS will issue a written determination on an initial dispute no later than 60 calendar days from the dispute submission deadline.

We propose at § 423.2764(b) that an agreement holder that receives an unfavorable determination from CMS on its initial dispute, or that has not received a determination within 60 calendar days of the dispute submission deadline, may request review by the independent review entity (IRE) contracted by CMS. Such independent review is considered the second level of the dispute resolution framework.

We propose at § 423.2764(b)(1) that an agreement holder must file a request for review by the IRE in the manner specified by CMS no later than the earlier of 30 calendar days from the date of the unfavorable determination on the initial dispute, or 90 calendar days from the dispute submission deadline if no determination was made within 60 calendar days of the dispute submission deadline.

We propose at § 423.2764(b)(2) that the IRE may seek additional information from any agreement holder that requests an independent review, for the purpose of considering the appeal. An agreement holder's failure to comply with an information request from the IRE within the timeframe specified could result in the IRE issuing a denial. In addition to the information provided by the agreement holder, the IRE will base its decision on information received by CMS, the TPA, the Part D sponsor, and other databases compiled by CMS or other sources.

We propose at § 423.2764(b)(3) that the IRE will issue a written notice of decision to the agreement holder and to CMS no later than 90 calendar days from receipt of the request. Under proposed § 423.2764(b)(4), the notice must include a clear statement indicating whether the decision is favorable or unfavorable to the agreement holder; an explanation of the rationale for the IRE's decision; and instructions on how to request a review by the CMS Administrator. Under proposed § 423.2764(b)(5), a decision by the IRE is binding on all parties unless the agreement holder or CMS files a valid request for review by the CMS Administrator.

At § 423.2764(c)(1), we propose as the third level of the dispute resolution process that an agreement holder or CMS may request review by the CMS Administrator following receipt of an unfavorable determination from the IRE. Under proposed § 423.2764(c)(2), such request must be filed in the manner specified by CMS, no later than 30 calendar days from the date of the IRE decision. After completing the review and making a decision, under proposed § 423.2764(c)(3), the CMS Administrator will issue written notice of their decision to both parties. Such decision by the CMS Administrator is final and binding under proposed § 423.2764(c)(4). CMS proposes at § 423.2764(d) that it will adjust future invoices, or implement an alternative reimbursement process if determined necessary, if a dispute is resolved in favor of the agreement holder. As discussed earlier in this preamble at II.C.13.b., CMS proposes at § 423.2756(b)(3) that agreement holders cannot withhold payment for any disputed invoiced amount, including while a dispute is pending, except as specified at § 423.2756(b)(3).

Under proposed § 423.2764(e) agreement holders cannot use this dispute resolution process to dispute a decision by CMS to terminate an agreement holder's participation in the Manufacturer Discount Program under § 423.2752(c)(1) or a decision by CMS about a manufacturer's eligibility for discount phase-ins described at § 423.2720. As described earlier in this section of the preamble, the dispute resolution process must be used specifically for the purpose of resolving disputes regarding applicable discounts invoiced to agreement holders under § 423.2756(a).

Under section 100.2 of the Manufacturer Discount Program Final Guidance, CMS does not permit Part D sponsors to dispute invoiced amounts under the Manufacturer Discount Program. Section 423.505(f) requires sponsors to submit information to CMS that is necessary for CMS to administer and evaluate the Part D program, which includes information relevant to disputes under the Manufacturer Discount Program. CMS relies on the information received in PDE data submitted by sponsors when applicable discounts are advanced at the point of sale for calculating quarterly invoices for agreement holders. Because sponsors provide the data CMS uses to calculate invoices for agreement holders, sponsors do not have the right to directly dispute invoiced amounts under the processes described in this section. Part D sponsors should note that a determination about a dispute at any level of the dispute resolution process described in this section also cannot be appealed directly by a sponsor. However, as part of the adjudication process for manufacturer disputes, sponsors will have an opportunity to confirm the accuracy of a disputed discount, when applicable.

Regarding beneficiary disputes, the IRA does not require a dispute resolution mechanism for Part D enrollees with respect to the Manufacturer Discount Program and, as a practical matter, an individual would likely not be aware if a discount is provided on their claim, because in most cases, the Manufacturer Discount Program will not affect enrollee cost sharing, and consistent with section 1860D–14C(g)(4) of the Act, applicable discounts are not counted toward an enrollee's incurred costs. Nevertheless, any Part D enrollee who has a dispute about their plan's decision not to provide or pay for a Part D drug, including a dispute about whether a drug is excluded from Part D or about the amount of cost sharing, has the right to request a coverage determination from the plan and the right to appeal any coverage determination not fully favorable to the enrollee under the procedures specified in subpart M of part 423.

16. Civil Money Penalties (§§ 423.1000, 423.1002 and 423.2768)

Section 1860D–14C(e) of the Act requires that a manufacturer that fails to provide, in accordance with the terms of its Manufacturer Discount Program agreement and the requirements of the Manufacturer Discount Program, applicable discounts for applicable drugs covered by the manufacturer's Manufacturer Discount Program agreement and dispensed to applicable beneficiaries is subject to a civil money penalty (CMP) for each such failure. CMS proposes codifying this general rule at § 423.2768(a), in alignment with processes established in section 120 of the Manufacturer Discount Program Final Guidance.

Under proposed § 423.2756(b)(1), agreement holders must pay invoiced amounts to relevant Part D sponsors within 38 calendar days of receipt of a TPA invoice. CMS considers an agreement holder to have failed to provide applicable discounts if payment is not made within 38 calendar days,

with limited exceptions as proposed at § 423.2756(b)(2) and (b)(3). It is imperative that agreement holders make timely payments under the Manufacturer Discount Program, and an agreement holder's failure to establish sufficient controls to ensure compliance with this requirement will not relieve the agreement holder of penalties imposed under section 1860D–14C(e)(1) of the Act.

We propose at § 423.2768(b) that CMS will issue a notice of non-compliance to an agreement holder that fails to make a timely payment as required under § 423.2756(b). We propose allowing the agreement holder 5 business days to respond to the notice of non-compliance with additional context, evidence refuting the violation, or other factors that CMS may consider when determining whether to impose a CMP.

Consistent with section 1860D–14C(e)(1) of the Act, we propose at § 423.2768(c) that a CMP will be equal to the sum of the amount the agreement holder would have paid with respect to the applicable discount, plus 25 percent of such amount. In situations where an agreement holder pays an invoice in part, but not in full, within the required timeframe, any CMP imposed by CMS would be based only on the outstanding invoiced amount that was not paid within the required timeframe. Additionally, while the amount of a CMP may be reduced by any invoiced amount the agreement holder pays after the 38-day timeframe, such late payments will not relieve the agreement holder of its obligation to pay the additional 25 percent penalty, which will be assessed on all invoiced amounts not paid within the required timeframe, as proposed at § 423.2756(b).

We propose at § 423.2768(d) that, if after issuing a notice of non-compliance CMS makes a determination to impose a CMP on an agreement holder, CMS will send to such agreement holder a written notice of the determination to impose a CMP. Under our proposal, CMS would include the following 6 elements in the notice: a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the agreement holder's right to a hearing according to the administrative appeal process and procedures established in 42 CFR part 423, subpart T, and information about where to file the request for a hearing.

To ensure a consistent approach to CMPs, we propose at § 423.2768(e) applying existing appeal procedures for CMPs in 42 CFR part 423, subpart T to agreement holders appealing a CMP imposed under the Manufacturer Discount Program. CMS has utilized this appeal process for many years for CMP determinations affecting MA organizations and Part D sponsors, including with respect to the Manufacturer Discount Program under the Manufacturer Discount Program Final Guidance. CMS therefore proposes to amend regulations in 42 CFR part 423, subpart T by replacing paragraph § 423.1000(a)(3), with new paragraphs (a)(3)(i) and (a)(3)(ii). Our proposed revisions would specify that CMS must impose a CMP on a manufacturer that fails to provide applicable discounts for applicable drugs of the manufacturer pursuant to both the terms of such manufacturer's Coverage Gap Discount Program agreement and such manufacturer's Manufacturer Discount Program agreement.

We also propose to amend the definition of ''affected party'' at § 423.1002 to conform to other regulatory changes proposed in this rule. Currently ''affected party'' is defined, in part, to include a ''any manufacturer (as defined in § 423.2305)''. As discussed in section II.C.3. of this preamble, however, we are proposing to revise and move the definition of ''manufacturer'' from § 423.2305 to § 423.100. As such, we propose to revise the definition of ''affected party'' to refer to ''for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100)''. For purposes of the Manufacturer Discount Agreement, the appeal procedures in 42 CFR part 423, subpart T could apply only to a manufacturer that is an ''agreement holder'' since an ''agreement holder,'' as defined at proposed § 423.2704, is a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1). As such, we further propose to revise the definition of ''affected party'' at § 423.1002 to specify ''for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704)''.

Section 1128A(c)(2) of the Act specifically requires that CMS not collect a CMP until the affected party has received written notice and been given an opportunity for a hearing. Accordingly, we propose to codify at § 423.2768(f)(1) that CMS may not collect a CMP until the affected party (as defined at § 423.1002) has received notice and the opportunity for a hearing under section 1128A(c)(2) of the Act.

We propose to codify timing requirements for collecting CMPs that are assessed under the Manufacturer Discount Program in alignment with section 120.3 of the Manufacturer Discount Program Final Guidance and with existing CMP appeal procedures codified in 42 CFR part 423, subpart T. Specifically, we propose at § 423.2768(f)(2) that an agreement holder that has received from CMS a notice of determination to impose a CMP must pay such CMP in full within 60 calendar days of the date of the CMS notice of determination, except as provided in § 423.2768(f)(3). At § 423.2768(f)(3), we propose that if the agreement holder requests a hearing to appeal in accordance with 42 CFR part 423, subpart T, the CMP is due, as applicable, once the administrative process specified in subpart T has concluded. We further propose at § 423.2768(f)(4) that CMS will initiate the collection of a CMP owed by an agreement holder either following the expiration of 60 days from the date of the CMS notice of determination to impose a CMP, or, if later, the conclusion of the administrative process specified in 42 CFR part 423, subpart T, as applicable.

Section 1860D–14C(e)(2) of the Act makes the provisions of section 1128A of the Act (except for subsections (a) and (b) of section 1128A of the Act) applicable to CMPs imposed under the Manufacturer Discount Program. We propose to codify this requirement at § 423.2768(g).

At § 423.2768(h), we propose that, in the event an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and, as a result of such bankruptcy, fails to pay the total sum of the CMPs imposed, the government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any CMPs imposed by CMS under these proposed regulations.

17. Severability

The Manufacturer Discount Program 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.

D. Definition of Creditable Coverage

Section 1860D–13(b) of the Act contains provisions related to late enrollment penalties (LEPs), which are

increases in monthly beneficiary premiums for individuals without creditable coverage for a continuous period of Part D eligibility of 63 days or longer prior to Part D enrollment. Per section 1860D–13(b)(5) of the Act, coverage meets the creditable coverage requirement ''only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage.''

The allowable methodologies used to determine creditable coverage have been updated a few times since the start of the Part D program, including most recently for CY 2025 and CY 2026 in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions.[31] Under changes to Part D made by the IRA, the definition of creditable prescription drug coverage at § 423.56(a) was modified in these Program Instructions. Prior to the Final CY 2025 Part D Redesign Program Instructions, § 423.56(a) specified that prescription drug coverage would be considered creditable ''only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.'' We now describe historical changes to the creditable coverage definition and allowable methodologies in greater detail.

Since the start of the Part D program in 2006, CMS, consistent with section 1860D–13 of the Act, has permitted an entity offering a group health plan that is not applying for the retiree drug subsidy (RDS) under section 1860D–22(a) of the Act[32] to use either actuarial equivalence testing or the creditable coverage ''simplified determination methodology'' to determine whether its prescription drug coverage is creditable. Some group health plans would undertake considerable workloads in conducting in-house actuarial testing, while others would use the simplified approach presented in the ''Updated Creditable Coverage Guidance,'' which we released on September 18, 2009. Under the simplified approach, coverage would be considered creditable if it:

- Provides coverage for brand and generic prescriptions;
- Provides reasonable access to retail providers;
- The plan is designed to pay on average at least 60 percent of participants' prescription drug expenses; and
- Satisfies at least one of the following:

++ The prescription drug coverage has no annual benefit maximum or a maximum annual benefit payable by the plan of at least $25,000, or

++ The prescription drug coverage has an actuarial expectation that the amount payable by the plan will be at least $2,000 annually per Medicare eligible individual.

++ For entities that have integrated health coverage, the integrated health plan has no more than a $250 deductible per year, has no annual benefit maximum, or a maximum annual benefit payable by the plan of at least $25,000, and has no less than a $1,000,000 lifetime combined benefit maximum.

The IRA eliminated the coverage gap phase and sunset the Coverage Gap Discount Program (CGDP) effective December 31, 2024. The Medicare Part D Manufacturer Discount Program (Manufacturer Discount Program) replaced the CGDP beginning January 1, 2025. The IRA revised section 1860D–22(a)(2)(A) of the Act to specify that any discount provided pursuant to the Manufacturer Discount Program established by the IRA under section 1860D–14C of the Act is not taken into account when determining the actuarial value of qualified retiree coverage. Additionally, section 1860D–14C(g)(1)(B) of the Act excludes enrollees in a qualified retiree prescription drug plan from the definition of applicable beneficiary for the purposes of the Manufacturer Discount Program. The changes made by the IRA required us to revise the existing regulatory definition of creditable prescription drug coverage in § 423.56(a). Under the requirement in section 11201(f) of the IRA that we use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025 and 2026, we issued a revised regulatory definition of creditable prescription drug coverage in § 423.56(a) in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions. In 2025 and 2026, the definition of creditable coverage reads as follows (bolded and italicized text indicates the language we added in light of the IRA):

Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount ***provided under section 1860D–14C of the Social Security Act,*** and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

In the Draft CY 2025 Part D Redesign Program Instructions, we proposed that because of the IRA changes to the Part D benefit, the simplified determination methodology would no longer be a valid methodology to determine whether such an entity's prescription drug coverage is creditable as of 2025. For instance, the increased plan liability in the catastrophic phase of the defined standard benefit requires sponsors to pay more than the 60 percent specified in the current simplified determination methodology and, therefore, continuing to use 60 percent would not satisfy requirements for actuarial equivalence for creditable coverage. We received several comments on the Draft CY 2025 Part D Redesign Program Instructions that raised concerns about the potential risk that a large number of Part D eligible individuals would no longer have creditable coverage through their group health plan if the existing simplified determination methodology were no longer available for 2025. Commenters were also concerned that group health plan sponsors would not have sufficient time to consider the impact of the Part D benefit changes made by the IRA to make decisions about their benefit offerings in time for 2025 coverage.

In response to those comments, in the Final CY 2025 Part D Redesign Program Instructions we recognized the IRA's sweeping changes to the Part D benefit in CY 2025, which, if coupled with the retirement of the creditable simplified

[31] Draft CY 2025 Part D Redesign Program Instructions available at *https://www.cms.gov/files/document/draft-cy-2025-part-d-redesign-program-instruction.pdf.*

Final CY 2025 Part D Redesign Program Instructions available at *https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.*

Draft CY 2026 Part D Redesign Program Instructions available at *https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.*

Final CY 2026 Part D Redesign Program Instructions available at *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf.*

[32] The attestation of actuarial equivalence requirements for qualified retiree prescription drug plans (also known as plans receiving the Retiree Drug Subsidy) are set forth in section 1860D–22 of the Act and codified in § 423.884.

determination methodology, could pose various challenges for group health plan sponsors and could have an adverse effect on certain Part D eligible individuals who could lose creditable coverage and be at risk for the Part D LEP. After consideration of the comments received and available options to mitigate potential disruptive effects of the Part D redesign on the group health plan market and the Part D eligible individuals served by such group health plans, we decided to continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for group health plan sponsors not applying for the RDS. By permitting continued use of the creditable coverage simplified determination methodology for 2025, we stated we would have additional time to better assess the various impacts of the Part D redesign and evaluate modifications to this methodology to ensure Part D eligible individuals with creditable coverage continue to have prescription drug coverage that is at least as good as defined standard Part D coverage. We committed to re-evaluating the continued use of the existing simplified determination methodology, or establish a revised one, for 2026.

For 2026, the Final CY 2026 Part D Redesign Program Instructions adopted a revised simplified determination methodology for non-RDS group health plans to determine whether their prescription drug coverage is creditable. Under the revised simplified determination methodology, coverage is deemed to provide prescription drug coverage with an actuarial value that equals or exceeds the actuarial value of defined standard Part D coverage if it meets all of the following standards:

- Provides reasonable coverage for brand name and generic prescription drugs and biological products;
- Provides reasonable access to retail pharmacies; and
- Is designed to pay on average at least 72 percent of participants' prescription drug expenses.

The revised simplified determination methodology retained some parameters of the prior methodology, such as a requirement for reasonable coverage of brand and generic prescription drugs and reasonable retail pharmacy access. We added coverage of biological products due to changes in the prescription drug landscape since the prior methodology was developed and made other updates for accuracy. We removed the requirements related to annual and lifetime benefit maximums because changes to the health insurance landscape under the Affordable Care Act have essentially eliminated such limitations among group health plans. We also removed requirements related to an annual deductible, because outside of the Medicare program it is unusual for health and drug coverage to be separate benefits, and integrated health and drug plans could have a significantly higher deductible than standard Part D coverage but still offer comparable drug coverage. Although plans with higher annual deductibles (including high deductible health plans) might have appeared less likely to meet the requirement to pay at least 72 percent of prescription drug expenses, such risk may be mitigated through other aspects of the benefit such as not applying a deductible to preventive (that is, maintenance) medications, a reasonable and supportable allocation of the deductible attributable to prescription drug expenses, or offering lower cost sharing than standard Part D coverage once the deductible is met.

Under the revised simplified methodology for 2026, the group health plan coverage must be designed to pay at least 72 percent of participants' prescription drug expenses, versus 60 percent under the prior methodology. We made this revision because of program changes in Part D—in particular, the benefit changes mandated by the IRA, which significantly enhanced the Part D defined standard benefit. These changes—which included a $35 cost sharing cap on a month's supply of each covered insulin product, access to recommended adult vaccines without cost sharing, the implementation of an annual out-of-pocket threshold ($2,100 for CY 2026), and the elimination of the coverage gap phase of the benefit—increased the proportion of drug costs paid by the Part D plan sponsor. In light of the more robust Part D benefit under the IRA, we determined that the 60 percent value was no longer an accurate representation of the value of the Part D benefit and that group health plan coverage for 2026 should be designed to pay on average at least 72 percent of participants' prescription drug expenses in order to provide coverage to the individual that equals or exceeds the actuarial value of standard Part D coverage, as required by section 1860D–13(b)(5) of the Act. We estimated the actuarial value of the defined standard benefit in 2026 using 2023 Part D claims experience under the projected 2026 benefit structure. The 2026 benefit parameters were deflated to a 2023 dollar basis. We estimated that the actuarial value increased to 72 percent, primarily as a result of the changes made by the IRA to the Part D defined standard benefit.

The Draft CY 2026 Part D Redesign Program Instructions stated that non-RDS group health plans could make the determination of creditable coverage either by (1) determining whether the actuarial value of the coverage equals or exceeds the actuarial value of defined standard Part D coverage, demonstrated through generally accepted actuarial principles, or (2) using the revised simplified determination methodology described previously. In response to comments received requesting a phased in approach to this change, in the Final CY 2026 Part D Redesign Program Instructions, we decided to allow for a transition year whereby non-RDS group health plans that opted to make the determination of creditable coverage through the simplified determination methodology were permitted for 2026 to use either the 2009 simplified determination methodology (that is, among other requirements, at least 60 percent of prescription drug expenses) or the revised simplified determination methodology (that is, among other requirements, at least 72 percent of prescription drug expenses) to determine whether their prescription drug coverage is creditable. We determined that this transitional policy for CY 2026 was appropriate to minimize potential risks to the employer group market and to Part D eligible individuals who may no longer have access to creditable coverage through an employer plan. In the Final CY 2026 Part D Redesign Program Instructions, we also stated our intention to propose to no longer permit use of the 2009 simplified determination methodology for CY 2027.

As the IRA's directive to implement the Part D redesign by program instruction or other forms of program guidance expires in 2027, we propose codifying in § 423.56(a) the revised definition of creditable coverage in the Final CY 2026 Part D Redesign Program Instructions to account for the Manufacturer Discount Program. We also propose to amend § 423.56(a) to sunset use of the 2009 simplified determination methodology and codify the revised simplified determination methodology, starting with 2027. In § 423.56(a), we propose to require that non-RDS group health plans may either use actuarial equivalence testing under § 423.56(a)(1) or the revised simplified determination methodology under § 423.56(a)(2) and in place for CY 2026, with one modification from 72 to 73 percent of prescription drug costs the

non-RDS group health plan must cover compared with coverage under a Part D defined standard plan.

To determine the percent of prescription drug costs that must be covered to be creditable, our modeling is based on the prescription drug event (PDE) data for a recent year. We modify the claims line by line to adjust for benefit differences while maintaining actual utilization patterns. For the purposes of determining what the simplified determination value should be for a given future year, we readjudicate all claims as they would have been paid under the defined standard benefit design for the year we are projecting. This process also requires estimating the benefit parameters for the year of interest and deflating the values to align with the historical PDE experience year we are using in our projection. After the PDE records are adjusted to the benefit design of the future year, we aggregate the results to determine the average percentage of gross drug cost that would be covered by a defined standard plan. We use this value rounded to the nearest whole percentage point as the minimum percent of participants' prescription drug expenses that the non-RDS health plan benefit needs to be designed to pay in order to qualify as creditable coverage.

As discussed and consistent with the methodology described previously in this section, we estimated the actuarial value of the defined standard benefit for 2026 using 2023 Part D claims experience under the projected 2026 benefit levels deflated to a 2023 dollar basis to arrive at the requirement that a non-RDS health plan's benefit must be designed to pay on average 72 percent of participants' prescription drug expenses to meet the conditions of the revised simplified determination methodology. For 2027, this model estimates an actuarial value of 73 percent for the defined standard benefit. In subsequent years, this value is projected to increase, ultimately reaching 75 percent in 2030 and stabilize thereafter. Accordingly, we propose a minimum of 73 percent instead of 72 percent for 2027. We further propose that we will update this figure for future years in a time and manner as we determine, consistent with the actuarial equivalence requirements in section 1860D–13(b)(5) of the Act and the methodology described earlier in this section, via subregulatory guidance, such as a memo issued by the Health Plan Management System (HPMS). We would release this guidance in advance of the yearly bid submission deadline for plan sponsors to take into account as they prepare their bids.

As described previously, the proposed changes to § 423.56 retire the simplified approach presented in the ''Updated Creditable Coverage Guidance'' that we released on September 18, 2009, and generally proposes to codify the options available to plans in the Final CY 2026 Part D Redesign Program Instructions: choosing between conducting actuarial equivalence testing themselves or the revised simplified determination methodology. Non-RDS plans using either approach in the proposed § 423.56(a) can attest to the creditable coverage of their plan offerings, thereby ensuring individuals in creditable non-RDS plans will not owe an LEP upon enrollment in a Part D plan. The proposed § 423.56 requirements have mostly been previously implemented and our proposal in this rulemaking is similar to the ways plans assessed creditable coverage in 2026. We do not believe that the proposed changes to the regulatory text would have a significant impact on plan sponsors or individuals. There is no change to paperwork burden to plans or individuals.

E. Outlier Prescriber Criteria

1. Background

Section 6065 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) added subparagraph (D) to section 1860D–4(c)(4) of the Act, which requires the Secretary to identify Part D outlier prescribers of opioids, using the valid prescriber National Provider Identifier (NPI) included on claims for covered part D drugs, and notify those prescribers that they have been identified as outliers. The notifications provided to prescribers identified as outliers include information on how the prescriber compares to other prescribers within the same specialty and geographic area, as well as resources on proper prescribing methods.

The Secretary is required to establish thresholds for identifying whether a prescriber is an outlier based on prescribers in the same specialty and geographic area, with certain exclusions. We currently define outlier prescribers as those in the top 25th percentile when compared to their peers (that is, prescribers in the same National Plan & Provider Enumeration System (NPPES) taxonomy and State) for both (1) co-prescribing opioids and benzodiazepines, and (2) the average daily morphine milligram equivalent (MME) prescribed to those patients. Exclusions to this methodology include (1) beneficiaries who have cancer or sickle cell disease diagnosis, are enrolled in hospice, or reside in a long-term care facility; and (2) providers subject to a current CMS or HHS Office of Inspector General (''HHS–OIG'') investigation. Over time, should the opioid crisis continue to evolve and CDC practice guidelines change, we will make further adjustments to the methodology, as appropriate, to ensure beneficiary safety, as well as alignment with clinical standards and regulatory requirements that govern the Medicare Part D program. Our current outlier prescriber methodology is available on the CMS website (*https://www.cms.gov/files/document/methodology-comparison.pdf*), and any future updates to the methodology will be made at this website location.

Section 6065 of the SUPPORT Act also established additional requirements for outlier prescribers that are identified by us as ''persistent'' at section 1860D–4(c)(4)(D)(v) of the Act, although it does not provide criteria or thresholds to determine persistently identified outlier prescribers of opioids. First, we may require a persistent outlier to enroll in the Medicare program but only after other appropriate remedies have been provided, such as receiving technical assistance on best practices related to prescribing opioid and non-opioid pain management therapies through entities funded through section 6052 of the SUPPORT Act. Second, we are required to communicate information on such prescribers to Part D plan sponsors no less frequently than annually. Considering the significant implications of being identified as an outlier prescriber of opioids, including a persistent outlier, we believe it prudent to clearly outline the key criteria for such a designation in regulation.

2. Proposed Provisions

First, to reflect the requirements surrounding the Secretary's identification of an outlier prescriber of opioids under section 1860D–4(c)(4)(D)(ii) of the Act, we propose to define an outlier prescriber of opioids as a statistical outlier when compared to their peers based on NPPES taxonomy and state. Second, given the potential impact(s) of being identified as a persistent outlier prescriber of opioids (for example, the potential for becoming a lead for a Part D plan sponsor investigation), we are proposing and seeking public comment on what criteria should apply for designation as a persistent outlier prescriber of opioids. We propose to establish a threshold to identify persistent outlier prescribers of

opioids as those outlier prescribers who receive three consecutive outlier prescriber notifications from CMS based on the same methodology. If there is an update to the methodology, only prescribers that have been identified three times by the same methodology would be considered ''persistent.'' We seek comments on this threshold.

Specifically, we propose to add a paragraph (f) under § 423.504:

• (f) Outlier Prescribers of Opioids.

++ CMS will identify and send notifications to outlier prescribers of opioids, which includes information about how the prescriber compares to other specified prescribers and resources on proper prescribing methods.

++ At least annually, CMS will communicate information about persistent outlier prescribers of opioids to all Part D plan sponsors.

We also propose to add the following definitions under § 423.4:

Outlier prescriber of opioids means a prescriber who is a statistical outlier compared to their peers in a specialty and geographic area.

Specialty means the National Plan and Provider Enumeration System (NPPES) taxonomy of a prescriber.

Geographic area means the State in which a prescriber is practicing.

Persistent outlier prescriber of opioids means an outlier prescriber identified by CMS in three consecutive outlier prescriber notifications.

F. Reopening and Payment Appeals

The Inflation Reduction Act of 2022 (Pub. L. 117–169) made several amendments to Part D of Title XVIII of the Social Security Act (the Act), including adding section 1860D–14C of the Act, which describes the Manufacturer Discount Program; section 1860D–14D of the Act, which describes the Selected Drug Subsidy Program; and section 1860D–15(h) of the Act, which describes the temporary retrospective subsidy for the reduction in cost-sharing and deductible for adult vaccines recommended by the advisory committee on immunization practices (ACIP) and insulin. The temporary retrospective subsidy for ACIP-recommended adult vaccines and insulin was limited to contract year 2023 and is hereinafter referred to as the Inflation Reduction Act Subsidy Amount (IRASA).

In subregulatory guidance, we described the reconciliation and payment determination processes for the Manufacturer Discount Program, selected drug subsidy, and IRASA.[33] For the Manufacturer Discount Program and the selected drug subsidy, we make monthly prospective payments for estimated costs submitted with bids, then make final payments based on the a plan's actual costs after a coverage year after obtaining all of the information necessary to determine the amount of payment through cost-based reconciliations.

IRASA is the difference between the beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan's 2023 benefit design and the applicable statutory maximum cost-sharing ($35 for each covered insulin product and $0 for ACIP-recommended adult vaccines). The difference was reimbursed by Medicare during the 2023 Part D payment reconciliation. We propose to amend § 423.308 to add the definition of Inflation Reduction Act Subsidy Amount (IRASA).

We propose that the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and IRASA reconciliation payment determinations would be payment determinations that may be reopened by CMS under § 423.346 and would also be appealable by the Part D sponsors under § 423.350. Therefore, we propose to update the existing regulation concerning the reopening of final payment determinations and the existing payment appeals regulation by adding the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and IRASA reconciliation payment determinations. We also propose to amend the time for filing a payment appeal under the existing payment appeals provision.

1. Definition of Inflation Reduction Act Subsidy Amount (IRASA)

Section 1860D–2(b)(9) of the Act imposes a $35 monthly limit on cost sharing for a month's supply of each covered insulin product throughout all phases of the Part D benefit for CYs 2023, 2024, and 2025. For CY 2026 and each subsequent year, this limit is the lesser of: (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 title XI of the Act; or (3) an amount equal to 25 percent of the negotiated price, as defined in § 423.100, of the covered insulin product under the Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MA–PD) plan. Section 1860D–2(b)(8) of the Act requires the elimination of beneficiary cost sharing for ACIP-recommended adult vaccines that are administered in accordance with the ACIP recommendation (hereafter referred to as ''ACIP-recommended adult vaccines'') under a Part D plan throughout the entire Part D benefit beginning January 1, 2023. Section 1860D–15(h) of the Act requires that a temporary retrospective subsidy be paid to Part D plans for the reduction in cost sharing and the elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products during the 2023 plan year—the Inflation Reduction Act Subsidy Amount (IRASA).

We propose to amend § 423.308 to add the definition of Inflation Reduction Act Subsidy Amount (IRASA). Under our proposed rule, Inflation Reduction Act Subsidy Amount (IRASA) would mean a temporary retrospective subsidy paid to Part D plan sponsors for contract year 2023 for the statutory reduction in cost-sharing and deductible for covered insulin products or for advisory committee on immunization practices (ACIP)-recommended adult vaccines administered in accordance with the ACIP recommendation and is equal to the difference between the following: (1) The beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan's approved bid submitted under § 423.265 for contract year 2023, and (2) the applicable statutory maximum cost-sharing for the covered insulin product or for the ACIP-recommended adult vaccine for contract year 2023.

2. Reopenings

Under the authority under section 1860D–15(f)(1)(B) of the Act, the Secretary has the right to inspect and audit any books and records of a Part D sponsor or MA organization that pertain to the information regarding costs provided to the Secretary. We stated in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit,'' which appeared in the January 28, 2005 **Federal Register** (70 FR 4194, 4316), that this right to inspect and audit would not be meaningful, if upon finding mistakes under such audits, the Secretary was not able to reopen final payment determinations. Therefore, we

[33] See the HPMS memorandum, *Revised Medicare Part D Manufacturer Discount Program Final Guidance,* December 20, 2024 (available at *https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf*); Final CY 2026 Part D Redesign Program Instructions (available at *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf*); and HPMS memorandum, *PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023,* September 26, 2022 (available *https://www.cms.gov/files/document/2023-pde-reporting-instructions.pdf*).

established the reopening provision at § 423.346, which allows CMS, at its discretion, to reopen and revise initial or reconsidered specified payment determinations. Paragraph (a) of § 423.346 lists the payment determinations that we may reopen and revise. These payment determinations include the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low-income subsidy described in § 423.329(d), and final risk corridor payments as described in § 423.336. In our final rule, ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' which appeared in the February 12, 2015 **Federal Register** (80 FR 7912, 7936), we added the Coverage Gap Discount Program reconciliation payment to the list of payment determinations that we may reopen and revise.

We propose to amend § 423.346(a) to add the Manufacturer Discount Program reconciliation payment determination, the selected drug subsidy reconciliation payment determination, and the IRASA reconciliation payment determination to the list of payment determinations that we may reopen and revise. Under our proposal, these payment determinations would be subject to reopening consistent with the current reopening guidelines described at § 423.346, which are explained in detail in our final rule, ''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),'' which appeared in the April 23, 2024 **Federal Register** (89 FR 30448, 30460) (hereinafter referred to as the Contract Year 2025 Final Rule).

Under our proposal, the selected drug subsidy reconciliation payment determination and the IRASA reconciliation payment determination would be included in scheduled global reopenings and could be included in targeted reopenings, which are defined at § 423.308 (definition of *Reopening*). However, similar to the Coverage Gap Discount Program reconciliation payment determination, we anticipate that we would rarely reopen the Manufacturer Discount Program reconciliation payment determination. This is because Manufacturer Discount Program invoicing continues after the Manufacturer Discount Program reconciliation, and sponsors receive payments from the pharmaceutical manufacturers for a total of 17 quarters.[34] Under our proposal and similar to current guidance in the CY 2025 Final Rule, we would also be able to reopen and revise the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and the IRASA reconciliation payment determinations, as necessary, to correct certain issues such as a CMS-identified problem with an internal CMS file that we used in a payment reconciliation.

3. Payment Appeals

Section 1860D–15(d)(1) of the Act gives the Secretary broad authority to develop payment methodologies for payments described in section 1860D–15 of the Act, and we use this broad authority to establish a payment appeals process. Accordingly, in our final rule, ''Medicare Program; Medicare Prescription Drug Benefit,'' which appeared in the January 28, 2005 **Federal Register** (70 FR 4194, 4316), we added § 423.350 to establish a payment appeals process for the reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b); the reconciled reinsurance payments under § 423.343(c); the reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); and the final risk-sharing payments made under § 423.336. In our final rule, ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' which appeared in the February 12, 2015 **Federal Register** (80 FR 7912, 7938), we added the reconciled Coverage Gap Discount Program payment to the list of payment determinations that could be appealed under § 423.350.

We propose to amend § 423.350(a)(1) to add the following payment determinations that would be subject to appeal under § 423.350—the reconciled IRASA payment for contract year 2023, reconciled Manufacturer Discount Program payment, and reconciled selected drug subsidy payment. We note that the IRASA reconciliation payment for contract year 2023 has already been made to Part D sponsors. In subregulatory guidance, we explained that the Part D sponsors could appeal the IRASA reconciliation payment determination.[35] We propose to include the IRASA reconciliation payment determination in the appeals provision for consistency with the proposed updates to § 423.346, under which we would be able to reopen the IRASA reconciliation payment determination. Indeed, we anticipate that we would reopen the IRASA reconciliation during the global reopening of the contract year 2023 Part D payment reconciliation. Under our proposal, the reopened IRASA reconciliation payment determination would be appealable under § 423.350.

The Part D payment appeals process only applies to perceived errors in the application of our payment methodology. The payment information submitted by the Part D sponsor cannot be appealed through this process. Part D sponsors are expected to submit payment information correctly and within the established timeframes. We codified at § 423.350(a)(2) that payment information submitted to us under § 423.322 and reconciled under the various payment provisions is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. We propose to amend the regulation at § 423.350(a)(2) to add language specifying that information that is submitted and reconciled or used in the payment calculations for the Manufacturer Discount Program reconciliation, the selected drug subsidy reconciliation, and the IRASA reconciliation are final and would not be appealable nor would the appeals process be used to submit new information after the submission of information necessary to determine these retroactive adjustments and reconciliations.

We also propose to amend § 423.350(a)(2) to add a reference to § 423.336, which describes the risk corridor payment, to correct an inadvertent omission. The information that is submitted and used in the payment calculations under § 423.336 is final and would not be appealable nor would the appeals process be used to submit new information after the

[34] See the *Medicare Part D Coverage Gap Discount Program (CGDP) and Manufacturer Discount Program (MDP) Calendar,* available at *https://tpadministrator.com/internet/tpaw3_files.nsf/F/TPACGDP_MDP_Calendar_2024-2028_12062024.pdf/$FILE/CGDP_MDP_Calendar_2024-2028_12062024.pdf.*

[35] HPMS memorandum, *Completion of the 2023 Final Part D Payment Reconciliation and the 2023 Inflation Reduction Act Subsidy Amount (IRASA) Reconciliation,* September 27, 2024 (available at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-23-27*).

submission of information necessary to determine that payment determination.

4. Payment Appeals—Time for Filing

Under existing § 423.350(b)(1), the payment appeal (specifically, the request for reconsideration of the payment determination) must be filed within 15 days from the date of the final payment. We propose two amendments to § 423.350(b)(1) to reflect actual practice. First, we propose to amend 15 days to 15 calendar days. Second, we propose that the appeal deadline would be based on the release of the reconciliation reports to the Part D sponsors, as opposed to the date of the final payment. The reconciliation reports that CMS releases to the Part D sponsors are detailed reports that specify the inputs and results of the payment reconciliation at the plan-level. These detailed reports allow plans to understand how their Part D payment reconciliation was calculated by us. Part D sponsors currently appeal their payment determinations based on information in the reconciliation reports. Therefore, we propose to update that the time for filing an appeal would be within 15 calendar days from the date we issue the payment reconciliation report for the payment determination that is being appealed by the Part D sponsor.

The proposals described in this section of the final rule are consistent with our current guidance and requirements. The proposed changes are updates that do not place additional requirements on Part D sponsors, nor do the proposed changes place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs).

Part D sponsors' compliance with this reopening process is evidenced by each Part D sponsor's signed attestation certifying the cost data (under § 423.505(k)(3) and (5)) that we use in each of the reopenings. In addition, the burden associated with the submission of cost data is already approved under the OMB control numbers 0938–0982 (CMS–10174) and 0938–0964 (CMS–10141).

We believe that the payment appeals process at § 423.350 is an administrative action or investigation with respect to a specific party, which is exempt from the COI process. Therefore, as our changes do not result in additional burden, we have not included a discussion of this provision in the COI section of this rule.

We are not scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Revise List of Non-Allowable Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

The ''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 Final Rule'' appeared in the April 15, 2025, **Federal Register** (90 FR 15792), hereafter referred to as the April 2025 final rule. In this rule, CMS codified new regulation language at 42 CFR 422.102(f)(1)(iii)(G) that cannabis products are not allowable Special Supplemental Benefits for the Chronically Ill (SSBCI), as they are illegal substances under federal law.

Section 10113 of the Agriculture Improvement Act of 2018, also known as the 2018 Farm Bill (Pub. L. 115–334,[36]) added a definition of ''hemp'' to the Agricultural Marketing Act of 1946. Under this definition, ''[t]he term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.'' In addition, section 12619 of the 2018 Farm Bill amended the Controlled Substances Act (CSA) to exclude hemp from the CSA's definition of marijuana.[37] The Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026, amends the definition of hemp to exclude any cannabinoids that are not naturally found or produced in the cannabis plant, cannabinoids that are synthesized outside of the plant, and final form products for human use that contain more than 0.4 milligrams per container combined total of naturally occurring tetrahydrocannabinols and other naturally produced cannabinoids determined by the Secretary of Health and Human Services to have the same effect. This amended definition of hemp takes effect on November 12th, 2026. Consequently, hemp and hemp-derived cannabis products that meet the current 2018 definition are not federally controlled substances through November 11th, 2026, and those that meet the amended definition beginning on November 12th, 2026, will remain not federally controlled substances as of that date. If such products comply with all other applicable federal laws, including any future changes to the definition of hemp and applicable provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), then they are not illegal under federal law. To reflect this distinction, CMS proposes amending § 422.102(f)(1)(iii)(G) to state more precisely that cannabis products that are illegal under applicable State or Federal law, including the FFDCA, are not allowable as SSBCI.

Currently, only one product that meets the definition of hemp under the 2018 Farm Bill has been approved as a drug in the United States: the prescription drug Epidiolex. CMS notes that Epidiolex has been approved by the FDA to treat seizures and is covered under Medicare Part D, so it would not be permitted to be offered as a Part C supplemental benefit. In addition, in December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil.[38] FDA had no questions at that time about the notifier's conclusion that the ingredients were GRAS for their intended use in food. An ingredient that meets the GRAS standard can be used in food without being required to undergo premarket review and approval by FDA for that intended use.[39]

Therefore, this proposal would allow MA organizations to offer hulled hemp seed, hemp seed protein powder, and hemp seed oil, consistent with FDA's review of the GRAS notices,—as SSBCI to qualifying enrollees, to the extent otherwise appropriate as SSBCI and under federal and applicable state law. Additionally, at this time, any cannabis product with a delta-9 THC content above the 0.3 percent threshold is still considered marijuana, remains a Schedule I controlled substance, and therefore is illegal under federal law and would be subject to CMS's prohibition. Any product that does not comply with the amended definition of hemp after the November 12th, 2026, effective date will be a Schedule I controlled

[36] Agriculture Improvement Act of 2018, H.R.2, 115th Congress (2018). *https://www.congress.gov/bill/115th-congress/house-bill/2.*

[37] *https://www.congress.gov/crs-product/R44742#:~:text=The%202018%20farm%20bill%20further,regulations%2C%20and%20applicable%20state%20regulations.*

[38] *https://www.fda.gov/food/hfp-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.*

[39] *https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.*

substance as of that date, and therefore will be illegal under federal law [40] and subject to CMS's prohibition.

Section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. There may be situations in which foods containing one or more of these three specific ingredients meet the ''reasonable expectation of improving or maintaining the health or overall function'' standard for SSBCI. For example, there is evidence that hemp seed protein powder may offer nutritional benefits.[41] CMS reminds MA organizations about the importance of ensuring that the items and services provided to enrollees, including any foods containing these specific hemp-derived ingredients, meet the requirements for being offered as an SSBCI. CMS notes that if this proposal is finalized and MA organizations choose to offer any of these three hemp-derived ingredients, they would be subject to all applicable SSBCI requirements under § 422.102(f), including the bibliography requirements for SSBCI items and services set forth at 42 CFR 422.102(f)(3) to demonstrate through relevant acceptable evidence that the item has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.

The proposed amended language also clarifies that MA organizations remain prohibited from covering any cannabis product, including any hemp-derived cannabis product, that is illegal under state law within their service area regardless of the product's federal legal status.

While this proposal would modify existing policy, it is not expected to have an impact on current operating expenses for MA organizations as the proposal would not impose any new burden or collection of information requirements.

CMS seeks comments on all aspects of this proposal and may consider revisions to the final policy based on the comments received.

[40] Under the Controlled Substances Act, Schedule I controlled substances may only be used for research purposes by practitioners who are registered with DEA to conduct such research. 21 U.S.C. 822(b), 823(g)(2).

[41] *https://www.sciencedirect.com/science/article/pii/S221345302200235X.*

IV. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies (Operational Changes)

A. Special Enrollment Period for Provider Terminations (§ 422.62(b)(23))

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 Final Rule (85 FR 33796) we codified at § 422.62(b)(23) the special election period (SEP) for Significant Change in Provider Network. Currently, when CMS determines a change in a plan's provider network to be significant, affected enrollees are eligible for this SEP and may use it to request enrollment in another MA plan or to disenroll to original Medicare from the MA plan that has changed its network. As described in § 422.62(b)(23)(ii), enrollees are ''affected'' by a significant network change and eligible for this SEP when they are assigned to, are currently receiving care from, or have received care within the past three months from a provider or facility being terminated from the MA (or MA–PD) plan's provider network.

Changes to provider networks occur routinely throughout the year; individual clinicians may relocate their practice, retire or expire over the course of the year. For the discussion that follows, we wish to distinguish these routine, smaller scale, changes in provider networks from the more substantial changes, such as a large medical group or hospital system leaving the network. CMS requires that MA organizations notify enrollees of changes in a provider network resulting from the termination—with or without cause—of a contract with a provider organization pursuant to §§ 422.111(e) and 422.2267(e)(12). This notification requirement is separate from, and therefore not impacted by, the question of whether CMS would consider the network change to be significant for purposes of the SEP described in § 422.62(b)(23). Further, it is longstanding CMS policy that MA plan enrollees who believe they may be adversely impacted by a provider termination may contact 1–800–MEDICARE to request an SEP due to exceptional circumstances, such as situations where access to services is compromised and adverse health consequences may result, including interruptions in treatment. CMS reviews the supporting details and documentation for these requests and determines eligibility for an exceptional circumstances SEP on a case-by-case basis.

Historically, the types of provider network changes that have been more likely to convey eligibility for the SEP for Significant Change in Provider Network are those that go beyond individual or limited provider terminations that occur during the routine course of plan operations or have the potential to substantially impact a large number of the MA organization's enrollees, such as terminated relationships with multispecialty group practices or hospital systems. MA organizations notify CMS of any no-cause provider termination that the MA organization deems to be a significant provider termination at least 90 days prior to the effective date. After receiving such notification, CMS implements an internal review process that evaluates the totality of the circumstances around each termination to determine whether the change in provider network is significant. The timeframe for CMS determinations of a significant network change varies depending on the circumstances of each case. If CMS determines that a provider termination represents a significant change in the plan's provider network, the CMS Account Manager for the MA organization notifies the organization of the CMS determination and of the requirement to issue written notification to affected enrollees of their eligibility for an SEP, the start and end dates of the SEP, how to make use of the SEP and also Medigap guaranteed issue (GI) rights in accordance with § 422.62(b)(23)(iii) and Section 1882(s)(3)(D) of the Act. CMS provides model language regarding the SEP and Medigap GI rights for the MA organization to use in its notice to affected enrollees.[42] Currently, the requirement for written notification to enrollees regarding their eligibility for the SEP for Significant Change in Provider Network (§ 422.62(b)(23)(iii)) is separate and distinct from the requirement that MA organizations provide enrollees advance notice of routine provider terminations (§§ 422.111(e) and 422.2267(e)(12)).

Although CMS evaluates cases of possible significant network change carefully and strives to reach a determination as expeditiously as possible, we continue to look for ways to reduce the time it takes to inform beneficiaries of their rights and their enrollment options. Specifically, we are looking to streamline the currently

[42] Medicare Advantage Enrollment and Disenrollment Guidance Appendices and Exhibits.

separate notification requirements for provider terminations and the SEP for Significant Change in Provider Network. Accordingly, we are proposing several enhancements to the current process by which an MA enrollee is provided the option to change plans when one or more of their plan providers are leaving the plan's network.

Specifically, at § 422.62(b)(23) we propose to change the eligibility criteria for the current SEP for Significant Change in Provider Network to reflect that a determination of significant provider network change by CMS or an MA organization is not necessary for an enrollee who is affected by the provider network change to be eligible for the SEP. As noted, it is longstanding CMS policy that MA plan enrollees who believe they may be adversely impacted by any provider termination, significant or otherwise, may contact 1–800–MEDICARE to request an SEP due to exceptional circumstances. We propose to retain the definition of an ''affected enrollee'' as an enrollee who is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated. As is the case for the current SEP for Significant Change in Provider Network, the revised SEP, which we propose to name the SEP for Provider Terminations, would begin the month the individual is notified of eligibility for the SEP and would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP.

While we are not proposing any changes to the provider termination notification timeliness requirements at § 422.111(e), we believe that it is in the best interests of both the MA organization and the enrollee for this SEP information to be included in the provider termination notice for affected enrollees, rather than require the MA organization to issue a separate notice, as is most often the case currently when CMS determines a network change to be significant. Accordingly, at § 422.2267(e)(12)(ii)(D), we are proposing that the following information, currently provided to enrollees affected by a network change determined by CMS to be significant, be included in the provider termination notice.

- Information about the Annual Coordinated Election Period (AEP) and the MA Open Enrollment Period (MA–OEP);
- Notification that the affected enrollee is eligible for a special election period (SEP), as specified in § 422.62(b)(23), including the start and end dates of the SEP;
- Medigap guaranteed issue (GI) rights; and
- A note stating that individuals who have coverage through an employer or union should contact their benefits administrator before leaving their current MA plan to find out how making such a change may affect their employer or union health benefits.

Requirements related to the model MA Provider Termination Notice content are codified at § 422.2267(e)(12); we propose to revise § 422.2267(e)(12)(ii)(D) to require that the information described above be included in the notice.

Consistent with the current SEP for Significant Change in Provider Network, the proposed SEP for Provider Terminations could be used by an affected enrollee only once per provider network change. MA organizations would be able to determine eligibility for the proposed SEP for Provider Terminations based on beneficiary attestations of election period eligibility, such that beneficiaries would not be limited to requesting enrollment via 1–800–MEDICARE. An individual would be able to attest directly to the plan that they were affected by a provider termination.

In the final rule in which we codified the SEP for Significant Change in Provider Network (85 FR 33796) we also codified the SEP to enroll in a PDP for MA enrollees using the SEP provided in CMS's regulations at 42 CFR 422.62(b)(23) to disenroll from an MA plan. We are not proposing any changes to the eligibility criteria for § 423.38(c)(30), meaning that this coordinating Part D SEP, codified at § 423.38(c)(30), will continue to allow MA enrollees to request enrollment in a PDP if and when they use the SEP at § 422.62(b)(23) to disenroll from an MA plan.

CMS data suggests that use of the current SEP for Significant Change in Provider Network by eligible beneficiaries is low. In 2024, of the MA enrollees who were notified that they were eligible for the SEP and could switch to another MA plan or disenroll from MA to original Medicare, approximately 3.6 percent made an election of any type. Thus, our experience shows that when enrollees are affected by a provider termination and notified that they are eligible for a SEP to change plans or switch to Original Medicare, presumably to follow their provider, very few actually use the SEP. This leads us to conclude that other factors, such as formulary, benefits, plan premium, cost sharing, familiarity, and other plan attributes may play a role in the affected enrollee's decision and may result in the enrollee choosing not to leave their current plan.

We anticipate a one-time burden on MA organizations to update their existing written provider termination notice in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii). We conclude that the proposed changes to the regulatory text will not have any impact on the Medicare Trust Funds. All information impacts related to the procedural steps plans must take to determine eligibility for an election period have already been accounted for under OMB control number 0938–0753 (CMS–R–267).

B. Coordination of Election Mechanisms for MA and Part D (§§ 422.62, 422.66, 423.32, 423.36, and 423.38)

Section 1851(c) of the Act provides the Secretary with the authority to establish a process by which MA enrollment elections (hereinafter referred to as ''elections'') are made and changed, including the form and manner in which they are changed. Section 1851(e)(4)(D) of the Act provides the Secretary with the authority to establish Special Election Periods for exceptional conditions, during which individuals may make elections. Section 1860D–1(b)(1)(B) of the Act directs the Secretary to use rules related to enrollment, disenrollment, termination, and change of enrollment for Part D sponsors that are similar to those established for MA plans under specified subsections of section 1851 of the Act. Section 1860D–1(b)(1)(B)(ii) of the Act specifies that the Secretary shall use section 1851(c) of the Act, other than paragraph (3)(A) and paragraph (4) of such section, for Part D rules relating to exercise of choice.

Consistent with these sections of the Act, in 1998, we published a final rule (63 FR 34968) to codify the Part C election process required under section 1851(c) of the Act at § 422.66. In 2005, we published a final rule (70 FR 4194) to codify the Part D election process required under section 1860D–1(b)(1)(B) of the Act at §§ 423.32 and 423.36. The Parts C and D subpart B regulations set forth our requirements with respect to the election process under §§ 422.60 (election process), 422.66 (coordination of enrollment and disenrollment through MA organizations), 423.32 (enrollment process), and 423.36 (disenrollment process).

MA election requests, with few exceptions, are submitted by the individual requesting enrollment in or disenrollment from a particular MA plan. In certain circumstances, namely passive enrollment (a process where

CMS initiates enrollment into another plan in cases of immediate plan terminations, harm to beneficiaries, or for the promotion of integrated care with state Medicaid agency approval) and default enrollment (a process available only for integrated D–SNP enrollments), CMS directly enrolls individuals and transmits an enrollment transaction to the plan, which bypasses the usual process discussed later in this section.

Current Part C regulations at § 422.60(e) specify that MA organizations must have effective systems for receiving, controlling, and processing election requests. After satisfying those requirements and accepting an individual's election request, the MA organization transmits the information necessary for CMS to add the individual to its records as an enrollee of the MA organization. Current Part C regulations at §§ 422.66(a) and (b) specify that elections may be made by filing appropriate election forms with the MA organization or through other mechanisms as determined by CMS. The same process is mirrored in current Part D regulations at §§ 423.32(a) through (d) and 423.36(a) and (b), whereby the Part D sponsor receives an election request from an individual and then submits necessary information to CMS.

Outside of circumstances where CMS directly enrolls an individual into a plan (passive, default enrollment, etc.) most election requests are filed with the MA organization or Part D sponsor, though the election form or mechanism may differ. Election mechanisms are how an individual communicates their election request to the MA organization or Part D sponsor, whether on paper, over the phone, electronically, etc. Even if an individual uses a CMS-operated election mechanism (1–800–MEDICARE or the Online Enrollment Center), the election request is still filed with the plan for processing.

Historically, CMS has regulated the required content of election mechanisms under the ''form and manner'' authority specified at section 1851(c)(1) of the Act and codified at §§ 422.60(c), 422.66(a), 423.32(a), and 423.36(a). Consistent with section 1851(e)(4) of the Act, CMS has required CMS approval for certain election periods. For example, consistent with the provisions in section 1851(e)(4)(C) providing that a SEP may be available where an ''individual demonstrates (in accordance with guidelines established by the Secretary) that . . . the organization offering the plan substantially violated a material provision of the organization's contract under this part in relation to the individual . . . ,'' CMS's current regulations governing the special enrollment period (SEP) for contract violation (§§ 422.62(b)(3) and 423.38(c)(8)) provides that the SEP is available where an individual demonstrates to CMS that specified criteria have been met. This SEP is only available once CMS determines that a contract violation has occurred. An individual alleging a contract violation must call 1–800–MEDICARE to explain their circumstances and demonstrate to CMS that there was a violation. Once eligibility is demonstrated, the individual can elect a new plan or disenroll from their current plan and the election request is subsequently transmitted to the plan to process. The requirement that the individual demonstrate eligibility to CMS has been in place since the SEP was first codified in a 1998 final rule (63 FR 34968, 34980) and the process to demonstrate eligibility to CMS is also described in section 30.6.28 of the Medicare Advantage and Part D Enrollment and Disenrollment Guidance, *see also* MA–PD Plan Communications User Guide, pg. 3–38.

There are other SEPs that are currently only available with prior CMS approval, provided by CMS sending a notice or election request to the MA organization or Part D sponsor. These SEPs are: SEP for individuals who disenroll in connection with CMS sanction (§§ 422.62(b)(5) and 423.38(c)(12)); SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage (§§ 422.62(b)(20) and 423.38(c)(2)); and SEP for other exceptional circumstances (§§ 422.62(b)(27) and 423.38(c)(36)). As described in CMS's Medicare Advantage and Part D Enrollment and Disenrollment Guidance, Section 30.6, in order for CMS to review that appropriate circumstances apply to allow for an SEP based on a CMS sanction, an individual not receiving adequate information about loss of creditable prescription drug coverage, or other exceptional circumstances, plans must have prior approval from CMS to submit enrollment transactions based on these SEPs.

We are proposing to codify our current policy that for elections that are made based on certain special election periods, the beneficiary at issue must either have CMS approval for the use of that SEP through the use of a CMS-operated election mechanism (for example, 1–800–MEDICARE or the Online Enrollment Center (OEC)) or other means, such as enrollee receipt of a notice. We propose this change to codify longstanding guidance and practice requiring CMS approval for certain SEPs. This policy allows for control over election periods and mechanisms to ensure appropriate use and allows us to delineate a clear process for each election. To accomplish this, we would propose to establish at §§ 422.66(g), 423.32(k), and 423.36(g) the requirement that elections may require CMS approval based on the use of specified SEPs. CMS approval would be provided for plan elections either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. As CMS approval would be an eligibility criterion of the SEP, MA organizations and Part D plan sponsors may not transmit elections to CMS using the specified SEPs without prior CMS approval.

Under this proposal, we would codify these limitations for the following SEPs:

- SEP for individuals who disenroll in connection with CMS sanction (§§ 422.62(b)(5) and 423.38(c)(12));
- SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage (§§ 422.62(b)(20) and 423.38(c)(2));
- SEP for contract violation (§§ 422.62(b)(3) and 423.38(c)(8));
- SEP for other exceptional circumstances (§§ 422.62(b)(27) and 423.38(c)(36)).

These limitations would be codified at §§ 422.62(b)(3), (b)(5), (b)(20), (b)(27), and 423.38(c)(2), (c)(8), (c)(12), and (c)(36). Language would be added to each SEP we propose to limit to require CMS approval. The language would indicate that CMS approval is required and reference how CMS approval would be indicated, either through providing a notice or the acceptance of an election through a CMS-operated mechanism. These limitations and applicable SEPs are also described at §§ 422.66(g)(2), 423.32(k)(2), and 423.36(g)(2).

We are proposing to codify these limitations in order to better oversee the use of SEPs which may not be appropriate for plans to use without prior CMS eligibility determination and approval. It would, for example, be inappropriate for an organization to evaluate the claim that another organization violated their contract with an individual, or that the individual was impacted by conduct that was sanctioned by CMS. In those cases, other organizations are not neutral arbiters of eligibility as they have a financial interest in deeming the conduct of other organizations as a contract violation or they lack the complete information about the

circumstances of the sanctioned conduct. The SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage is similarly justified as requiring CMS approval prior to the election request being filed with the plan for processing. The eligibility determination for this SEP also requires evaluation of the conduct of another organization or entity and whether they provided adequate notice of the loss of creditable coverage. We believe these SEP limitations would prevent organizations, who do not have appropriate context, from incorrectly determining eligibility. This is especially true for the SEP for other exceptional circumstances, which covers situations not otherwise captured in the SEPs in regulation. This SEP is determined on a case-by-case basis for circumstances that warrant an enrollment opportunity given the exceptional conditions experienced by the individual. In these types of cases, only CMS can appropriately consider the circumstances of an individual's eligibility.

In order to best facilitate CMS approval prior to the election request being filed with the plan, these SEPs should only be available through a CMS-operated mechanism, to allow the approval for the SEP to be sent to the plan along with the election request for processing. The requirement for certain SEPs to be approved by CMS first, before the election is filed with the plan, does not preclude the involvement of an agent or broker assisting the enrollee. The enrollee can meet with an agent/broker for assistance in selecting the best plan for the enrollee. The enrollee can then use the CMS mechanism, for example, call 1–800–MEDICARE on their own or with the assistance of the agent/broker. 1–800–MEDICARE and the OEC are capable of capturing the involvement of the agent/broker and transmitting that information to the newly selected plan when CMS sends the approved election request.

As the pre-existing limitations have been long-standing, previously implemented and are currently being followed by plan sponsors, we conclude that the proposed changes to the regulatory text will not adversely impact plan sponsors, individuals, or agents/brokers, nor would the proposed changes have any impact on the Medicare Trust Funds or result in a paperwork burden. All information impacts related to the procedural steps plans must take to receive and process election requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

CMS welcomes comments on this proposal as well as comments on how these SEPs can be further improved for beneficiaries.

C. Use and Release of Risk Adjustment Data

Section 1853(a) of the Act requires CMS to risk adjust payments made to Medicare Advantage (MA) organizations. In order to carry out risk adjustment, section 1853(a)(3)(B) of the Act requires MA organizations to submit data regarding inpatient hospital services and data regarding other services and other information the Secretary deems necessary. Risk adjustment data are the data submitted to CMS by MA organizations to carry out risk adjustment, including the development and application of a risk adjustment payment model. Regulations at 42 CFR 422.310 establish requirements regarding the collection and submission of risk adjustment data, as well as the allowable uses of risk adjustment data and conditions under which the data can be released.

The MA program now comprises 51 percent of the Medicare population, and there has been a coinciding increase in the number and variety of requests that CMS receives for risk adjustment data. This increase is due to both the utility of the more detailed risk adjustment data that CMS started collecting in 2012 (that is, encounter data) and growing enrollment in MA. With the increased variety of requests for risk adjustment data and CMS's better understanding of the data requests received, CMS has come to recognize that the limits on the use and release of risk adjustment data imposed by § 422.310(f) may be unnecessary, burdensome, and overly restrictive for CMS, and for private and public stakeholders requesting the data. The existing restrictions may limit innovative uses of the data by CMS and non-CMS entities that may improve program integrity, increase efficiency, or reduce waste. The proposal described later in this section would lead to more efficient use of public and private sector resources by removing the existing restrictions on the use and release of risk adjustment data while maintaining the protections in place for beneficiary identifying information through CMS data sharing procedures and for plan-submitted dollar amounts reported for an associated encounter. CMS believes that easing the use and release requirements for risk adjustment data would support the goals of Executive Order 14243 ''Stopping Waste, Fraud, and Abuse by Eliminating Information Silos'' (March 20, 2025) by reducing barriers to sharing government data across agencies, improve CMS's ability to effectively and efficiently administer and oversee MA and other Federal health care programs, as well as encourage research into improving health care delivery.

1. Background

Section 1853(a) of the Act requires the Secretary to make monthly payments to MA organizations for each beneficiary enrolled in an MA plan. Section 1853(a)(1)(C) of the Act requires the Secretary to adjust the monthly payments based on risk factors of a plan's enrolled beneficiaries, such as demographic factors and other factors that the Secretary determines are appropriate, including health status. To support risk adjustment, section 1853(a)(3)(B) of the Act requires MA organizations to submit data regarding the services provided to enrollees and other information the Secretary deems necessary.

The requirements for the submission of risk adjustment data by MA organizations are set forth at § 422.310. In accordance with these regulations, MA organizations must submit the data necessary to characterize the context and purposes of each item and service provided to their enrollees by a provider, supplier, physician, or other practitioner in accordance with CMS instruction. Paragraphs (a) through (d) of § 422.310 define risk adjustment data, the basic rules of risk adjustment data collection, the sources and extent of risk adjustment data, and other risk adjustment data requirements. There are two forms of risk adjustment data: (1) data equivalent to Medicare fee-for-service (FFS) data, when appropriate, and to all relevant national standards, referred to as encounter data, and (2) data submitted by MA organizations prior to 2022 in an abbreviated format, referred to as Risk Adjustment Processing System (RAPS) data.[43] [44] Both encounter data and RAPS data submissions include beneficiary diagnoses.

Though section 1853(a)(3)(B) of the Act does not limit the Secretary's use or disclosure of risk adjustment data, Federal laws, such as the Privacy Act of 1974 (as amended), impose restrictions on the disclosure of data collected by Federal agencies, and section 1106(a) of the Act [42 U.S.C. 1306(a)] generally

[43] Refer to the CSSC Operations website for information about the submission of encounter data and RAPS data.

[44] RAPS remains available to MA organizations for the submission of data corrections for years prior to 2022.

prohibits the disclosure of any information obtained by HHS except as the Secretary may prescribe by regulations and except as otherwise provided by Federal law. Over time, CMS has regulated the scope of permissible uses and releases of the MA risk adjustment data, including RAPS and encounter data, in order to achieve a balance between protection of beneficiary identifying information and the interests of MA organizations with the need to effectively administer Federal programs and to encourage research into better ways to provide health care. In the final rule establishing the MA program, published in January 2005 (70 FR 4661), CMS adopted regulations at § 422.310(f) such that CMS may use risk adjustment data to determine the risk adjustment factor used to adjust payments, and for unspecified other purposes, with an exception made to limit CMS's use of medical record data collected under § 422.310(e) to validation studies.

In April 2008, CMS proposed to amend § 422.310 to provide that CMS will collect data from MA organizations regarding each item and service provided to an MA plan enrollee,[45] which would allow CMS to include utilization data and other factors in developing CMS-Hierarchical Condition Categories (CMS–HCC) risk adjustment models that reflect patterns of diagnoses and expenditures in the MA program. In response to the April 2008 proposal and CMS's efforts to collect encounter data, some stakeholders raised concerns that the use of risk adjustment data for ''other purposes,'' as finalized in the January 2005 final rule, was too broad. Some stakeholders also believed that the data collected for risk adjustment, including encounter data, could not be used for purposes other than risk adjustment. CMS disagreed with this assertion. As stated in the August 2008 final rule, ''Section 1853(a)(3)(B) of the Act obligates MA organizations to submit inpatient and outpatient encounter data for purposes of use in implementing a risk adjustment methodology. Unlike the case of information collected under section 1860D–15 of the Act, however, which the statute restricts to being used solely for purposes of implementing that section (see section 1860D–15(d)(2)(B) and (f)(2) of the Act), section 1853(a)(3)(B) of the Act does not impose any such restrictions on other legitimate uses of the encounter data collected'' (73 FR 48653). While CMS is not subject to specific statutory restrictions on our own use of risk adjustment data, the agency responded to industry concerns by establishing in regulation limits on the agency's use of risk adjustment data. Specifically, in the August 2008 final rule, CMS revised § 422.310(f) to establish the following five specific uses of risk adjustment data: (i) calculating the risk adjustment factors used to adjust payments, (ii) updating risk adjustment models, (iii) calculating Medicare Disproportionate Share Hospital (DSH) percentages, (iv) conducting quality review and improvement activities, and (v) for Medicare coverage purposes (73 FR 48651, 48653–48654).

CMS made further revisions to § 422.310(f) in the August 2014 final rule to strengthen program management and increase transparency in the MA program by adding four more uses of risk adjustment data at § 422.310(f)(1)(vi) through § 422.310(f)(1)(ix) and by adding two subparagraphs § 422.310(f)(2) and § 422.310(f)(3) to address the terms under which risk adjustment data could be released to non-CMS entities (79 FR 50324–50334). Specifically, the four uses added to § 422.310(f)(1) in the August 2014 final rule are: (vi) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (vii) for activities to support the administration of the Medicare program; (viii) for activities conducted to support program integrity; and (ix) for purposes authorized by other applicable laws.

The subparagraph CMS added in the August 2014 final rule at § 422.310(f)(2) provided that the agency may release the minimum data it determines is necessary for one of the purposes listed in § 422.310(f)(1) to other HHS agencies, other Federal executive branch agencies, States, and external entities where that disclosure would be in accordance with: (i) applicable Federal laws; (ii) CMS data sharing procedures; (iii) subject to the protection of beneficiary identifier elements and beneficiary confidentiality, (iv) subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data; and (v) risk adjustment data other than that described in paragraphs (f)(2)(iii) and (f)(2)(iv) of § 422.310 will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv), respectively. CMS clarified that an external entity could be an individual, a group, or an organization, and that CMS would not release payment data (that is, dollar amounts) submitted by MA organizations at the level of the encounter as that data might reveal proprietary negotiated payment rates between MA plans and providers (79 FR 50328).

The subparagraph CMS added at (f)(3) in the August 2014 final rule stipulates additional conditions related to the timing of release of risk adjustment data in response to comments from some stakeholders that there should be a delay in releasing the data. CMS added subparagraph (f)(3) in response to comments to clarify that CMS did not plan to regularly release risk adjustment data for a data collection year prior to the completion of the reconciliation period. Risk adjustment reconciliation refers to the period provided to MA organizations to identify and correct errors in data they have submitted for a data collection year to ensure that the risk adjustment data is complete and accurate based on the MA organization's best knowledge, information, and belief. Risk adjustment data are not considered reconciled for a given payment year until after the final risk adjustment data submission deadline, established at § 422.310(g)(2)(ii), which can be no earlier than January 31 of the year following the payment year (for example, January 31, 2025, for payment year 2024). Specifically, § 422.310(f)(3)(i) specifies that risk adjustment data submitted for a given payment year are not available for release by CMS unless the risk adjustment reconciliation has been completed for that payment year except under limited circumstances, such as when CMS determines that releasing risk adjustment data before reconciliation is necessary for emergency preparedness (§ 422.310(f)(3)(ii)) or due to extraordinary circumstances (§ 422.310(f)(3)(iii)) (79 FR 50331).

Since the August 2014 final rule was published, CMS has identified additional circumstances that warranted releasing risk adjustment data prior to reconciliation outside of emergency preparedness and extraordinary circumstances. In the final rule issued in November 2023, CMS provided an additional circumstance (§ 422.310(f)(3)(iv)) to allow for releasing aggregate risk adjustment data prior to risk adjustment reconciliation (88 FR 79397–79400). This provision was added to provide MA utilization data measures on the Care Compare website, along with FFS utilization data, to support the administration of the Medicare program and to more

[45] Refer to **Federal Register**, 73 FR 23528, section H: *https://www.federalregister.gov/documents/2008/04/30/08-1135/medicare-program-proposed-changes-to-the-hospital-inpatient-prospective-payment-systems-and-fiscal.*

completely fulfill the public reporting required by section 104 of the Medicare Access and CHIP Reauthorization Act (MACRA) and section 10331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) and provide beneficiaries with useful and appropriate information when selecting a Medicare provider.

The following year, in April 2024, CMS issued a final rule in which CMS revised two of the allowable uses (§ 422.310(f)(1)(vi) and (vii)) to support the administration of the Medicaid program as well as the Medicare program. CMS further allowed for the release of risk adjustment data to State Medicaid agencies before reconciliation for the specific purpose of coordinating care for dually eligible individuals if CMS determined it was necessary and appropriate to support the administration of the Medicare and Medicaid programs (§ 422.310(f)(3)(v)) (89 FR 30536–30541). This expansion of CMS's use of risk adjustment data to support the administration of the Medicaid program is consistent with the goals of better integrating benefits and improving care coordination for dually eligible individuals as established at section 2602 of the Affordable Care Act.

2. Overview of Proposed Regulatory Changes

CMS is proposing to increase access to risk adjustment data while reducing regulatory burden and the resources expended by public and private organizations when requesting risk adjustment data by removing the uses enumerated in § 422.310(f)(1). This change would enable CMS to align more closely with standards applicable to FFS claims and other MA and Part D data and allow the data to be used for more purposes than are permitted under the existing regulations. CMS receives requests to use risk adjustment data for a broad range of purposes including research, health care operations, and oversight of public benefit programs, and from a broad range of entities including academic institutions, government entities, and oversight bodies. CMS believes the limitations imposed by § 422.310(f)(1) may be excessive and does not think that MA risk adjustment data should have a different or more restrictive standard for use and release than the standard applied to Medicare FFS claims. Similarly, the list of external parties to whom the data can be released at § 422.310(f)(2) (''other HHS agencies, other Federal executive branch agencies, States, and external entities'') may unnecessarily limit access to risk adjustment data to some external entities for legitimate uses that are in the public's interest. CMS believes the proposed removal of § 422.310(f)(2), which would eliminate the restriction on which types of entities can access the data, would be in keeping with our approach to make the risk adjustment data more broadly available. CMS also believes that the provisions on the timing of release of risk adjustment data at § 422.310(f)(3) may be overly restrictive, and there should be more flexibility to release data before reconciliation.

We emphasize, however, that CMS release of the data would remain contingent on Federal law and CMS data sharing procedures, per the proposal at § 422.310(f). CMS data sharing procedures include an evaluation of requests to ensure that data requests comply with applicable Federal laws, regulations, and CMS data policies. Additionally, as part of the request process, unless the requester is a beneficiary requesting his or her own data, a data sharing agreement is established between CMS and the requesters prior to disclosing the data. Data sharing agreements include, but are not limited to, information exchange agreements (IEA),[46] memoranda of understanding (MOU), and data use agreements (DUAs),[47] all of which are agreements that document the terms and conditions under which CMS data may be used to ensure that data requesters adhere to CMS privacy and security requirements and data release policies. Included in the terms and conditions are safeguards to protect beneficiary identifying information and confidentiality. Also, consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requesters are required to acknowledge these mechanisms. For example, penalties under section 1106(a) of the Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties imposed under 18 U.S.C. 641 (79 FR 50333). Requesters of CMS data are responsible for abiding by the law, policies, and restrictions of the data sharing agreements.

Over time, § 422.310(f) has become increasingly complex and cumbersome to implement as CMS receives more requests and identifies additional reasonable uses that CMS did not anticipate. As described previously, CMS has revised the regulation over the years by adding specific uses or exceptions for release of risk adjustment data as they are identified, which is burdensome, slows progress, and limits opportunities to effectively and efficiently administer, oversee, and improve Federal programs, and to conduct health care research that can improve health care delivery. The proposal outlined later in this section would address these concerns by easing restrictions on the use and release of risk adjustment data while maintaining the current protections for plan-submitted payment amounts for an associated encounter that are currently in place. Protections for beneficiary identifying information currently specified in regulation would be maintained through CMS data sharing procedures and other applicable Federal laws as described previously.

CMS expects that transparency in the MA program would be improved by removing: (1) the specific uses at § 422.310(f)(1), aside from protections of the plan-submitted payment amounts that currently exist; (2) the restrictive conditions regarding which external government entities the data can be released to at § 422.310(f)(2); and (3) the timing of when the data can be released at § 422.310(f)(3). We believe these revisions would also allow for more streamlined access to information on the Medicare program as MA grows, thereby strengthening program management, continuing to advance program integrity, supporting public health initiatives, and reducing burden through the implementation of practices and processes for the use and release of MA risk adjustment data that align more closely with standards applicable to other Medicare data, such as FFS claims. The proposed revisions to § 422.310(f) are consistent with Executive Order 14192 ''Unleashing Prosperity through Deregulation'' (January 31, 2025) by reducing the burden for CMS and external entities associated with the increasingly complex regulation surrounding the use and release of risk adjustment data and would support the goals of Executive Order 14243 ''Stopping Waste, Fraud, and Abuse by Eliminating Information Silos'' (March 20, 2025) by reducing barriers to sharing government data across agencies.

[46] Centers for Medicare & Medicaid Services. (n.d). CMS Information Exchange Agreement (IEA). U.S. Department of Health and Human Services. *https://security.cms.gov/learn/cms-information-exchange-agreement-iea.*

[47] Centers for Medicare & Medicaid Services. (n.d.). CMS data: Data disclosures and data use agreements (DUAs). U.S. Department of Health and Human Services. *https://www.cms.gov/data-research/cms-data/data-disclosures-and-data-use-agreements-duas.* An example of a research DUA can be found on the ResDAC website at *https://resdac.org/request-form/rif-data-use-agreement.*

3. Proposed Broadening of the Use and Release of Risk Adjustment Data

CMS proposes to ease restrictions on the use of risk adjustment data at § 422.310(f)(1) and repeal the limitations surrounding the release of risk adjustment data at § 422.310(f)(2) and (f)(3), other than the protections currently in place for plan-submitted payment amounts, to allow for the use and release of risk adjustment data that is more aligned with the use and release of FFS claims and other MA data. The limited uses of risk adjustment data were established when CMS resumed activities to collect encounter data to alleviate concerns from some stakeholders that risk adjustment data would be used in ways that they thought were inappropriate. As stated previously, CMS does not believe the statute restricts our use of risk adjustment data, and over time CMS has identified unanticipated uses and releases of the data that are in the public's interest beyond the nine listed at § 422.310(f)(1). Historically, this has necessitated CMS resources to conduct rulemaking to add to or amend the list, resulting in regulatory burden and increasingly complex requirements. For example, as previously discussed, CMS could not use risk adjustment data to conduct evaluations and other analyses to support the Medicaid program, nor could CMS use the data to support the administration of the Medicaid program, like care coordination, before amending § 422.310(f)(1)(vi) and (vii) in the final rule CMS issued in April 2024 (89 FR 30536 through 30541).

Given the growth of MA, risk adjustment data is increasingly important to understanding the Medicare program and health care delivery more broadly. CMS anticipates that the number and variety of requests for risk adjustment data will continue to increase, as will the resources required to enforce the more restrictive requirements and to develop revised regulations when unanticipated yet warranted uses are identified. We believe that removing the specified uses and easing restrictions for data release at § 422.310(f) would provide CMS flexibility to release MA risk adjustment data in a way that more closely aligns with the release of FFS claims and other MA data, which is crucial to burden reduction and the ability of CMS and external entities to be innovative in the pursuit of improved health care delivery and program integrity, greater transparency, and reduced fraud, waste, and abuse.

Specifically, CMS proposes to revise § 422.310(f) as follows: ''Regarding the data described in paragraphs (a) through (d) of this section, CMS may use and release the minimum data it determines is necessary in accordance with CMS data sharing procedures and applicable Federal laws, subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data, unless authorized by other applicable laws.'' The proposal provides for the stipulation that this proposal does not limit CMS disclosure of data as authorized under separate statutory authority.[48] We propose to repeal the nine specified uses currently listed in § 422.310(f)(1) that, under the proposal, would be encompassed under the revised (f) text. We also propose to repeal the release restrictions specified at § 422.310(f)(2) and § 422.310(f)(3), other than the existing restrictions on the release of the minimum necessary data and on the release of dollar amounts at the encounter level, which were moved to § 422.310(f). We note, however, that under this proposal, protections to the beneficiary identifying information would be encompassed under the data sharing procedures in the revised (f) text.

Though CMS is proposing to repeal the regulatory language at § 422.310(f)(2) that stipulates protections for beneficiary confidentiality, the protections of beneficiary identifying information currently specified at § 422.310(f)(2) would remain in place in accordance with applicable Federal laws, such as the Privacy Act, section 1106(a) of the Act, and CMS information disclosure regulations at 42 CFR part 401, subpart B, that continue to govern this data sharing. CMS would be able to release an individual's risk adjustment data when authorized by that individual and, for other kinds of requests for release of risk adjustment data, CMS would release such information in accordance with CMS data sharing procedures, consistent with current practice. We intend to continue to protect beneficiary data through, for example, encryption, or removal of the confidential fields when risk adjustment data is released. CMS has an established process to evaluate requests for data and enters into data sharing agreements with data requesters for disclosures of risk adjustment data to ensure that data requesters adhere to CMS privacy and security requirements and data release policies. We believe this process contains the necessary checks and safeguards to ensure that the risks of disclosure of beneficiary identifying information are minimal.

CMS is also maintaining the protections that currently exist regarding the release of plan-submitted dollar amounts associated with the items or services submitted to CMS pursuant to § 422.310(b) that characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. In the August 2014 final rule (79 FR 49854), we stated our belief that release of payment data at the level of the encounter record might reveal proprietary negotiated payment rates between MA plans and providers and, therefore, we restricted the release of payment data by only allowing for its release if aggregated. CMS is maintaining the guardrails for payment data (dollar amounts) at the level of the encounter as they were originally finalized in the August 2014 final rule. Per the proposed change to § 422.310(f), CMS may only release aggregated dollar amounts reported for an associated encounter, retaining the regulatory text that currently exists at § 422.310(f)(2)(iv)—risk adjustment data is ''subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.'' As stated previously, this proposal would not limit CMS disclosure of risk adjustment data as authorized under separate statutory authority.

Currently, § 422.310(f)(3) imposes the restriction that risk adjustment data will not become available for release before reconciliation for the applicable payment year has been completed, unless CMS determines that it is necessary for one of four specific exceptions.[49] Consistent with our proposed changes to remove the list of permissible uses and conditions for release of risk adjustment data, CMS is also proposing to remove the detailed list of exceptions for release of risk adjustment data prior to reconciliation in paragraph (f)(3). The proposed change would continue to allow for the release of risk adjustment data prior to reconciliation for the four previously identified exceptions and provide flexibility when CMS receives novel requests for data that have not been reconciled.

As discussed previously, because MA plans have a window of time in which they should submit data corrections for a given payment year (typically January

[48] For example, 31 U.S.C. 716, 2 U.S.C. 166(d)(1) and 601(d), section 1805 of the Act (42 U.S.C. 1395b–6), section 1128J of the Act (42 U.S.C. 1320a–7k), and section 6(a) of the Inspector General Act of 1978 (5 U.S.C. 406).

[49] § 422.310(f)(3)(ii) through (f)(3)(v).

31 of the year following the payment year), risk adjustment data are not considered reconciled for payment purposes before that date has passed. For this reason, there is currently a prohibition against releasing the data prior to the final submission deadline except in specific, limited circumstances. However, over time CMS identified more purposes for which using the data prior to reconciliation may be appropriate and that the original reasons and concerns that led to delaying the release of risk adjustment data in the August 2014 final rule may not always apply or may no longer apply. Some of the purposes identified are reflected in the recent changes to § 422.310(f)(3) where additional exceptions for early release were added, one of which is care coordination, but others may include program integrity initiatives that necessitate timelier data or to support beneficiaries in managing their health by allowing them to access and share their current data. For example, currently, through the CMS Blue Button 2.0 Application Programming Interface (API), an individual may choose to share their own Medicare A, B, and D claims data with Medicare-approved applications or websites that a third party (not Medicare) creates, thereby allowing an individual to use health technology and their own data to improve their health outcomes and decision making. In removing restrictions related to releasing pre-reconciled risk adjustment data, this tool could also be made available to MA enrollees.

While this proposal would allow for release of risk adjustment data prior to reconciliation broadly, CMS understands that it is not always necessary and appropriate for risk adjustment data to be released prior to reconciliation. For example, relying on diagnosis information for research or program operations may not be appropriate before the final risk adjustment data submission deadline since plans have at least 13 months after the end of the service year to submit additional diagnoses for payment. CMS would review requests for the release of risk adjustment data prior to reconciliation to assess whether pre-reconciled data is necessary and appropriate for the requester's purpose. CMS's proposal to remove restrictions on the use and release of pre-reconciled risk adjustment data would provide greater flexibility in the release of risk adjustment data, supporting the goals of Executive Order 14243 ''Stopping Waste, Fraud, and Abuse by Eliminating Information Silos'' (March 20, 2025). Additionally, by no longer restricting release to prescribed purposes, CMS is supporting the goals of Executive Order 14192 ''Unleashing Prosperity through Deregulation'' (January 31, 2025) by reducing the burden for CMS and external entities associated with the increasingly complex regulation that necessitates rulemaking when an unanticipated use of the data is identified.

CMS is seeking public comments on all aspects of the proposed revisions to the use and release of risk adjustment data at § 422.310(f) and allowing for greater flexibility in the release of data prior to the final risk adjustment data submission deadline.

D. Strengthened Documentation Standards for Part D Plan Sponsors

1. Background of Part D Coverage Determinations and Point-of-Sale (POS) Claim Adjudications

CMS regulations at § 423.566 specify that each Part D plan sponsor must have a procedure for making timely coverage determinations regarding the prescription drug benefits an enrollee is entitled to receive under the plan and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. In addition to a standard procedure for making such determinations, it must also have an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570. When a Part D plan sponsor requires a drug to be reviewed for coverage under Part D, there is coordination between the Part D plan sponsor and another entity, such as the prescriber, pharmacy, enrollee, or enrollee representative, to ensure that the drug meets the criteria for coverage prior to accepting the claim for payment under the Part D benefit.

Coverage determinations can be requested by the Part D enrollee, the enrollee's representative, or the prescriber on behalf of the enrollee. Current regulations at § 423.566(b) outline the actions that are considered Part D coverage determinations, such as a decision not to provide or pay for a Part D drug, including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy, or the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D.

A POS claim adjudication occurs when a claim is submitted by a pharmacy for payment after the presentation of a valid prescription, regardless of whether the Part D plan sponsor treats the POS transaction as a coverage determination. In general, Part D plan sponsors do not treat POS claim adjudications as coverage determinations.[50] However, Part D plan sponsors may implement utilization management edits in various situations to determine a drug's coverage at the POS. In such cases, the Part D sponsor may or may not choose to treat the POS claim adjudication as a coverage determination, leading to variance among plan sponsors. One reason a Part D plan sponsor might require a coverage determination or POS claim adjudication edit is to verify a drug's coverage under the Part D benefit. For example, Part D plan sponsors can use prior authorization for drugs with the highest likelihood of non-Part D covered uses, such as when coverage is available under Part A or Part B (versus D) for the drug as prescribed and dispensed or administered, or when the drug is not used for a medically accepted indication (MAI).[51]

Depending on the drug, Part D plan sponsors vary the scope of review when determining coverage or conducting a POS claim adjudication that determines coverage, and therefore, CMS must be able to review the plan sponsors' original documentation to ensure that a Part D plan sponsor asked relevant questions and received appropriate responses for the drug being reviewed. For example, in the instance of reviewing a drug for an MAI, the Part D plan sponsor needs to verify the diagnosis that led to the drug being prescribed to ensure that it is being prescribed and dispensed for an MAI and is eligible for coverage under Part D.

2. Audits of Part D Program Integrity Prescription Drug Event Records

Under section 1860D–12(b)(3)(C) of the Act and 42 CFR 423.505(d)–(e), Part D plan sponsors are required to maintain certain categories of documentation for specified periods of

[50] Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Section 40.2 (found at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*).

[51] Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements, Section 30.2.2.3 (found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf*).

time. Specifically, § 423.505(d) requires that the contract between a Part D plan sponsor and CMS include an agreement by the Part D plan sponsor to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years that are sufficient to meet certain requirements, including enabling CMS to evaluate the quality, appropriateness, and timeliness of services performed under the contract and to audit the services performed or determinations of amounts payable under the contract. In addition, § 423.505(e) requires that Part D plan sponsors agree to allow HHS, the Comptroller General or their designee to evaluate through audit, inspection, or other means (1) the quality, appropriateness, and timeliness of those services furnished to Medicare enrollees; (2) compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees; (3) facilities of the Part D sponsor; and (4) enrollment/disenrollment records for the current contract period and 10 prior periods. Furthermore, §§ 423.568(a)(3), 423.570(c)(2), and 423.584(c)(1) outline requirements for Part D plan sponsors to establish and maintain a method of documenting and to retain documentation for oral requests for coverage determinations under standard timeframes, expedited timeframes, and redeterminations respectively.

Although the statute and current regulatory requirements address documentation maintenance and availability, these requirements do not detail the documentation needed to be maintained to support the appropriateness of a Part D coverage determination or POS claim adjudication that is used to determine coverage under the Part D benefit. The availability of complete and accurate documentation in its original format (for example, fax, call notes, electronic PA), is a key component of ensuring that taxpayer dollars are spent appropriately in the Part D program. Through CMS's Part D program integrity prescription drug event (PDE) record review audits, we have observed a large degree of variation among the documentation that Part D plan sponsors maintain when conducting coverage determinations, including prior authorizations, and POS claim adjudication edits, used to determine a drug's coverage under Part D, and subsequently provide to CMS upon audit. While some Part D plan sponsors have robust documentation standards that outline the information the Part D plan sponsor obtained that led to coverage under the Part D benefit, others provide or maintain little to no documentation. In some instances, plan sponsors maintain a summary of the original coverage request or refer to a past coverage determination to extend an authorization. In these instances, CMS is unable, upon audit, to review the original documentation to ensure that the information obtained was accurate. For CMS to provide proper oversight of the Part D program and the approvals made for drugs covered under the Part D benefit, it is imperative that Part D plan sponsors provide and maintain original documentation that describes how and why the Part D plan sponsor approved a drug for coverage. Without sufficient documentation, CMS cannot fully review, during an audit or educational analyses, or other program integrity efforts, Part D plan sponsor coverage determinations and POS claim adjudications for accuracy. The standardization and availability of sufficient documentation to support a drug's coverage under the Part D benefit will allow CMS to conduct more effective audits and help ensure CMS can verify that a drug was accurately paid under Part D.

3. Proposed Provisions

We are proposing standardized, detailed documentation requirements for coverage determinations and POS claim adjudications, used for purposes of determining coverage under the Part D benefit. We are proposing documentation requirements that include but are not limited to certain written, verbal, and electronic communications, such as the date and time the request was received; the name and title of the individual who submitted or verified the request; and the information used to make the coverage determination. These requirements would not apply to POS claim adjudications for purposes that are unrelated to the determination of coverage under the Part D benefit or the correct Medicare benefit for coverage, such as those POS claim adjudications for safety, dose limitations, and quantity limits. Any additional documentation recorded or maintained will be subject to existing protected health information (PHI) and personally identifiable information (PII) rules and regulations.

Specifically, we propose the following revisions to the documentation requirements:

- First, to revise § 423.505(d)(1) to add new paragraph (vi) to enable CMS to review original format documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon by the Part D plan sponsor to make a coverage determination or otherwise permit a point-of-sale claim adjudication that determines a drug's coverage under the Part D benefit. In instances when a coverage determination is extended, the original coverage determination must be maintained as documentation. The documentation covered by these standards must be made available to CMS during Part D program integrity prescription drug event (PDE) record review audits. Failure to produce this documentation will result in an improper Part D audit determination and will be subject to PDE record deletion in accordance with § 423.325(a)(2).
- Second, to revise § 423.505 to add the following new paragraphs:

++ Paragraph (d)(2)(xiii) to include all documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon when a Part D plan sponsor makes a coverage determination or otherwise permit a point-of-sale claim adjudication that determines coverage of a drug under the Part D benefit, consistent with paragraph (d)(1)(vi). This includes:

++ Paragraph (d)(2)(xiii)(A) to include the date and time the request for a coverage determination or point-of-sale claim adjudication was received and the identity of the individual who submitted the request.

++ Paragraph (d)(2)(xiii)(B) to include the name and title (as applicable) of the individual the Part D plan sponsor contacted to verify the request (for example, pharmacist, prescriber, enrollee, or enrollee representative).

++ Paragraph (d)(2)(xiii)(C) to include information obtained, including the questions asked and the responses received, and the final decision rendered.

++ Paragraph (d)(2)(xiii)(D) to include the diagnosis code for a coverage determination or point-of-sale claim adjudication used to support a medically accepted indication.

++ Paragraph (d)(2)(xiii)(E) to include any additional information that the Part D plan sponsor utilized to determine the final outcome of the coverage determination or point-of-sale claim adjudication request.

- Third, to revise § 423.505(e)(2) to add a phrase to reference the

requirement to make available the records containing information used to make the coverage determination or POS claim adjudication.

E. Updating Third-Party Marketing Organizations (TPMO) Disclaimer Requirements (§§ 422.2267 and 423.2267)

As a part of the 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 Final Rule which appeared in the **Federal Register** on May 9, 2022 (hereafter referred to as the May 2022 final rule) (87 FR 27704), as a part of a broader effort to address concerns with TPMOs, CMS finalized regulations at §§ 422.2267(e)(41) and 423.2267(e)(41) to improve regulatory oversight of Third-Party Marketing Organizations (TPMOs). One provision required Medicare Advantage (MA) organizations and Part D sponsors to ensure that the TPMOs, with whom MA organizations and Part D sponsors directly or indirectly do business, verbally convey a standardized disclaimer during sales calls with beneficiaries. CMS implemented these regulations after listening to TPMO-based sales calls and hearing first-hand beneficiary confusion about the information the TPMO was conveying and to help ensure that TPMOs were not marketing information in a misleading way that might lead beneficiaries to join a plan contrary to their intention, or a plan that did not best meet their health care needs. The disclaimer, as finalized, consisted of the following statement: ''We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.''

After these regulations were implemented, CMS continued to monitor TPMOs' interactions with beneficiaries during these sales calls. In CMS's review of hundreds of sales, marketing, and enrollment audio calls, CMS found that only one plan option from one MA organization was discussed in over 80 percent of the calls reviewed. These reviews also showed that TPMOs rarely, if ever, informed the beneficiary that there were multiple plans available in their service area. Although the TPMO may have researched other plans, the TPMO rarely communicated information about those plan options to the beneficiary; thus, the beneficiary may not have known about other available options. These monitoring efforts heightened CMS's concern that beneficiaries were not receiving comprehensive information about all their plan choices, thus limiting their ability to make an informed decision about the plan best able to meet their health care needs.

To address those concerns, CMS issued 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, hereinafter referred to as the April 2023 final rule (88 FR 22120). In this final rule, CMS amended §§ 422.2267(e)(41) and 423.2267(e)(41) revising the existing disclaimer, which was applicable to TPMOs that represented more than one, but not all, MA organizations or Part D sponsors in a given service area, to notify the beneficiary about the number of organizations and the number of plans the organizations offered. Additionally, CMS revised §§ 422.2267(e)(41) and 423.2267(e)(41) to include a new required disclaimer for TPMOs that contracted with every MA organization or Part D sponsor in a service area. Finally, CMS added State Health Insurance Assistance Programs (SHIPs) as a source of information for beneficiaries to both versions of the disclaimer and required TPMOs convey the applicable disclaimer within the first minute of a sales call, among other requirements for the TMPO to communicate the disclaimer through other electronic means or materials (as described under §§ 422.2267(e)(41) and 423.2267(e)(41)).

In the April 2023 final rule, CMS addressed comments received in response to the proposed rule (88 FR 22120). Some industry stakeholders raised concerns about the new disclaimer requirements. For example, some asserted that requiring TPMOs to list all the plans with which they contract would confuse or distract beneficiaries; or for those TPMOs that represent many plans, the disclaimer would be too long to read within the first minute. Similarly, some stakeholders pointed out that budget constraints and limited training would hinder a SHIP's ability to effectively assist beneficiaries with plan choices. While CMS understood those concerns, given CMS's observations about common TPMO interactions with beneficiaries during the sales and enrollment calls previously described, the agency determined that these regulatory changes were warranted.

CMS regularly reviews MA and Part D program requirements and how they affect Medicare beneficiaries and industry stakeholders. Based on CMS's review and industry feedback, CMS determined that additional changes to the TPMO disclaimer may be appropriate. CMS is proposing to modify the TPMO disclaimer requirement in §§ 422.2267(e)(41) and 423.2267(e)(41) to: (1) replace the existing requirement to read the disclaimer within the first minute of the call, so that TPMOs are instead required to read the disclaimer ''prior to the discussion of any benefits'' during the call, and to: (2) remove SHIPs as a source of information from the disclaimer. CMS has determined that requiring TPMOs to convey the disclaimer during the first minute of a sales call is not always the appropriate time to notify the beneficiary of the number of plan choices available. CMS believes that many calls typically begin with the TPMO obtaining basic demographic information from the beneficiary, which allows the TPMO to immediately determine if the call should proceed to the benefit discussion phase. In other instances, the TPMO may determine that the beneficiary does not have a valid election period, which would end the call, making the disclaimer unnecessary. Notifying the beneficiary of the number of plans that a TPMO represents in the first minute does not always promote clear communication with the beneficiary or mitigate beneficiary confusion. By permitting TPMOs to read the disclaimer at an appropriate point during the call, provided it is read prior to the discussion of any benefits, the disclaimer will fit in better with the flow of the conversation. CMS does not consider the mere mention of a benefit, for example pointing out that nearly all MA organizations offer routine dental care, constitutes a discussion of benefits. Rather, CMS believes that discussing the specificity of a benefit with the intent to draw a beneficiary's attention to an MA or Part D plan(s), or to influence a beneficiary's decision-making process when making an MA or Part D plan selection, or to influence a beneficiary's decision to stay enrolled in a plan, could represent a discussion of benefits, as defined by the marketing definition under §§ 422.2260 and 423.2260. This could include, for example, talking with a beneficiary about the benefits listed in a plan's Evidence of Coverage document, or how beneficiary out of pocket cost sharing

might work given a plan's benefit structure and the beneficiary's previous health care experience or needs. If there is no discussion of benefits, CMS would not expect TPMOs to provide the disclaimer to beneficiaries. CMS seeks comment on how the Agency should identify when a ''discussion of benefits'' occurs.

CMS is proposing changes only to the TPMO disclaimer provision at §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii). Thus, this proposal would not alter the existing requirements provided within §§ 422.2267(e)(41)(i), (iii), (iv), and (v); and 423.2267(e)(41)(i), (iii), (iv), and (v). That is, any TPMO, as defined under §§ 422.2260 and 423.2260, that sells plans on behalf of more than one MA organization or Part D sponsor, must electronically convey the TPMO disclaimer when communicating with a beneficiary through email, online chat, or other electronic means of communication, prominently display the disclaimer on TPMO websites, and include the disclaimer in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

CMS is also proposing to remove SHIPs as a source of information from the disclaimer. CMS recognizes that, while SHIPs can be a source of unbiased information about plan choices, informing beneficiaries on every sales call about the SHIP may cause additional issues. SHIP volunteers may not always have the expertise to help beneficiaries navigate increasingly complex MA and Part D programs. CMS believes that beneficiaries enrolled in the MA and Part D programs may be more effectively served by information and entities for which CMS has direct oversight. Moreover, a recent article in the Journal of the American Medical Association Network [52] details a study conducted to determine if SHIP counselors provided accurate and complete information to Medicare beneficiaries about their coverage options. In this study, mystery shoppers posed as individuals newly eligible for Medicare. While over 94 percent of the responses differentiating Original Medicare from MA were accurate, fewer than half of counselors mentioned Dual-Eligible Special Needs Plans (D–SNPs) as an option for mystery shoppers posing as dually eligible beneficiaries. The results suggested that SHIPs may not always be able to address the needs of Medicare beneficiaries seeking unbiased information on coverage options

CMS also recognizes that each SHIP works differently and provides different training to its counselors, which can vary further at the local level. This can result in Medicare beneficiaries receiving different information based on the SHIP and SHIP counselor that is ultimately reached. CMS believes that, for the TPMO disclaimer, 1–800–MEDICARE is a better option to assist beneficiaries with health care choices. 1–800–MEDICARE has representatives available 24/7 to assist beneficiaries, provides standardized training to its customer service representatives, is centrally monitored and controlled by CMS, which facilitates efficient and consistent information sharing, and is a one-stop shop for all beneficiaries, regardless of the state in which they live.

For reasons previously discussed, CMS is proposing to revise §§ 422.2267(e)(41) and 423.2267(e)(41) to remove references to the SHIPs, while maintaining guidance for beneficiaries to contact *Medicare.gov* or 1–800–MEDICARE for plan advice. Additionally, CMS is proposing to revise §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii) to require TPMOs to provide the TPMO disclaimer during sales calls before engaging in discussions about benefits rather than requiring TPMOs to verbally convey the disclaimer during the first minute of a sales call.

CMS solicits comment on this proposal.

F. Removing Rules on Time and Manner of Beneficiary Outreach (§§ 422.2264, 423.2264, 422.2274, and 423.2274)

Section 1851(h) and (j) of the Act provides a structural framework for how MA organizations may market and communicate with beneficiaries and directs CMS to adopt standards related to prohibitions and limitations on marketing and communications activities. 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) of the Act relating to approval of marketing material and application forms for Part D sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations (and agents, brokers, and other third parties representing MA organizations).

CMS has adopted regulations related to marketing and communications by MA organizations and Part D sponsors in 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V; these regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under 42 CFR 417.428, most marketing and communications requirements in subpart V of part 422 also apply to section 1876 cost plans. CMS has long provided further interpretation and sub-regulatory guidance for these regulations in the form of a manual titled, ''Medicare Communications and Marketing Guidelines'' (MCMG), previously known as ''Medicare Marketing Guidelines.'' Because this proposed rule is applicable to MA organizations, Part D sponsors, and cost plans, CMS refers to each of these regulated entities as a ''plan.''

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 (hereinafter referred to as the January 2021 final rule), CMS codified guidance contained in the MCMG by integrating it with existing regulations. 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 (hereinafter referred to as the April 2023 final rule), CMS then finalized several changes to 42 CFR parts 422 and 423, subpart V, to strengthen beneficiary protections and improve MA and Part D marketing.

In this current proposed rule, CMS is proposing several changes to requirements regarding the time and manner of plans' outreach to beneficiaries. The primary proposals include three changes to §§ 422.2264(c) and 423.2264(c) to remove rules on the time and manner of beneficiary outreach. In addition, at §§ 422.2264(c)(3), 423.2264(c)(3), 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii), CMS is proposing a few other regulatory changes to add specificity and clarify policy. In total, these proposals and clarifications are designed to improve the enrollment decision-making process by creating a more convenient, beneficiary-friendly outreach experience and to reduce the burden on beneficiaries, plans, and agents/brokers. Furthermore, these proposals align with the January 31, 2025, Executive Order 14192, ''Unleashing Prosperity Through

[52] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2832052#google_vignette.*

Deregulation'' (hereinafter referred to as E.O. 14192).[53] E.O. 14192 describes the Administration's policy goals to promote prudent financial management and alleviate unnecessary regulatory burdens. Section 2 of E.O. 14192 states that it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people. The changes CMS proposes here are deregulatory and therefore support the Administration's policy goals.

1. Marketing Events Following Educational Events in Same Location

In the January 2021 final rule, CMS codified guidance existing in the MCMG regarding events with beneficiaries. The finalized regulation text at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) required that if a marketing event directly followed an educational event, the beneficiary must be made aware of the change from an educational to a marketing event and be given the opportunity to leave prior to the marketing event beginning. In the April 2023 final rule, CMS modified §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) to prohibit marketing events from taking place within 12 hours of an educational event in the same location (that is, the entire building or adjacent buildings). This prohibition was intended to protect beneficiaries from feeling pressured to stay for a marketing event after having attended an educational event. However, it also created additional barriers for plans or agents/brokers as well as beneficiaries who wished to discuss potential enrollment options with respect to specific plan products following an educational event.

As described in the April 2023 final rule, approximately half of the commenters opposed this provision. Some commenters stated that agents/brokers were not hurting seniors by holding a marketing event after an educational event, that this provision would result in beneficiaries being upset with agents/brokers for something that is out of their control, that it would not add any additional protection from marketing abuses, that it would degrade the consumer experience, and that the proposal was both heavy-handed and unworkable. Furthermore, some commenters were concerned that the number of educational events would decrease, resulting in beneficiaries being less informed regarding plan options overall and increasing the likelihood of a beneficiary enrolling in a plan that did not meet their health care needs. Other commenters said that the 12-hour delay was burdensome, specifically for dually eligible, low-income, disabled, and other underserved beneficiaries, who might experience transportation barriers or lack access to transportation. Such barriers factor in when beneficiaries are forced to travel to separate locations to attend an educational event and a separate marketing event 12 or more hours later, thus making access to information and resources in just one interaction a critical component. For greater detail on the different types of burden potential identified by commenters, see the April 2023 final rule.

Following the April 2023 final rule, CMS has continued to receive stakeholder feedback reiterating concerns about the burden placed on both plans or agents/brokers and beneficiaries regarding the 12-hour delay requirement. While CMS considered similar hypothetical concerns prior to finalizing the April 2023 rule, the agency is now reconsidering these requirements based on valuable input, such as the real-world experience cited in stakeholder feedback. After reevaluating these impacts, CMS is concerned that the requirements at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i) do impose an unnecessary burden on beneficiaries and plans and agents/brokers. Furthermore, CMS believes, based on stakeholder input, that the 12-hour delay requirement between an educational event and a marketing event may also create an unnecessary barrier to accessing important MA and Part D information for beneficiaries, especially those who live far from the events or those who lack access to transportation. Moreover, based on a lack of evidence of a quantifiable protection to the beneficiary from the existing regulatory requirement, CMS believes that the beneficiary protections that CMS previously identified in the April 2023 final rule have not materialized. For example, in the April 2023 final rule, CMS explained that its concern about inappropriate pressure on beneficiaries (especially dually eligible individuals and other vulnerable groups) that may occur when marketing events occur directly after educational events outweighed some of the access and transportation concerns. However, CMS is now reconsidering these previous positions taken in 2023 because for vulnerable beneficiaries, especially those in SNPs, it is common to have caregivers or other friends or family members provide assistance in gathering information on plan options (and often ultimately make decisions on behalf of the beneficiary), thus, there is often a built-in layer of added protection from any potential undue pressure. CMS notes that there are also various beneficiary protections in place, including the possibility of providing special enrollment periods (SEPs) when appropriate, or, if warranted, processing a retrospective enrollment to place the beneficiary back into their prior coverage, if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. CMS thus proposes that plans and agents/brokers should be able hold an educational event and a marketing event back-to-back and in the same location.

For these reasons, CMS is proposing to eliminate the 12-hour delay requirement, so that a marketing event may take place directly following and in the same location as an educational event. This proposal aligns with section 1851(j)(1)(D)(ii) of the Act, which prohibits sales and marketing activities at educational events but does not require a specific timeframe between an educational event and a marketing event. This proposal, permitting marketing events to follow educational events, provided there is an appropriate break, is consistent with the statutory requirement. CMS is proposing to amend paragraph (c)(2)(i) in both §§ 422.2264 and 423.2264 to state that if a marketing event directly follows an educational event, plans and agents/brokers would be required to notify the beneficiary that the educational event is ending and a marketing event will begin shortly. Examples of appropriate beneficiary notification might be in the form of a verbal announcement at the educational event or a clear and distinct notation on a written schedule of the day's event. In addition to the beneficiary notification, CMS is proposing that plans and agents/brokers would also be required to give the beneficiary a sufficient opportunity to leave the educational event prior to the start of the marketing event. An example of ''a sufficient opportunity to leave'' appropriately given by the plan or agent/broker would be a brief restroom or snack break between the educational event and the marketing event. This deregulatory change is expected to significantly reduce burden and cost for plans and agents/brokers in terms of event planning. It would also likely ease burden on beneficiaries when they attend an educational event and

[53] *https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/.*

subsequently want to obtain more plan-specific information at a marketing event. By allowing both types of events to occur at the same location once beneficiaries are made aware of both events and given a sufficient opportunity to leave, beneficiaries would not need to return on a different day or to a different venue to attend a marketing event. As such, this proposal would provide greater convenience for beneficiaries and enhance the beneficiary experience in shopping for a plan.

2. Timing of Personal Marketing Appointment After Scope of Appointment (SOA) Form Completion

Sections 1851(j)(2)(A) and 1860D–4(l)(2) of the Act direct that the Secretary shall establish limitations with respect to the scope of any marketing appointment and that such limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and that documentation of such agreement must be done by the plan. In situations where the marketing appointment is in person, the statute further provides that such documentation shall be in writing. The advance agreement documentation is commonly referred to as the Scope of Appointment (SOA) form. The SOA requirement helps to ensure beneficiaries understand what types of plans will be discussed prior to meeting with a plan or an agent/broker.

Over the course of the past several years, CMS SOA policy has evolved as reflected in CMS's regulatory requirements. This is in part due to changes in the MA market over time, which has led to an evolving understanding of what measures may be appropriate to regulate for improper marketing activities and to ensure that beneficiaries are able to make informed decisions about their enrollment choices. CMS first codified the SOA statutory requirement at §§ 422.2268(g) and 423.2268(g) in the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs Interim Final Rule with Comment Period (hereinafter referred to as the September 2008 IFC) (73 FR 54226), prohibiting plans from marketing during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment occurring. Aligning with the statute, CMS explained that the beneficiary must have the opportunity to agree to the range of choices that will be discussed, and that agreement would have to be documented. Then in the Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs Final Rule (hereinafter referred to as the September 2011 final rule) (76 FR 54634), CMS modified §§ 422.2268(g) and 423.2268(g) by designating a specific timeframe standard for the SOA advance agreement—48 hours in advance of the marketing appointment, when practicable. This CMS interpretation was also memorialized in the MCMG at the time. In the January 2021 final rule, CMS made some structural changes to 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V, removed §§ 422.2268 and 423.2268, and shifted the SOA rule to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i). Also, in this January 2021 final rule (86 FR 5890), CMS removed the 48-hour SOA standard again, stating that prior to the personal marketing appointment beginning, the plan (or agent/broker, as applicable) must agree upon and record the SOA with the beneficiary(ies).

In the April 2023 final rule, CMS reverted to the 48-hour SOA standard, prohibiting personal marketing appointments from taking place until after 48 hours have passed since the time the SOA was completed by the beneficiary. However, this change did not include the previously codified ''when practicable'' because CMS, at the time, believed this phrase nullified the purpose of the 48-hour timeframe given the various reasons why waiting 48 hours may not be practicable.[54] Therefore, in the April 2023 final rule (88 FR 22336), CMS added the phrase ''At least 48 hours'' to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) to require such a timeframe prior to the personal marketing appointment for the SOA to be agreed upon and recorded with the beneficiary. CMS also finalized two exceptions to the 48-hour SOA rule—one for SOAs that are completed during the last four days of a valid election period for the beneficiary and the other for unscheduled in-person meetings (walk-ins) initiated by the beneficiary (see §§ 422.2264(c)(3)(i)(A)–(B) and 423.2264(c)(3)(i)(A)–(B)). These are the current policies for the 48-hour SOA rule.

Similar to the reasoning for proposing to eliminating the 12-hour delay requirement at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), CMS believes that the strict 48-hour SOA requirement may create an unnecessary barrier to accessing important MA and Part D information for impacted beneficiaries, and also barriers for plans and agents/brokers distributing this information, without offering a quantifiable protection to the beneficiary. For example, after both the September 2011 final rule and the April 2023 final rule, CMS received numerous inquiries from plans and agents/brokers questioning the logistics of the 48-hour SOA rule and objecting to the rule's tendency to create obstacles to promoting beneficiaries' smooth, informed, and timely decision-making when faced with various enrollment options. The 48-hour delay may have a negative impact on a beneficiary's freedom to engage with a plan or an agent/broker on a schedule that works best for them. On the other hand, the 48-hour delay may require a beneficiary to dedicate more time than they wished to spend should they wish to engage with multiple plans or agents/brokers and need to wait 48 hours before engaging with them and deciding in which plan they wish to enroll.

Consequently, CMS is proposing to eliminate the 48-hour waiting period required between the SOA completion and a personal marketing appointment, as well as eliminate the two corresponding exceptions to the 48-hour SOA rule. Under this proposal, plans and agents/brokers would no longer be required to wait 48 hours between obtaining an SOA and speaking with a beneficiary about plan products. Beneficiaries would be able to learn about plan products in real time, rather than having to come back for a personal marketing appointment 48 hours later. This rule, if finalized, would still require an advance agreement, as statutorily required, but without a specified timeframe. Beneficiaries would be able to fill out an SOA just prior to discussing plan products or may fill out an SOA for a future personal marketing appointment. For this proposed change, paragraph (c)(3)(i) in both §§ 422.2264 and 423.2264 would revert to its original language as finalized in the January 2021 final rule by removing the phrase ''At least 48 hours'' and the phrase '', except for:'' and by removing the two exceptions listed at paragraphs (c)(3)(i)(A) and (B). CMS is also proposing a minor technical correction in § 422.2264(c)(3)(i) to add the missing word ''appointment'' after ''marketing.''

CMS believes that eliminating the 48-hour SOA rule would benefit all parties,

[54] For more details, please refer to the 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 Proposed Rule (hereinafter referred to as the December 2022 proposed rule).

especially beneficiaries, by allowing for a discussion of plan products on the beneficiary's schedule. Similar to the 12-hour delay requirement between an educational event and a marketing event, the 48-hour SOA rule potentially inhibits a beneficiary from receiving information. While the current requirement has an exception for in-person meetings (walk-ins) initiated by the beneficiary, it does not account for other interactions that may take place between the beneficiary and a plan or an agent/broker. For example, beneficiaries who live far away or those with transportation issues who sign an SOA with a plan or an agent/broker when attending a marketing event would be required to come back no less than 48 hours later to meet with that plan or agent/broker again.

CMS acknowledges that in the April 2023 final rule, CMS stated that the burden caused by the 48-hour SOA rule was outweighed by the potential benefit of providing beneficiaries, especially vulnerable beneficiaries, time to speak with caregivers and others who they may rely upon for help or advice or just provide the beneficiary additional time to consider their options. However, CMS believes that a different approach may be appropriate now for a similar reason as mentioned for the proposal to eliminate the 12-hour delay requirement. There is often a built-in layer of added protection from any potential undue pressure, as evidenced by the tendency for vulnerable beneficiaries to have other people help them with plan options and making decisions (for example, caregivers or authorized representatives), together with previously mentioned existing beneficiary protections if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. CMS is now reexamining the relative protection offered by these other factors and based on additional information that CMS has received about the relative benefit or burden of the 48-hour SOA rule. As described earlier in the proposal, since the September 2011 final rule, and more recently, the April 2023 final rule, CMS has received numerous clarifying questions regarding the 48-hour timeframe, as well as stakeholder commentaries providing anecdotal and hypothetical concerns and reasons why the 48-hour SOA rule may be harmful to beneficiaries. Criticism regarding the potentially adverse effects on beneficiaries led CMS to further review the unintended consequences of the ''cooling off'' period. This leads CMS to conclude that it may be appropriate for plans and agents/brokers to meet with the beneficiary or the beneficiary's representative sooner than 48 hours after the collection of the SOA form. In other cases, the plan or agent/broker may need to travel long distances, possibly hundreds of miles, to have a follow-up appointment based on the current 48-hour SOA rule, therefore, the proposal here would also reduce the burden on plans and agents/brokers in addition to beneficiaries and their representatives.

Furthermore, by returning to the same regulatory language as in the January 2021 final rule (and similar language as in the September 2008 IFC)—which aligned with section 1851(j)(2)(A) of the Act—CMS is closely aligning with statute. CMS believes this proposal to eliminate the 48-hour SOA rule is consistent with the statutory requirement at section 1851(j)(2)(A) of the Act that requires an advance agreement with a prospective enrollee, given the statute does not define the timeframe between the agreement and the marketing appointment with the plan or agent/broker.

In conjunction with proposing to eliminate the 48-hour SOA rule, CMS is also proposing a few additional associated regulation changes and clarifying various SOA policies that would further bolster the precision of the remaining requirements should the agency finalize the elimination of the 48-hour SOA rule. CMS has received questions from plans and agents/brokers regarding SOA policies, and these proposed regulation changes and policy clarifications are necessary and responsive to those questions. CMS is requesting that plans and agents/brokers review the following information carefully and provide feedback through the comment process. If this portion of the rule is finalized as proposed, the SOA policy clarifications contained herein will supersede any existing SOA guidance.

First, CMS is proposing to more clearly define what qualifies as a personal marketing appointment. The introductory language at §§ 422.2264(c)(3) and 423.2264(c)(3) currently states that personal marketing appointments are those appointments that are tailored to an individual or small group and that personal marketing appointments are not defined by the location. CMS proposes to clarify this regulatory definition by adding language to paragraph (c)(3) in both §§ 422.2264 and 423.2264 stating that personal marketing appointments are for purposes of discussing marketing topics, so that the proposed language reads as follows: ''Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics.''

In addition to this proposed change to the regulatory text, CMS is also clarifying here that a small group, for purposes of an SOA, is a limited number of people, generally related or living in the same household. While the regulation provides an example of a married couple, another example would be a parent and child who are both Medicare-eligible. Meetings with unrelated beneficiaries in a home or a public space, such as a book club at a house or a small group at a library, would require separate SOAs for each individual. In addition, §§ 422.2264(c)(3) and 423.2264(c)(3) state that personal marketing appointments are not defined by the location, meaning that such an appointment could take place in-person, telephonically, or virtually.

For more context on what a personal marketing appointment is, CMS reminds plans and agents/brokers of the types of activities that may take place at such an appointment. Per §§ 422.2264(c)(3)(ii) and 423.2264(c)(3)(ii), plans and agents/brokers holding a personal marketing appointment may do any of the following: (1) provide marketing materials; (2) distribute and accept plan applications; (3) conduct marketing presentations; and (4) review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

Following the introductory definition of a personal marketing appointment, §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) describe the current 48-hour SOA rule. CMS is proposing to remove the word ''scheduled'' before ''personal marketing appointment'' at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), so that the proposed text would state that ''prior to the personal marketing appointment,'' the MA/Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). Likewise, CMS is proposing to amend §§ 422.2274(b)(3) and 423.2274(b)(3) to more closely align with §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) by replacing ''prior to meeting with potential enrollees'' with ''prior to a personal marketing appointment.'' CMS believes these regulatory text changes are necessary to avoid ambiguity and prevent misinterpretation.

If finalized as proposed, CMS's removal of the word ''scheduled'' would mean that an SOA would be required for

all appointments that meet the definition of personal marketing appointments. For example, an SOA would be required for plan/agent/broker-initiated outbound contact and for beneficiary-initiated inbound contact (including walk-ins, unscheduled calls and web-based chats, and web-based forms), as long as the contact is tailored to an individual or small group (as explained earlier in the proposal) for purposes of discussing marketing topics. To be clear, this means that an SOA would be required regardless of whether the personal marketing appointment was initiated by the plan, an agent/broker, or the beneficiary.

Other relevant requirements regarding the SOA are related to the method of delivery and where SOAs may and may not be accepted or collected. In order to align with the statutory requirements at section 1851(j)(2)(A) of the Act, CMS is proposing to add that the SOA must be in writing for in-person personal marketing appointments by adding new regulatory text to §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i). This proposed change mirrors the statutory requirement which provides that if the marketing appointment is in person, then the SOA must be in writing. The proposed new regulatory text at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i) would read, ''The Scope of Appointment must be in writing for in-person personal marketing appointments.'' Additionally, §§ 422.2274(c)(9)(ii) and 423.2274(c)(9)(ii) require agents/brokers to establish and maintain a system for confirming that agents/brokers appropriately complete SOA records for all marketing appointments (including telephonic and walk-in). Here, CMS is proposing to add the word ''personal'' to §§ 422.2274(c)(9)(ii) and 423.2274(c)(9)(ii), so that it reads ''personal marketing appointments'' to ensure consistency with the other regulation sections previously mentioned. CMS is also clarifying that there are many ways that an agent/broker can complete an SOA record. For example, an audio or audio-visual recording or an electronic record would suffice as an SOA record for a personal marketing appointment that does not occur in person. Instances in which SOAs may be accepted or collected include: (1) plan activities in the health care setting (§§ 422.2266(e)(1) and 423.2266(e)(1)); (2) marketing events (§§ 422.2264(c)(2)(ii)(C) and 423.2264(c)(2)(ii)(C)); and (3) educational events—if the proposed changes to §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D) are finalized as proposed. Instances in which SOAs may not be accepted or collected include: (1) plan-initiated provider activities (§§ 422.2266(d)(1)(i) and 423.2266(d)(1)(i)); and (2) activities performed by social workers of an I–SNP (employees, agents, or contracted providers) (§ 422.2266(f)(3)).

Regarding the content of the SOA, CMS is clarifying here that, because §§ 422.2264(c)(3)(iii) and 423.2264(c)(3)(iii) require that plans and agents/brokers holding personal marketing appointments may not market any health care related product during an appointment beyond the scope agreed upon by the beneficiary and documented in an SOA, the SOA must therefore include, at a minimum, the type of product(s) to be discussed. This aligns with section 1851(j)(2)(A) of the Act's reference to ''the scope of the marketing appointment.'' Examples of types of products to be discussed include, but are not limited to, MA plans, MA–PD plans, and standalone PDPs. As a best practice, in addition to the type of product(s) to be discussed, CMS encourages plans to also include other pertinent information in the SOA, such as the date of the appointment and beneficiary contact information. In addition, on the SOA form, CMS permits plans to have check boxes or requests from the beneficiary regarding the type of product(s) to be discussed, for example, an internet site with an online form that requests a plan or an agent/broker to contact the beneficiary. Provided this type of SOA form addresses the type of product(s) to be discussed, the plan or agent/broker may contact the beneficiary after the form has been filled out. CMS also clarifies that Business Reply Cards (BRCs), voicemails, online forms, or other requests for information that include the type of product(s) to be discussed are, in effect, SOAs. CMS currently does not provide a model document for SOAs.

Lastly, CMS would like to remind plans and agents/brokers of and clarify the requirements regarding the validity time period for an SOA. Pursuant to §§ 422.2264(c)(3)(iii)(A) and (B) and 423.2264(c)(3)(iii)(A) and (B), SOAs, BRCs, and other requests for additional information are valid for 12 months following the beneficiary's signature date or the date of the beneficiary's initial request for information. During this 12-month period, plans or agents/brokers may contact beneficiaries regarding the agreed upon scope of products documented in the SOA. This does not grant permission to discuss products not previously agreed upon in the original SOA; any new product discussion outside the scope previously agreed upon would require a new SOA. This includes the same product for a different year (for example, if there is an SOA to discuss contract year 2026 plans, then a new SOA would be required to discuss contract year 2027 plans). Finally, the signed SOA can be used for multiple telephonic or in-person contacts or appointments. With that said, a plan or agent/broker should respect a beneficiary's request to no longer be contacted, even if that additional contact would take place within the 12-month window.

3. Scope of Appointment (SOA) Forms at Educational Events

In the January 2021 final rule, at §§ 422.2264(c)(1)(ii)(E) and 423.2264(c)(1)(ii)(E), CMS codified rules permitting plans and agents/brokers holding or participating in educational events with beneficiaries to obtain beneficiary contact information, including SOA forms, at educational events. In the April 2023 final rule, at §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D), CMS finalized rules that revised these regulations by prohibiting plans and agents/brokers from making available and receiving SOA forms from beneficiaries at educational events (other forms of beneficiary contact information, including BRCs, were still permitted). This is the current policy regarding SOA forms at educational events.

CMS is proposing to rescind these requirements as finalized in the April 2023 final rule and revert to the language established in the January 2021 final rule, to permit plans and agents/brokers to obtain SOA forms at educational events. Although section 1851(j)(1)(D)(ii) of the Act prohibits sales and marketing activities from occurring at educational events, the statute does not prohibit the collection of SOA forms at educational events. The collection of an SOA form is not a sales or marketing activity but is the making of an agreement regarding what type of product(s) will be discussed in advance of a personal marketing appointment between the beneficiary and the plan or agent/broker. By permitting plans and agents/brokers to obtain SOA forms at educational events, the burden on beneficiaries, plans, and agents/brokers would be reduced, and parties would be allowed to conveniently schedule personal marketing appointments to discuss plan options in the future, instead of having to wait until after the educational event ends to schedule an appointment. If plans and agents/brokers are allowed to collect SOAs at educational events, then it decreases the likelihood that beneficiaries might face

undue burden and the potential challenge of reconnecting with a plan or agent/broker or traveling back to a venue to locate a plan or agent/broker at the conclusion of an educational event.

CMS acknowledges that this proposal reflects a change in the agency's position as described in the April 2023 final rule where CMS most recently adopted the ban on collecting SOA forms at educational events. For example, as part of its previous reasoning, CMS stated that it was concerned that beneficiaries may feel uncomfortable refusing to fill out an SOA form, or that they may feel obligated to provide this information in exchange for attending an educational event. Upon reconsideration, CMS now recognizes that these concerns regarding beneficiary pressure appear to be outweighed by the importance of maximizing beneficiary access to information on available plan options, which could be accomplished by allowing the collection of SOA forms at educational events. In addition, as previously mentioned, there are also beneficiary protections in place should a beneficiary make an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics.

Thus, CMS proposes to modify §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D) to permit plans and agents/brokers holding or participating in educational events with beneficiaries to make available and receive SOA forms at those same educational events. Specifically, at paragraph (c)(1)(ii)(D) in both §§ 422.2264 and 423.2264, CMS proposes to replace the phrase ''Cards, but not including Scope'' with the phrase ''Cards and Scope'' so that it reads ''including Business Reply Cards and Scope of Appointment forms.'' CMS notes that the remaining distinctions and inherent beneficiary protections between educational events as required under §§ 422.2264(c)(1) and 423.2264(c)(1) and marketing or sales events as required under §§ 422.2264(c)(2) and 423.2264(c)(2) remain.

In summary, CMS is proposing to modify §§ 422.2264(c) and 423.2264(c) to improve rules regarding beneficiary outreach and §§ 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii) to add specificity and clarify policy in conjunction with the primary proposals at §§ 422.2264(c) and 423.2264(c). These primary proposals include: (1) allowing a marketing event to directly follow an educational event in the same location; (2) allowing a personal marketing appointment to occur at any point following completion of an SOA form; and (3) allowing the SOA form to be collected from beneficiaries at educational events. CMS's proposed regulatory changes would remove current rules on the time and manner of beneficiary outreach, reduce burden on beneficiaries, plans, and agents/brokers, foster a convenient, beneficiary-friendly experience in the enrollment decision-making process, and ensure consistency and clarity in the regulatory text.

These proposals are not expected to have any economic impact on the Medicare Trust Fund, nor are they expected to have any negative impacts based on capital investments associated with the requirements that CMS is proposing to remove. CMS solicits comments on these proposed amendments to §§ 422.2264(c), 423.2264(c), 422.2274(b)(3), 423.2274(b)(3), 422.2274(c)(9)(ii), and 423.2274(c)(9)(ii), including on the accuracy of assumptions regarding information collection requirements. CMS thanks commenters in advance for their feedback.

G. Relaxing the Restrictions on Language in Advertising (§§ 422.2262(a)(1)(i), 422.2262(a)(1)(ii), 423.2262(a)(1)(i), and 423.2262(a)(1)(ii))

In the Medicare and Medicaid Program; 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 (*86 FR 5864*), hereinafter referred to as the January 2021 final rule, CMS codified 42 CFR 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii), which prohibited MA organizations and Part D sponsors from making unsubstantiated statements, except when used in logos or taglines. Prior to the January 2021 final rule, this requirement was in the Medicare Communications and Marketing Guidelines (MCMG). 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 (*88 FR 22120*), hereinafter referred to as the April 2023 final rule, CMS updated §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) to prohibit MA organizations and Part D sponsors from using superlatives, unless sources of documentation or data supportive of the superlative is also referenced in the marketing or communications material where the superlative is being used. CMS finalized this current requirement asserting that, without the updated requirement, a beneficiary may have no knowledge of how the superlative is determined, which may mislead the beneficiary into believing a statement that is not accurate. At the time, CMS noted that providing current, reliable, and valid data as the basis for superlatives is critical for beneficiaries to review the data themselves (88 FR 22238).

When CMS first codified §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) in the January 2021 final rule, CMS explained that the policies being codified were not new to MA organizations and Part D sponsors as they were already included in the MCMG, on which the industry heavily relied at that time (86 FR 5981). After years of implementation and oversight, including one revision to the requirement, CMS now believes the current restrictions regarding use of superlatives at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) are unnecessary as, per §§ 422.2262 and 423.2262, MA organizations and Part D sponsors are already broadly prohibited from providing beneficiaries marketing and communications materials that are misleading, confusing, or materially inaccurate. Although CMS is proposing to remove the prohibition on the use of superlatives, MA organizations and Part D sponsors would still be required to ensure that all statements, including superlatives, included in marketing and communications materials do not mislead, confuse, or provide materially inaccurate information to current or potential beneficiaries. CMS will continue to review materials as described at §§ 422.2261 and 423.2261, and may request data, reports, or other documentation that supports the MA organization or Part D sponsor's statements in these materials either as a part of the formal review process or based on beneficiary complaints after the materials are actively being used. If finalized, CMS would continue to encourage MA organizations and Part D sponsors to make available to beneficiaries and the public the data, reports, or other documentation that supports the superlative to promote informed enrollment decisions.

Sections 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) were intended to strengthen protections for beneficiaries to ensure they had access to all necessary information needed to make an informed enrollment decision. However, because §§ 422.2262 and 423.2262 already broadly prohibit misleading, confusing, and inaccurate marketing and communications materials, CMS believes that removing

§§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) will not affect the existing beneficiary protections, which will still be in effect, but will reduce the administrative burden for all parties. Although removing §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) does not remove the prohibition on providing misleading, confusing, or materially inaccurate information to beneficiaries, it does remove the requirement for MA organizations and Part D sponsors to reference supporting documentation or data directly in the material. CMS notes, however, that if this proposed change to CMS's regulations is finalized, MA organizations and Part D sponsors can still choose to make data available to beneficiaries as they determine appropriate, which may reduce the administrative burden.

CMS will continue to review applicable materials to ensure they do not provide misleading, confusing, or materially inaccurate information to beneficiaries. To aid CMS in determining if a material is misleading, confusing, or materially inaccurate; in some instances, it may expedite the review process if the MA organization or Part D sponsor provides supporting documentation when submitting marketing materials that include the use of superlatives. Moreover, when the Agency is investigating a material based on a complaint that it was misleading, confusing, or materially inaccurate, CMS may request the plan provide documentation that supports the superlative, per the Agency's oversight authority at §§ 422.504(f)(2) and 423.505(f)(2).

For example, quantifiable superlatives such as ''highest rated providers in Chester County,'' ''largest provider network in Florida,'' or ''highest rated plan in Virginia'' would be acceptable if this proposed rule is finalized. Further, MA organizations and Part D sponsors must be able to factually support such superlatives through data, surveys, studies, or other type of information, and when requested, provide that information to CMS. In addition, when including superlatives based on older data, to ensure that they are not misleading or confusing, MA organizations and Part D sponsors should indicate the year or in some way show the statement is based on data older than the current or prior contract year. For example, the use of a superlative such as ''The most popular Medicare Prescription Drug plan in Montgomery County in 2023'' would be acceptable if this proposed rule is finalized. Conversely, CMS would generally find the same statement to be misleading if the date was missing.

CMS recognizes that not all superlatives can be quantified or reasonably measured. For example, the use of superlatives such as ''our plan cares about you the most'' and ''we have the most dedicated providers in our network.'' Both examples would be permissible if this proposed rule is finalized, and CMS would not expect MA organizations or Part sponsors to provide supporting documentation as a part of submission, nor would the agency request such information as a part of a complaint investigation.

Consistent with Executive Order 14267,[55] Reducing Anti-Competitive Regulatory Barriers, issued on April 9, 2025, CMS believes that removing the prohibition on the use of superlatives and underscoring the continued requirement of not misleading, confusing, or providing inaccurate information to beneficiaries will likely promote competition as this revision provides more opportunities for MA organizations and Part D sponsors to innovate while simultaneously protecting beneficiaries' access to accurate materials to help with their enrollment decisions.

For the reasons discussed, CMS proposes to delete current paragraphs at §§ 422.2262(a)(1)(ii) and (a)(1)(ii)(A), and 423.2262(a)(1)(ii) and (a)(1)(ii)(A) in their entirety to remove the prohibition of using superlatives in marketing and communications materials without providing supporting documentation. With this revision, CMS will renumber current paragraphs §§ 422.2262(a)(1)(iii)–(xix) and 423.2262(a)(1)(iii)–(xviii).

Consistent with Executive Order 14192,[56] Unleashing Prosperity Through Deregulation, issued on January 31, 2025, CMS also proposes deleting the current paragraphs at §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), which reiterate the prohibition on MA organizations and Part D sponsors providing misleading and inaccurate information to beneficiaries. This is a technical change that would remove the duplication of §§ 422.2262 and 423.2262, which already require MA organizations and Part D sponsors to not provide misleading, confusing, or materially inaccurate information to current and potential beneficiaries.

CMS welcomes comments on the proposed changes to §§ 422.2262(a)(1)(i) and (ii) and 423.2262(a)(1)(i) and (ii), and thanks commenters in advance for their feedback.

H. Third-Party Marketing Organization (TPMO) Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings (§§ 422.2274(g)(2) and 423.2274(g)(2))

CMS is proposing to revise the marketing and sales recording requirements at 42 CFR 422.2274(g)(2) and 423.2274(g)(2). Consistent with the 10 year record retention requirements and access to records requirements described in §§ 422.504(d) and (e)(1)(iv) and §§ 423.505(d) and (E)(1)(iv), MA Organizations and Part D sponsors are expected to retain the sales and marketing call recordings described in §§ 422.2274(g)(2) and 423.2274(g)(2) for 10 years. CMS is proposing to update §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to reduce the amount of time that MA Organizations and Part D sponsors are required to retain recordings of marketing and sales calls to 6 years, while maintaining the requirement that enrollment records be retained for 10 years, as required under §§ 422.504(e)(1)(iv) and 423.505(e). This proposal modifies only the record retention requirements for the marketing and sales portions of calls at 42 CFR part 422, subpart V and Part 423, Subpart V. CMS has long required enrollment records to be maintained for 10 years and this proposal does not remove applicable enrollment documentation and retention requirements set forth in other regulations, specifically the requirement to file and retain enrollment forms as required in §§ 422.60(c)(2), 422.504(e)(1)(iv) and 423.505(e)(1)(iv). To meet enrollment documentation requirements for enrollments that occur over the phone, plans would still be required to record the enrollment portion of the call, as the recording in this instance serves as the enrollment form and provides proof that the beneficiary attested to their intent to enroll in accordance with § 422.60(c)(2) and the Medicare Managed Care Manual, Chapter 2, Medicare Advantage Enrollment and Disenrollment, Section 40.1.3. The enrollment portion of the call begins when the beneficiary is advised that they are completing an enrollment request, after which they provide the information as required by the enrollment form and attest to their intention to enroll.

As a part of the 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

[55] *https://www.federalregister.gov/documents/2025/04/15/2025-06463/reducing-anti-competitive-regulatory-barriers.*

[56] *https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.*

COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Final Rule (hereafter referred to as the May 2022 final rule) (87 FR 27704), CMS finalized regulations at §§ 422.2274(g)(2) and 423.2274(g)(2) regarding plan oversight of Third-Party Marketing Organizations (TPMOs). Under these regulations, MA organizations and Part D sponsors must have certain requirements in their contracts, written arrangements, and agreements with TPMOs, or between the TPMO and MA organization or Part D sponsor's first tier, downstream, and related entities (FDR). In §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii), CMS finalized the requirement that an MA organization or a Part D sponsor's contract, written arrangement and/or agreement with the aforementioned entities must ensure that all calls with beneficiaries are recorded in their entirety. In addition, in order to ensure compliance with the 10-year record retention and access to records requirements described in §§ 422.504(d) and (e)(1)(iv) and § 423.505(d) and (e)(1)(iv), MA organizations and Part D sponsors are expected to retain the sales and marketing call recordings described in §§ 422.2274(g)(2) and 423.2274(g)(2) for 10 years.

Following the finalization and implementation of the May 2022 final rule, CMS received questions regarding retention requirements for recorded calls, as MA organizations and Part D sponsors were unsure if calls regarding marketing, sales, and enrollment were subject to the 10-year record retention requirements at §§ 422.504(d) and 423.505(d). CMS also received questions about the scope of ''all calls'' for recording purposes, including if the recording requirement extended to calls that merely set an appointment with a potential enrollee, calls to enrollees to confirm welcome packets were received, and other non-marketing or non-sales calls to prospective enrollees. CMS notes that the May 2022 final rule did not provide exceptions or otherwise establish a more defined boundary for the type of call that was subject to recording and retention. To rectify any potential unintended consequences stemming from the standard that CMS codified in the May 2022 final rule, CMS issued 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 Policy Final Rule (hereafter referred to as the April 2023 final rule) (88 FR 22120), to address the requirement that all calls be recorded and retained. In the April 2023 final rule, CMS modified §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) to require only the recording of marketing, sales, and enrollment calls, including the audio portion of calls via web-based technology. The implementation of this revised and less burdensome call recording requirement was to ensure the necessary calls were recorded and available for oversight and monitoring while still reducing some level of burden on plans.

CMS has continued to oversee and monitor agent and broker behavior by reviewing call recordings to determine compliance. In addition to CMS, other governmental entities (*e.g.,* Department of Justice) have relied on call recordings for investigations. CMS has requested call recordings based on complaints from CMS's Complaint Tracking Module (CTM). The requested recordings were chosen based on the severity of the allegations in the complaint in the CTM and used to determine if the merit of the claims against the agent or broker. The outcome of CMS's review of the marketing and sales portion of the call recordings has been mixed. In some instances, the recordings did not support the beneficiary's complaint as detailed in the CTM. In other instances, the complaints were substantiated by the recording. These reviews have shown examples where agents and brokers fail to provide sufficient information for a beneficiary to make an informed decision or the information provided by the agent or broker is inaccurate. For reviewed complaints that are substantiated, CMS has notified the MA organization or Part D sponsor of the agency's findings and requested the organization review the results and take appropriate action against the agent, broker, or TPMO. MA organizations and Part D sponsors have responded to CMS's findings with actions such as retraining or discontinuing contracts with certain entities.

MA organizations and Part D sponsors are responsible for ensuring all downstream entities meet CMS's requirements. There are over 68 million Medicare beneficiaries, of which 51.1 percent are enrolled in MA and other health plans.[57] Of the approximately 34 million beneficiaries enrolled in an MA plan or other health plan, 31 percent use agents to assist with plan choices,[58] resulting in 10,540,000 beneficiaries discussing plan options with agents annually. Each year, only three out of every ten beneficiaries compare plans during Medicare's Annual Election Period,[59] resulting in approximately 3.1 million beneficiaries using agents or brokers to review their plan choices. Based on these data, CMS conservatively estimates that MA organizations, Part D Sponsors, and their TPMOs must record hundreds of thousands of calls each year to comply with these regulatory requirements, resulting in millions of calls being subject to the 10-year retention requirement.

CMS recognizes the cost and burden of these requirements. CMS has received comments from industry groups noting the costs associated with recording and retaining the marketing and sales portion of calls. Audio call files are large, taking a substantial amount of data storage, especially when the record retention requirement is to store these calls for 10 years. In addition, to the cost of maintaining these calls, CMS is highly unlikely to review calls past the 6-year mark. To best address marketing complaints, the review of calls typically needs to be much closer to the timeframe of the actual complaint. Reviewing complaints that are 10 years old may result in the discovery of issues that are irrelevant and that will not result in identifying current issues that affect beneficiaries. Because of these reasons, CMS is proposing to reduce the timeframe for the retention of the marketing and sales portion of calls from a 10-year requirement to a 6-year requirement. If finalized, this revised retention requirement would also apply to currently retained call recordings, meaning that any marketing and sales portion of calls older than 6 years that are currently being retained would no longer need to be retained.

CMS believes a 6-year record retention requirement for the marketing and sales portion of calls is sufficient for the purpose of enabling CMS review of agent and broker behavior and balances the need for appropriate oversight while also providing consideration of the burden imposed by record retention. It is helpful to CMS to review the marketing and sales portion of audio recordings when the Agency receives complaints from of beneficiaries related to being misled into choosing a plan and

[57] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.*

[58] *https://www.medpac.gov/wp-content/uploads/2024/08/Medicare-agents-MedPAC-03.25sec.pdf.*

[59] *https://www.kff.org/medicare/issue-brief/nearly-7-in-10-medicare-beneficiaries-did-not-compare-plans-during-medicares-open-enrollment-period/.*

then enrolling in that plan. The marketing and sales portion of these recordings is most useful when it is recent and permits CMS to provide timely feedback to MA organizations and Part D sponsors, so they may, in turn, quickly address any compliance issues that are identified by CMS review.

While proposing a revised 6-year record retention requirement for the marketing and sales portion of calls, CMS is also considering several other alternatives described below and CMS might finalize a policy that includes, but is not limited, to the specific alternatives discussed below. CMS is considering alternatives based on the cost and burden of recording and storing calls when CMS only reviews a few hundred calls each year.

One alternative to the proposed 6-year retention requirement is to reduce the 10-year retention requirement for the marketing and sales portion of calls to a 3-year retention requirement. This alternative would also further decrease existing burden and costs on MA organizations and Part D sponsors but would provide both CMS and other oversight organizations with a shorter lookback period. A shorter lookback period could make it more challenging to identify longer-term trends, including potential trends associated with TPMOs. However, a 3-year retention requirement would result in a more significant decrease in burden as compared to the proposed 6-year retention requirement.

CMS is also considering alternatives such as whether audio recordings of the marketing and sales portion of calls are necessary for record retention purposes or whether the ability to review agent and broker behavior could be achieved via other, less expensive means. Specifically, CMS is considering whether permitting written retention of the marketing and sales portion of calls (*i.e.,* a transcript) in lieu of retaining audio recordings of such calls, or a hybrid approach that requires audio recordings for 3 years followed by written retention for remainder of the retention period would be sufficient to achieve the purpose articulated by CMS within this proposal. An important factor to this alternative is the ability of current technology to automate the transcription with sufficient accuracy. CMS believes these transcripts might still provide CMS with enough ability to review interactions between beneficiaries and agents and brokers to identify non-compliance similar to the review of audio recordings. On the other hand, transcripts would not capture the tone by which the agent or broker interacted with the beneficiary. Either way, the data storage costs of retaining transcripts may be less than the data storage costs of audio recordings, further reducing burden if new costs from automated transcription did not outweigh those savings.

Finally, based on the mixed findings from the review of call recordings, CMS is also considering, as an alternative, whether maintaining a recording, either audio or otherwise, of the marketing and sales portion of calls is necessary at all. The results of the review of these portions of calls, as identified earlier in this proposal, have provided examples that agents and brokers do not always provide accurate and truthful information. Conversely, in other instances, the call recordings offer a way to refute beneficiary complaints, such as those filed through 1–800–MEDICARE. However, by eliminating these requirements, CMS and other oversight organizations would not have the ability to directly review agent and broker behavior to ensure beneficiaries select a plan that best meets their needs. CMS acknowledges there are differences between MA, Part D, Marketplace, Medicaid, and commercial insurance, however, CMS notes the elimination of recording the MA and Part D marketing and sales portion of calls would result in more parity with the requirements of these programs.

To reiterate, CMS is specifically seeking comment on: (1) the appropriate duration of the recording retention requirement, *i.e.,* 3 years, 6 years, or other timeframes, for the marketing and sales portion of calls; (2) alternative means of recording the marketing and sales portion of calls, such as transcription, in lieu of requiring an audio recording, including input on other technologies to aid in capturing the interaction between a TPMO and a Medicare beneficiary; (3) whether the agency should completely remove the requirement to record the marketing and sales portion of calls, including what alternative means of oversight the agency could implement to ensure an appropriate level of oversight; and (4) the impact of proposed and alternative requirements on beneficiaries. CMS also welcomes other options for reducing the burden and costs associated with these requirements. In providing alternatives, CMS is also seeking the savings attributed to each of the alternatives. We are also seeking rationale, including the accuracy of transcriptions, for each alternative.

CMS solicits comments on all aspects of this proposal and may consider alternatives and other revisions based on the comments received, including, but not limited, to the specific alternatives discussed above, which, based on comments, may be finalized rather than the proposal.

I. Rescinding the Requirement for the Notice of Availability (§§ 422.2267(e)(31) and 423.2267(e)(33))

The Notice of Availability of language assistance services and auxiliary aids and services (NoA) material, formerly known as the Multi-language insert (MLI), required at 42 CFR 422.2267(e)(31) and 423.2267(e)(33), has been modified in conjunction with changes to the Health and Human Services Office for Civil Rights (OCR) language assistance notification requirements (currently at 45 CFR 92.11), implementing section 1557 of the Affordable Care Act (ACA), 42 U.S.C. 18116. Currently, CMS's NoA requirements are closely aligned with and broadly duplicate OCR's NoA requirements. On March 1, 2025, Executive Order (E.O.) 14224 was issued: ''Designating English as the Official Language of The United States'' (hereinafter referred to as E.O. 14224).[60] E.O. 14224 designates English as the official language of the United States and includes the revocation of E.O. 13166 of August 11, 2000 (Improving Access to Services for Persons with Limited English Proficiency). On January 31, 2025, E.O. 14192 was issued: ''Unleashing Prosperity Through Deregulation'' (hereinafter referred to as E.O. 14192).[61] E.O. 14192 describes the Administration's policy goals to promote prudent financial management and alleviate unnecessary regulatory burdens. Section 2 of E.O. 14192 states that ''it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people.'' Lastly, a recent memorandum from the Office of the Attorney General, released on July 14, 2025,[62] which provides guidance for compliance with E.O. 14224, introduces additional uncertainty regarding the future of language assistance requirements. To ensure consistency and reduce the risk of misalignment, CMS believes it is prudent to defer to OCR as to how this guidance will impact language assistance and auxiliary aid and service

[60] *https://www.whitehouse.gov/presidential-actions/2025/03/designating-english-as-the-official-language-of-the-united-states/.*

[61] *https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-prosperity-through-deregulation/.*

[62] *https://www.justice.gov/opa/pr/justice-department-releases-guidance-implementing-president-trumps-executive-order.*

requirements throughout the programs under HHS's purview.

CMS's requirements under §§ 422.2267(e)(31) and 423.2267(e)(33) currently duplicate OCR requirements at 45 CFR 92.11. To ensure clarity, minimize administrative burden, and limit confusion for MA organizations and Part D sponsors regarding language assistance and auxiliary aids and services notification requirements, CMS is proposing to eliminate the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) and to defer to OCR's oversight and management of any requirements related to language assistance and auxiliary aids and services notifications. This would mitigate the potential for future misalignment and the need for additional modifications to CMS's requirements as policy evolves.

CMS historically has looked to OCR's language requirements when promulgating regulations for the MA and Part D programs. On May 18, 2016, OCR published the Nondiscrimination in Health Programs and Activities final rule (81 FR 31376), hereinafter referred to as the ''2016 section 1557 final rule,'' implementing the requirement that all covered entities—any health program or activity that receives Federal financial assistance—include taglines with all ''significant communications.'' On June 19, 2020, the Department of Health and Human Services (Department) published a new section 1557 final rule, ''Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority,'' hereinafter referred to as the 2020 section 1557 final rule (85 FR 37160), rescinding the 2016 section 1557 final rule's tagline requirements (84 FR 27860).

To address the gap after the rescission of OCR's tagline requirements in the 2020 section 1557 final rule, CMS finalized an MLI requirement in the ''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'' final rule (87 FR 27704), hereinafter referred to as the ''May 2022 final rule.'' CMS, at §§ 422.2267(e)(31) and 423.2267(e)(33), required the MLI to have a CMS-provided standardized tagline in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. Additionally, the MLI required that MA organizations and Part D sponsors include additional languages in the plan's service area that met the 5 percent service area threshold, as required under §§ 422.2267(a)(2) and 423.2267(a)(2). Sections 422.2267(a)(2) and 423.2267(a)(2) require that, for all required materials and content under §§ 422.2267 and 423.2267, MA organizations and Part D sponsors must, ''for markets with a significant non-English speaking population, be in the language of these individuals.'' Specifically, MA organizations and Part D sponsors ''must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.''

On August 4, 2022, OCR proposed a new rule, Nondiscrimination in Health Programs and Activities (hereinafter referred to as the ''2022 proposed rule'') for section 1557 of the ACA (87 FR 47824), to require covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities at no cost using a NoA and requiring that the NoA be provided in English and at least in the 15 most common languages spoken by individuals with limited English proficiency in the relevant State or States, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications.'' [63]

To ensure consistency, following OCR's 2022 proposed rule, CMS finalized the current NoA 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 (89 FR 30448), hereinafter known as the ''April 2024 final rule.'' In this rule, CMS renamed the required document from the MLI to the Notice of availability of language assistance services and auxiliary aids and services at §§ 422.2267(e)(31) and 423.2267(e)(33) to align with OCR's language. Additionally, the notice was recategorized from a standardized communications material to a model communications material, requiring plans to include in the notice that, at a minimum, the MA organization or Part D sponsor provide language assistance services and appropriate auxiliary aids and services free of charge (89 FR 30534). The updated NoA also updated the language criteria to align with OCR's proposed language at the time. To align with OCR, CMS finalized the requirement for plans to provide the NoA ''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 must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.'' CMS maintained the requirement that the NoA also include any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area, provided it was beyond 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. This update resulted in the potential for MA plans and Part D sponsors to develop a NoA with more than 15 languages, exceeding OCR's requirements.

While currently, OCR's and CMS's requirements are mostly aligned, CMS notes minor differences in the language of the current regulations. The OCR NoA requirement applies to the ''State or States in which a covered entity operates'' which is broader than CMS's requirement. CMS's NoA requirement applies to the ''State or States associated with the plan's service area'' which CMS defined as the plan benefit package level. Additionally, CMS requires the NoA to be included on all CMS required materials at §§ 422.2267(e) and 423.2267(e), whereas OCR's language regarding where the NoA should be placed (45 CFR 92.11(c)(5)) is less specific, though its guidance still aligns with many of CMS's required materials.

As discussed in the April 2024 final rule, the ACA (42 U.S.C. 18116(c)) provides that, except where otherwise provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, or national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits

[63] The proposed rule was finalized, with minor modifications on May 6, 2024, (89 FR 37522), creating the requirements for the notice of the availability of language assistance services and auxiliary aids and services at 45 CFR 92.11.

of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance); any program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act.

In the April 2024 final rule, CMS cited discussions from the May 2022 final rule, that ''solely relying on the requirements delineated in the 2020 section 1557 final rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans'' (89 FR 30529). At the time, CMS took the position that ''informing Medicare beneficiaries that interpreter services are available is essential to realizing the value of our regulatory requirements for interpreter services'' (89 FR 30529). CMS further explained that through additional insights ''regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries the materials required under §§ 422.2267(e) and 423.2267(e) were vital to the beneficiary's decision-making process'' (87 FR 27821). CMS also cited complaint tracking module (CTM) cases in the Health Plan Management System (HPMS) related to ''language'' and found a pattern of beneficiary confusion stemming from not fully understanding materials based on a language barrier.

In the April 2024 final rule, CMS also explained that updating the NoA requirements in Parts C and D would help align with the Medicaid requirement under § 438.10(d)(2), in which ''States must require Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management programs to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State explaining the availability of oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services in the State'' (89 FR 30529). Therefore, CMS finalized NoA requirements that also aligned with Medicaid materials requirements, such as updating the NoA to require the 15 most common languages in the State rather than the 15 most common languages nationally (89 FR 30529).

While CMS's and OCR's current requirements are now mostly aligned, CMS is concerned that the duplicative nature of these requirements may potentially result in additional regulatory updates, and corresponding burdens as policy evolves. Because CMS and OCR regulatory schedules vary, the potential differences in requirements can be confusing and burdensome to MA organizations and Part D sponsors who are subject to CMS requirements and the broader OCR requirements as covered entities. Additionally, uncertainty regarding broad changes to language assistance and notification requirements, or how OCR may modify their requirements as policy evolves may result in additional confusion, administrative burden and potential for misalignment of the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33). Eliminating the NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) will ensure consistency and clarity for covered entities as these requirements will be addressed centrally by OCR. CMS notes that dual eligible special needs plans would still be subject to any notice requirements that may be included in the State Medicaid agency contract or State statute for Medicaid as applicable. Overall, CMS's position is that eliminating the duplicative nature of OCR's and CMS's regulatory requirements supports the principles set forth in E.O. 14192 by promoting prudent financial management and alleviating unnecessary regulatory burdens.

In summary, this proposal will reduce administrative burden on CMS, MA organizations and Part D sponsors by eliminating duplicative requirements. CMS is not scoring this provision in the COI section as CMS believes there will be no burden impacts for this provision. In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund. CMS solicits comments on the agency's proposed amendments.

J. Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits

1. Background

Section 423.505(e) authorizes CMS to evaluate, through audit, inspection, or other means, the appropriateness of services furnished to Medicare enrollees under a Part D contract. Consistent with this authority, CMS conducts Part D prescription drug event (PDE) record review audits under the Center for Program Integrity (CPI) that identify improper PDE records paid under the Medicare Part D benefit, herein referred to as Part D program integrity PDE record review audits, including instances in which the drug, item, or service does not meet the definition of a covered Part D drug under section 1860D–2(e) of the Act. As part of these audits, CMS identifies PDE records that it believes are potentially improper, and plan sponsors submit supporting documentation to rebut this finding and demonstrate that the drug, item, or service was appropriate for coverage under the Medicare Part D program. If CMS determines, based on a review of this documentation, that Medicare Part D rules and regulations were not met and therefore the PDE is improper, CMS notifies the Part D plan sponsor to submit PDE deletion or adjustment records for the associated record(s) in accordance with § 423.325(a)(2) and subregulatory guidance. The deleted PDE records result in savings to the Medicare Trust Fund when the PDE record for a given plan year is included in that plan year's global reopening, described at § 423.308 and § 423.346(a)(2).

Currently, Part D plan sponsors have one opportunity to submit documentation demonstrating that a PDE record was appropriate for coverage under the Part D program, which occurs during the audit itself. Because there is currently no process for Part D plan sponsors to further appeal determinations that a PDE record was improper, we propose to establish a three level appeals process for Part D program integrity PDE record review audits. Specifically, we propose to amend 42 CFR part 423 subpart Z, which currently outlines the Recovery Audit Contractor (RAC) Part D appeals process, to include any Part D program integrity PDE record review audits. We also propose several conforming revisions to achieve alignment and streamlining of the Part D program integrity PDE record review audit appeals processes. Under this revised appeals process, Part D plan sponsors would receive an audit close out letter including: (1) an explanation of the drug, item, or service under audit; (2) a high-level overview of improper and proper PDE record counts; (3) an attached PDE level record file denoting improper and proper PDE records; (4) requirements for the submission of deletion records or adjustment records for the PDEs determined to be improper; and (5) instructions on how the Part D

plan sponsor may appeal the findings. There would be no minimum threshold for an appeal at any level.

2. Appeals Process

In this rule, we are proposing to codify at 42 CFR part 423 subpart Z changes to the existing RAC appeals process to include any CMS Part D program integrity PDE record review audits. To reflect the proposed expansion of the appeals process, we propose to revise the regulatory text title of subpart Z from ''Recovery Audit Contractor Part D Appeals Process'' to ''Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits''. This change will establish an appeals process for Part D plan sponsors to appeal findings for Part D program integrity audits conducted by CMS that review PDE records for appropriateness.

Currently, 42 CFR part 423 subpart Z sections 423.2600 to 423.2615 describe what may or may not be subject to appeal and the processes for each of the three levels of appeal, which include: (1) request for reconsideration, (2) hearing official review, and (3) review by the Administrator. To align with the changes being proposed concurrently under subpart Z, these regulations would likewise remove the mention of the RACs specifically, as the appeals process will include any Part D program integrity audits that review PDE records for appropriateness.

Furthermore, the proposed modifications would establish review timeframes for the different review entities at each level of appeal. The RAC Part D payment audits recovered improper payments from Part D plan sponsors through the monthly capitation payment, and therefore, could recover funds at any time without constraints. As such, the current regulatory text for the RAC audit appeals did not have a need to require that the independent reviewer make their decision within a certain timeframe. However, current Part D program integrity PDE record review audits require the plan sponsors to submit deletion records to CMS for all PDE records deemed improper during audit, in accordance with § 423.325(a)(2) and prior to the global reopening for any given plan year, to ensure the integrity of the Medicare Trust Fund. For these reasons, we believe it is necessary to provide timeframes for decisions to be made at each appeal level. We believe that three levels of appeal, with review timeframes, would allow sufficient opportunity for Part D plan sponsors to appeal a determination and ensure that timely and accurate determinations are made consistent with the rules and regulations of the Part D program.

a. Payment Appeals (§ 423.2600)

The current payment appeals language at § 423.2600 describes for the Part D plan sponsor what is or is not considered appealable during a RAC payment audit. To align with the broadened scope of subpart Z, as proposed, we are proposing to also amend the language describing what is or is not considered appealable to reflect the scenarios that apply to Part D program integrity PDE record review audits. As such, we propose to modify the existing regulatory language at § 423.2600 to state Medicare Part D plan sponsors may appeal program integrity PDE prescription drug even record review audit determinations. We propose to add a new paragraph (a) to § 423.2600, which would identify the issues that may be appealed through the audit appeals process. Specifically, under (a) Issues eligible for appeal, we propose to add paragraph (a)(1) to state CMS's application of Part D policy(ies). Part D policy(ies) refer to any Part D sponsor requirement from CMS outlined in the Code of Federal Regulations CFR, CMS manuals, or other communications from CMS. Proposed paragraph (a)(2) would specify that Part D sponsors may appeal factual or data errors. Examples of appealable issues at (a)(1) or (a)(2) would include: (1) a determination that a drug, item or service was excluded from coverage under the Medicare Part D program; or (2) a determination that a Medicare Part D payment was a duplicate payment. Errors of this nature would be appealable given there would be documentation for the reviewers to review to ensure that the payment was proper under the Medicare Part D benefit. The independent reviewer would review the documentation to determine and ensure that the payment was proper and in accordance with Medicare Part D policies. Furthermore, the independent reviewer may also determine, based on documentation submitted, whether the error resulted from actions made by CMS.

We propose to further amend § 423.2600 by adding a new paragraph (b), which would identify issues ineligible for appeal. Proposed paragraph (b)(1) would specify that Part D plan sponsors may not appeal the failure to submit documentation in the timeframes specified by CMS during the audit. Failure to submit documentation would not be appealable, given the plan sponsor has the opportunity to provide the documentation to CMS for review within a specified audit timeframe. Historically, during Part D program integrity PDE record review audits, the audit timeframes are extended due to the documentation lacking specific information needed to evaluate the PDE records appropriateness. This greatly affects the overall length of the audit and causes undue burden on both the plan sponsor and CMS. Therefore, CMS is proposing to require that plan sponsors provide documentation in accordance with the provisions in this proposed rule that propose updates at § 423.505, and accordingly, failure to provide this information would result in an improper determination that is not appealable. Providing documentation in accordance with the provisions proposed at § 423.505 will greatly reduce the burden and overall audit timeline for both CMS and Part D plan sponsors, as CMS will not have to request additional information from the plan sponsors. Proposed paragraph (b)(2) would state that Medicare Part D plan sponsors may not appeal the program integrity PDE record review audit methodology. That is, while CMS's application of Part D policy(ies) and factual or data errors may be appealed, the Part D plan sponsor may not appeal the underlying audit methodology, such as the manner in which data was extracted.

b. Reconsiderations (§ 423.2605)

In existing paragraph (a), we propose to replace the term ''demand letter'' with the term ''close out letter'' for consistency with current terminology in CMS's Part D program integrity PDE record review audits. In existing paragraph (e), we propose to add a timeframe for when the independent reviewer's decision needs to be decided and communicated to the Part D plan sponsor and CMS. Specifically, we propose to amend the language from ''[t]he independent reviewer informs CMS and the Part D plan sponsor of its decision in writing'' to ''the independent reviewer decides the reconsideration within 60 calendar days after the timeframe for filing a rebuttal has expired, and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.'' Adding a timeframe for the independent reviewer's decision gives CMS the opportunity to ensure that any upheld improper PDE records can be submitted as a deletion record by the plan sponsor within the global reopening timeframe.

c. Hearing Official Review (§ 423.2610)

In the existing regulatory text at § 423.2610, CMS outlines the process for a hearing official review. We propose to

revise paragraph (d)(2)(i), to replace ''Part D RAC'' with ''CMS'' for consistency with the changes, discussed previously, regarding the audits to which these appeals processes apply. We propose to revise paragraph (d)(3) to remove the phrase ''nor CMS may submit'' and replace it with ''nor CMS is permitted to submit'' to establish stronger verbiage that the submission of new evidence is not permitted by either the plan sponsor or by CMS and will not be considered by the hearing official. In addition, we propose to revise paragraph (e), to replace ''60 days'' with ''60 calendar days after the timeframe for filing a rebuttal has expired,'' to be explicit that 60 days refers to calendar days rather than business days. Furthermore, we propose to revise paragraph (f), to replace the existing language that states ''§ 423.2610'' with ''§ 423.2615'', to fix a citation error in the existing regulatory text. The existing text in paragraph (f) refers to the hearing official's decision being binding unless overturned in the third level of appeal by the CMS Administrator. The Administrator level of appeal is found at § 423.2615 not at § 423.2610, and therefore, the citation needs to be corrected.

d. Review by the Administrator (§ 423.2615)

In the existing regulatory text at § 423.2615, CMS outlines the process for the review by the Administrator. We propose to revise paragraph (b)(2) to remove the phrase ''nor CMS may submit'' and replace it with ''nor CMS is permitted to submit'' to establish stronger verbiage that the submission of new evidence is not permitted by either the plan sponsor or by CMS and will not be considered by the Administrator. In existing paragraph (d), we propose to replace ''45 days'' with ''30 calendar days.'' Furthermore, in existing paragraph (e), we propose to add a 45-calendar day timeframe for the Administrator to furnish a final decision. Specifically, the regulatory text will be amended to read, ''If the CMS Administrator agrees to review the hearing official's decision, he or she determines, after reviewing the hearing record and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and CMS within 45 calendar days after the timeframe for filing a rebuttal has expired.'' Both reducing the timeframe for the Administrator to decide if they will review the case and adding a timeframe for furnishing a final decision would help ensure that any upheld improper PDE records can be submitted as a deletion record by the plan sponsor within the global reopening timeframe. The timeframes proposed are critical to ensure the appeals process is completed by the PDE submission deadline for the global reopening. Completion within the global reopening timeframe enables CMS to properly oversee the Medicare Part D program by ensuring CMS has accurate, complete, and truthful claims data, in accordance with § 423.505(k)(3), and to protect the integrity of the Medicare Trust Fund.

K. Prescription Drug Event Submission Timeliness Requirements (§ 423.325)

1. Background

CMS codified its requirements for the timely submission of prescription drug event (PDE) records at 42 CFR 423.325 in the final rule titled ''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,'' which appeared in the April 15, 2025, **Federal Register** (hereinafter referred to as the April 2025 final rule). In that rule, we described the General PDE Submission Timeliness Requirements at § 423.325(a) and the Selected Drugs PDE Submission Timeliness Requirement at § 423.325(b).

Under the General PDE Submission Timeliness Requirements, a Part D sponsor must submit an initial PDE record within 30 calendar days from the date the Part D sponsor receives the claim, 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, and resolve rejected PDE records within 90 calendar days of the rejection. The General PDE Submission Timeliness Requirements apply unless the Selected Drugs PDE Submission Timeliness Requirement is applicable.

In this rule, we propose to modify the General PDE Submission Timeliness Requirements by modifying existing § 423.325(a)(3) related to the submission of PDE records to resolve a rejected PDE record. Under the current rule, Part D sponsors must submit a revised PDE record to resolve a PDE record that CMS rejected through the PDE editing process within 90 calendar days of the receipt of rejected record status from CMS. We recognize that submission of a revised PDE record is not always appropriate. As the regulation is currently written, a Part D sponsor may not be able to comply with the current rule under various scenarios. Therefore, we propose to set forth new requirements related to the resolution of rejected PDE records.

a. Rejected PDE Records

Part D sponsors submit PDE records to CMS through the Drug Data Processing System (DDPS). The DDPS performs checks on the data to validate and help ensure its accuracy, including checks for missing and invalid information, beneficiary eligibility, and calculation checks on costs and payment fields.[64] These checks can result in the PDE data being accepted or rejected by the DDPS. Consistent with our long-standing guidance[65] and pursuant to § 423.325(a)(3), Part D sponsors must resolve those rejections within 90 calendar days, that is, resubmit corrected PDE records to CMS within 90 calendar days of receiving the rejection.

CMS recognizes there are a range of situations where it might be inappropriate to submit a revised PDE record after receiving a rejection. For example, if a rejected record is no longer associated with a valid claim, it would not be appropriate for the Part D sponsor to submit a corrected PDE record. A valid claim would not exist, for example, if a pharmacy reversed the claim and returned the drug to stock because the beneficiary never obtained the prescription.

Likewise, if the PDE record that was rejected should never have been submitted to CMS in the first instance because the record was contrary to CMS's requirements, it would not be appropriate to resubmit a PDE record that continues to be contrary to CMS's requirements. For example, if a PDE record was rejected because the prescriber listed on the applicable claim is on the HHS–OIG's List of Excluded Individuals/Entities (LEIE) without an applicable waiver, CMS does not expect that the Part D sponsor would resubmit the PDE record if the claim continues to list an excluded prescriber without an applicable waiver.

Given the scenarios described in this Background, it may not be appropriate

[64] See generally, DDPS Edit Spreadsheet, at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References.*

[65] 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.cms.gov/httpsedit cmsgovresearch-statistics-data-andsystemscomputer-data-and-systemshpmshpms memos-archive/hpms-memo-qtr1-4.*

to resolve a PDE rejection with submission of a revised PDE record. The submission of a PDE record implies that there was and continues to be a valid claim. Resubmission of a previously rejected PDE record associated with an invalid claim could be harmful to the Part D program. Such data could inadvertently cause problems with the analysis of the rejected data, with no visibility into why such rejected data was never corrected.

In addition, it is not possible for the Part D sponsor to ''delete'' the rejected PDE record to avoid non-compliance with the requirement when these scenarios arise. This is due to operational constraints. CMS's DDPS does not allow Part D sponsors to submit PDE deletion records associated with rejected PDE records.

2. Requirements

As explained in the Background, CMS does not always have insight into why a Part D sponsor might not submit a revised PDE record to resolve certain rejected PDE records. Ensuring greater transparency regarding the status of rejected PDE records would enhance CMS's oversight of Part D sponsors' compliance with PDE submission timeliness requirements. We propose to modify the existing regulation at § 423.325(a)(3) to account for the scenarios described in the Background, increase transparency, and construct the requirement to account for circumstances where resubmission of PDE records is not appropriate.

We propose that Part D sponsors must submit a PDE record within 90 calendar days from receipt of the rejection and within every 90 calendar days thereafter until a revised PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error. We believe that submissions at least once every 90 calendar days will allow CMS to know that the rejected PDE record continues to reflect an active claim that the sponsor believes is valid and for which the sponsor is working to resolve the bases for the PDE rejection. The sponsor is not required to submit revised PDE records at least once every 90 calendar days, if the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error. This additional information will provide CMS with greater insight into the PDE revision process and ensure that a rejected PDE record must be corrected by the plan sponsor unless it is not appropriate to do so.

CMS believes that it is beneficial for program integrity for the agency to have increased visibility into the processing and progression of revisions of rejected PDE records. This includes ensuring that rejected PDE records that are not resubmitted within 90 days, in accordance with § 423.325(a)(3), are limited to claims that are no longer active and where resubmission is inappropriate (because for example, the pharmacy has since reversed the claim).

We note that since 2011, the vast majority of the PDE records that are rejected are resolved by sponsors within the 90-day timeframe, and in more recent years, nearly all the PDE rejections are resolved within the 90-day timeframe. Therefore, CMS expects no additional costs or savings from the proposed change and is not scoring these requirements in the Regulatory Impact Analysis section. There are no new reporting requirements.[66] We do not anticipate additional paperwork burden. Therefore, no increase is included in the Collection of Information section.

We welcome feedback on these proposed changes.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (Star Ratings) (§§ 422.164, 422.166, 423.186, and 423.184)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,[67] 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 the 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 that 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 MA and Part D Prescription Drug Program Quality Rating System. As a result, the regulatory changes proposed here will apply to the quality ratings for MA plans and cost 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[68] evolves over time to increase the health and wellbeing of enrollees. In this proposed rule, we are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set. We also propose to not move forward with the implementation of the Health Equity Index reward and to continue to include the historical reward factor in the Star Ratings methodology. We propose to add additional information about the data available to MA organizations and Part D sponsors during the plan preview periods before each Star Ratings release. We also solicit comments on ways to further simplify and modify the Star Ratings program to further drive improved quality of care, and whether there are ways to streamline the timeline from measure development to implementation. We solicit additional feedback related to Star Ratings in the Request for Information on Future Directions in Medicare Advantage in section XXXX of this proposed 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 Part D Star Ratings program. As has been historically operationalized and as described at 83 FR 16533, measure removals are proposed and finalized through rulemaking unless they meet the requirements at §§ 422.164(e)(1) and 423.184(e)(1), which allow for measure removals through the process described

[66] *See* OMB 0938–0982, CMS–10174, expiration April 30, 2027 (available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202403-0938-002*).

[67] We generally use ''Part C'' to refer to the quality measures and ratings system that apply to MA plans and cost plans.

[68] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This subregulatory process for measure removal was codified at §§ 422.164(e)(1) and 423.184(e)(1) to allow CMS to remove measures quickly, and without separate rulemaking, in certain circumstances where it is appropriate and necessary to do so. We are proposing language at §§ 422.164(e)(3) and 423.184(e)(3) to clarify our existing policy that removal of measures for any other reasons not stated in paragraph (e)(1) will be proposed and finalized through rulemaking. We are also proposing language at §§ 422.164(e)(2) and 423.184(e)(2) to clarify that removals for the reasons stated in paragraph (e)(1) will either be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act or proposed and finalized through rulemaking. This language would reflect that where one of the bases for measure removal identified in paragraph (e)(1) applies, we would pursue removal using the process that allows for the most expedient notice to MA organizations and Part D sponsors at that time. For example, if a measure steward announces a measure retirement, we would use the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act or rulemaking depending on the timing of the announcement so that we can provide this information as quickly as possible to MA organizations and Part D sponsors.

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) (''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-substantive updates. (See also 83 FR 16534 through 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.

1. Removing Measures

As the Part C and Part D Star Rating program continues to evolve and align with the measures included in the Universal Foundation,[69] a strategy to align measures across the agency's quality and value-based care goals, we propose to simplify and refocus the measure set on clinical care, outcomes, and patient experience of care measures where performance is not topped out and where there is more variation in performance across contracts. Reducing the number of measures would increase the focus on the remaining measures, including those consistent with the Make America Healthy Again (MAHA) initiative, such as Reducing the Risk of Falling and Monitoring Physical Activity. Additionally, reducing the number of measures is consistent with recommendations from MedPAC[70] and other interested parties that CMS consider having fewer measures in the Part C and Part D Star Ratings program. This is also consistent with the Universal Foundation which attempts, among other things, to focus attention on measures that are meaningful for the health of broad segments of the population and to reduce provider burden by streamlining and aligning measures—in other words, to focus the measure set on clinical care, outcomes, and patient experience of care measures. We initially solicited feedback on simplifying and refocusing the measure set in the Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (''2026 Rate Announcement''),[71] as well as from the Star Ratings Technical Expert Panel (TEP) in October 2024.[72]

Although the TEP recommended keeping the measure set as large as possible to avoid the ratings being influenced by a single measure, the TEP did support rethinking the measures included. Overall, the TEP supported measures from the current Healthcare Effectiveness Data and Information Set (HEDIS), Consumer Assessment of Healthcare Providers and Systems (CAHPS), Health Outcomes Survey (HOS), and some of the operational measures. Suggestions included the following: adding more evidence-based, clinical outcomes measures or redesigning current measures to assess patient outcomes (such as medication adherence); considering relevance, reliability, and the small denominator for some measures; considering ''gameability,'' attribution issues, provider burden, and the sensitivity of measures to small changes; and considering measures focused on trust enrollees have in the plan and network issues.

After taking into consideration feedback from the TEP and from interested parties that commented on the Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,[73] we are proposing to remove seven Star Ratings measures focused on operational and administrative performance, three additional measures focused on process of care, and two additional measures focused on patient experience of care. There is a balance between streamlining the measure set and continuing to include enough measures to assess performance across the range of health care quality and to avoid contracts ''teaching to the test'' or focusing performance improvement efforts on a limited number of measured areas. We aim to achieve this balance by proposing initially to remove measures focused on operational and administrative performance, along with some additional process and patient experience of care measures with high performance and less variability across contracts, while retaining many measures focused on clinical care, outcomes, and patient experience and continuing to see where we can add additional outcomes measures in the future.

There are various measures currently in the Part C and Part D Star Ratings measure set that focus on operational performance or on completion of required administrative processes. While these measures have been invaluable to CMS's efforts to monitor and improve plan performance and compliance in critical operational areas, many of these measures may be better suited as measures to monitor plan performance and compliance rather than as quality measures in the Part C and Part D Star Ratings program,

[69] *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

[70] Replacing the Medicare Advantage quality bonus program—MedPAC.

[71] *https://www.cms.gov/files/document/2026-advance-notice.pdf.*

[72] *https://www.rand.org/pubs/conf_proceedings/CFA3973-1.html.*

[73] See pages 107–110 at *https://www.cms.gov/files/document/2026-announcement.pdf* for a summary of comments.

especially since ratings for many of these measures are sensitive to small changes in performance because they have smaller denominators, such that small changes in the numerator can have a large impact on the measure Star Rating. Additionally, we have seen improvement on these measures since the inception of the Part C and Part D Star Ratings program, and MA organization and Part D sponsor performance rates are consistently fairly high.

We also propose to remove three additional process measures (Diabetes Care—Eye Exam, Statin Therapy for Patients with Cardiovascular Disease, and Members Choosing to Leave the Plan) and two patient experience of care measures (Customer Service and Rating of Health Care Quality) to further streamline the Star Ratings measure set. We want to focus more on clinical care, outcomes, and patient experience of care measures where performance is not topped out and where there is more variability in performance across contracts. This is where there is more room for improvement and measures where we see MA organization and Part D sponsors need more incentives to perform well. Additionally, when there is little variation in performance across contracts for a measure, this does not provide meaningful information to beneficiaries or their caregivers when choosing a plan. One purpose of providing quality and performance information is to highlight differences in performance across contracts that can impact the care and services provided by the plan. Reducing the number of operational and administrative measures and removing some additional process and patient experience of care measures would also increase the relative weight of the outcome measures in the summary and overall ratings.

We propose to remove the twelve measures in Table 1 beginning with the Star Ratings year shown in the table for each measure. Following the table, we provide additional details on our rationale for proposing to remove each measure. We expect that removing these measures would result in an overall decrease in ratings since performance on many of these measures is very high; however, we also expect that the proposed removal of the Health Equity Index (HEI; also called Excellent Health Outcomes for All) reward along with keeping the historical reward factor, discussed in more detail in section V.D. of this proposed rule, would generally increase ratings. We provide the estimated combined impact of these proposed changes in section XI.C.7. of this proposed rule.

CMS is also considering removing additional measures in the future as we continue to simplify and refocus the program. Removal of any additional measures would need to be proposed and finalized through rulemaking.

TABLE 1: MEASURES PROPOSED TO BE REMOVED FROM THE STAR RATINGS

Part C or D	Measure Name	Star Ratings Year Proposed for Removal
C	Plan Makes Timely Decisions about Appeals	2029 Star Ratings
C	Reviewing Appeals Decisions	2029 Star Ratings
C	Special Needs Plan (SNP) Care Management	2029 Star Ratings
C	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
D	Call Center – Foreign Language Interpreter and TTY Availability	2028 Star Ratings
C and D	Complaints about the Health/Drug Plan	2029 Star Ratings
D	Medicare Plan Finder Price Accuracy	2029 Star Ratings
C	Diabetes Care – Eye Exam	2029 Star Ratings
C	Statin Therapy for Patients with Cardiovascular Disease	2028 Star Ratings
C and D	Members Choosing to Leave the Plan	2029 Star Ratings
C	Customer Service	2029 Star Ratings
C	Rating of Health Care Quality	2029 Star Ratings

a. Plan Makes Timely Decisions About Appeals (Part C) and Reviewing Appeals Decisions (Part C)

We propose removing the Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C) measures because average performance on these measures has increased from 90 to 96 percent and 88 to 95 percent from the 2015 to 2025 Star Ratings, respectively. There is also not a lot of variation across the vast majority of contracts on these measures and the measures can have small denominators for some contracts, both of which can lead to shifts in ratings as a result of small changes in the numerator. Since the appeals process is critical to monitor as it impacts access to care, CMS would continue to monitor plan performance and issue compliance actions based on appeals data as needed and would continue to monitor access issues through the CAHPS survey measures.

b. Special Needs Plan (SNP) Care Management (Part C)

We propose removing the SNP Care Management (Part C) measure as part of our effort to increase the focus on patient experience and outcome measures. This administrative-focused process measure indicates how often a contract completed the required health risk assessment. The goal of this assessment is to then use the results to help enrollees get the care they need. CMS is ultimately interested in whether enrollees receive needed care as indicated by this assessment and not only whether the assessment is completed. We are proposing to remove this measure since the current measure does not provide any information about whether enrollees received care as indicated by their assessments. We would move this measure to the display page.

c. Call Center—Foreign Language Interpreter and TTY Availability (Part C and Part D)

We propose removing the Call Center—Foreign Language Interpreter and TTY Availability (Part C and Part D) measures. Average performance on these measures in the 2025 Star Ratings was very high at 94 percent on the Part C measure, and 94 percent for MA–PD contracts and 97 percent for PDP contracts on the Part D measure. Additionally, there is not a lot of variation across the vast majority of contracts on these measures, and the measures have relatively small denominators, both of which can lead to shifts in ratings as a result of small changes in the numerator. If these measures were removed, CMS would continue to monitor plan performance

and compliance, and the Star Ratings would continue to capture similar issues related to customer service through the CAHPS survey measures.

d. Complaints About the Health/Drug Plan (Part C and Part D)

We propose removing the Complaints about the Health/Drug Plan (Part C and Part D) measure. Average performance on this measure was high at 0.23 percent for MA–PD contracts and 0.04 percent for PDP contracts in the 2025 Star Ratings (lower scores are better). The volume of complaints has significantly decreased since this measure was first introduced, and there is also not a lot of variation in this measure across contracts. CMS would continue to monitor plan performance and issue compliance actions as needed, and the Star Ratings would continue to capture similar issues related to access to care and patient experience through the CAHPS survey measures.

e. Medicare Plan Finder (MPF) Price Accuracy (Part D)

We propose removing the MPF Price Accuracy (Part D) measure. Average scores on this measure were very high at 98 for MA–PD contracts and 97 for PDP contracts in the 2025 Star Ratings. Additionally, there is not a lot of variability across most contracts on this measure. If this measure were removed, CMS would continue to monitor plan performance related to drug prices posted on MPF.

f. Diabetes Care—Eye Exam (Part C)

We propose removing the Diabetes Care—Eye Exam (Part C) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. There are several other measures currently in the Star Ratings that focus on diabetes care, thus, covering a similar topic area as this measure. Given the importance of diabetes care, we would move this measure to the display page.

g. Statin Therapy for Patients With Cardiovascular Disease (Part C)

We propose removing the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. There is not a lot of variation in performance across contracts on this measure, and there are other measures, such as Medication Adherence for Cholesterol (Statins), currently in the Star Ratings that cover a similar topic area as this measure. As noted in the Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, the National Committee for Quality Assurance (NCQA) reevaluated the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure for the 2026 measurement year. The changes finalized by NCQA expand the eligible population and are considered a substantive change to the measure. CMS will include the updated Statin Therapy for Patients with Cardiovascular Disease on the 2028 display page and monitor changes in performance for this measure since statin therapy is important in lowering cholesterol and reducing the risk of cardiovascular disease.

h. Members Choosing To Leave the Plan (Part C and Part D)

We propose removing the Members Choosing to Leave the Plan (Part C and Part D) measure as part of our effort to streamline the Star Ratings measure set and increase the focus on patient experience and outcome measures. We are proposing to remove the measure based on previous feedback from Part C and D sponsors that they would prefer this measure be at the parent organization level versus the contract level or that they would like additional exclusions for the measure such as exclusions for terminations of provider networks. Additionally, without knowing the reasons for disenrollment, it is hard for enrollees to interpret what this measure score means and make meaningful comparisons between contracts. The current measure at the contract level would move to the display page.

i. Customer Service and Rating of Health Care Quality (Part C)

We propose removing the Customer Service and Rating of Health Care Quality (Part C) measures as part of our effort to streamline the Star Ratings measure set. Compared to other patient experience of care measures, there is less variation in performance across contracts on these measures. We would continue to collect these data for quality improvement purposes and report the measures on the display page.

We welcome feedback on all the potential measure removals discussed in this proposed rule, including feedback on the timing of measure removals.

2. Adding Measure

a. Depression Screening and Follow-Up (Part C)

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. (83 FR 16533). For example, we regularly review measures developed by NCQA and the Pharmacy Quality Alliance (PQA). As we continue to align with the Universal Foundation, we also propose to add the Part C Depression Screening and Follow-Up (DSF) measure to the 2029 Star Ratings (measurement year 2027). CMS will begin reporting the DSF measure on the display page for the 2026 Star Ratings. 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 solicited feedback regarding whether to add the DSF measure to the 2026 Star Ratings display page (using data from the 2024 measurement year) in 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 and noted that it would need to go through rulemaking to be added to the Star Ratings.[74] DSF measures the percentage of eligible MA plan members who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care within 30 days. This aligns with the U.S. Preventive Services Task Force recommendations regarding screening and follow-up for depression,[75] supports CMS's efforts to implement the Universal Foundation set of measures across quality programs, and focuses on improving the well-being of beneficiaries as well as MAHA priorities by encouraging MA health plans to screen for depression and follow-up with appropriate care. Although this is a process measure, health outcomes can be improved by identifying individuals with depression and providing treatment. There are currently no measures specific to behavioral health care in the Part C and D Star Ratings, so adding this measure would fill an important gap.

Depression is a common mental disorder that occurs in people of all ages, and estimates of major depression were 13.1 percent in people age 12 and older and 8.7 percent in people age 60 and older during the period from

[74] See page 162 at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf* for a summary of comments.

[75] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-depression-suicide-risk-adults.*

August 2021 through August 2023.[76] Depression can exacerbate other chronic medical conditions, and it increases the risk of morbidity and mortality. There is evidence that screening tools used in primary care settings can accurately identify depressed individuals and treatment can improve depression outcomes.[77]

We submitted the DSF measure through the 2024 Pre-rulemaking Review Process for review by the Measures Application Partnership, which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, and the Measures Application Partnership provided support for this measure.[78] Consensus was not reached on this measure. The committee recommended that the Merit-based Incentive Payment System (MIPS) program consider replacing their similar measure with this one to improve alignment across quality programs[79] and to report the screening and follow-up rates separately. The HEDIS measure differs slightly from the MIPS measure since the specification is at the health plan level and also focuses on examining follow-up actions when positive screenings occur. CMS will display separate rates for screening and follow-up on the display page and take an average of the rates for the Star Ratings measure.

3. Summary of Measure Changes for the Part C and Part D Star Ratings

Table 2 summarizes the additional measure addressed in this proposed rule, beginning with the 2029 Star Ratings. The measure description listed in this table is a high-level description. 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 2029 are produced in the fall of 2028. If a measurement period is listed as ''the calendar year 2 years prior to the Star Ratings year'' and the Star Ratings year is 2029, the measurement period is referencing the January 1, 2027 to December 31, 2027 period. As noted earlier in section V.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.

TABLE 2: SUMMARY OF NEW INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2027

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								
Depression Screening and Follow-Up	The average percentage of eligible MA plan members who were screened for clinical depression using a standardized instrument and, if screened positive, received follow-up care within 30 days.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS	The calendar year 2 years prior to the Star Ratings year	Not available	Clustering	MA-PD and MA-only

C. Streamlining the Methodology, Further Incentivizing Quality Improvement, and Suggestions for New Measures

Finally, we are also soliciting feedback on ways to streamline and modify the Star Ratings methodology to further incentivize quality improvement and suggestions for new outcomes measures to promote prevention and wellness of health and drug plan enrollees to make the Star Ratings program more aligned with MAHA efforts related to healthy aging, such as nutrition and patient well-being. We are also soliciting feedback on additional measures that could be removed in future years.

D. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

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) (''April 2023 final rule''), we finalized the addition of the Health Equity Index (HEI) reward (also called the Excellent Health Outcomes for All (EHO4all) reward)[80] along with the removal of the historical reward factor at the same time. The HEI reward was intended to further incentivize Part C and Part D contracts to focus on improving care for enrollees that are dually eligible, receive a low-income subsidy, or are disabled because these groups are at risk for poor health outcomes and Star Ratings data show gaps in the quality of care for these enrollees. This reward was finalized at 42 CFR 422.166(f)(3) and 423.186(f)(3) to be implemented

[76] *https://www.cdc.gov/nchs/data/databriefs/db527.pdf.*

[77] *https://pmc.ncbi.nlm.nih.gov/articles/PMC7661597/* and *https://www.amjmed.com/article/S0002-9343(22)00524-1/fulltext.*

[78] *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[79] The MIPS measure differs from the NCQA one in that the MIPS version requires a qualifying encounter, whereas the NCQA-stewarded version looks for a screen at any time in the measurement period; the follow-up component of the MIPS version entails documentation of a follow-up plan, whereas the NCQA-stewarded version is more intensive requiring follow-up care; the follow-up timeframe in the MIPS version is on or up to 2 days after the date of the qualifying encounter, whereas the NCQA-stewarded measure uses a timeframe of on or up to 30 days after the date of the positive screen; and the MIPS version only excludes individuals with a diagnosis of bipolar disorder, whereas the NCQA version excludes individuals with bipolar disorder or a current diagnosis of depression.

[80] In the 2026 Rate Announcement, we began to rebrand the Health Equity Index reward with a new name, the EHO4all reward. *https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026.*

beginning with the 2027 Star Ratings using data from the 2024 and 2025 measurement years. The historical reward factor, which incentivizes consistent high performance across Star Ratings measures, was finalized at §§ 422.166(f)(1) and 423.186(f)(1) to be removed from the Star Ratings methodology with the implementation of the HEI reward in the 2027 Star Ratings using data from the 2025 measurement year. The historical reward factor was included in the Star Ratings beginning with the 2009 Star Ratings with the purpose of adding incentives for contracts to achieve high and stable relative performance across all measures.

Since the April 2023 final rule, we have reviewed the HEI reward consistent with the Executive Order 14192, ''Unleashing Prosperity Through Deregulation'' and propose to remove the HEI reward from the Star Ratings methodology. We propose not to implement the HEI reward with the 2027 Star Ratings and instead continue the historical reward factor. Rather than incentivizing improvement among certain populations like those included in the HEI, CMS would instead incentivize improvement efforts on clinical care, outcomes, and patient experience, in line with the proposal in section V.B. of this proposed rule to refocus the Star Ratings measure set. We recognize that some health plans may have already expended resources on performance improvement focused on the populations included in the HEI reward; however, any improvements in performance among these populations will still contribute to higher performance on the Star Ratings by increasing measure-level scores even without the implementation of the HEI reward. Higher measure-level scores benefit health plans by improving overall performance on the Star Ratings.

This shift is part of a broader effort to refocus the Star Ratings on clinical care, outcomes, and patient experience. In section V.B. of this proposed rule, we provide more detail about the efforts to refocus the measurement set. Improvements in clinical care can lead to better patient outcomes and, ultimately, higher Star Ratings.

This shift also aligns with our focus on exploring ways to simplify and modify the Star Ratings methodology to further drive quality improvement. Rather than implement the change to the methodology to add the HEI reward and remove the historical reward factor, we instead propose to keep the methodology consistent for now as we explore ways to simplify the methodology in the future. See section V.C. where we solicit comments on ways to simplify and modify the Star Ratings methodology to further drive quality improvement. Any such simplifications or modifications would be proposed in future rulemaking.

Typically, CMS has proposed and finalized changes to the Star Ratings methodology in advance of the measurement year (which aligns with the rules for measure updates). However, this proposal would avoid the need for updates to the Star Ratings methodology, including a significant amount of programming, as well as updates to the Star Ratings technical documentation and data display in the Health Plan Management System (HPMS), to reflect the temporary addition of the HEI reward and removal of the historical reward factor. Therefore, we do not propose to implement the HEI reward and to continue to implement the historical reward factor beginning with the 2027 Star Ratings. To remove the HEI reward and revert to the historical reward factor in the Star Ratings methodology, we propose to remove the paragraphs at §§ 422.166(f)(3) and 423.186(f)(3), and to modify §§ 422.166(f)(1) and 423.186(f)(1) to remove ''Through the 2026 Star Ratings.''

E. Plan Preview of Star Ratings (§§ 422.166(h)(2) and 423.186(h)(2))

We are proposing to add additional information about the data available to MA organizations and Part D sponsors during the plan preview periods before each Star Ratings release described at §§ 422.166(h)(2) and 423.186(h)(2). During the first plan preview, CMS expects Part C and D sponsors to closely review the methodology and their posted numeric data for each measure in HPMS prior to display on MPF. The second plan preview provides an opportunity for Part C and D sponsors to review any updates from the first plan preview and preliminary Star Ratings for each measure, domain, summary rating, and overall rating. When the Star Ratings methodology was first codified in the April 2018 final rule, we anticipated that the plan preview periods would continue to evolve and it was not necessary to codify the specific display content. As the plan previews have continued to evolve, CMS has added de-identified contract-level sample data for one of each type of measure needed for MA organizations and Part D sponsors to replicate the calculation of the measure-level cut points (that is, one CAHPS measure, one measure for Part C and one for Part D that use clustering, and any measures requiring a different type of calculation such as Complaints about the Plan). These data allow MA organizations and Part D sponsors to validate CMS's cut point calculations. The same cut point programming is used for all other measures as the sample measures, so de-identified contract-level data for only the sample measures are displayed in HPMS during the second plan preview. We are proposing to codify our current practice of providing sample data for one of each type of measure during the second plan preview described at §§ 422.166(h)(2) and 423.186(h)(2).

F. Impact of Proposed Changes

Simulations of the impact of removing the HEI reward, keeping the historical reward factor, and removing the 12 measures as proposed in section V.B. of this proposed rule, using data from the 2025 Star Ratings (2022 and 2023 measurement years) but updating the measure set and measure weights for changes consistent with the 2026 Star Ratings (for example, reducing the weight of patient experience/complaints and access measures from 4 to 2) show most contracts (62 percent) would have no change in the overall rating. The overall rating would increase by a half star for 13 percent of contracts, would decrease by a half star for 25 percent of contracts, and would decrease by one star for one contract. Five percent of contracts would gain QBPs, and four percent of contracts would lose QBPs.

As described in this proposed rule, we are proposing adding and removing certain Star Ratings measures. The proposed new measure entails moving an existing measure from the display page to Star Ratings, which would have no impact on plan burden. The measures proposed for removal are either calculated from administrative data[81] or would still be submitted by plan sponsors and, as such, there would be no decrease in plan burden. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS's Star Ratings related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–1028 for HEDIS (CMS–10219), and OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261). Since the provisions would not impose any new or revised information collection requirements or burden, we

[81] The following measures proposed for removal are calculated from administrative data: Plan Makes Timely Decisions about Appeals, Reviewing Appeals Decisions, Complaints about the Health/Drug Plan, Medicare Plan Finder Price Accuracy, Members Choosing to Leave the Plan.

are not making changes under any of the aforementioned control numbers.

We welcome feedback on these proposed changes.

VI. Improvements for Special Needs Plans

A. Model of Care (MOC) Off-Cycle Submission Window (42 CFR 422.101)

Congress first authorized special needs plans (SNP) through the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). The law authorized CMS to contract with Medicare Advantage (MA) coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Section 1859(f)(5)(A) of the Act, as added by section 164 of the Medicare Improvements for Patients and Providers Act (*Pub. L. 110–275*), imposes specific care management requirements for all SNPs effective January 1, 2010. As a result, all SNPs are required to implement care management requirements which have two explicit components: a National Committee for Quality Assurance (NCQA) approved, evidence-based model of care (MOC) and a series of care management services.[82]

All SNPs must submit their MOCs to CMS for NCQA evaluation and approval and an MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers as required at §§ 422.4(a)(1)(iv), 422.101(f)(3)(i), and 422.152(g). The NCQA MOC evaluation and approval process scores each of the clinical and non-clinical elements of the MOC. The Institutional Special Needs Plan (I–SNPs) and Dual-Eligible Special Needs Plan (D–SNPs) MOCs that receive a passing score from NCQA are then approved for one-, two-, or three-year periods as set forth at § 422.101(f)(3)(iii). A Chronic Condition Special Needs Plan (C–SNP) MOC that receives a passing score is approved for one year as required by section 1859(f)(5)(B)(iv) of the Act. As the MOC approval periods end, SNPs submit new MOCs to CMS for NCQA evaluation and approval during an annual renewal MOC submission window. This ensures that all operating SNPs have a current, NCQA approved, MOC in place.

CMS has acknowledged in the past that to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care during its approved MOC timeframe. A SNP that seeks to revise a MOC before the end of the MOC approval period may do so between June 1st and November 30th of each calendar year via the ''off-cycle MOC submission process'' outlined at § 422.101(f)(3)(iv). A D–SNP or I–SNP that decides to make revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Health Plan Management System (HPMS) Model of Care module for NCQA review and approval. The off-cycle submission requirements apply to substantial changes in policies or procedures as described at § 422.101(f)(3)(iv)(B)(1) and other revisions identified at § 422.101(f)(3)(iv)(B)(2) to (5). These types of MOC changes are at the discretion of the applicable MA organization offering the SNP and it is the responsibility of the MA organization to notify CMS of revisions and electronically submit their summary of changes to their MOC in HPMS for review and approval.

Since the beginning of the MOC approval process, CMS has developed, issued, and updated guidance on the MOC to support plan performance and assist in improved health outcomes. CMS had previously required initial and renewal MOCs to be submitted mid-February of the preceding plan contract year, aligning with the MA application deadline. However, as announced in an HPMS email titled ''Contract Year 2027 Model of Care Submission Timeline Updates'' on September 3, 2025, CMS has moved the initial and renewal MOC submission deadline to the Friday before the first Monday of June, starting with the contract year (CY) 2027 MOC submission period. The new MOC submission deadline and subsequent NCQA evaluation overlap with the current off-cycle MOC submission window. To accommodate the CY 2027 MOC submission deadline change and ensuing operational considerations both for NCQA and CMS's HPMS, a new timeline for the off-cycle submission process is needed. As such, CMS is proposing that for CY 2027 and subsequent years, D–SNPs and I–SNPs seeking to revise their NCQA-approved MOC during the MOC approval period must submit updates and corrections between January 1st and March 31st and October 1st and December 31st of each calendar year. This would functionally provide SNPs with two separate windows of opportunity to submit off-cycle MOC changes each year. Of note, SNPs currently have a six-month window to update or correct their MOCs; this new proposed timeline would split that period to accommodate the operational needs of CMS and NCQA as staff review initial and annual MOC submissions. CMS seeks comment on these proposed technical changes to the timeline and opportunities for improving the off-cycle MOC process for potential future rulemaking.

CMS believes there would be no change in the estimated burden from this changed timeline for SNPs submitting off-cycle MOC changes. Additionally, there would be no expected collection of information that would be new for this rule, only maintenance of past expectations around the off-cycle MOC process.

B. Passive Enrollment by CMS (§ 422.60)

Individuals who are dually eligible for both Medicare and Medicaid typically face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible individuals with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.

Integrated care options are increasingly available for dually eligible individuals, which include a variety of integrated D–SNPs. Integrated D–SNPs can provide greater integration of Medicare and Medicaid services and experiences than enrollees would otherwise receive in other MA plans or Original Medicare, particularly when an individual is enrolled in both a D–SNP and Medicaid managed care organization (MCO) offered by the same organization. When referring to integrated D–SNPs, we are referring to: applicable integrated plans (AIPs), which include fully integrated dual eligible special needs plans (FIDE SNPs), many highly integrated dual eligible special needs plans (HIDE SNPs), and a small subset of coordination-only D–SNPs. These D–SNP types meet higher standards of integration, quality, and performance benchmarks, and for AIPs, exclusively aligned enrollment (when enrollment in a parent organization's D–SNP is limited to individuals with aligned enrollment), which we believe is a critical part of improving experiences and outcomes

[82] For more discussion of the history of SNPs, please see Chapter 16B of the Medicare Managed Care Manual (MMCM).

for dually eligible individuals. These D–SNP types more meaningfully integrate Medicare and Medicaid services and administrative processes (such as unified appeals and grievances) than coordination-only D–SNPs that are not also AIPs.

While enrollment in integrated care options continues to grow, there are instances in which enrollees may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D–SNPs and State re-procurements of affiliated Medicaid MCOs. Such disruptions can result in enrollees being enrolled with two separate health plan organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same health plan organization offers both benefit packages. In an effort to protect the continuity of integrated care for dually eligible individuals, in the April 2018 final rule (83 FR 16502), we finalized a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible individuals in instances where integrated care coverage would otherwise be disrupted.

Section 1851(c)(1) of the Act authorizes us to develop mechanisms for enrollees to elect MA enrollment, and in the April 2018 final rule (83 FR 16502), we amended the regulation at § 422.60(g) by adding § 422.60(g)(1)(iii) and (g)(2) to allow passive enrollment for full-benefit dually eligible enrollees from a non-renewing integrated D–SNP into another comparable plan. A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.

In the April 2018 final rule, we finalized language authorizing CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D–SNP into another integrated D–SNP, after consulting with the State Medicaid agency that contracts with the D–SNP, when CMS determines that the passive enrollment will promote continuity of care and integrated care under § 422.60(g)(1)(iii). We also finalized, under § 422.60(g)(2), requirements an MA plan would have to meet to qualify to receive passive enrollments under paragraph (g)(1)(iii). However, in multiple situations where we have attempted to implement these requirements, we have encountered difficulty with receiving integrated D–SNPs meeting the requirement in § 422.60(g)(2)(ii) that they have provider networks and facility networks that are substantially similar to those of the relinquishing integrated D–SNP. In our attempts to utilize passive enrollment, we found that while prospective receiving integrated D–SNPs had Medicare provider and facility networks that meet the MA network adequacy criteria at § 422.116, these networks weren't substantially similar to the provider and facility networks in the relinquishing integrated D–SNPs.

We acknowledge that the substantially similar provider and facility networks requirement that is used to assess receiving integrated D–SNPs is undefined in regulation. On August 1, 2018, we published a Health Plan Management System (HPMS) memo that provided further technical guidance on how we would assess for substantially similar networks.[83] In this memo, we noted that, using National Provider Identifier (NPI) numbers, we would compare the MA network of the relinquishing integrated D–SNP to that of a receiving integrated D–SNP to assess overlap in provider and facility specialty types across an array of provider specialty types with the highest utilization by dually eligible individuals, which were outlined in the same HPMS memo. However, even with the additional operational guidance, a network comparison between the relinquishing and receiving plans did not result in networks that we could consider substantially similar. As such, we have not been able to implement passive enrollment as outlined in § 422.60(g).

We continue to find value in the concept of allowing passive enrollment for full-benefit dually eligible enrollees from a non-renewing or terminating integrated D–SNP to another comparable integrated D–SNP, and we continue to hear from States interested in using this provision. In order to operationalize this function, we are proposing to amend § 422.60(g)(2)(ii) to remove the requirement that the receiving integrated D–SNPs have substantially similar networks to the relinquishing integrated D–SNPs and, instead, require receiving integrated D–SNPs to provide continuity of care for all incoming enrollees for a minimum of 120 days. Specifically, we are proposing to replace the current language in § 422.60(g)(2)(ii) with the requirement that a receiving integrated D–SNP provide continuity of care for all incoming enrollees that complies with § 422.112(b)(8)(i)(B), except that the minimum transition period would be 120 days. We note that this proposed requirement would not affect a receiving integrated D–SNP's requirement to meet network adequacy standards per § 422.116, potential compliance actions that may result from a failure to meet those requirements. We are also proposing to amend § 422.60(g)(2)(vi) to specify that an integrated D–SNP receiving passive enrollment must have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. We expect this coordinator staffing capacity to be sufficient to conduct required enrollee onboarding activities such as health risk assessments and care plans and meet ongoing D–SNP care coordination requirements, including those outlined at § 422.107(c). Lastly, in an effort to use consistent and accurate language throughout our processes and documentation, we are proposing to amend § 422.60(g)(2)(i) to instead describe the MA plans that can receive passive enrollment as plans that operate as an applicable integrated plan (AIP) as described at § 422.561.

We are proposing to amend § 422.60(g)(2)(ii) to require that the plan receiving passive enrollment provide continuity of care to all incoming enrollees for 120 days because we believe that this length of time for continuity of care would address the issue that we attempted to address at 83 FR 16504 in the April 2018 final rule, namely that the provider network comparability analysis would minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment and encourage retention following enrollees' transition to a new integrated D–SNP, while creating an approach that can be more feasibly implemented than the current substantially similar network requirement.

We are specifically tying the proposed amendment in § 422.60(g)(2)(ii) to § 422.112(b)(8)(i)(B) because in keeping with the spirit of the passive enrollment regulation, as discussed in the April 2018 final rule, the goal of passive enrollment is continuity of care. 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, we finalized

[83] CMS, HPMS memorandum titled ''Guidance on the Process for Implementing Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dual Eligible Beneficiaries'', August 2018. Retrieved from: *https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2018-week1-aug-1-3.*

the provision at § 422.112(b)(8)(i)(B) requiring that, with respect to basic benefits, coordinated care plans are required to provide a minimum 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan, during which time the new MA plan may not disrupt or require reauthorization for the active course of treatment (88 FR 22205). We explain this requirement in the corresponding notice of proposed rulemaking, 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 **Federal Register** on December 27, 2022, by stating the following: ''The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 day. This means that for a minimum of 90 days, when an enrollee switches to a new MA coordinated care plan, any active course of treatment must not be subject to any prior authorization requirements. During the initial 90 days of an enrollee's enrollment with an MA coordinated care plan, the MA coordinated care plan cannot subject any active course of treatment (as defined at the proposed § 422.112(b)(8)(ii)(B)) to additional prior authorization requirements, even if the service is furnished by an out-of-network provider. We expect any active course of treatment to be documented in the enrollee's medical records so that the enrollee, provider, and MA plan can track an active course of treatment and avoid disputes over the scope of this proposed new requirement. We also intend that an active course of treatment can include scheduled procedures regardless of whether there are specific visits or activities leading up to the procedure. To further illustrate, if an enrollee has a procedure or surgery planned for January 31st at the time of enrollment in a new MA coordinated care plan effective January 1, the new MA coordinated care plan must cover this procedure without subjecting the procedure to prior authorization. The planned surgery is a part of an active course of treatment and thus cannot be subjected to prior authorization by the MA coordinated care plan in which the beneficiary has newly enrolled.'' (87 FR 79504)

We believe that the requirements captured in § 422.112(b)(8)(i)(B) are consistent with the intention behind passive enrollment at § 422.60(g), and as such, we are proposing to apply the requirements at § 422.112(b)(8) to § 422.60(g)(2)(ii), except that continuity of care would be applicable for 120 days as opposed to 90 days, as is currently required at § 422.112(b)(8). This proposal is an attempt to balance the current 90 day requirement applicable to all coordinated care plans with the intention behind the current regulation at § 422.60(g) to minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment.

Additionally, we would like to note that in our proposed revision of § 422.60(g)(2)(ii), we are also proposing to remove the language that requires the receiving plan to have substantially similar Medicare- and Medicaid-covered benefits as the relinquishing integrated D–SNP. 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 **Federal Register** on April 16, 2019 (hereafter referred to as the April 2019 final rule; 84 FR 15710), we finalized a series of provisions codifying specific integration requirements for D–SNPs pursuant to the requirements in the Bipartisan Budget Act of 2018. Since integration levels are defined both in statute and in regulation at §§ 422.2 and 422.107(d), and Medicare Part A, B, and D benefits and Medicaid benefits do not tend to differ across D–SNPs with the same integration level within a State, we do not believe that a specific assessment for substantially similar coverage of Medicare and Medicaid covered benefits is required. In such a situation where passive enrollment is implemented, we believe that an assessment of level of integration between the relinquishing and receiving integrated D–SNPs would suffice.

Our continued goal with passive enrollment is to ensure that the integrated D–SNPs receiving passive enrollments provide high-quality care, coverage and administration of benefits. Passive enrollments benefit a plan by providing an enrollee and associated payments without the plan having to successfully market to the enrollee. Thus, we continue to believe that it is important that these enrollments are limited to plans that have demonstrated commitment to quality and are able to provide longer continuity of care to minimize service disruption for receiving dually eligible enrollees, who have complex and unique care needs. We are not proposing any other changes to § 422.60(g) or the process; receiving plans would still be held to all other standards set forth at § 422.60(g)(2). Similarly, we are not proposing changes to the current regulation at § 422.60(g)(4) regarding beneficiary notification requirements. Further, passively enrolled enrollees would still have the opportunity to opt out of the receiving plan, and § 422.60(g)(5), which describes an enrollee's access to the special election period at § 423.38(c)(10), would still be in effect.

We welcome comments on the changes we propose at § 422.60(g)(2)(i) and (ii). Similarly, we solicit comment on our proposed revision to § 422.60(g)(2)(vi) which would require that an integrated D–SNP receiving passive enrollment have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. Our proposal does not define a minimum staffing capacity threshold in order to give integrated D–SNPs flexibility in implementing this proposed change. We invite comment on the feasibility of this proposed requirement, and request suggestions for potential refinement.

C. Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D–SNP and Medicaid Fee-for-Service (§§ 422.107 and 422.514)

The Contract Year 2025 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 23, 2024 (hereafter referred to as the April 2024 final rule; 89 FR 30448), included several provisions to simplify options for dually eligible individuals and promote greater alignment of D–SNPs and Medicaid MCOs. We explained at 89 FR 30675 that, despite progress, there remain a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment). As expressed in the April 2019 final rule (84 FR 15699 through 15730), we continue to believe that aligned enrollment, and especially exclusively aligned enrollment, is a critical part of improving the experiences and outcomes of dually eligible individuals.

In the April 2024 final rule, we finalized a package of provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) that require that, beginning in contract year 2027, where an MA organization offers a D–SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in contract year 2030, such D–SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D–SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). To minimize enrollment disruption associated with achieving compliance, in the April 2024 final rule, we finalized a provision at § 422.530(c)(4)(iii) that would provide a new crosswalk exception to allow one or more MA organizations that share a parent organization and offer D–SNPs subject to the new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D–SNPs to comply with the new rules at §§ 422.504(a)(20) and 422.51(h).

In addition, in the April 2024 final rule, we codified at § 422.514(h)(3) two exceptions to the requirements at § 422.514(h)(1) and (2) for exceptions related to instances where (a) the State Medicaid agency contract (SMAC) with the MA organization differentiates enrollment into D–SNPs by age group or to align enrollment in the D–SNP with the eligibility or benefit design used in the State's Medicaid managed care program and (b) the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNPs and PPO D–SNPs. To promote integrated care through aligned Medicare and Medicaid products, at § 422.514(h)(3)(ii) we finalized that the MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may only accept new enrollment in one D–SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and such new enrollment is limited to the full-benefit dually eligible individuals who are enrolled (or are enrolling) in the Medicaid MCO.

As articulated in the April 2024 final rule (89 FR 30680), overall these changes would have several benefits. These include boosting the percentage of D–SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment, increasing access to the comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D–SNPs; prompting MA organizations to consolidate PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps with the D–SNP service area; removing some incentives for agents and brokers to target dually eligible individuals; lessening assistance needed from advocates and SHIP counselors to correct enrollment issues; and simplifying provider billing and lower the risk of inappropriate billing. For a more detailed discussion of the provisions finalized at § 422.514(h), we direct readers to the proposed rule titled ''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,'' which appeared in the **Federal Register** November 15 2023, (hereafter referred to as the November 2023 proposed rule; 88 FR 78566 through 78575) and the April 2024 final rule (89 FR 30675 through 30681).

In response to our proposals in the November 2023 proposed rule, a number of commenters suggested that the enrollment limitations could create barriers to care for dually eligible individuals in States where they are not required to be in or are explicitly carved out from Medicaid managed care. (89 FR 30689 through 30690) For example, in New York, only dually eligible individuals with significant long-term care needs are required to enroll in Medicaid managed care, with the majority of dually eligible individuals remaining in Medicaid fee-for-service (FFS). These commenters noted that D–SNPs that also contract with States as Medicaid MCOs can currently enroll individuals into their D–SNP that are enrolled in Medicaid FFS but, under the requirements finalized in the April 2024 final rule, those D–SNPs would not be able to enroll these individuals beginning in 2027 and would be required to disenroll them as of 2030. Commenters indicated that these individuals are better served in D–SNPs where they receive coordination of their Medicare and Medicaid FFS services. The commenters offered several suggestions for how CMS could address these concerns: (a) limiting the proposal to States that require mandatory enrollment for dually eligible individuals, including those who do not receive long-term care services, (b) implementing a limited exception process for States that would allow MA organizations with an affiliated Medicaid MCO to offer at least one D–SNP PBP that is not exclusively aligned and that can enroll dually eligible individuals who maintain Medicaid FFS coverage and (c) phasing in the proposal over time.

In the April 2024 final rule, we did not adopt any of these suggestions. At 89 FR 30690, we outlined potential drawbacks to limiting the § 422.514(h) provisions to only States that require mandatory Medicaid managed care enrollment for dually eligible individuals. These drawbacks included narrowing the number of States in which these policies would apply, thus reducing the extent to which we would achieve the benefits. It would also raise potential complexity in States where certain subpopulations of dually eligible individuals are mandatorily enrolled, but others are not. We further stated that allowing each MA organization with an affiliated Medicaid MCO to offer at least one D–SNP that is not exclusively aligned with its affiliated Medicaid MCO for the purpose of enrolling dually eligible individuals who are enrolled in Medicaid FFS would similarly reduce the extent to which we would achieve the benefits described in the proposed rule, create additional operational complexity for States and CMS to administer and monitor, and would likely be more complicated to explain from a beneficiary communications and messaging perspective compared to the proposal that we finalized in the April 2024 final rule. Finally, we stated our belief that the phase-in of the policy would provide ample time for transition; the finalized requirement limits new enrollment to individuals

enrolled in both a D–SNP and affiliated Medicaid MCO offered under the same parent organization starting in 2027 and then disenrolling those enrollees who do not have aligned enrollment in the D–SNP's affiliated Medicaid MCO in 2030. MA organizations would have two bid cycles and contract years (2025 and 2026) during which D–SNPs with affiliated Medicaid MCOs may prepare for the first phase of enrollment limitations.

Since we codified the package of provisions in the April 2024 final rule, we have received feedback from stakeholders on some challenges in implementing these provisions in States without mandatory Medicaid managed care for the dual eligible population. For example, given that New York does not require mandatory Medicaid managed care for its Integrated Benefits for Dually Eligible Enrollees (IB-Duals) program, participating HIDE SNPs may enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS or an unaffiliated Medicaid MCO. These HIDE SNPs do not have aligned enrollment. Without any change, in 2030, these HIDE SNPs would need to disenroll any enrollees who do not have aligned enrollment in the HIDE SNP's affiliated Medicaid MCO. In other words, beginning in 2027, these HIDE SNPs could no longer enroll any new dually eligible individuals who are enrolled in Medicaid FFS or an unaligned Medicaid MCO, and, in CY 2030, these HIDE SNPs would need to disenroll Medicaid FFS enrollees and any individuals enrolled in an unaligned Medicaid MCO.

In States that do not require mandatory Medicaid managed care for all of their full-benefit dually eligible individuals, we are also concerned about the § 422.514(h) requirements potentially disadvantaging MA organizations offering coordination-only D–SNPs and HIDE SNPs that both enroll full-benefit dually eligible individuals in the same service areas. Pennsylvania is one of these States with its Community HealthChoices program for Medicaid managed care plan for long-term services and supports. In this preamble, we will use the D–SNP landscape in Pennsylvania as an illustration of this potentially disadvantaging situation. The requirements at § 422.514(h) do not apply to MA organizations in the State that only offer coordination-only D–SNPs since these MA organizations, their parent organizations, or any entity that shares a parent organization with the MA organization do not also contract with Pennsylvania as a Medicaid MCO that enrolls full-benefit dually eligible individuals. However, the § 422.514(h) requirements do apply to the State's HIDE SNPs. In CY 2025, several MA organizations offer HIDE SNPs and coordination-only D–SNPs in Pennsylvania that both enroll full-benefit dually eligible individuals. We note that in Pennsylvania, these HIDE SNPs do not have aligned enrollment. Per § 422.2, a HIDE SNP requires the provision of coverage of Medicaid benefits under a capitated contract between the State Medicaid agency and the MA organization; MA organization's parent organization, another entity that is owned and controlled by its parent organization; or a local nonprofit public benefit corporation. As we noted previously in this preamble, in the April 2024 final rule, we finalized a policy that, beginning in 2027, where an MA organization offers a D–SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

In a State like Pennsylvania that does not mandate Medicaid managed care, those MA organizations offering a HIDE SNP with unaligned enrollment will no longer be permitted to enroll unaligned full-benefit dually eligible individuals into the HIDE SNP or allow full-benefit dually eligible individuals to enroll in the coordination-only D–SNP, unlike those MA organizations that only offer coordination-only D–SNPs in the State and do not contract with Pennsylvania as a Medicaid MCO. In 2030, MA organizations with unaligned HIDE SNPs would need to disenroll any unaligned full-benefit dually eligible individuals from their HIDE SNP. In a State like Pennsylvania that does not mandate Medicaid managed care, we believe that our regulation as-is at § 422.514(h) could create an incentive for MA organizations to terminate their HIDE SNP and transition dually eligible enrollees to the coordination-only D–SNP, which could continue to enroll full-benefit dually eligible individuals regardless of whether an enrollee receives their Medicaid coverage through Medicaid FFS or an unaligned Medicaid managed care plan, allowing such a plan to maintain maximum enrollment. For these reasons, we believe that the application of § 422.514(h) to the MA organizations with unaligned HIDE SNPs and coordination-only D–SNPs puts them at a disadvantage in comparison to those MA organizations with only coordination-only D–SNPs, since full-benefit dually eligible individuals are able to, and do, remain in Medicaid FFS in States without mandatory Medicaid managed care. This is an unintended consequence of § 422.514(h), inconsistent with our goals to promote integrated care. While our goal is to have full-benefit dually eligible individuals enrolled in integrated D–SNPs, we do not want to inadvertently prevent integrated D–SNPs from continuing to enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS. We believe MA organizations offering integrated D–SNPs in other States with voluntary Medicaid managed care for the dually eligible population, such as Michigan and the District of Columbia, may face similar challenges.

We are proposing to amend §§ 422.107(d)(1) and 422.514(h) to allow D–SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D–SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where those individuals are enrolled in Medicaid FFS. These proposed changes would address the challenges of MA organizations complying with the requirements at § 422.514(h) in States where there is no mandatory Medicaid managed care program and avoid the need for MA organizations in those States to cease enrolling full-benefit dually eligible individuals who are in Medicaid FFS starting in 2027 and disenroll those members in 2030 as currently required under § 422.514(h).

We propose to amend SMAC requirements at § 422.107(d)(1) through adding a new paragraph (i). For any SMACs that allow coordination-only D–SNPs (as established under § 422.107(d)(1)) to enroll full-benefit dually eligible individuals, the newly proposed paragraph (i) would require the SMAC to stipulate that such full-benefit dually eligible beneficiaries cannot be enrolled in a Medicaid MCO that is owned and controlled by an entity other than the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization. In other words, the proposed amendment to § 422.107(d)(1)

would permit coordination-only D–SNPs that enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS.

At § 422.514(h)(3), we propose to add new paragraphs (iii) and (iv). For any SMACs that permit full-benefit dually eligible individuals to enroll in (a) a coordination-only D–SNP per proposed amendment at § 422.107(d)(1)(i) or (b) a HIDE SNP with a majority of individuals enrolled in Medicaid FFS, the new paragraph proposed at § 422.514(h)(3)(iii) would allow the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization to offer one or more additional D–SNPs for full-benefit dually eligible individuals in the same service area. Limiting the proposed exception at § 422.514(h)(3) to HIDE SNPs with a majority of enrollees in Medicaid FFS would prevent application of this exception to HIDE SNPs with a minority of Medicaid FFS enrollees and a majority of Medicaid managed care enrollees whose Medicaid MCO is unaligned with the HIDE SNP. HIDE SNPs with a majority of enrollees in unaligned Medicaid MCOs would have less incentive to achieve aligned membership and detract from the intended goals of § 422.514(h). We propose adding a new paragraph (iv) at § 422.514(h)(3) that would require MA organizations with D–SNPs subject to § 422.514(h)(3)(iii) to comply with care coordination responsibilities at § 422.562(a)(5). Per § 422.562(a)(5)(i), D–SNPs must offer to assist an enrollee in that D–SNP with obtaining Medicaid-covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid FFS or a Medicaid managed care plan, such as a Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) as defined in § 438.2. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance are outlined at § 422.562(a)(5)(i)(A). We are considering amending § 422.562(a)(5)(i)(A) to require MA organizations with D–SNPs subject to proposed § 422.514(h)(3)(iii) to report to CMS on the proactive outreach they provide to Medicaid FFS enrollees, the type of assistance they offered to these enrollees, and whether these enrollees received the relevant Medicaid services. We are not proposing to require MA organizations with D–SNPs subject to proposed § 422.514(h)(3)(iii) to report their efforts to meet § 422.562(a)(5)(i) to CMS since such reporting would add burden for MA organizations and we may be able to leverage existing oversight mechanisms, such as models of care (MOCs), CMS program audits, monthly calls between MA organizations and CMS account managers, and existing State Medicaid FFS reporting to CMS instead of adding new plan reporting requirements. We solicit comments on whether we should amend § 422.562(a)(5)(i)(A) to require MA organizations with D–SNPs to report on their activities for assisting Medicaid FFS enrollees in obtaining Medicaid covered services instead of or in addition to the existing oversight mechanisms outlined.

Collectively, we believe these proposals at §§ 422.107(d)(1)(i) and 422.514(h)(3) would benefit MA organizations operating multiple D–SNPs that enroll full-benefit dually eligible individuals in States without mandatory Medicaid managed care. In States like New York, our proposed changes would remove the disadvantage MA organizations that offer HIDE SNPs will encounter starting (a) in 2027, when they would need to stop enrolling full-benefit dually eligible individuals into HIDE SNPs that enroll Medicaid FFS enrollees and (b) in 2030, when they would need to disenroll full-benefit dually eligible individuals from HIDE SNPs that enroll Medicaid FFS enrollees. Similarly, in States like Pennsylvania, our proposed changes would address the disadvantage MA organizations that offer HIDE SNPs and coordination-only D–SNPs will encounter starting (a) in 2027, when they would need to stop enrolling full-benefit dually eligible individuals into coordination-only D–SNPs and (b) in 2030, when they would need to disenroll full-benefit dually eligible individuals from coordination-only D–SNPs that enroll Medicaid fee-for-service enrollees. We do not believe these changes would detract from the goal of the provisions we codified in the April 2024 final rule, which was to increase the percentage of D–SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment. When Medicaid FFS is available and HIDE SNPs can enroll individuals who are in Medicaid FFS, exclusively aligned enrollment cannot be achieved.

In the April 2024 final rule, we received comments concerning the applicability of the enrollment limitation policies at § 422.514(h) on unique Medicaid managed care programs. Among others, commenters raised specific questions about the applicability of this rule to D–SNPs in Puerto Rico (89 FR 30697). We responded to these comments and noted that MA organizations that offer multiple D–SNPs participating in the Platino program in Puerto Rico would be required to only offer one D–SNP starting in 2027 for full-benefit dually eligible individuals in a service area where an MA organization, its parent organizations, or an entity that shares a parent organization with the MA organization also offers an affiliated Medicaid MCO unless those D–SNPs meet the exception finalized at § 422.514(h)(3).

Currently, Puerto Rico is the only U.S. Territory that offers D–SNPs. We note that the U.S. Territories, including Puerto Rico, are unique, as the Medicaid program in the U.S. Territories differs from Medicaid programs operating in the States and the District of Columbia in several notable ways. The Medicare Savings Programs, as defined at section 1144(c)(7) of the Act and 42 CFR 435.4, are Medicaid eligibility groups through which Medicaid assists low-income Medicare beneficiaries with their Part A and/or Part B premiums, and for many enrollees, cost-sharing. The MSPs are mandatory Medicaid eligibility groups for the 50 States and the District of Columbia, but optional for the U.S. Territories per section 1905(p)(4)(A) of the Act. Currently, no U.S. Territory has adopted the MSPs. Additionally, per section 1860D–14(a)(3)(F) of the Act and 42 CFR 423.907(a)(1), low-income Part D eligible individuals who reside in the U.S. Territories are ineligible for the Part D low-income subsidy, which provides cost-sharing and premium assistance to low-income Part D-eligible in the 50 States and the District of Columbia in accordance with section 1860D–14 of the Act and 42 CFR part 423 subpart P. While traditional funding sources for Medicare premiums are unavailable in the U.S. Territories, D–SNPs have the discretion to apply their MA rebate toward the Part B premium amount. (For CY 2026, we note that D–SNPs in Puerto Rico differentiate their PBPs by level of Part B premium reduction amount and supplemental benefits.) Additionally, premiums for Part D are covered by the Enhanced Allotment Plan (section 1935(e) of the Act), a specific source of funding for prescription drugs for the U.S. Territories.

Upon further consideration and given the unique landscape in the U.S. Territories, including Puerto Rico, we are proposing an exception at

§ 422.514(h)(3)(v). The proposed exception would exempt MA organizations operating in U.S. Territories that have not adopted MSP from the requirements at § 422.514(h)(1)(i) that otherwise would require—beginning in contract year 2027—the MA organization to only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals.

We acknowledge that this proposal is a change from what we previously stated in response to comments in the April 2024 final rule. We also acknowledge that upon further consideration and review, we may, in future rulemaking, reconsider this proposed exception at § 422.514(h)(3)(v). These proposed changes target MA organizations in States with voluntary Medicaid managed care enrollment and seek to level the playing field in the marketplace for impacted D–SNPs. The proposed change at § 422.514(h)(3)(v) is intended to acknowledge the uniqueness of D–SNP landscapes in the U.S. Territories.

We solicit comments on all aspects of our proposal, including whether the advantages of the proposed changes would excessively detract from the original goal of the provisions codified in the April 2024 final rule. For example, we are interested in stakeholders' perspectives on the value of non-AIP HIDE SNPs with a majority of Medicaid FFS enrollees and whether we should establish an exception for them at proposed § 422.514(h)(3)(iii) at all or limit that exception to a shorter period of time, such as 2027 through 2029. While we identified a few States that we expect would benefit from our proposals, we invite commenters to identify other States that could benefit or be negatively impacted. As outlined earlier in this section, we also solicit comments on whether we should amend § 422.562(a)(5)(i)(A) to require MA organizations with D–SNPs subject to proposed § 422.514(h)(3)(iii) to report on their activities to assist Medicaid FFS enrollees with obtaining Medicaid covered services enrollees instead of or in addition to the existing oversight mechanisms. Further, we solicit comment on the likely effectiveness of our proposed regulation in balancing the roles of D–SNPs in the U.S. Territories to fill the gaps of MSP and Part D LIS while also providing robust Medicare benefits to dually eligible individuals. We are also interested in perspectives on how limiting D–SNPs in the U.S. Territories would affect enrollees and the consumer choice in U.S. Territories.

D. Contract Modifications for D–SNPs Following State Medicaid Agency Contract Termination (§ 422.510)

MA organizations are required to have contracts with CMS to operate each year. Section 1857(h)(2) of the Act provides authority for the Secretary to immediately terminate a contract with an MA organization in instances where the Secretary determines that a delay in termination resulting from compliance with the procedures in section 1857(h)(1) of the Act would pose an imminent and serious risk to the health of enrolled Medicare beneficiaries. In the final rule titled ''Medicare Program; Establishment of the Medicare+Choice Program,'' which appeared in the **Federal Register** on June 26, 1998 (hereafter referred to as the June 1998 final rule; 63 FR 35018), we finalized regulations at § 422.510 which outline processes for terminations of contracts by CMS, while providing conditions in which contracts may be found terminable. Such conditions include failure to carry out the contract, carrying out the contract in a manner that is inconsistent with the efficient and effective administration of MA regulations, and no longer being able to meet the applicable conditions put forth in MA regulations. In the decades since this rule was first finalized, we have continued to refine the conditions in which CMS may terminate an MA contract at § 422.510 and elsewhere in Part 422.

D–SNPs are MA plans that coordinate the delivery of Medicare and Medicaid services for individuals who are eligible for such services and enrolled in the plan. In addition to the standard contract an MA organization must have with CMS to operate, per section 1859(f)(3)(D) of the Act, MA organizations offering D–SNPs must also have a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for individuals entitled to Medicaid. Because D–SNPs are required to have contracts with the State Medicaid agency (SMACs), States have significant control over the availability of D–SNPs in their markets given the State's discretion in contracting with D–SNPs in combination with the State's control over its Medicaid program. We discussed this relationship between States and MA organizations 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, specifically at 87 FR 27763.

Because of the relationship between the State and the D–SNP, the provision and continuation of SMACs are sensitive to State policy changes and operational choices. To illustrate this, we look to Medicaid MCO procurement timelines and decisions. Some States use procurement processes to select the Medicaid MCOs that will provide Medicaid benefits to the enrollees in the State. The timeline for these procurements is distinct to each State and may operate off-cycle from MA contracting at the Federal level. Additionally, the duration of the procurement may vary based on several factors. If a State decides not to contract with a particular Medicaid MCO, which may occur off-cycle from the calendar year, such a procurement decision may require termination of a Medicaid MCO contract. Termination of the Medicaid MCO contract would trigger termination of the SMAC, if the terminating Medicaid MCO is an affiliated entity with a D–SNP that has a SMAC in effect. For example, if a State with FIDE SNPs reprocured their Medicaid MCOs and one of the existing Medicaid MCOs lost the reprocurement, that FIDE SNP would need to terminate when the Medicaid MCO terminates.

As was noted earlier in this preamble, D–SNPs are statutorily required to have a SMAC to operate in a State. In the example given previously, if a Medicaid MCO that is an affiliated entity with a D–SNP loses a State procurement or otherwise has its Medicaid MCO contract terminated, the State also terminates the SMAC and the D–SNP cannot continue to operate. This action requires that the contract between the D–SNP and CMS be terminated. As more States move towards integrated care and contract with Medicaid MCOs through the result of procurements, we have encountered instances where a SMAC is terminated by a State during the plan year. In those instances, CMS has worked with the respective State and the MA organization whose SMAC is being terminated to mutually terminate the contract per § 422.508, a process by which CMS, the State and the D–SNP are able to agree on a timeline for termination and the provision of notice to enrollees of such termination, in an effort to create a smoother transition to an alternative plan for the plan's enrollees.

However, an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS. Absent the cooperation of the MA organization to mutually terminate in situations where the MA organization no longer holds a SMAC with the State, we are concerned that enrollees may experience harm by losing access to their integrated care, including access to known providers and care plans, as the D–SNP in which they are enrolled is no longer able to provide benefits, or arrange for benefits to be provided, for individuals entitled to Medicaid. In these instances, CMS will need to seek immediate termination to protect beneficiaries.

At § 422.510(a)(4), we are first proposing to add a new paragraph (xvii) to establish that CMS may terminate a contract if the MA organization is no longer eligible to offer a D–SNP because the MA organization does not hold a contract with the State Medicaid agency consistent with § 422.107(b). Our goal in adding this new clause is to codify that the loss of a SMAC constitutes a valid basis for contract termination under CMS authority per section 1859(f)(3)(D) of the Act.

Secondly, at § 422.510(b)(2)(i), we are proposing to add paragraph (D) to state that the procedures specified in paragraph (b)(1), related to when CMS notifies the MA organization and when the MA organization must notify its enrollees and the general public, do not apply if the contract is being terminated based on the proposed addition of § 422.510(a)(4)(xvii). We are proposing that when a D–SNP contract is terminated because the State has terminated the affiliated contract with the Medicaid MCO or the State has terminated the SMAC, it is cause for CMS to make the MA contract termination immediate. When a State terminates the Medicaid MCO affiliated with the D–SNP or terminates the SMAC, D–SNP enrollees who are otherwise entitled to medical assistance under a State plan under title XIX of the Act would be in jeopardy of not having access to the Medicaid services to which they are entitled, given that, as required by § 422.2, D–SNPs coordinate the delivery of Medicare and Medicaid services for eligible individuals and may provide coverage of Medicaid services. It is our belief that a delay in D–SNP contract termination could disrupt access to Medicaid benefits for those who are eligible, which would pose an imminent and serious risk to the health of the organization's enrollees, rising to the standard put forth in section 1857(h)(2) of the Act and warranting immediate termination of contract by CMS. We believe that where the MA organization does not agree to a mutual termination in coordination with the termination of the affiliated Medicaid MCO contract and/or SMAC, an immediate termination would be appropriate. However, we note that our proposed amendments to §§ 422.510(a)(4)(xvii) and (b)(2)(i)(D) do not preclude a MA organization from seeking termination of a contract by mutual consent, per § 422.508.

We note that when an MA organization has multiple plans under one contract, per § § 422.503(e) CMS may sever the D–SNP from the rest of the contract, in effect allowing CMS to renew only the portion of the contract that does not include the D–SNP affiliated with the terminated SMAC.

Proposed § 422.510(b)(2)(i)(D) would codify the process of immediate termination of contract by CMS when the D–SNP does not have a SMAC. We believe that the MA organization in this situation does not need and would not benefit from an opportunity to develop and implement a corrective action plan as required at § 422.510(c)(1) given that the only way to correct the issue would be to execute a SMAC with the State. States have the ability to issue corrective action plans to the D–SNPs with whom they hold contracts. Many States, in their SMACs, include language to this effect. Additionally, as in the example given previously, if a Medicaid MCO that is an affiliated entity with a D–SNP loses a State procurement, the State also terminates the SMAC. In either of these instances, allowing D–SNPs the opportunity to develop and implement a corrective action plan per § 422.510(c)(1) would not provide the D–SNP with an avenue to correct any underlying issue that resulted in the State's termination of the SMAC. The SMAC termination, including any related opportunity to pursue a corrective action plan offered by the State, will have already occurred by the time the MA contract is terminated. Moreover, State procurement decisions operate separately from MA contracting decisions through CMS and would not be amenable to a cure or a corrective action plan as described in § 422.510(c)(1). Furthermore, any further delay in termination of the D–SNP contract poses imminent and serious risk to the health of the organization's enrollees as previously described in this preamble, rising to the standard put forth in section 1857(h)(2) of the Act. As such, we are lastly proposing that termination of a SMAC be included as an exception to the opportunity for plans to develop and implement a corrective action plan, at § 422.510(c)(2)(iv).

We request comment on this proposal, including but not limited to whether this package of provisions will accomplish the goals we have laid out in this preamble and whether there should be any other additional modifications to consider.

E. Limitation on D–SNP-Only Contracts Submitting Materials Under the Multi-Contract Entity Process (§§ 422.2261 and 423.2261)

Sections §§ 422.2261(a) and 423.2261(a) require MA organizations and Part D sponsors to submit all marketing materials, all election forms, and certain designated communication materials for CMS review. These regulations state that the HPMS Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for CMS review. They also specify that materials must be submitted to the HPMS Marketing Module by the MA organization or Part D sponsor or, where materials have been developed by a Third Party Marketing Organization (TPMO) for multiple MA organizations or plans, by a TPMO with prior review of each MA organization on whose behalf the materials were created or will be used. In addition, §§ 422.2262(d) and 423.2262(d) describe how MA organizations and Part D sponsors must use a standardized method of identification for oversight and tracking for materials received by beneficiaries including the MA organization's contract or Multi-Contract Entity (MCE) number (such as an ''H'' number for MA plans or ''Y'' number for an MCE).

Under § 422.107(e), a State Medicaid agency may require MA organizations offering D–SNPs with exclusively aligned enrollment to do both of the following: (1) apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more D–SNPs with a service area limited to the State; and (2) use required materials that integrate Medicare and Medicaid content including, at a minimum, the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of Title 42 of the CFR. We refer to MA contracts that only include one or more D–SNPs with a service area limited to the State as D–SNP-only contracts. If a State elects to require D–SNP-only contracts under § 422.107(e)(1), per § 422.107(e)(3)(i), CMS grants State Medicaid agency officials access to

HPMS for purposes of oversight and information sharing for these D–SNP-only contracts. For CY 2026, 13 States have D–SNP-only contracts and therefore have access to HPMS for oversight of these contracts in their State. This State oversight includes access to the HPMS Marketing Module for purposes of reviewing materials submitted by D–SNP-only contracts. These States only have access to review materials submitted under the contract number (H number) in HPMS for D–SNP-only contracts.

For material oversight, per § 438.10(c)(5), States are required to ensure, through their Medicaid managed care contracts, that each MCO, PIHP, PAHP, and primary care case management (PCCM) entity provides the information to each enrollee consistent with § 438.10(f)–(i), as applicable. In addition, per § 438.104(b), MCO, PIHP, PAHP, PCCM, or PCCM entities cannot distribute marketing materials without first obtaining State approval. The entity's contract with the State must also specify the methods by which the entity ensures that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State Medicaid agency.

Since contracts with exclusive alignment of Medicare and Medicaid must meet the material requirements of both CMS and the State, prior to the adoption of § 422.107(e), MA organizations were required to submit materials to the State and CMS separately. However, States requiring D–SNP-only contracts have access to HPMS for reviewing these materials, and they can require the MA organizations offering D–SNP-only contracts to submit materials in the HPMS marketing module for State review. This State access decreases plan burden by allowing the D–SNP to submit the material once in HPMS for concurrent joint review by CMS and the State, as applicable, rather than having to separately submit materials to the State for review and then to CMS. This can also shorten the total review time for the MA organization and give it more time to meet tight timeframes for releasing materials to enrollees.

If an MA organization were to submit a material under an MCE number that applies to multiple contracts, the applicable State Medicaid agency would not be able to either view or review that material in the HPMS Marketing Module. States only have access to information in HPMS for the specific D–SNP-only contracts in their State. Because MCE numbers cover multiple contracts across multiple States, CMS doesn't allow State staff to access materials submitted under an MCE number, even if an MA organization includes materials for their State. MA organizations could potentially submit a substantial number of materials in HPMS under the MCE number, including their D–SNP-only contracts, but the State would not be able to view any of them due to their submission under the MCE number. To address this challenge, CMS has programmed the HPMS marketing module so that D–SNP-only contracts cannot submit materials under an MCE number. In addition, States with D–SNP-only contracts have added language in their SMACs to prohibit submission of materials in the HPMS Marketing Module under the MA organization's MCE number. Instead, States are requiring that MA organizations with D–SNP-only contracts submit materials for review under their contract ID number.

To ensure that D–SNP-only contracts are meeting the material requirements of both Medicare and Medicaid, we believe that it is important to clarify that MA organizations with D–SNP-only contracts cannot submit materials using the MA organization's MCE number for D–SNP-only contracts, nor can TPMOs submit materials on behalf of the MA organization for D–SNP-only contracts using an MCE number. This requirement applies to all plan benefit packages within D–SNP-only contracts under § 422.107(e)(1). Since States have already been requiring this approach through their SMACs and the HPMS Marketing Module is set up to prevent D–SNP-only contracts from submitting materials under an MCE number, we do not expect this update to add burden for any MA organizations; the current process will not change.

The Medicare Communications and Marketing Guidelines (MCMG) provide additional detail on §§ 422.2261(a)(3) and 423.2261(a)(3) noting that the multi-plan submission process is intended for TPMOs that submit for multiple organizations. The MCMG states that if the third party's marketing materials only mention one MA organization, then the plans should submit the material directly to CMS using the standard submission process. Since we are prohibiting submissions under the MCE number for D–SNP-only contracts and TPMOs cannot submit materials under the contract ID number, there is no way for TPMOs to submit materials directly for D–SNP-only contracts in the HPMS Marketing Module. The MA organization must submit all materials to be used by TPMOs for D–SNP-only contracts.

Under our authority to interpret, implement, and carry out the Part C and D programs under sections 1851(h), 1851(j), 1852(c), 1860D–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, we are proposing to add a requirement at §§ 422.2261(a)(3) and 423.2261(a)(3) that MA organizations offering D–SNPs with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the MA organization's contract number. MA organizations and TPMOs may not submit materials for the contract under the organization's MCE number as described in §§ 422.2262(d)(2)(i) and 423.2262(d)(2)(i).

We welcome comment on our proposal.

F. Request for Information: C–SNP and I–SNP Growth and Dually Eligible Individuals

Please note, this is a request for information (RFI) only. In accordance with implementing regulations of the PRA, specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Per the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), chronic condition special needs plans (C–SNPs), dual eligible special needs plans (D–SNPs), and institutional special needs plans (I–SNPs) are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. C–SNPs restrict enrollment to special needs individuals with specific severe or disabling chronic conditions as defined at § 422.2. The April 2024 final rule amended the definition of severe or disabling chronic conditions at § 422.2 by outlining the specific co-morbid and medically complex chronic conditions that qualify for C–SNP enrollment (89 FR 30661 through 30666). I–SNPs restrict enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent per § 422.2. The April 2024 final rule added three additional I–SNP subtypes: facility-based institutional

special needs plan (FI–SNP), hybrid institutional special needs plan (HI–SNP), and institutional-equivalent special needs plan (IE–SNP). (89 FR 30649 through 30653) D–SNPs are specialized MA plans for individuals who are entitled to medical assistance under a State plan under Title XIX, per § 422.2.

1. Growth in C–SNPs With High Proportion of Dually Eligible Enrollees

The number of C–SNPs offered by MA organizations has increased substantially in recent years. As outlined in Table FF1, MA organizations offered 207 C–SNPs in CY 2021 and 385 C–SNPs in CY 2025, representing growth of 85% over that timeframe. C–SNP enrollment grew from 387,920 enrollees in CY 2021 to 1,103,194 enrollees in CY 2025, an increase of 184%. Higher levels of enrollment growth occurred between CY 2023 and CY 2024 (41.7%) and between CY 2024 and CY 2025 (67.5%).

TABLE FF1: C-SNPS AND THEIR ENROLLMENT: CY 2021 - 2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Percent Annual Growth in C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Percent Annual Growth Total Dually Eligible Individual Enrollment in C-SNPs	Total Dually Eligible Individual Enrollment as Percent of Total C-SNP Enrollment
2021	207	387,920		103,877		26.8
2022	271	407,199	5.0	104,986	1.1	25.8
2023	306	464,837	14.2	113,765	8.4	24.5
2024	312	658,710	41.7	133,706	17.5	20.3
2025	385	1,103,194	67.5	210,983	57.8	19.1

Source: CMS analysis of Integrated Data Repository (IDR) data for January enrollment for CY 2021 – 2025.

The number of dually eligible individuals enrolled in C–SNPs also increased over the same period of time. As shown in Table FF1, the number of dually eligible individuals enrolled in C–SNPs grew from 103,877 enrollees in CY 2021 to 210,983 enrollees in CY 2025, an increase of more than 100 percent. The highest level of growth during that timeframe occurred between CY 2024 and CY 2025 with enrollment of dually eligible individuals increasing from 133,706 enrollees in CY 2024 to 210,983 enrollees in CY 2025, an increase of 57.8 percent in one year.

Over the same timeframe, the number of C–SNPs with a high proportion of dually eligible enrollees increased. Per § 422.514(d), we define D–SNP look-alikes as non-SNP MA plans with 60 percent or more dually eligible enrollment. We used this threshold to identify C–SNPs in CY 2021 through CY 2025 with a similarly high level of dually eligible enrollees. Table FF2 shows the number of C–SNPs with dually eligible individuals representing 60 percent or more of total enrollment grew from 16 C–SNPs in CY 2021 with 59,164 dually eligible enrollees to 66 C–SNPs in CY 2025 with 104,237 dually eligible enrollees. This experience represents a 313 percent increase in the number of C–SNPs with high concentrations of dually eligible enrollees. The most substantial level of enrollment growth (63.5 percent) during this timeframe occurred from CY 2024 to CY 2025 with dually eligible enrollment increasing from 63,738 enrollees in 49 C–SNPs to 104,437 enrollees in 66 C–SNPs.

At least one C–SNP with 60 percent or more dually eligible enrollees has been offered in the following 26 States for at least one year during the CY 2021 through CY 2025 time span: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Iowa, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nevada, New Hampshire, New Mexico, Ohio, Oregon, South Carolina, Tennessee, Texas, Vermont, and Virginia. For CY 2025, MA organizations offered C–SNPs with high concentrations of dually eligible individuals in 14 States, listed in order of number of such C–SNPs per State: California (31 C–SNPs); Arizona (7 C–SNPs); Illinois (6 C–SNPs); New Mexico (5 C–SNPs); Indiana, Minnesota, Nevada, Oregon (2 C–SNPs); Connecticut, Idaho, Kansas, New Hampshire, Texas, Vermont (1 C–SNP). The vast majority (85.4 percent) of the dually eligible individuals enrolled in these CY 2025 C–SNPs are full-benefit dually eligible individuals. We provide more detail on C–SNPs with a high concentration of dually eligible individuals in California, Arizona, Illinois, and New Mexico given these States have the largest number of such C–SNPs during the CY 2021 through CY 2025 timeframe.

TABLE FF2: C-SNPS WITH DUALLY ELIGIBLE INDIVIDUALS REPRESENTING 60 PERCENT OR MORE OF TOTAL ENROLLMENT: CY 2021-2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Partial-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment as Percent of Total Dually Eligible C-SNP Enrollment
2021	16	71,150	59,164	35,788	23,376	60.5
2022	33	77,349	60,881	36,392	24,489	59.8
2023	39	76,392	62,688	44,515	18,173	71.0
2024	49	71,573	63,738	53,748	9,990	84.3
2025	66	122,374	104,237	89,008	15,229	85.4

Source: CMS analysis of IDR data for January enrollment for CY 2021 – 2025.

Over the last five years, California is the State with the largest number of C–SNPs with a high proportion of dually eligible individuals. Table FF3 details the growth of these C–SNPs in California. Dually eligible enrollment in these C–SNPs represents more than 90 percent of total enrollment. Of the 49 C–SNPs and 66 C–SNPs nationally with 60 percent or more of total enrollment in CY 2024 and CY 2025, respectively, nearly half of these high proportion C–SNPs (24 in CY 2024 and 31 in CY 2025) were offered in California. The vast majority of dually eligible individuals enrolled in these C–SNPs were full-benefit dually eligible individuals. Like C–SNP enrollment nationally, the California C–SNPs experienced a high degree of annual enrollment growth (98.7 percent increase) from CY 2024 (27,065 enrollees) to CY 2025 (53,786 enrollees).

TABLE FF3: C-SNPS WITH DUALLY ELIGIBLE INDIVIDUALS REPRESENTING 60 PERCENT OR MORE OF THE TOTAL ENROLLMENT IN CALIFORNIA: CY 2021-2025

Year	Number of C-SNPs	Total C-SNP Enrollment	Total Dually Eligible Individual Enrollment in C-SNPs	Total Full-Benefit Dually Eligible Individual Enrollment in C-SNPs	Total Partial-Benefit Dually Eligible Individual Enrollment in C-SNPs	Dually Eligible Individual Enrollment as Percent of Total C-SNP Enrollment	Full-Benefit Dually Eligible Individual Enrollment as Percent of Total Dually Eligible C-SNP Enrollment
2021	10	12,154	11,044	10,889	154	90.9	98.6
2022	13	15,750	14,783	14,607	176	93.9	98.8
2023	17	20,571	19,898	19,744	154	96.7	99.2
2024	24	27,065	25,859	25,645	214	95.5	99.2
2025	31	53,786	51,367	51,144	223	95.5	99.6

Source: CMS analysis of IDR data for January enrollment for CY 2021 – 2025.

While Arizona and Illinois have substantially fewer C–SNPs with a high concentration of dually eligible individuals than California, C–SNPs in Arizona and Illinois also experienced sizable growth in enrollment from CY 2021 through CY 2025. In Arizona, enrollment in these C–SNPs with a high concentration of dually eligible individuals increased from zero enrollees in CY 2021 (zero C–SNPs) to 2,547 in CY 2025 (7 C–SNPs), with the highest level of annual growth (78.1 percent) occurring between CY 2023 (890 enrollees) and CY 2024 (1,585). These C–SNPs with a high proportion of dually eligible enrollees continued to grow (60.7 percent increase) between CY 2024 (1,585 enrollees) and CY 2025 (2,547 enrollees). Approximately 60 percent of dually eligible individuals enrolled in these C–SNPs are full-benefit dually eligible individuals.

In Illinois, C–SNPs with a high proportion of dually eligible individuals increased from 36 enrollees in CY 2021 (one C–SNP) to 41,218 enrollees in CY 2025 (6 C–SNPs), representing a growth of more than 3,180 percent. While the number of C–SNPs remained steady at 6 C–SNPs from CY 2024 to CY 2025, enrollment increased from 24,875 enrollees to 41,318 enrollees, a 66 percent increase. Nearly 85 percent of the dually eligible individuals enrolled in these C–SNPs are full-benefit dually eligible individuals.

New Mexico also experienced growth in C–SNPs with a high concentration of dually eligible individuals from CY 2021 (0 enrollees and 0 C–SNPs) through CY 2025 (5,203 enrollees and 5 C–SNPs). Unlike California, Arizona, and Illinois, the C–SNPs in New Mexico lost enrollment from CY 2024 (7,582 enrollees) to CY 2025 (5,203 enrollees), a reduction of 31.4 percent, after annual increases from CY 2021 to CY 2024. Also, the proportion of full-benefit and partial-benefit dually eligible individuals enrolled in the C–SNPs has been approximately equal. We also note that Connecticut, Idaho, Illinois, New Hampshire, New Mexico, Oregon, and Vermont are States where dually eligible individuals comprise 60 percent or more of total C–SNP enrollment in 2025.[84]

[84] CMS analysis of IDR data for January enrollment for 2025.

2. Growth in I–SNPs With High Proportion of Dually Eligible Enrollees

Compared to C–SNPs, the number of I–SNPs offered by MA organizations has remained relatively consistent in recent years. As outlined in Table FF4, MA organizations offered 139 I–SNPs in CY 2021 and 144 I–SNPs in CY 2025 with an increase to 171 I–SNPs in CY 2023. I–SNP enrollment grew from 87,037 enrollees in CY 2021 to 121,188 enrollees in CY 2025, an increase of 39 percent. Dually eligible individuals represented the vast majority of I–SNP enrollees at approximately 90 percent of total enrollment each year.

TABLE FF4: I-SNPs AND THEIR ENROLLMENT: CY 2021 - 2025

Year	Number of I-SNPs	Total I-SNP Enrollment	Percent of Annual Growth in I-SNP Enrollment	Total Dually Eligible Individual Enrollment in I-SNPs	Percent of Annual Growth in Total Dually Eligible Individual Enrollment in I-SNPs	Total Dually Eligible Individual Enrollment as Percent of Total I-SNP Enrollment
2021	139	87,037		79,608		91.5
2022	156	96,230	10.6%	87,755	10.2	91.2
2023	171	105,992	10.1%	96,342	9.8	90.9
2024	164	117,964	11.3%	104,302	8.3	88.4
2025	144	121,037	2.7%	110,006	5.5	90.8

Source: CMS analysis of IDR data for January enrollment for CY 2021–2025.

For the most recent year reviewed (CY 2025), New York had the largest number of I–SNPs (12). The following other States had five or more I–SNPs in CY 2025: Florida (10); Ohio and Texas (8); North Carolina (7); California, Indiana, Missouri, Oregon (6); and Arizona and Pennsylvania (5).

Table FF5 provides total I–SNP enrollment in the three I–SNP subtypes: FI–SNPs, HI–SNPs, and IE–SNPs for CY 2021 through CY 2025. On average over this time period, 73 percent of I–SNP enrollees were beneficiaries enrolled in a FI–SNP (institutional-only), 22 percent were enrolled in a HI–SNP (institutional and institutional-equivalent) and 5 percent were enrolled in an IE–SNP (institutional-equivalent).

TABLE FF5: I-SNP ENROLLMENT BY PLAN TYPE AND DUAL ELIGIBLE STATUS: CY 2021 – 2025

Year	Enrollment in FI-SNPs			Enrollment in HI-SNPs			Enrollment in IE-SNPs		
	Total	Full	Partial	Total	Full	Partial	Total	Full	Partial
2021	67,225	65,263	136	17,019	12,263	185	2,619	1,609	53
2022	71,755	69,626	198	20,638	15,276	255	3,716	2,297	63
2023	76,172	73,871	260	24,302	18,631	300	5,399	3,166	77
2024	83,319	79,817	404	24,759	19,523	338	9,757	3,804	382
2025	85,749	82,312	368	29,609	23,792	286	5,679	3,141	107

Source: Data retrieved by CMS from Eligibility Enrollment Medicare Online in September 2025 for January enrollment for CY 2021–2025. The difference between total enrollment and sum of full-benefit and partial-benefit dually eligible individual enrollment reflects non-dually eligible individual enrollment in I-SNPs.

3. Challenges With C–SNPs and I–SNPs With High Proportion of Dually Eligible Enrollees

Dually eligible individuals encounter fragmentation in the health care system as they navigate the Medicare and Medicaid programs. CMS has been working to address these fragmented experiences 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. Our efforts in recent years have increased opportunities for enrollment in D–SNPs that are aligned with Medicaid managed care plans operated through a common parent organization (integrated D–SNPs).

The challenges with C–SNPs and I–SNPs enrolling high proportion of dually eligible individuals are similar to the challenges of D–SNP look-alikes. CMS established contracting limitations on D–SNP look-alikes at § 422.514(d) whereby CMS does not (a) enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 60 percent or more of its enrollees are dually eligible or (b) renew a contract with a non-SNP MA plan that has 60 percent or more dually eligible enrollees. We established these contract limitations to address proliferation and growth of D–SNP look-alikes, which raised concerns related to effective implementation of requirements for D–SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvement for Patients and Providers Act of 2008 (Pub. L. 110–275) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123)). As stated in the final rule titled ''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 (hereafter referred to as the June 2020 final rule; 85 FR 33805 through 33806), we adopted the D–SNP look-alike contracting limitations to ensure full implementation of requirements for D–SNPs, such as SMACs, a minimum integration of

Medicare and Medicaid benefits, care coordination through health risk assessments (HRAs), and evidence-based models of care (MOCs). These requirements promote coordination of care. Additionally, the SMAC requirement allows States the flexibility to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets. For example, to develop products that integrate Medicare and Medicaid coverage, in CY 2025, 14 States (Arizona, California, District of Columbia, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Puerto Rico, Tennessee, Virginia, and Wisconsin) operate Medicaid managed care programs for dually eligible individuals in which the State requires that the Medicaid MCOs enrolling dually eligible individuals offer an affiliated D–SNP product and limit D–SNP enrollment in those plans to full-benefit dually eligible enrollees. The number of States with these requirements will increase in CY 2026 to include Indiana, Delaware, and several States (Illinois, Michigan, Ohio, Rhode Island, and South Carolina) previously participating in the Financial Alignment Initiative where Medicare-Medicaid Plans are transitioning to integrated D–SNPs effective January 1, 2026. Through their annual SMACs, these States are implementing intentional strategies to better coordinate care for dually eligible individuals. The analysis outlined earlier in this section shows that a number of these States (for example, California, Illinois, Arizona) have experienced increased growth in C–SNPs and increasing concentrations of dually eligible individuals in those C–SNPs in recent years.

C–SNPs could be serving as a workaround to Federal and State integration efforts. Among full-benefit dually eligible individuals newly enrolling in C–SNPs in January 2024 (40,048), 13.0 percent (5,206) were previously enrolled in plans with high-levels of Medicare-Medicaid integration (AIP D–SNPs, non-AIP FIDE SNPs, PACE, MMPs), 4.8 percent (1,902) were previously enrolled in D–SNPs with moderate-level integration (non-AIP HIDE SNPs)), and 7.0 percent (2,808) were previously enrolled in D–SNPs with low-level integration (non-AIP coordination-only D–SNPs).[85] Among full-benefit dually eligible individuals newly enrolling in C–SNPs in January 2025 (68,554), 14.2 percent (9,732) were previously enrolled in plans with high-level integration (AIP D–SNPs, non-AIP FIDE SNPs, PACE, MMPs), 4.4 percent (3,037) were previously enrolled in D–SNPs with moderate-level integration (non-AIP HIDE SNPs)), and 8.9 percent (6,083) were previously enrolled in D–SNPs with low-level integration (non-AIP coordination-only D–SNPs). These data show a one-year increase of 71 percent in the number of full-benefit dually eligible individuals who were enrolled in a D–SNP, PACE plan, or MMP in January 2024 (40,048) vs. January 2025 (68,554) and enrolled in a C–SNP the next year. The highest percentage of these enrollees transitioned out of the plans with the highest level of Medicare-Medicaid integration. We note that other publications have analyzed these data.[86] For purposes of this analysis, we categorized plans as highly integrated based on presence of exclusively aligned enrollment, which may differ from estimates in other publications. The level of Medicare and Medicaid service integration in D–SNPs is also important.

Like D–SNPs, C–SNPs and I–SNPs must have approved MOCs and develop HRAs and individualized care plans (ICPs). C–SNPs and I–SNPs can offer benefits specific to chronic disease and institutionalization-level needs, respectively. In CY 2024, 84 percent of C–SNPs offered Special Supplemental Benefits for the Chronically Ill (SSBCI), with food and produce and general living support being the most common SSBCI offerings.[87] These benefits may be attractive to dually eligible individuals who have a higher prevalence of chronic conditions than non-dually eligible Medicare beneficiaries; 26 percent of dually eligible individuals have five or more chronic conditions, compared to 15 percent of Medicare beneficiaries without Medicaid coverage.[88] Dually eligible individuals are also more likely than non-dually eligible beneficiaries Medicare beneficiaries to live in an institution (11 percent vs. 3 percent) and report being in poor health (11 percent vs. 4 percent).[89] However, C–SNPs and I–SNPs are not subject to State contracting requirements applicable to D–SNPs nor do they reflect the key elements of integrated care: maximized person-centered coordination of Medicare and Medicaid services; mitigation of cost-shifting incentives between the two programs; and a seamless experience for dually eligible individuals. Although research has not yet uniformly shown an advantage for dually eligible individuals enrolling in plans with Medicare and Medicaid integration, preliminary evidence suggests that dually eligible individuals enrolled in integrated plans, on average, experience, reduced emergency department and inpatient hospital admissions, fewer long-term nursing facility stays, greater use of patient care, and slightly better experience and clinical outcomes than those in non-integrated plans.[90]

C–SNPs and I–SNPs are currently exempt from the D–SNP look-alike contracting limitations. As stated in the June 2020 final rule (85 FR 33813) and April 2024 final rule (89 FR 30722), we excluded SNPs from evaluation against the prohibition on D–SNP look-alikes. Our rationale for the exclusion was to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. Nonetheless, we stated that we would monitor enrollment in other types of SNPs to assess whether such plans are structured primarily to serve dually

[85] CMS analysis of IDR data for CY 2023–2025.

[86] For example, Stein R, Ma Y, Phelan J, Figueroa JF. Growth of C–SNPs May Be Jeopardizing Medicare-Medicaid Integration. Health Affairs. September 2025. Retrieved from: *https://www.healthaffairs.org/content/forefront/growth-c-snps-may-jeopardizing-medicare-medicaid-integration*.

[87] Milliman, Chronic Condition Special Needs Plans: 2024 Market Landscape and Future Consideration, April 2024. Available from: *https://www.milliman.com/en/insight/chronic-condition-special-needs-plans-2024-market-landscape*.

[88] KFF, A Profile of Medicare-Medicaid Enrollees (Dual Eligibles). January 2023. Available from: *https://www.kff.org/medicare/issue-brief/a-profile-of-medicare-medicaid-enrollees-dual-eligibles/*.

[89] MedPAC and MACPAC. Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid. January 2024. Exhibits 7 and 8. Available from: *https://www.macpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508.pdf*.

[90] Roberts ET, Duggan C, Stein R, Jonnadula S, Johnston KJ, Figueroa JF. Quality, spending, utilization, and outcomes among dual-eligible Medicare-Medicaid beneficiaries in integrated care programs: a systematic review. JAMA Health Forum. July 2024. Available from: *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2821202;* Feng Z, Wang J, Gadaska A, Knowles M, Haber S, Ingber M, Grouverman, V. Comparing Outcomes for Dual Eligible Beneficiaries in Integrated Care: Final Report, September 2021. Available from: *https://aspe.hhs.gov/sites/default/files/documents/9739cab65ad0221a66ebe45463d10d37/dual-eligible-beneficiaries-integrated-care.pdf;* and *https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf;* and MACPAC Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps, August 2020. Available from: *https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf*.

eligible enrollees without meeting D–SNP requirements. In their comments on the November 2023 proposed rule (89 FR 30719), MACPAC suggested that we monitor growth in enrollment of dually eligible beneficiaries in other types of SNPs, including C–SNPs and I–SNPs, and identify any potential effects on integration efforts.

The number of D–SNP look-alikes transitioning enrollees to C–SNPs has increased in recent years. That increase could, at least in part, be driven by the exclusion of C–SNPs from the D–SNP look-alike prohibition. CY 2023 D–SNP look-alikes transitioned zero enrollees into C–SNPs effective for January 1, 2024. CY 2024 D–SNP look-alikes transitioned approximately 3,600 enrollees into 3 receiving C–SNPs effective for January 1, 2025. We expect the CY 2025 D–SNP look-alikes to transition approximately 16,500 enrollees into 8 receiving C–SNPs effective for January 1, 2026.

4. Potential Policy Changes for Comment Solicitation

We solicit comments on potential policy changes to support integrated care and improved health outcomes given the significant growth of dually eligible individuals enrolling in C–SNPs and I–SNPs.

First, we solicit comment on establishing a SMAC requirement similar to the existing requirement for D–SNPs. Under this idea, MA organizations seeking to offer a C–SNP or I–SNP with a high concentration of dually eligible individuals would need to have an executed contract with the State Medicaid agency that allows that plan to operate in the State during a particular contract year. Such a contract would allow States to proactively consider and coordinate their integration strategy for dually eligible individuals with the existence of such C–SNPs and I–SNPs enrolling a 60 percent or more dually eligible individuals. A State Medicaid agency contract for C–SNPs or I–SNP could include additional Federal or State-specific requirements similar to the D–SNP SMAC requirements at § 422.107. We solicit comments on whether or not we should adopt a SMAC requirement for C–SNPs and/or I–SNPs with high concentrations for dually eligible individuals as well as potential Federal requirements for those SMACs.

Second, we solicit comments on methods to increase care coordination for dually eligible individuals enrolled in C–SNPs and I–SNPs. Section 438.208 includes coordination and continuity of care requirements for Medicaid MCOs, PIHPs, and PAHPs. Many of the requirements mirror the care coordination and MOC requirements for SNPs and closely involve the populations served by C–SNPs and I–SNPs. The requirement at § 438.208(a)(3)(i) states that for each Medicaid MCO that serves enrollees who are also enrolled in and receive Medicare benefits from an MA organization, the State determines to what extent the MCO must meet the identification, assessment, and treatment planning requirements for enrollees with special health care needs or who need long-term services and supports. These are the types of beneficiaries who, by definition per eligibility criteria at § 422.2, are enrolled in C–SNPs and I–SNPs.

While all SNPs must have approved MOCs, conduct HRAs, and develop ICPs, currently more care coordination requirements apply to D–SNP enrollees than C–SNP and I–SNP enrollees. For example, in the final rule titled ''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'', which appeared in the **Federal Register** on April 15, 2025 (90 FR 15792) (hereinafter referred to as the April 2025 final rule), we amended § 422.101(f)(1)(v) to require that AIP D–SNPs conduct a single comprehensive HRA that meets the Medicaid requirements at § 438.208(b)(3) as well as Medicare requirements. In addition, we published MOC submission requirements for SNP MOC approval in the **Federal Register** (90 FR 26591; CMS–10565; OMB control number 0938–1296),[91] which require D–SNPs to describe how the ICP coordinates Medicare and Medicaid services and, if applicable, provides those services, including long-term services and supports and behavioral health services, and describes how the D–SNP coordinates with providers of Medicaid-covered services during care transitions. We are considering whether to extend any of these existing D–SNP care coordination requirements to C–SNPs and I–SNPs given the high proportion of dually eligible individuals enrolled in these plans. We solicit comments on whether we should (a) adopt any new care coordination requirements for dually eligible C–SNP and/or I–SNP enrollees; (b) add any MOC requirements for these SNP types; and (c) what those care coordination or MOC requirements should include.

Third, we solicit comment on three approaches to applying the D–SNP look-alike contracting limitations at § 422.514(d) through (g) to C–SNPs. Applying these contracting limitations would ensure that enrollees in C–SNPs with a significant proportion of dually eligible individuals would benefit from the requirements for integrated care that protect D–SNP enrollees. First, CMS could consider applying the D–SNP look-alike contracting limitations as is to C–SNPs and remove the current exemption on C–SNPs from the D–SNP look-alike contracting limitations at § 422.514(d) through (g). CMS would not (a) enter into a contract for any non-D–SNP or non-I–SNP MA plan that projects, in its bid submitted under § 422.254, that 60 percent or more of its enrollees are dually eligible or (b) renew a contract with any MA plan that has 60 percent or more dually eligible enrollees. Consistent with § 422.514(e), existing C–SNPs with 60 percent or more dually eligible individuals could transition enrollees to a D–SNP. Under a potential alternative approach, CMS could apply the D–SNP look-alike contracting limitations at § 422.514(d) through (g) to C–SNPs but exempt partial-benefit dually eligible individuals from the 60-percent threshold calculation. Partial-benefit dually eligible individuals do not have Medicaid benefits to coordinate with Medicare benefits in the same way as full-benefit dually eligible individuals, and the benefits that a C–SNP may offer could outweigh the role of Federal and State requirements outlined in a SMAC. We solicit comments on the potential approaches to apply the D–SNP look-alike contracting limitations as is to C–SNPs and excluding partial-benefit dually eligible individuals from the 60-percent threshold calculation.

We recognize that one of the challenges with these policy options is that many C–SNPs do not have a D–SNP in the same service areas as the C–SNP, which could lead to a large proportion of C–SNP enrollees transitioning to a non-SNP MA plan or Original Medicare and a standalone Part D plan. Exempting partial-benefit dually eligible individuals from the 60-percent threshold calculation could reduce the number of C–SNPs subject to transition. Another approach for consideration would be to exempt C–SNPs from the 60-percent threshold in States that do not have any integrated D–SNPs (that is, FIDE SNPs, HIDE SNPs, or AIPs), targeting it to States with Medicare-

[91] CMS, Model of Care Submission Requirements, June 23, 2025. Retrieved from: *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10565.*

Medicaid integration strategies. Thus, C–SNPs could continue in States with D–SNPs meeting the minimum integration requirements. If this potential policy proposal applied in CY 2025, that would mean we would not apply the 60-percent threshold to C–SNPs in the following 24 States: Alabama, Arkansas, Colorado, Connecticut, Delaware, Georgia, Iowa, Louisiana, Maryland, Michigan, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nevada, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Utah, West Virginia, and Wyoming. We expect some of these States (Delaware, Michigan, Ohio, Rhode Island, and South Carolina) to establish SMACs with integrated D–SNPs for CY 2026 as well as Illinois which is contracting with D–SNPs for the first time in several years. We welcome comments on the benefits and challenges of C–SNP enrollees transitioning to non-SNP MA plans and Original Medicare and a standalone Part D plan as well as other suggestions for potential transitions.

Fourth, we request that stakeholders submit for our consideration any other policy suggestions that could help ensure that there are appropriate protections in place to support high-quality, integrated care for dually eligible enrollees given the increasing proportion of them enrolling in C–SNPs and I–SNPs.

Fifth, we welcome comments on the policy ideas outlined in this section to help inform potential future regulatory action. Also, we are monitoring the performance of D–SNPs, C–SNPs, and I–SNPs on quality metrics and differences in Medicare supplemental benefits provided and expect to have more comparable quality and benefits information available within the next year to further inform policymaking. We welcome commenters to share any evidence they have on comparable quality and benefits information for consideration as well.

Finally, CMS is also interested in how to support improved access to treatment and care coordination for individuals with mental health conditions or substance use disorders as we believe SNPs could be situated to perform a critical role in supporting the improvement of care provided to individuals with serious mental illness (SMI). In particular, C–SNPs offer plans focused on chronic conditions such as chronic alcohol and other drug dependence and chronic and disabling mental health conditions (42 CFR 422.4(a)(1)(iv)(B)). However, despite the growth in C–SNPs, CMS has observed that few MA organizations have sponsored C–SNPs focusing on these categories since the beginning of the program, with only two Chronic Mental Health C–SNPs that serve 2,646 enrollees in Florida and California currently operating as of September 2025.[92] We invite public comment on the difficulties of creating C–SNPs focused on these conditions, as well as recommended incentives, outcome-based measures, or strategies that would make it easier for MA plans to design and offer these plans. In addition, we welcome comments on how other SNP types, such as D–SNPs and I–SNPs, are serving this population and what improvements could be made to ensure individuals with SMI are connected to appropriate services. We also invite comments on the advantages and disadvantages of dually eligible individuals with SMI receiving care through enrollment in a C–SNP where we would expect extra emphasis on addressing mental health needs versus through enrollment in a D–SNP that would coordinate Medicare and Medicaid benefits that may also be helpful in addressing mental health needs. Finally, CMS welcomes commenters to share any other considerations or regulatory changes they believe may be necessary to support the availability of high-quality SNPs to serve individuals with SMI.

VII. Reducing Regulatory Burden and Costs in Accordance With Executive Order (E.O.) 14192

As noted previously, we are seeking public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. Please refer to the RFI at *https://www.cms.gov/medicare-regulatory-relief-rfi* and submit all comments via this link.

A. Exclusion of Account-Based Medical Plans From Entities Required To Make Disclosures of Creditable Coverage (§ 423.56)

Section 1860D–13(b)(6)(B)(i) of the Act provides that each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of section 1860D–13(b)(4) of the Act shall provide for disclosure, to the Secretary and Part D eligible individuals, of whether the coverage is creditable coverage, that is, equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–11(c) of the Act), or whether such coverage is changed so it no longer meets such requirement. Section 1860D–13(b)(6)(B)(ii) of the Act requires such entities to disclose if coverage does not meet such requirement, and that the disclosure to Part D eligible individuals shall include information that there are limitations on the periods in a year in which the individual may enroll in Part D coverage, and that any such enrollment is subject to a Part D late enrollment penalty (LEP). In addition, section 1860D–13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify ''other coverage'' that could be considered creditable coverage. The types of coverage that are subject to the creditable coverage requirements and the procedures to determine and document creditable status of prescription drug coverage were codified at § 423.56 in the final rule entitled ''Medicare Program; Medicare Prescription Drug Benefit (Part D final rule)'' that appeared in the January 28, 2005, **Federal Register** (70 FR 4532).[93]

Section 1860D–13(b)(4)(C) of the Act includes Group Health Plans (GHPs) as entities that are required to provide creditable coverage disclosures. The statute states that GHPs include health benefits plans under chapter 89 of title 5 (commonly known as the Federal Employees Health Benefits Program) and qualified retiree prescription drug plans as defined at section 1860D–22(a)(2) of the Act. The term, ''Group Health Plan'' was codified at § 423.882 in the 2005 Part D final rule (70 FR 4577),[94] and this definition includes account-based medical plans such as health reimbursement arrangements (HRAs) as defined in Internal Revenue Service (IRS) Notice 2002–45, 2002–28 I.R.B. 93, health Flexible Spending Arrangements (FSAs) as defined in Internal Revenue Code (Code) section 106(c)(2), health savings accounts (HSAs) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b) (29 U.S.C. 1003(b)) for governmental plans or church plans).

[92] SNP Comprehensive Report for September 2025. Retrieved from: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/special-needs-plan-snp-data/snp-comprehensive-report-2025-09.*

[93] *https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit.*

[94] *https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit.*

Section 1860D–13(b)(6)(B)(i) of the Act requires ''entities that offer prescription drug coverage'' to provide for these creditable coverage disclosures to the Secretary and Part D eligible individuals, but account-based plans (for example, HRAs, FSAs, HSAs, etc.) do not actually offer prescription drug coverage; rather, they are arrangements created by employers and designed to provide individuals savings on healthcare costs through pre-tax contributions and reimbursements, that are often provided to supplement other coverage, such as another group health plan or individual market coverage. Therefore, the benefit design of account-based plans makes concepts, such as disclosure of creditable coverage, inapplicable to those arrangements.

As an example, HRAs,[95] which are arrangements that are paid solely by the employer, reimburse employees only for their, their spouse's, and their dependents' medical care expenses [96] (including premiums), provide reimbursements up to a maximum dollar amount, and carry forward unused balances in the arrangement from one year to the next. Individual Coverage HRAs (ICHRAs), which were more recently recognized by the Labor, Health and Human Services, and Treasury Departments in the June 20, 2019 final rule titled, ''Health Reimbursement Arrangements and Other Account-Based Group Health Plans'' (84 FR 28888),[97] are also a type of reimbursement arrangement; however, to receive reimbursements for medical care expenses from an ICHRA, employees and any covered dependents must actually be enrolled in individual health insurance coverage or Medicare Parts A and B, or Part C.

HRAs, including ICHRAs, are group health plans that are not, as section 1860D–13(b)(6)(B)(i) of the Act requires, entities that offer prescription drug coverage. Comparing a reimbursement arrangement, such as an HRA, against the intricacies of a prescription drug plan, including whether the reimbursement provided equates to coverage that would be considered creditable (that is, offers coverage at least as good as the Medicare standard drug benefit), is not an 'apples to apples' comparison because account-based plans are fundamentally different from prescription drug plans. While account-based plans generally only provide a financial benefit to employees, for example, tax savings, prescription drug coverage conveys numerous benefits to beneficiaries.

As discussed previously, section 1860D–13(b)(6)(B)(i) of the Act requires that ''entities that offer prescription drug coverage'' must provide creditable coverage disclosures. Under that requirement, we propose that account-based entities, which do not offer such coverage, are not required to provide the creditable coverage disclosures. Requiring account-based plans, such as HRAs, including ICHRAs, to determine if their coverage is creditable, and requiring them to report the creditable status of that coverage, unduly increases administrative burden on these entities by causing them to expend additional resources and expertise that they may not possess. If these entities disclose that they do not offer creditable coverage (because they do not directly offer prescription drug coverage), and the individual's plan that directly offers the prescription drug benefit coverage discloses that the benefit is creditable, this could result in an individual receiving potentially contradictory and confusing information. Ultimately, this confusion disadvantages the Part D Medicare-eligible individual in their ability to make an informed choice about their prescription drug coverage, and ensuring that beneficiaries receive clear information is crucial. Moreover, as the number of account-based plans has grown in recent years, we have received feedback from organizations who offer these products that they believe the requirement to report creditable coverage does not comport with the account-based model. This proposal to exclude account-based plans from making these disclosures is a possible solution to address the feedback we have received from the industry, as it will provide clarity and ensure consistency for Medicare-eligible individuals as well as other industry interested parties. This proposal also aligns with the President's January 31, 2025, Executive Order (E.O.), titled *Unleashing Prosperity Through Deregulation,* as, if finalized, it would eliminate the need to acquire and maintain resources and expertise to comply with federal regulations to provide creditable coverage disclosures.

Therefore, we are proposing to modify regulations at § 423.56(b)(3) to codify that account-based plans, such as HRAs and ICHRAs, are excluded from group health plans that are required to make creditable coverage disclosures.

B. Deregulate § 422.102(e) Pathway for Certain D–SNPs To Offer Supplemental Benefits (§ 422.102)

We provide several avenues for MA plans to provide enrollees with supplemental benefits. In the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes,'' which appeared in the **Federal Register** on April 12, 2012 (hereafter referred to as the April 2012 final rule), we codified § 422.102(e). As we described in the preamble to the April 2012 final rule (77 FR 22075), § 422.102(e) specifies that, subject to our approval, and as specified annually by us, certain D–SNPs that meet integration and performance standards may offer additional Medicare supplemental benefits beyond those we currently allowed other MA plans to offer at the time of publication, where we find that the offering of such benefits could better integrate care for the dual eligible population. Such benefits may include nonskilled nursing services, personal care services, and other long-term care services and supports designed to keep dual eligible beneficiaries out of institutions.

In the Announcement of CY 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter issued on April 2, 2018, we announced its expanded interpretation of the ''primarily health related'' standard applied to supplemental benefits in light of section 1852(a)(3) of the Act, which requires supplemental benefits to be ''health care benefits.'' Under the expanded interpretation, for an item or service to be considered as primarily health related, it must 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 healthcare utilization. In the call letter, we expressed the belief that the expanded standard for ''primarily health related'' provided MA plans with more flexibility in designing and offering supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes.[98] We note that CMS codified this standard at § 422.100(c)(2)(ii)(A).

[95] HRAs were first recognized in 2002 in guidance—Internal Revenue Service (IRS), ''Health Reimbursement Arrangements,'' Notice 2002–45, at *https://www.irs.gov/pub/irs-drop/n-02-45.pdf.*

[96] IRC § 213; IRS, ''Medical and Dental Expenses,'' Publication 502, January 11, 2022, at *https://www.irs.gov/pub/irs-pdf/p502.pdf;* and IRS, *Health Savings Accounts and Other Tax-Favored Health Plans,* IRS Publication 969, February 11, 2021, p. 18, at *https://www.irs.gov/pub/irs-pdf/p969.pdf.*

[97] *https://www.govinfo.gov/app/details/FR-2019-06-20/2019-12571.*

[98] CMS, Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final

Continued

Additionally, the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1852(a) of the Act to expand the types of supplemental benefits that may be offered by MA plans to chronically ill enrollees, called special supplemental benefits for the chronically ill (SSBCI). We codified the parameters for SSBCI at § 422.102(f) in the June 2020 final rule. (85 FR 33800) SSBCI includes supplemental benefits that are not primarily health related and may be offered non-uniformly to eligible chronically ill enrollees. MA plans can offer a ''non-primarily health related'' item or service to chronically ill enrollees if the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

In recent years, few MA plans have used § 422.102(e) to provide supplemental benefits, as shown in Table G–B 1. Our analysis of the bid data from 2013 to 2026, as seen in Table G–B 1, shows that the supplemental benefits D–SNPs have offered through § 422.102(e) are meals benefits and assistive devices for home safety. We note that these benefits can currently be covered under the expanded definition of primarily health related supplemental benefits and SSBCI. Specifically, the April 2019 HPMS memo titled ''Implementing Supplemental Benefits for Chronically Ill Enrollees'' refers to Chapter 4 of the Medicare Managed Care Manual that indicates that meals are a primarily health related supplemental benefit (PBP category B13c) in limited situations: when provided to enrollees for a limited period immediately following surgery, or an inpatient hospitalization, or for a limited period due to a chronic illness. In those situations, a meals supplemental benefit is permissible if the meals are: (1) needed due to an illness; (2) consistent with established medical treatment of the illness; and (3) offered for a short duration. Meals may be offered beyond a limited basis as a non-primarily health related supplemental benefit (PBP category B19b/13i) to chronically ill enrollees. Meals may be home-delivered and/or offered in a congregate setting.[99]

TABLE G-B 1: SUPPLEMENTAL BENEFITS OFFERED THROUGH § 422.102(e) FOR CONTRACT YEARS 2013 TO 2026

Contract Year	# of D-SNP PBPs Offering Benefits	Supplemental Benefits Offered
2026	0	None
2025	2	Meals provided to members with a chronic condition
2024	2	Meals provided to members with a chronic condition
2023	2	Additional meal delivery
2022	2	Additional meal delivery
2021	1	Additional meal delivery
2020	1	Additional meal delivery
2019	2	Additional meal delivery, Assistive devices for home safety
2018	2	Additional meal delivery, Assistive devices for home safety
2017	0	None
2016	0	None
2015	0	None
2014	0	None
2013	2	Safety assessment / home adaptation

Source: HPMS

We believe the small number of D–SNPs offering supplemental benefits through § 422.102(e) is due to the availability of other pathways to provide the same supplemental benefits that can be covered under § 422.102(e). Based on this experience, we believe that § 422.102(e) is no longer needed and propose to remove and reserve § 422.102(e) for future rulemaking. The two D–SNPs offering supplemental benefits through § 422.102(e) in CY 2025 have 27,888 enrollees as of June 2025. For CY 2026, no plan requested to offer supplemental benefits through § 422.102(e). We do not anticipate any adverse consequences to removing § 422.102(e) since D–SNPs could offer the same benefits in their annual bid through primarily health related supplemental benefits or SSBCI. By comparison, 905 MA plans offered supplemental benefits through SSBCI in CY 2025. Of those 905 MA plans, 45 plans offered limited meals benefits (four of which were D–SNPs), and 229 MA plans offered meals beyond a limited basis (71 of which were D–SNPs).

We do not anticipate this proposal will add burden to plans given the small number of D–SNPs utilizing the § 422.102(e) pathway. Also, given primarily health related supplemental benefits and SSBCI are the more common pathways for offering supplemental benefits, deregulating § 422.102(e) could streamline the bid submission process for D–SNPs and us

Call Letter, page 208. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[99] CMS, HPMS Memorandum, ''Implementing Supplemental Benefits for Chronically Ill Enrollees''. Retrieved from: *https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2019-week4-apr-22-26.*

by simplifying the avenues for offering supplemental benefits.

We solicit comments on our proposal. We request that commenters consider whether there is any value to us retaining § 422.102(e), such as whether there are any Medicare supplemental benefits that could only be offered under § 422.102(e) and not through primarily health related supplemental benefits or SSBCI. We also recognize that participating D–SNPs will no longer be able to offer benefits through the MA Value-Based Insurance Design (VBID) model beginning in CY 2026 and solicit comments on whether § 422.102(e) provides any advantages in D–SNPs offering supplemental benefits previously offered under VBID.

C. Rescind Mid-Year Supplemental Benefits Notice (§§ 422.111(l) and 422.2267(e)(42))

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 Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' final rule appeared in the April 23, 2024 **Federal Register** (89 FR 30448), hereinafter referred to as the April 2024 final rule, which included a new requirement, beginning January 1, 2026, that MA organizations must notify enrollees mid-year of any unused supplemental benefits available to them (89 FR 30448, 30561). The notice, referred to as the Mid-Year Notice, would list any supplemental benefits not utilized by the enrollee during the first 6 months of the plan year.

The Mid-Year Notice was intended to address what appeared to be a gap in enrollee awareness and utilization of supplemental benefits for which MA organizations designate rebate dollars. After further review of interested parties' feedback and more current data on supplemental benefit utilization (as described later in this proposal), CMS has determined that the frequency of utilization was higher than previously believed. In addition, CMS has concerns about the administrative and financial burden, especially on smaller MA organizations, and believes this new requirement is duplicative of already existing requirements. As a result, via the agency's authority to establish standards consistent with, and to carry out, Part C under section 1856(b)(1) of the Act, CMS proposes to rescind the Mid-Year Notice of Supplemental Benefits requirement established in §§ 422.111(l) and 422.2267(e)(42), that requires MA organizations to provide annual mid-year notices to enrollees regarding unused supplemental benefits.

Rescission of this requirement is consistent with E.O. 14192, ''Unleashing Prosperity through Deregulation.'' E.O. 14192 instructed federal agencies to review all regulations to alleviate unnecessary regulatory burdens placed on the American people. CMS has reviewed this regulation in accordance with E.O. 14192 and determined that this requirement is unnecessary for the reasons outlined in this section. The Mid-Year Notice would impose a significant burden on MA organizations that outweighs the intended benefit. As documented in the April 2024 final rule responses to public comments, MA organizations expressed numerous concerns about the burden and complexity of compliance. The requirement necessitates the development, implementation, and maintenance of tracking systems to monitor individual enrollee utilization of each supplemental benefit from January 1st to June 30th of the plan year. It also requires MA organizations to compile and send the individualized information to each corresponding enrollee in paper format between June 30th and July 31st of the plan year, providing about a 1-month window to mail information to potentially millions of enrollees. Additionally, MA organizations have stated that they predict the substantial task of printing and mailing several pages of individualized documents within a compressed time frame would exceed CMS's original estimate for administrative costs. The impact would be substantially higher for smaller MA organizations and could contribute to competitive disadvantages that result in reduced plan choice for MA enrollees.

Further, with respect to MA organizations of all sizes, the administrative complexity and operational costs associated with meeting the Mid-Year Notice requirement would consume resources that could be better utilized for activities with more direct impact on enrollee health outcomes and satisfaction. Instead, the Mid-Year Notice risks diversion of organizational capacity away from more beneficial work such as patient care coordination or quality improvement activities—both of which are required under statute.

Another factor considered in this proposal is the unnecessary duplication of information already provided to enrollees through existing statutory disclosure requirements. Section 1852(c)(1) of the Act requires MA organizations to provide detailed descriptions of all plan provisions, including supplemental benefits, in a clear, accurate, and standardized form through the Evidence of Coverage (EOC) document. MA organizations must furnish this information to enrollees at the time of enrollment and annually thereafter. As specified in regulation at § 422.2267(e)(42), the Mid-Year Notice must include, for each unused mandatory and optional supplemental benefit, the information that appears for those benefits, in the EOC. The Mid-Year Notice would therefore be redundant of information that enrollees already received about their benefits no more than 6 months earlier.

Finally, the original justification for implementing the Mid-Year Notice requirement is not supported by the most current evidence available. In a recent survey [100] of 1,846 MA enrollees, 70 percent of respondents reported they had used at least one supplemental benefit in the past year; 19 percent reported they did not use their supplemental benefits because they did not need them. These findings suggest enrollees are generally aware of their supplemental benefits and are utilizing them, although CMS acknowledges that at this time, information on MA enrollee use of supplemental benefits is limited.

Market competition naturally incentivizes MA organizations to ensure enrollees are aware of and utilize the supplemental benefits that differentiate their plans. MA organizations have demonstrated that they can effectively promote awareness and utilization of supplemental benefits through existing channels. Moreover, a requirement to send additional information to enrollees, promoting benefits they will not necessarily be eligible for, could lead to enrollee confusion. Current care coordination activities, existing communication requirements, and proactive, voluntary outreach programs have proven successful in promoting supplemental benefit utilization. The particular regulatory requirement for a Mid-Year Notice would likely not result in improved communication of supplemental benefits information and could create undue burden for MA organizations. Further, recent evidence suggests that enrollees are utilizing supplemental benefits when they need them. Therefore, CMS proposes to rescind the Mid-Year Notice

[100] *https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage.*

requirement at §§ 422.111(l) and 422.2267(e)(42).

CMS welcomes comments on the rescission of this regulatory requirement.

D. Revisions to Ensuring Equitable Access to Medicare Advantage (MA) Services (§ 422.112(a)(8))

Under § 422.112(a)(8), MA organizations are required to ensure that services are provided in a culturally competent manner to all enrollees. In the final rule titled ''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'' (88 FR 22120) (hereinafter referred to as the April 2023 final rule), CMS retitled the paragraph heading from ''Cultural considerations'' to ''Ensuring Equitable Access to Medicare Advantage (MA) Services'' and added more populations to the existing list of groups in the regulation. These changes were implemented in accordance with the previous administration's E.O. 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (E.O. 13985) issued on January 20, 2021. CMS explained in the preamble that the list of populations was clarifying in nature, non-exhaustive, and was intended to provide additional examples of populations MA organizations should be mindful of in their plan designs. CMS emphasized that the protections of the provision were already in effect prior to the proposed change and that MA organizations must provide all enrollees, without exception, accommodations to access services (88 FR 22152 and 22153). CMS determined there was no additional regulatory impact to MA organizations in terms of burden, resources for implementation, or collection information as MA organizations were already held to and in compliance with these requirements.

On January 20, 2025, E.O. 14148: ''Initial Rescissions of Harmful Executive Orders and Actions'' was issued and revoked E.O. 13985. E.O. 14148 states the ''previous administration embedded deeply unpopular, inflationary, illegal, and radical practices within every agency and office of the Federal Government. The injection of 'diversity, equity, and inclusion' (DEI) into our institutions has corrupted them by replacing hard work, merit, and equality with a divisive and dangerous preferential hierarchy.'' Additionally, on January 31, 2025, President Trump issued E.O. 14192, ''Unleashing Prosperity through Deregulation'' which instructed Federal agencies to review regulations in their jurisdiction to alleviate unnecessary regulatory burdens placed on the American people. CMS has reviewed § 422.112(a)(8) in accordance with E.O.s 14148 and 14192 and determined that the revisions made in the April 2023 final rule were unnecessary as they did not change the underlying requirements for MA organizations and the modification of the regulatory text created additional and unnecessary complexity in interpreting the provision. As such, CMS is proposing to amend the regulation at § 422.112(a)(8) to revert to the prior paragraph heading and text which reads, ''*Cultural considerations.* 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.'' This proposed change will streamline the regulatory text and avoid confusion about the list of different sub-populations in implementation, while maintaining the protections for access to services for all enrollees.

CMS invites comments on this proposal.

E. Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 422.137(c)(5), (d)(6) and (d)(7))

The final rule titled ''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'' appeared in the April 12, 2023 **Federal Register** (88 FR 22120) (hereinafter referred to as the April 2023 final rule). The April 2023 final rule required that MA plans establish a Utilization Management (UM) Committee to annually review all UM policies and procedures, including for the use of prior authorization, and ensure that these policies are consistent with the coverage requirements, including Original Medicare's current national and local coverage decisions and guidelines.

Then, in November 2023, CMS issued 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 (88 FR 78476) notice of proposed rulemaking (hereinafter referred to as the November 2023 proposed rule) wherein CMS proposed additional requirements related to the UM Committee. Specifically, at § 422.137(c)(5) CMS proposed a requirement that beginning in 2025, the UM Committee must include at least one member with ''expertise in health equity.'' In addition, at § 422.137(d)(6), CMS proposed a requirement that the UM Committee must conduct an annual health equity analysis of the use of prior authorization by examining the impact of prior authorization at the plan level, on enrollees with one or more specified Social Risk Factors (SRFs), defined as (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE) or (2) disability status, by reporting specific metrics aggregated for all items and services. Finally, CMS proposed a requirement at § 422.137(d)(7) that by July 1, 2025, and annually thereafter, this analysis must be posted on the plan's publicly available website.

In response to the November 2023 proposed rule, CMS received a significant number of comments regarding concerns about the annual health equity analysis. Commenters expressed concerns there was not sufficient evidence that adding a role to the UM Committee would improve health equity. Some commenters indicated that prior authorization denial rates are not necessarily attributable to or correlated with an enrollee's SRF status. Other commenters cautioned that some of the information gathered as part of this type of analysis may be confidential or proprietary to the MA plan. Overall, interested parties raised concerns about the rationale, feasibility, and administrative burden associated with meaningful implementation of the regulatory requirements.

In April 2024, CMS issued 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 (89 FR 30448) (hereinafter referred to as the April 2024 final rule) and finalized new requirements related to the UM Committee. In response to comments, CMS took the position that while changes to the health equity analysis requirement would be helpful to provide a more in-depth analysis, the

health equity analysis requirement as proposed and finalized would provide useful baseline of data. CMS also signaled the intent to consider further changes to these requirements in subsequent rulemaking based on comments received.

The proposed rule titled ''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'' appeared in the December 10, 2024 **Federal Register** (89 FR 99340). CMS proposed 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 to be reported by each item or service, rather than aggregated for all items and services. Many commenters expressed concerns that the expanded analysis requirements could be misrepresented due to the complexity of the disaggregated data and variance in plan sizes. Several commenters also stated the proposed policy change would be costly and burdensome for MA organizations. CMS did not finalize the proposal to expand the annual health equity analysis of UM policies and procedures.[101]

CMS implemented the additional UM Committee requirements in the April 2024 final rule based on the previous administration's health equity related initiatives. Specifically, the regulatory requirements were implemented in accordance with feedback from interested parties, based on research, and the prior administration's E.O. 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' issued on January 20, 2021.[102] This E.O. has since been revoked by E.O. 14148: ''Initial Rescissions of Harmful Executive Orders and Actions,'' [103] which states the ''previous administration has embedded deeply unpopular, inflationary, illegal, and radical practices within every agency and office of the Federal Government. The injection of 'diversity, equity, and inclusion' (DEI) into our institutions has corrupted them by replacing hard work, merit, and equality with a divisive and dangerous preferential hierarchy.''

The health equity requirements implemented in the April 2024 final rule increased regulatory burden for MA organizations by requiring the addition of a member of the UM Committee with expertise in health equity, additional data collection, and the public posting of an annual health equity analysis. The increased regulatory burden is inconsistent with E.O. 14192, ''Unleashing Prosperity Through Deregulation,'' issued on January 31, 2025,[104] which seeks to address the significant burden that complex Federal regulations impose on Americans, which may hinder economic growth, innovation, and global competitiveness. E.O. 14192 states, ''It is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people.''

Since the issuance of the April 2024 final rule, the CMS position on the health equity analysis requirement has changed. CMS now believes that this analysis is not the best vehicle to obtain baseline data on the use of prior authorization and that there are more effective ways to gain this information, including through robust interoperability efforts. CMS will continue to explore ways to collect data regarding the use of prior authorization in a manner that best represents all MA enrollees. CMS is taking steps to reduce the regulatory burdens imposed by the UM Committee requirements implemented in the April 2024 final rule consistent with the focus on streamlining regulations and reducing administrative burdens for those participating in the Medicare program. In response to interested parties concerns about the limited impact on health equity, the questionable utility of the required data analysis, and the additional administrative burden, deregulating the requirements at § 422.137(c)(5), (d)(6), and (d)(7) aligns with CMS policy goals and E.O.s 14148 and 14192.

Additionally, on June 16, 2025, CMS released a Health Plan Management System (HPMS) memorandum exercising enforcement discretion regarding the requirements under § 422.137(c)(5), (d)(6) and (d)(7) until further notice. As explained in the HPMS memorandum, CMS received numerous questions and requests for guidance regarding the implementation of the requirements and determined that a temporary pause in enforcement was necessary to reevaluate the requirements and consider potential changes. CMS now proposes to remove the requirement at § 422.137(c)(5) that the UM Committee includes at least one member with expertise in health equity. In addition, CMS proposes to remove § 422.137(d)(6), which requires that the UM Committee conduct an annual health equity analysis of the use of prior authorization. Finally, CMS proposes to remove § 422.137(d)(7), which requires the health equity analysis to be posted on the plan's website in a prominent manner that is publicly accessible.

In summary, CMS is proposing to rescind the requirements for MA organizations' UM Committees at § 422.137(c)(5), (d)(6) and (d)(7), consistent with the cited E.O.s. and in response to interested parties concerns about the requirements' rationale, feasibility, and administrative burden. This proposal aligns with CMS' broader regulatory approach, including the decision not to finalize proposed expansions to the health equity analysis requirements in the April 2025 final rule.

CMS welcomes comments on this proposal. CMS also requests comments on ways to reduce administrative burdens associated with other UM Committee requirements for consideration in future rulemaking, including, but not limited to, recommendations on the following:

- Whether CMS should revise UM Committee composition requirements, including that members represent various clinical specialties; and
- Whether CMS should revise the UM Committee responsibilities, including the UM Committee's role in the implementation of internal coverage criteria.

CMS is particularly interested in policy solutions that eliminate redundant reporting, reduce unnecessary requirements, and minimize duplicative processes to address inefficiencies and reduce financial burdens. More broadly, CMS welcomes suggestions for deregulating, simplifying, and streamlining MA organization governance requirements in ways that benefit enrollees, health care providers, suppliers, and MA organizations while ensuring continued delivery of high-quality care to Medicare beneficiaries.

[101] 90 FR 15792, 15795.

[102] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[103] *https://www.federalregister.gov/documents/2025/01/28/2025-01901/initial-rescissions-of-harmful-executive-orders-and-actions.*

[104] *https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation.*

F. Rescinding the Quality Improvement Program Health Disparities Requirement (§ 422.152(a)(5))

In accordance with section 1852(e) of the Act, all MA organizations must have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees. QI program requirements appear at 42 CFR 422.152. In April 2023, the ''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'' appeared in the **Federal Register** (88 FR 22120), hereinafter referred to as the April 2023 final rule. In the April 2023 final rule, CMS added a requirement at § 422.152(a)(5) that directs MA organizations to incorporate one or more activities that reduce disparities in health and health care as part of their QI program to comply with health equity mandates stemming from E.O. 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.''

On January 20, 2025, E.O. 14148, ''Initial Recission of Harmful Executive Orders and Actions,'' revoked several executive orders, including E.O. 13985. Additionally, on January 31, 2025, E.O. 14192, ''Unleashing Prosperity Through Deregulation,'' was issued to address the significant burden that complex Federal regulations impose on Americans, and hinder economic growth, innovation, and global competitiveness. E.O. 14192 states, ''It is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and to alleviate unnecessary regulatory burdens placed on the American people.''

Consistent with E.O.s 14148 and 14192, CMS propose to eliminate the regulatory requirement for QI programs under § 422.152(a)(5), which reads in full, ''Incorporate one or more activities that reduce disparities in health and health care. These activities must be broadly accessible irrespective of race, ethnicity, national origin, religion, sex, or gender. These activities may be based upon health status and health needs, geography, or factors not listed in the previous sentence only as appropriate to address the relevant disparities in health and health care.'' The provision at § 422.152(a)(5) is not aligned with E.O. 14148 because it mandates race and ethnicity-conscious health equity activities that were originally implemented in accordance with E.O. 13985's racial equity requirements, which E.O. 14148 explicitly revoked as part of its directive to eliminate federal programs and policies that prioritize considerations based on race, ethnicity, and other demographic characteristics.

With E.O. 14148's elimination of federal policies to promote ''diversity, equity, and inclusion,'' the requirement to ''incorporate one or more activities that reduce disparities in health and health care'' no longer aligns with current administrative priorities. Moreover, CMS will retain the QI Program requirements under § 422.152(a)(1) through (4) to meet the requirements of section 1852(e) of the Act. The statute is clear and no further regulatory language to specify reducing health disparities is necessary to carry out the QI program. Additionally, this proposal aligns with the directives of E.O. 14192, to deregulate and reduce the administrative burden on MA organizations while preserving quality.

When this regulation was proposed, CMS received public comments asserting that some MA organizations were already addressing disparities in care for underserved populations through a variety of quality initiatives without the need for regulation. If this requirement is repealed as proposed, MA organizations would retain the flexibility to implement quality initiatives that address the needs of all enrollees, including the option to continue their current QI program or otherwise make their own determinations regarding whether and how to target health disparities. This will ensure services are delivered with equal dignity and respect to each individual and that MA organizations are not required to direct federal resources towards services limited to specific mandated subsets of enrollees. This proposed deregulation reflects CMS's continued commitment to high-quality health care, while reducing unnecessary administrative burden associated with the prior regulatory requirements, including those established under earlier directives that prioritized narrow equity-focused initiatives driven by exclusively equity-focused executive orders.

CMS invite comments on this proposal.

G. Deregulate Special Rule for Non-Compliant D–SNPs (§ 422.752)

The Bipartisan Budget Act of 2018 (BBA of 2018; Pub. L. 115–123) amended section 1859 of the Act to establish new minimum standards for all D–SNPs related to integration with Medicaid services (section 1859(f)(8)(D)(i) of the Act). The BBA of 2018 also amended section 1859 of the Act to authorize the Secretary to impose an enrollment sanction on an MA organization offering a D–SNP that has failed to meet at least one of the new integration standards in plan years 2021 through 2025 (section 1859(f)(8)(D)(ii) of the Act). In the April 2019 final rule (84 FR 15719 through 15720), we codified this enrollment sanction at § 422.752(d). From plan years 2021 through 2025, we used this sanction authority in numerous instances and found it helpful for States and new D–SNPs since it created a mechanism to suspend enrollment for D–SNPs when contracting with the State Medicaid agency is unexpectedly delayed. However, since the statutory authority for the enrollment sanction expires at the end of plan year 2025, we propose to remove § 422.752(d).

H. Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET (§ 423.2536)

Division CC, title I, subtitle B, section 118 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260) amended section 1860D–14 of the Act by redesignating subsection (e) of section 1860D–14 of the Act as subsection (f) and by establishing a new subsection (e) Limited Income Newly Eligible Transition (LI NET) Program. Subsection (e)(1) directs the Secretary to carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals no later than January 1, 2024. We published 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 22342) in April 2023 establishing the LI NET program as a permanent part of Medicare Part D at 42 CFR part 423 subpart Y, beginning at § 423.2500.

Sections 1860D–14(e)(4) and (5) of the Act require that the program be administered through a contract with a single program administrator and exempts the LI NET program from certain beneficiary protection requirements for qualified prescription drug coverage under section 1860D–4 of the Act. Further, the Secretary may waive other such requirements of title XVIII of the Act as necessary to carry out the purpose of the program. Under our authority under section 1860D–14(e)(5)(B) of the Act, we propose to codify a waiver for the LI NET program with respect to customer call center

hours of operation for all regions served by LI NET.

Under § 423.128(d), a Part D sponsor is required to have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. Specifically, § 423.128(d)(1)(i)(A) requires that for coverage beginning on and after January 1, 2022, such mechanisms include a toll-free customer call center that is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. Due to the nature of the LI NET program, maintaining a toll-free customer call center that is open Monday through Friday, except holidays, from 8:00 a.m. to 7:00 p.m. Eastern Time (ET) is sufficient because the customer call volume for LI NET after 7:00 p.m. ET has historically been low due to automatic enrollment of beneficiaries, the transitional nature of LI NET coverage, and LI NET's open formulary. The majority (for example, 90 to 95 percent) of LI NET beneficiaries are enrolled automatically by us and, as such, prospective enrollees rarely require customer call center assistance. Further, the requirement at § 423.128(d)(1)(i)(B) requires that any call center serving pharmacists or pharmacies be open so long as any network pharmacy in that region is open. Accordingly, these calls centers are available to address the majority of inquiries for the LI NET program and ensures that there is no impact on access. This proposal also aligns with the President's January 31, 2025, E.O., titled Unleashing Prosperity Through Deregulation, as we estimate that waiving the requirement for customer call center hours in all regions served by LI NET will save the program approximately $800,000 to $1,000,000 a year.

We propose to add the customer call center hours of operation for all regions served by the Part D plan in § 423.128(d)(1)(i)(A) to the list of Part D requirements waived for the LI NET program at § 423.2536.

We do not believe that the proposed changes to the regulatory text would adversely impact the LI NET sponsor, individuals' access to prescription drug benefits, the Medicare Trust Fund, or result in a paperwork burden.

VIII. Request for Information on Future Directions in Medicare Advantage (Risk Adjustment, Quality Bonus Payments, and Well-Being and Nutrition)

A. Introduction

The MA program has grown considerably in the past two decades and now covers over half of all Medicare beneficiaries.[105] In light of this growth, CMS is interested in exploring opportunities for modernizing and strengthening the program, including with regard to payment, risk adjustment, and quality policy, with the aim of supporting competition and maximizing the value of the program for beneficiaries and taxpayers. Specifically, CMS believes that meaningful opportunities exist for enhancing the risk adjustment system and the quality bonus payment (QBP) program, consistent with findings from multiple studies by the Medicare Payment Advisory Commission (MedPAC)[106] [107] and other researchers.[108] [109] [110] CMS is particularly interested in changes that can enhance competition in the MA program; level the playing field for smaller, regional, and less well-resourced MA plans; and address factors that may place these types of plans at a competitive disadvantage. Enhancements to competition in MA would be expected to yield substantial benefits for beneficiaries, taxpayers, health plans, and the Medicare program as a whole. For example, leveling the playing field in MA can translate into greater innovation in benefit design and care models, including greater use of high-value supplemental benefits, reduced use of low-value benefits and services, and improved health outcomes for beneficiaries.

CMS could pursue changes in MA through two possible channels. The first is through rulemaking or other means authorized under law (*e.g.,* the annual announcement of methodological changes to MA payment rates through the Advance Notice and Rate Announcement pursuant to section 1853(b) of the Act), which institute changes that are national in scale. The second channel is by testing a model under section 1115A of the Act through which the CMS Innovation Center can test innovative payment and service delivery models on either a regional or national scale. Section 1115A(c) of the Act authorizes the Secretary to expand the scope and duration of the tested model if such expansion is expected to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending; the Chief Actuary for CMS certifies the expansion would reduce or not increase program spending, and the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. If these requirements are met, the model can be expanded nationally to all relevant stakeholders in a mandatory fashion through rulemaking. Examples of expanded CMS Innovation Center models include the Diabetes Prevention Program,[111] [112] the Home Health Value-Based Purchasing Model,[113] and Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT),[114] which were found to reduce costs, improve quality, and reduce adverse medical events under Original Medicare. Throughout its history, the CMS Innovation Center has implemented only one MA-specific model, the Value-Based Insurance Design (VBID) model,[115] which

[105] Medicare Payment Advisory Commission. (March 2025). ''Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report.'' *https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch11_MedPAC_Report_To_Congress_SEC.pdf.*

[106] Medicare Payment Advisory Commission. (March 2023). ''Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report.'' *https://www.medpac.gov/wp-content/uploads/2023/03/Ch11_Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

[107] Medicare Payment Advisory Commission. (2024). ''Report to the Congress: Medicare Payment Policy, Chapter 13, Estimating Medicare Advantage coding intensity and favorable selection,'' *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch13_MedPAC_Report_To_Congress_SEC.pdf.*

[108] Kronick, R., & Chua, F.M. (2021). Industry-wide and sponsor-specific estimates of Medicare Advantage coding intensity. *Available at SSRN 3959446.*

[109] Markovitz, A.A., Ayanian, J.Z., Sukul, D., & Ryan, A. M. (2021). The Medicare Advantage Quality Bonus Program Has Not Improved Plan Quality: Study examines the impact of the Medicare Advantage quality bonus program. *Health Affairs*, 40(12), 1918–1925.

[110] Layton, T.J., & Ryan, A.M. (2015). Higher incentive payments in Medicare advantage's pay-for-performance program did not improve quality but did increase plan offerings. *Health services research, 50*(6), 1810–1828.

[111] Centers for Medicare & Medicaid Services. Medicare Diabetes Prevention Program (MDPP): Expanded Model Fact Sheet. *https://www.cms.gov/files/document/mdpp-expansion-fact-sheet.pdf.*

[112] Centers for Medicare & Medicaid Services. (December 2024). Medicare Diabetes Prevention Program Expanded Model. *https://www.cms.gov/files/document/mln34893002-medicare-diabetes-prevention-program-expanded-model.pdf.*

[113] Centers for Medicare & Medicaid Services. Home Health Value-Based Purchasing Model. *https://www.cms.gov/priorities/innovation/innovation-models/home-health-value-based-purchasing-model.*

[114] Centers for Medicare & Medicaid Services. Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport. *https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/prior-authorization-repetitive-scheduled-non-emergent-ambulance-transport-rsnat.*

[115] Centers for Medicare & Medicaid Services. *https://www.cms.gov/priorities/innovation/innovation-models/vbid.*

terminates effective December 31, 2025.[116] A CMS Innovation Center Model can be a channel for testing policy ideas that would benefit from testing, for example, if a policy has uncertain implications. The Innovation Center has the resources and flexibility to identify, develop, rapidly test and encourage voluntary, widespread adoption of innovative care and payment models. A CMS Innovation Center model is also an option for testing innovations that require the statutory authority of the Innovation Center model, for example, statutory waivers.

B. Risk Adjustment

1. Background

Risk adjustment shapes many aspects of the MA program. Risk adjustment constitutes a key part of the payment process and can influence the MA program in a number of direct as well as indirect ways. MA plan payments are calculated at an individual level to account for a beneficiary's expected health care costs, based on their specific demographic and health characteristics. Risk adjustment is accomplished through the calculation of the risk score, a number representing the ratio between a specific enrollee's predicted Original Medicare costs and average costs within Original Medicare. Ultimately, because risk adjustment has such an important role in payment policy, it can influence the types of enrollees that MA plans target for enrollment, how they market to enrollees, the types of supplemental benefits that plans offer, the prescription drugs that they cover, the providers they contract with, and the types of care that MA enrollees receive.[117]

Moreover, risk adjustment impacts competition between MA organizations and may impose inherent disadvantages on certain types of organizations over others.[118] The existing risk adjustment model relies on medical diagnoses to predict health care costs, in addition to demographic factors, which could lead plans to code more intensely than what is observed in Original Medicare. And while risk adjustment policies are intended to adequately compensate MA plans for their enrollees' expected costs, higher payments associated with higher risk scores may encourage MA organizations to prioritize investments in coding activities over care management or treatment.

To account for differences in coding patterns between MA and Original Medicare, section 1853(a)(1)(C)(ii) of the Act requires CMS to apply a coding adjustment factor each year when risk adjusting payments. In 2019 and subsequent years, the adjustment must be at least 5.9 percent. Nevertheless, the higher rates of coding in MA relative to Original Medicare may increase taxpayer expenditures and impose administrative burdens on plans, without any accompanying improvements to quality of care.[119]

CMS is, therefore, soliciting feedback on options for risk adjustment, including near-term changes to the existing risk adjustment methodology and entirely new approaches for risk adjustment, such as those that account for recent advances in technology. For example, CMS has previously contemplated including MA encounter data in the calibration of risk adjustment models, rather than solely relying on FFS data, to better capture patterns specific to the MA population. CMS seeks ideas for additional data sources and data elements for risk adjustment, and for how those data sources should best be incorporated, particularly to minimize opportunities for gaming by MA organizations, incentivize positive health outcomes, and minimize administrative burden for plans and providers. In particular, CMS seeks ideas for risk adjustment approaches that do not rely on collection of diagnoses data and, instead, incorporate alternative factors to infer a patient's health risk as well as the severity of that risk. Finally, CMS is interested in risk adjustment approaches that advance competition and foster a level playing field between different types of MA plans and MA organizations.

2. Solicitation of Comments

We are soliciting comments on opportunities for improving risk adjustment, inviting comments from a broad range of stakeholders and interested parties, including MA organizations, beneficiary advocates, healthcare providers, and industry experts. We are particularly interested in comments on how to achieve the following goals with risk adjustment, relative to the current state:

- Advancing competition, removing anti-competitive barriers, and ensuring a level playing field for regional, smaller, and less well-resourced plans.
- Reducing manipulability of the risk adjustment system as well as the day-to-day administrative burden for both plans and providers.
- Ensuring accurate payments for sicker beneficiaries, while rewarding effective treatment and favorable patient outcomes.
- Mitigating unintended consequences and effectively navigating tradeoffs. (For example, how to approach a situation where a potential input to the risk adjustment model improves the predictive accuracy of the model but would also directly disincentivize valuable treatments for patients.)
- Incentivizing provision of tangible and high-value benefits and services and maximizing the value that beneficiaries, as well as taxpayers, get from payments to MA plans.

We are also soliciting more specific comments on potential methods for improving the MA risk adjustment program through the following questions:

- Which diagnoses are most essential for CMS to include in its MA risk adjustment model? In certain instances, should CMS limit the use of diagnoses in risk adjustment based on a minimum threshold of disease severity or to patient encounters within specific settings? Should CMS require diagnoses to be substantiated by follow-up encounters or treatments? Similarly, should CMS exclude diagnoses from plan-initiated encounters that do not lead to follow-up care, such as those resulting from in-home health risk assessments, or diagnoses not linked to specific services furnished to an enrollee?
- Over what timeframes should CMS incorporate diagnostic data for risk adjustment purposes? How can CMS account for certain illnesses and injuries that are likely to persist but may not be captured within a given data year by a patient encounter? Similarly, how should CMS account for past conditions that are no longer active, but continue appearing as diagnoses?
- When incorporating diagnostic data from particular encounters, should CMS account for the payment status of the

[116] Centers for Medicare & Medicaid Services. (2024). Medicare Advantage Value-Based Insurance Design (VBID) Model to End after Calendar Year 2025: Excess Costs Associated with the Model Unable to be Addressed by Policy Changes. *https://www.cms.gov/blog/medicare-advantage-value-based-insurance-design-vbid-model-end-after-calendar-year-2025-excess-costs.*

[117] Medicare Payment Advisory Commission. (June 2023). ''Report to the Congress: Medicare Payment Policy, Chapter 4, The Medicare Advantage Program: Status Report.'' *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch4_MedPAC_Report_To_Congress_SEC.pdf.*

[118] Kronick, R., Chua, F.M., Krauss, R., Johnson, L., & Waldo, D. (2025). Insurer-Level Estimates of Revenue From Differential Coding in Medicare Advantage. *Annals of internal medicine, 178*(5), 655–662.

[119] Medicare Payment Advisory Commission. (March 2025). ''Report to the Congress: Medicare Payment Policy, Chapter 11, The Medicare Advantage Program: Status Report.'' *https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch11_MedPAC_Report_To_Congress_SEC.pdf.*

services associated with that encounter? For example, should the risk adjustment model include diagnoses from encounters where a payment was denied, or approved and later found to be improper?

- CMS has publicly discussed the prospect of moving towards a risk adjustment model calibrated based on encounter data. In addition to these efforts, should CMS consider testing new risk adjustment methods that replace the current Hierarchical Condition Category (HCC)-based risk adjustment model, such as an inferred risk adjustment model? How should CMS think about a model that is not primarily or solely based off medical diagnoses, but instead uses other types of information, such as utilization of medical services to infer both the presence and the severity of different conditions? What are alternative inputs that CMS should consider, which would be effective at predicting future health care spending by a patient, incentivizing appropriate care, while not being readily susceptible to gaming and manipulation? Likewise, how can a next generation risk adjustment model be structured to minimize unnecessary administrative burden for plans and providers, and structured to minimize the sensitivity of risk scores to administrative effort or administrative skill? How should a model be structured to best support competition and to ensure a level playing field for all MA plans?
- How might CMS utilize technological innovations, such as artificial intelligence (AI) and machine learning, in calibrating current or future risk adjustment methodologies? What are the benefits and risks of shifting from the existing linear regression methodology to one that utilizes AI and/or machine learning? Do plans have best practices when using AI? What types of protections need to be established to ensure the use of AI is fair? Can the efficiencies of AI be leveraged so as to reduce fraud, waste, and abuse?
- As part of either the existing HCC model or a next generation risk adjustment model, should CMS draw on additional elements within existing data sources, as well as entirely new sources of data? For example, should CMS incorporate prescription drug event data, beneficiary survey data, electronic medical record data, or lab data to infer an MA patient's expected health care spending and the severity of their medical conditions? What kinds of data elements should CMS draw on within existing data sources, specifically from medical claims and beneficiary characteristics files (for example, procedure information)? Should CMS incorporate additional adjustments for a patient's place of residence to account for variation in costs within individual counties? How should CMS think about potential data sources that are not currently readily accessible or usable for the full population of Medicare beneficiaries, such as electronic medical record data? How should CMS go about making such novel data sources accessible and usable for risk adjustment, given that they would need to be accessible for every Medicare beneficiary?
- What other policy approaches should CMS consider to ensure that risk adjustment maximizes incentives for offering high-quality coverage rather than investment in coding practices that may not improve enrollee health?

In advance, we thank all commenters, as this feedback will help inform future CMS action in this area.

C. Quality Bonus Payments in Medicare Advantage

In this RFI, we solicit information from stakeholders and all interested parties to inform future policy development and potential refinement to the QBP structure for MA plans as authorized under section 1853(o) of the Act and the impact of QBPs on rebates as authorized under section 1854(b) of the Act.

The solicitation is meant to build upon information obtained from and issues that surfaced under past RFIs. For example, in the 2024 Consolidation in Health Care Markets RFI [120] jointly released by the Federal Trade Commission, the Department of Justice, and the Department of Health and Human Services, some respondents notably requested reforms to address potential gaming of risk and quality scores. Also, this solicitation is intended to address issues previously documented by MedPAC, academic researchers, and others, and in public comments on the annual Advance Notice of Methodological Changes for MA Capitation Rates and Part C and Part D Payment Policies (the Advance Notice).

It takes several years to test, validate, propose, and add a new measure to the Part C and Part D Star Ratings. Separately, for measures that are already implemented, a 2-year lag exists between the end of the measurement period and actual payment to the MA plan. CMS would like to explore potential options to shorten the timeline for implementation of new measures, as well as the lag between measurement and payment for existing measures.

The regulations at 42 CFR 422.164(c)(2) and 42 CFR 423.184(c)(2) require CMS to announce potential new measures and solicit feedback through the Advance Notice and Rate Announcement process described in section 1853(b) of the Act and subsequently propose and finalize new measures through rulemaking. In addition, 42 CFR 422.164(c)(3) and 423.184(c)(3) require measures be on the display page on the CMS website for a minimum of 2 years while being finalized as Star Ratings measures used for payment. We, therefore, solicit comments on potential methods to condense the timeline to add a new measure to the Star Ratings, for example, by reducing the display period for new measures.

For existing measures, the lag between the Star Ratings measurement year and payment year is due to the statutory requirements at sections 1853(o) and 1854(b)(1)(C)(v)–(vi) of the Act, which link the MA bid process to QBP ratings. Since section 1854(a)(1)(A) of the Act requires that MA plans submit their bids not later than the first Monday in June prior to the start of the contract year (which is more than 6 months prior to the start of the contract year), and an MA plan's quality bonus amount impacts their bid submission, CMS uses the latest QBP ratings available as of that date. The QBP ratings thus employed as of the time of the bid involve a measure period from two calendar years prior, ultimately translating into up to a three-year overall lag between measurement and payment. Meanwhile, the time lag between the measurement and payment years creates a disconnect between the quality and financial reward, as MA plans receive bonuses based on their quality performance two years prior, which does not reflect any remediation since that time. To that effect, CMS is also soliciting information on whether CMS should test an Innovation Center model that would delink QBPs from MA bids, with the aim of further incentivizing health plans to improve quality and providing beneficiaries with more timely and actionable quality information. Specifically, CMS is soliciting comments on the following questions:

- What could an alternative policy look like, if one is needed at all?
- What are the potential advantages and disadvantages of the suggested alternative?

[120] Request for Information on Consolidation in Health Care Markets. (June 2024). *https://www.regulations.gov/docket/FTC-2024-0022/document.*

• When should bonus payments be finalized and disbursed?\More broadly, how might CMS better incentivize cost containment within the MA program, while improving care quality?

D. Well-Being and Nutrition

The MA program offers a unique opportunity to bring high-value interventions designed to support overall well-being and nutrition to patients. To the extent that MA organizations are bearing financial risk related to the long-term health outcomes of the populations they serve, they will have an inherent incentive to support interventions that promote health over the long term by avoiding the high costs associated with chronic conditions.

We are seeking input on well-being policy changes for future years. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.[1] This comprehensive approach emphasizes person-centered care by promoting the well-being of patients and family members.

We are seeking comments on tools and policies that improve overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comments on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the MA program, with a particular emphasis on how incentives can be improved to ensure MA organizations are bearing long-term risk related to the health and well-being of their populations.

A second concept that we are seeking feedback on is for policy changes for nutrition. We are seeking comments on tools and policies that achieve optimal nutrition and improve preventive care in MA. Policies for nutrition improvement may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Such policies may also include aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventive care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs. We seek comment on the relevant aspects of optimal nutrition and preventive care for the MA program, with a particular emphasis on how incentives can be improved to ensure the risk borne by MA organizations provides them adequate incentive to support beneficiaries seeking to improve their nutritional habits.

While we will not be responding to specific comments in response to this RFI, we intend to use this input to inform our future policy development efforts.

IX. Technical Changes to Terminology in Risk Adjustment and in Payments to Sponsors of Retiree Prescription Drug Plans

We are proposing to update our regulations related to Medicare Advantage and the Medicare Prescription Drug Program to align with E.O. 14168—Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, issued on January 20, 2025. Per this E.O., we will replace the word ''gender'' with ''sex'' in §§ 422.308(c)(1) and 423.884(c)(2)(v)(D).

As these terms have no discernable operational difference in meaning with regard to risk adjustment and applications for qualified retiree prescription drug plans, there is no associated burden. Therefore, we have not included a discussion of this provision in the COI section of this rule.

We are not scoring this provision in the Regulatory Impact Analysis section because this technical change has no impact on program operations.

X. 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–4212–F, RIN 0938–AV63).

A. Wage Data

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/tables.htm*), which, at the time of publication of this proposed rule, provides May 2024 wages. In this regard, table J1 presents BLS's mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE J1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupational Title	Occupational Code	Mean Hourly Wage ($/hr)	Cost of Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Wage ($/hr)
Business Operations Specialists, All Other	13-1199	44.41	44.41	88.82
Compensation and Benefits Managers	11-3111	75.11	75.11	150.22
Compliance Officers	13-1041	40.86	40.86	81.72
Computer Support Specialists	15-1230	32.47	32.47	64.94
Human Resources Managers	11-3121	77.15	77.15	154.30
Software Developers	15-1252	69.50	69.50	139.00

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.

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 Manufacturer Discount Program (§ 423.100 and §§ 423.2700–423.2768)

As described in section II.C. of this proposed rule, we are proposing to codify the policies established under the Manufacturer Discount Program Final Guidance,[121] with certain refinements, as new subpart AA of part 423. Information collection requirements for the Manufacturer Discount Program are approved by OMB under control number 0938–1451 (CMS–10846). Codification of the Manufacturer Discount Program policies in this proposed rule would not impact the requirements or burden currently approved by OMB under this control number.

2. ICRs Regarding Special Enrollment Period for Provider Terminations (§ 422.62(b)(23))

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267). While the control number has expired, we are setting out this rule's collection of information requirements/burden to score the impact of such changes. We intend to use the standard PRA process (which includes the publication of 60- and 30-day non-rule **Federal Register** notices) to reinstate the control number with change. The initial 60-day notice will publish sometime after the publication of this proposed rule.

As described in section IV.A. of this proposed rule, at § 422.62(b)(23) we propose to change the name and eligibility criteria for the current SEP for Significant Change in Provider Network to reflect that neither an MA organization determination nor a CMS determination of significant provider network change is necessary for an enrollee who is affected by the provider network change to be eligible for the SEP. We also propose that information regarding eligibility for the SEP be included in the provider termination notice. The requirement to issue a provider termination notice is described at § 422.111, where § 422.2267(e)(12) is referenced as the source for notice content requirements. Accordingly, we are proposing changes in the required content of the provider termination notice by revising § 422.2267(e)(12).

This proposal to amend § 422.2267(e)(12) would not impact MA organizations in terms of the burden required to identify those enrollees who must be notified of provider contract terminations per CMS requirements or to develop and send the required written notices. Instead, the impact of this provision arises from the one-time effort for MA organizations to update their existing written provider termination notice so it is in compliance with the new required notice content that we are proposing at § 422.2267(e)(12)(ii)(D). We expect MA organizations to engage in some routine software development to update their notice template and related systems to incorporate the new proposed requirements, which we are proposing will be delineated in a provider termination model document developed by CMS. The proposed model will be posted for public review and comment in conjunction with this rule's proposed collection of information request under CMS–R–267.

We estimate it would take one or two software developers a total of 8 hours at $139.00/hr to update their MA organization's existing provider termination notice template and related systems based on CMS's model. With approximately 697 MA organizations impacted by this proposed change, we estimate a total one-time burden of 5,576 hours (697 MA organizations * 8 hr) at a cost of $775,064 (5,576 hr * $139.00/hr).

Our proposal to amend the provider termination notice content requirements at § 422.2267(e)(12) would not affect the volume or frequency of provider contract terminations and, therefore, on its own, would not have the effect of increasing or decreasing the number of enrollees who must be notified of provider contract terminations. This proposed change would not impact the burden required of MA organizations to identify enrollees to whom notices must be sent and to send the required written notices.

3. ICRs Regarding Strengthened Documentation Standards for Part D Plan Sponsors

Under section 1860D–12(b)(3)(C) of the Act and § 423.505(d) and (e), Part D plan sponsors are required to maintain certain categories of documentation for specified periods of time. Specifically, § 423.505(d) requires that the contract between a Part D plan sponsor and CMS include an agreement by the Part D plan sponsor to maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years that are sufficient to meet certain requirements, including enabling CMS to evaluate the quality, appropriateness, and timeliness of services performed under the contract and to audit the services performed or determinations of amounts payable under the contract. In addition, § 423.505(e) requires that Part D plan sponsors agree to HHS, the Comptroller General or their designee to evaluate through audit, inspection, or other means (1) the quality, appropriateness,

[121] Available at: *https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf.*

and timeliness of those services furnished to Medicare enrollees; (2) compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees; (3) facilities of the Part D sponsor; and (4) enrollment/disenrollment records for the current contract period and 10 prior periods. Furthermore, §§ 423.568(a)(3), 423.570(c)(2), and 423.584(c)(1) outline requirements for Part D plan sponsors to establish and maintain a method of documenting and to retain documentation for oral requests for coverage determinations under standard timeframes, expedited timeframes, and redeterminations respectively.

In this proposed rule, CMS proposes to standardize the documentation requirements that plan sponsors must maintain, in regulation at § 423.505, to ensure that Part D plan sponsors provide CMS with all the information that the plan sponsors use for determining payment responsibility under the Part D benefit. CMS is proposing to standardize the documentation requirements because information currently obtained from and relied upon during coverage determinations, or point-of-sale (POS) edits, utilized to determine payment responsibility, are not always maintained in the necessary detail by the Part D plan sponsors to allow for CMS to evaluate if the PDE record was covered and paid under the Medicare Part D benefit in compliance with CMS policy(ies).

CMS proposes to modify § 423.505 to further clarify and set expectations on the specific type of information needed to support final payment determinations for coverage determinations, and POS edits to determine payment responsibility under the Part D benefit. We are proposing documentation requirements that include certain written, verbal, and electronic communications, such as the date and time the request was received; the name and title of the individual who submitted or verified the request; and the information used to make the coverage determination.

Based on the current regulations and plan sponsor expectations, CMS believes that this proposal is exempt from PRA requirements as such recordkeeping is a usual and customary business practice (5 CFR 1320.3(b)(2)). The ability of the plan sponsor to demonstrate their compliance with the rules and regulations of the Medicare Part D program is a basic requirement upon entering a contractual relationship with CMS. Plan sponsors are expected to maintain documentation and produce that documentation upon request by CMS to evaluate the appropriateness of the services provided to the Medicare enrollee in accordance with the requirements at § 423.505. Based upon our past audit experience, plan sponsors maintain documentation to varying degrees and in some instances the documentation maintained is not sufficient for CMS to have confidence that the PDE record was covered and paid under the Part D benefit in accordance with CMS policy(ies). As such, CMS is proposing the documentation standards to allow CMS to perform the task of evaluating the appropriateness of the Medicare Part D coverage provided by plan sponsors for coverage determinations and POS edits that determine coverage. The documentation requirements must also be provided to CMS, in accordance with existing and proposed requirements at § 423.505 that allow CMS the right to evaluate and provide oversight of the program though audit. As such, we believe the proposed documentation standards that provide clarification of current expectations are exempt from any PRA.

4. ICRs Regarding Removing Rules on Time and Manner of Beneficiary Outreach (§§ 422.2264(c) and 423.2264(c))

The following proposed changes will be submitted to OMB for review under control number 0938–1442 (CMS–10837).

CMS is proposing three deregulatory changes to §§ 422.2264(c) and 423.2264(c) to remove rules on the time and manner of beneficiary outreach. These proposals are designed to improve the plan decision making process by creating a more convenient, beneficiary-friendly outreach experience and to reduce burden on beneficiaries, plans, and agents/brokers. The proposed deregulatory changes concern: (1) marketing events following educational events in the same location, (2) the timing of a personal marketing appointment after Scope of Appointment (SOA) form completion, and (3) SOA forms at educational events.

a. Marketing Events Following Educational Events in Same Location

For the proposed elimination of the requirement for a 12-hour delay between an educational and marketing event at §§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at $88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus $15,477 (174 hr × $88.82/hr).

b. Timing of Personal Marketing Appointment After Scope of Appointment (SOA) Form Completion

For the proposed elimination of the 48-hour waiting period required between the SOA completion and a personal marketing appointment at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at $88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus $15,477 (174 hr × $88.82/hr).

c. Scope of Appointment (SOA) Forms at Educational Events

For the proposed elimination of the prohibition of the collection of SOA forms at educational events at §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D), the information collection burden associated with this requirement is currently approved by OMB under the aforementioned control number. This rule proposes to remove the one-time burden to change the MA organization's policies and procedures. With 697 contracts and 15 minutes (0.25 hr) per response at $88.82/hr for a business operations specialist, we estimate a reduction of minus 174 hours (697 contracts × 0.25 hr) and minus $15,477 (174 hr × $88.82/hr).

5. ICRs Regarding Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits (Part 423 Subpart Z)

The effort associated with our proposed requirements under CITE consists of the time for plan sponsors to prepare and submit the appeal requests for: (1) reconsiderations, (2) hearing official review, and (3) review by the Administrator. However, the burden associated with the preparation and submission of appeals is exempt from the requirements of the PRA since such appeals would be submitted in response to an administrative action (5 CFR 1320.4(a)(2) and (c)).

We also believe that there would be no need for plan sponsors to establish a new appeals process or revise an existing appeals process.

6. ICRs Regarding Passive Enrollment by CMS (§ 422.60)

The proposed requirement and burden for D–SNPs will be submitted to OMB for review under control number 0938–TBD (CMS–XXXXX). At this time, the CMS number has yet to be assigned. Additionally, the OMB control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

In our April 2018 final rule, we finalized language authorizing CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D–SNP into another integrated D–SNP, after consulting with the State Medicaid agency that contracts with the D–SNP or other integrated managed care plan, when CMS determines that the passive enrollment will promote continuity of care and integrated care under § 422.60(g)(1)(iii). We also finalized, under § 422.60(g)(2), requirements an MA plan would have to meet to qualify to receive passive enrollments under paragraph (g)(1)(iii). However, in multiple situations where we have attempted to implement these requirements, we have encountered difficulty with receiving integrated D–SNPs meeting the portion of § 422.60(g)(2)(ii) requiring that receiving integrated D–SNPs have provider networks and facility networks that are substantially similar to the relinquishing integrated D–SNP. In our attempts to utilize passive enrollment, we found that while prospective receiving integrated D–SNPs had Medicare provider and facility networks that meet the MA network adequacy criteria at § 422.112, these networks were not substantially similar to the provider and facility networks in the relinquishing integrated D–SNPs.

We are proposing to amend § 422.60(g)(2)(ii) to require that the integrated D–SNP receiving passive enrollment provide a continuity of care to all incoming enrollees for 120 days. We believe that this extended continuity of care period would address the issue that we attempted to address at 83 FR 16504 in the April 2018 final rule, namely that the provider network comparability analysis would minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment.

In the April 2018 final rule (83 FR 16692), we estimated that approximately 1 percent of the 373 active D–SNPs offered at that time would meet the criteria and operate in a market where all of the conditions of passive enrollment are met and where CMS, in consultation with a State Medicaid agency, implements passive enrollment. We therefore estimated that there would be only four instances (373 D–SNPs × 0.01) in which CMS would conduct passive enrollment each year. Since we estimated fewer than 10 respondents, the information collection requirements and burden related to the final provisions under § 422.60(g) were exempt (5 CFR 1320.3(c)) from the requirements of the PRA. These estimates were accurate. In none of the years since § 422.60(g) has been in effect, have 10 or more D–SNPs met the criteria to participate in passive enrollment. We have no reason to believe that this will change.

For this rulemaking, we continue to estimate that approximately 1 percent of the projected 1,100 active D–SNPs expected for CY 2027 would meet the revised criteria and operate in a market where the conditions for passive enrollment are met and where CMS, in consultation with a State Medicaid agency, implements passive enrollment. We therefore estimate there would be 11 instances (1,100 D–SNPs × 0.01) in which CMS would conduct passive enrollment each year and the PRA requirements would apply. The actual number of D–SNPs eligible for passive enrollment primarily depends on State procurement decisions for affiliated Medicaid managed care contracts. Those State procurement calendars are not readily available. We welcome comments on our assumptions.

We believe that D–SNPs participating in passive enrollment, as proposed for amendment in this rulemaking, would require 40 hours at $88.82/hr for a business operations specialist to make necessary policy and systems updates in preparation for participating in passive enrollment and 40 hours at $64.94/hr for a computer support specialist. With 11 D–SNPs nationally participating in passive enrollment in any given year, we estimate a one-time burden of 880 hours (11 D–SNPs * 80 hr) at a cost of $67,654 [(440 hr * $88.82/hr) + (440 hr * $64.94/hr)] to update policies and procedures, training materials, systems.

Per § 422.60(g)(4), D–SNPs approved by CMS to participate in passive enrollment are currently required to distribute two notices to individuals. The D–SNP must provide the first notice no fewer than 60 calendar days prior to the enrollment effective date and the second notice no fewer than 30 days prior to the enrollment effective date. We believe a D–SNP business operation specialist would spend 20 hours at $88.82/hr developing these notices. We estimate a one-time burden of 220 hours (20 hr * 11 D–SNPs) at a cost of $19,540 (220 hr * $88.82/hr).

Based on July 2025 total D–SNP enrollment, we estimate 6,168,649 D–SNP enrollees or a CY 2025 average of 6,500 enrollees per D–SNP (6,168,649 D–SNP enrollees/949 D–SNPs). We are including this calculation to provide the average number of enrollees per D–SNP, which is used in calculations below.

We assume the following costs include paper, toner, envelopes, and postage (envelope weight is normally considered negligible when citing these rates and is not included) 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).
- *Envelope:* Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope.
- *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 (10.0 lb/1,000 sheets × 16 oz/lb), and do not anticipate additional postage for mailings in excess of 1 ounce.

We estimate the aggregate cost per mailed notice 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 2 double-sided pages (generally, weighing less than 1 ounce) will be needed for a passive enrollment notice. Because preparing and generating a hard-copy enrollment notice 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 $114,686 (6,500 enrollees * 2 mailings * 11 D–SNPs * $0.802/mailing).

7. ICRs Regarding Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D–SNP and Medicaid Fee-for-Service (§§ 422.107(d)(1) and 422.514(h))

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267). While the control number has expired, we are setting out this rule's collection of information requirements/burden to score the impact of such changes. We intend to use the standard PRA process (which includes the

publication of 60- and 30-day non-rule **Federal Register** notices) to reinstate the control number with change. The initial 60-day notice will publish sometime after the publication of this proposed rule.

We are proposing to amend §§ 422.107(d)(1) and 422.514(h) to allow D–SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D–SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where those individuals are enrolled in Medicaid FFS. As discussed in section VI.B. of this proposed rule, this proposed provision makes specific amendments to a finalized package of provisions from the April 2024 final rule, which limited enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and limited the number of D–SNP plan benefit packages an MA organization, its parent organization, or entity that shares a parent organization with the MA organization, could offer in the same service area as an affiliated Medicaid MCO. If finalized, our proposed provisions at §§ 422.107(d)(1) and 422.514(h) would create another exception to allow D–SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D–SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where those individuals are enrolled in Medicaid FFS.

In the information collection requirements in the April 2024 final rule (89 FR 30784), we stated that the provisions we finalized would create burden for MA organizations that offer multiple D–SNPs in a service area with a Medicaid MCO, noting that impacted MA organizations would need to non-renew or (more likely) combine plans and update systems as well as notify enrollees of plan changes. We also stated in the April 2024 final rule that we expected that MA organizations would need two software engineers with each working 4 hours at $127.82/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at $79.50/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimated a one-time burden (for plan year 2027) of 600 hours (50 plans * 12 hr/plan) at a cost of $67,028 (50 plans × [(8 hr * $127.82/hr) + (4 hr * $79.50/hr)]).

The modifications that we are proposing in section VI.B. of this proposed rule to §§ 422.107(d)(1) and 422.514(h) would allow D–SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D–SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where those individuals are enrolled in Medicaid FFS, and as such, would change which D–SNPs would be required to non-renew or combine plans, affecting the burden estimates finalized in the April 2024 final rule. Given the landscape of States that do not require mandatory Medicaid managed care for all of their full-benefit dually eligible individuals, we believe that based on our estimates, 15 MA organizations would be affected by this proposed exception. To account for the reduction in MA organizations affected by this proposed change to §§ 422.107(d)(1) and 422.514(h) as compared to the finalized burden estimates in the April 2024 final rule, we are reducing the previous burden calculation of 50 MA organizations by 15 MA organizations.

Because we believe that these proposed amendments to §§ 422.107(d)(1) and 422.514(h) would reduce the number of impacted MA organizations by 15 as compared to our finalized estimate in the April 2024 final rule, we are providing our estimate in the reduction of burden that would result if this proposal to amend §§ 422.107(d)(1) and 422.514(h) were to be finalized. The wage estimates in this notice of proposed rulemaking have been updated to reflect May 2024 BLS National Occupational Employment and Wage Estimates, where our estimates in the April 2024 final rule used BLS National Occupational Employment and Wage Estimates from May 2022.

We continue to expect that MA organizations would need two software engineers with each working 4 hours at $139.00/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at $88.82/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimate a revised one-time burden (for plan year 2027) of 420 hours (35 plans * 12 hr/plan) at a cost of $51,355 (35 plans × [(8 hr * $139.00/hr) + (4 hr * $88.82/hr)]).

In this regard, we estimate a burden reduced of minus 180 hours (420 hr − 600 hr) and minus $15,673 ($51,355 − $67,028).).

8. ICRs Removing Account-Based Medical Plans From Entities Required To Provide Creditable Coverage Disclosures

The following proposed changes will be submitted to OMB for review under control number 0938–1013 (CMS–10198).

As described in section VII.A. of this proposed rule, account-based plans, such as HRAs, including ICHRAs, are group health plans that are not, as section 1860D–13(b)(6)(B)(i) of the Act requires, entities that offer prescription drug coverage. Therefore, the benefit design of account-based plans makes concepts, such as disclosure of creditable coverage, inapplicable to those arrangements. This rule's proposal to exclude account-based plans from the group health plans that are required to disclose creditable coverage status to the Secretary and to Medicare-eligible individuals as required under § 423.56 will reduce private expenditures required to comply with federal regulations to provide creditable coverage disclosures, by avoiding duplicative efforts, and eliminating the need for these account-based plans to acquire additional resources and expertise to provide these disclosures.

The disclosure to the Secretary is required for certain entities listed at § 423.56(b) that are not excluded at § 423.56(e). The entities exempted under § 423.56(e) include PDPs, MA–PD plans, and PACE or cost-based HMOs or CMPs that provide ''qualified Part D coverage'' within the meaning of § 423.100. Among the plans that are required to submit this disclosure are group health plans (offered by employers, union/Taft-Hartley plans, church, State and local government, and other group-sponsored plans) including the Federal Employees Health Benefits Program; and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act. As described in section VII.A. of this proposed rule, the term, ''Group Health Plan'' (GHP) was codified at § 423.882 in the 2005 Part D final rule (70 FR 4577), and this definition includes account-based medical plans. The CMS online disclosure system allows entities to select the general type of GHP they offer (for example, employer-sponsored plans); however, the system does not provide for further subsets of the plan type. For example, account-based plans are not sub-categorized under the GHP category. Therefore, CMS does not have specific data on the number of account-based plans that may be making creditable coverage disclosures.

As stated in section VII.A. of this proposed rule, ICHRAs, a type of HRAs, are account-based plans that were more recently recognized by the Labor, Health and Human Services, and Treasury Departments in the June 20, 2019 final rule titled, ''Health Reimbursement Arrangements and Other Account-Based Group Health Plans'' (84 FR 28888). Generally, the impetus for this proposal to not require account-based plans to provide creditable coverage disclosures was feedback that CMS was receiving from stakeholders asking if ICHRAs were required to provide creditable coverage disclosures. To date, CMS has received minimal to no inquiries on the requirement for other types of account-based plans to make creditable coverage disclosures. Therefore, we will attempt to show a decrease in burden by comparing the number of ICHRA plans compared to the total universe of health plans, (about 5 percent), and inputting that percentage to estimate the number of ICHRA plans that are potentially making creditable coverage disclosures to the Secretary.[122]

Using this data, we estimate that about 5 percent of the 140,974 GHPs, or about 7,049 entities (140,974 × 0.05) in our active burden estimates would not be required to make creditable coverage disclosures to the Secretary. Taking approximately 5 total minutes (0.083 hr) for either a Human Resources Manager at $154.30/hr or a Compensation and Benefits Manager at $150.22/hr (whichever individual/occupational title is assigned by the plan) to complete the online disclosure form, we estimate a reduction of minus 585 hours (7,049 * 0.083 hr) and minus $90,266 (585 * $154.30/hr for a Human Resources Manager) or minus $87,879 (585 * $150.22/hr for a Compensation and Benefits Manager).

9. ICRs Regarding Rescinding the Annual Health Equity Analysis of Utilization Management (UM) Policies and Procedures (§ 422.137(c)(5), (d)(6), and (d)(7))

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

This rule proposes to remove § 422.137(c)(5), (d)(6), and (d)(7) which currently contain health equity reporting requirements related to UM. Rescission of these requirements would decrease the regulatory burden for MA organizations by removing reporting requirements for the UM Committee, reducing administrative complexity and eliminating ongoing compliance and monitoring. CMS proposes to remove the requirements since they impose compliance costs on MA organizations without corresponding benefits. The removal supports E.O.s 14148 and 14192 and addresses stakeholders' concerns about the requirements' lack of research foundation, feasibility, and administrative burden.

Section 422.137(c)(5) requires a member of the UM Committee to have expertise in health equity. CMS estimates it takes 30 minutes at $81.72/hr for a compliance officer to update the policies and procedures. By removing this requirement, CMS estimates a one-time burden reduction of minus 348 hours (697 contracts * 0.5 hr) and minus $28,438 (348 hr * $81.72/hr).

Section 422.137(d)(6) requires the UM Committee to conduct an annual health equity analysis of the use of prior authorization. CMS estimates it takes 8 hours at $139.00/hr for a software developer to collect and aggregate the health equity analysis data required to produce the report. By removing this requirement, CMS estimates an annual burden reduction of minus 5,576 hours (697 contracts * 8 hr/plan) and minus $775,064 (5,576 hr * $139.00/hr).

Finally, § 422.137(d)(7) requires that annually, the health equity analysis must be produced and posted to the plan's website. CMS estimates it takes 10 minutes (0.1667 hr) at $88.82/hr for a business operations specialist to produce, inspect, and post the report. By removing this requirement, CMS estimates an annual burden reduction of minus 116 hours (697 contracts * 0.1667 hr/plan) and minus $10,303 (116 hr * $88.82/hr).

C. Summary of Proposed Information Collection Requirements and Associated Burden

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[122] According to the 2024 KFF Employer Health Benefits Survey (available at *https://www.kff.org/health-costs/report/2024-employer-health-benefits-survey/*), of firms offering health benefits, 4 percent provide employees funds to purchase non-group coverage (such as through an ICHRA). Of firms not offering health benefits, 7 percent similarly provide employees funds to purchase non-group coverage (such as through an ICHRA). Based on these survey estimates, the weighted number of firms offering health benefits (1,670,244), and the estimated weighted number of firms not offering health benefits (1,589,106), it is estimated that there are 178,047 ICHRA plans in total. This is calculated as (1,670,244*0.04) + (1,589,106*0.07) = 178,047.

TABLE J5: 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 ($)
§ 422.62(b)(23)	Revise provider termination notice content requirements at 422.2267(e)(12)	0938-0753 (CMS-R-267)	697 MA organizations (contracts)	697	8	5,576	139.00	775,064	-
§§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i)	Removing Rules on Time and Manner of Beneficiary Outreach - Marketing Events Following Educational Events in Same Location	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i)	Removing Rules on Time and Manner of Beneficiary Outreach - Timing of Personal Marketing Appointment after Scope of Appointment (SOA) Form Completion	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D)	Removing Rules on Time and Manner of Beneficiary Outreach - Scope of Appointment (SOA) Forms at Educational Events	0938-1442 (CMS-10837)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	-
§ 422.60(g)	Passive Enrollment (plan burden)	0938-TBD	11 D-SNP (contracts)	11	100	1,100	79.27	87,195	87,195
§ 422.60(g)	Passive Enrollment (mailing costs)	0938-TBD	11 D-SNP (contracts)	11	N/A	N/A	N/A	114,686	114,686
§§ 422.107 and 422.514	Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service	0938-0753 (CMS-R-267)	15 MA organizations (contracts)	(15)	12	(180)	122.27	(15,673)	-
§ 423.56(b)(3)	Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures	0938-1013 (CMS-10198)	7,049 Group Health Plans	(7,049)	0.083	(585)	154.30	(90,266)	(90,266)
§§ 422.137(c)(5), (d)(6) and (d)(7)	Rescinding the Annual Health Equity Analysis of UM Policies and Procedures	0938–0964 (CMS 10141)	697 MA organizations (contracts)	(697)	8.667	(6,040)	103.18	(813,805)	(785,367)
Total				(9,133)	Varies	(651)	Varies	10,770	(673,752)

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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 CMS' PRA website at *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/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–4212–P), the ICR's CFR citation, and OMB control number.

XI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule addresses several critical needs in the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), and Medicare cost plan that require regulatory action to ensure program integrity, beneficiary protection, and statutory compliance. The provisions proposed in this rule are intended to codify and implement the statutory requirements of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), and provide greater clarity on the Star Ratings system for plans operating in the MA and Part D spaces.

One of the primary drivers for this rulemaking is the statutory mandate to implement changes made by the IRA. The IRA fundamentally restructured the Part D benefit design and established new payment obligations for enrollees, Part D plan sponsors, pharmaceutical manufacturers, and CMS. Without regulatory implementation of these statutory changes, the Medicare program cannot comply with Federal law or provide the intended beneficiary protections and cost savings envisioned by Congress. Specifically, the IRA requires CMS to codify changes to Part D benefit phases, including the deductible, initial coverage limit, coverage gap, and the annual out-of-pocket threshold, as well as to sunset the Coverage Gap Discount Program and to establish the Medicare Part D Manufacturer Discount Program.

The proposed changes to Star Ratings address the ongoing need to simplify and refocus quality measurement, improving transparency for MA organizations and Part D sponsors. The current Star Ratings system has grown in complexity over time, and stakeholders have requested streamlining to focus on the most impactful quality measures. The proposed modifications respond to these requests and should make the Star Ratings system more comprehensible and predictable.

The absence of regulatory action would result in statutory non-compliance regarding IRA implementation, ongoing operational inefficiencies, and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Medicare program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

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 13132, ''Federalism''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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, and distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OIRA has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866.

C. Detailed Economic Analysis

Many provisions of this proposed rule have negligible impact either because they are technical provisions or clarifications. 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 X. of this proposed rule, which estimates costs associated with paperwork burden resulting from this rule. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section X. of this proposed rule in order to arrive at the total impact. Table K1 summarizes the estimated transfers and costs associated with the various provisions in this proposed rule over a 10-year period. Further details are provided later in this RIA.

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TABLE K1: SUMMARY OF THE TRANSFERS AND COSTS OF THE PROPOSED RULE BY PROVISION FOR YEARS 2026-2036 (In $ Millions)

Category of Provisions	Year(s)											
Transfers	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2026-2036**
Star Ratings	-	-	5,020	2,320	780	700	730	840	940	900	950	13,180
Continuity in Enrollment for Full-Benefit Dually Eligible Individuals	-	-	-	-	5	5	5	5	7	7	7	41
TOTAL TRANSFERS	-	-	5,020	2,320	785	705	735	845	947	907	957	13,221
From the Medicare Trust Funds to MA Organizations and Part D Sponsors												
COSTS*	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2026-2036**
TPMO Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings	-	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-6.7	-67.2
Rescinding the Mid-Year Supplemental Benefits Notice	-1.9	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-1.4	-15.4
Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET	-	-1	-1	-1	-1	-1	-1	-1	-1	-1	-1	-10
Other Provisions†	-	-	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-0.7	-6.1
TOTAL COSTS	-1.9	-9.1	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-9.7	-98.7

* Figures in the Costs section of Table K1 have been rounded to the nearest tenth of one million. For that reason, numbers in the 2026-2036 column may not equal the sum of columns 2026 through 2036.

†The Other Provisions row includes estimates for first year and annually recurring impacts for the Information Collection Requirements of the following provisions: Special Enrollment Period for Provider Terminations; Removing Rules on Time and Manner of Beneficiary Outreach; Passive Enrollment; Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D-SNP and Medicaid Fee-for-Service; Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures; and Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures.

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1. Effects of Part D Redesign: Redesigned Part D Benefit

In this proposed rule, we are proposing to codify changes to the Part D benefit made by section 11201 of the IRA related to the deductible, initial coverage limit, the coverage gap, the annual out-of-pocket (OOP) threshold, and alternative prescription drug coverage options. Several of the changes made by section 11201 have taken effect already and other changes will go into effect in 2026.

The Part D defined standard benefit becomes richer because of these changes, providing Part D enrollees with more protection from prescription drug costs. As Part D plan offerings must satisfy equivalence testing with the new, more generous benefit structure, they must also cover a greater share of Part D drug costs. This leads to higher bids and increases in federal costs for the program. In particular, the creation of an out-of-pocket maximum shields enrollees entirely from cost sharing once they enter the catastrophic phase of the benefit, leading to cost increases for Part D plans and the government. The costs and transfers attributable to the Part D redesign are attributable to the IRA and are not a result of this rule.

2. Effects of Part D Redesign: Specialty Tier

a. Limit on Specialty-Tier Cost Threshold Adjustment (§ 423.104(d)(2)(iv)(B))

In this proposed rule, we are proposing to revise § 423.104(d)(2)(iv)(B)(1) and (2) to allow CMS to reduce the specialty-tier cost threshold under certain circumstances, in addition to the current authority to increase the threshold. This change would provide CMS with additional flexibility to reduce the threshold in response to market conditions, such as potential reductions in Part D drug costs resulting from the Medicare Drug Price Negotiation Program.

This provision does not impose new requirements on Part D sponsors or change existing operational processes. The methodology for determining whether a threshold adjustment is warranted remains the same (at least 10 percent change from the prior year), and the rounding methodology remains unchanged. Therefore, we do not anticipate that this provision will have a measurable economic impact on Part D sponsors, beneficiaries, or the Medicare program, as it is only providing CMS with flexibility in making threshold adjustments without altering the underlying methodology or operational requirements.

b. Specialty-Tier Maximum Allowable Cost Sharing (§ 423.104(d)(2)(iv)(D))

We are proposing to codify the methodology for determining the specialty-tier coinsurance/deductible ranges that were established in the Final CY 2025 Part D Redesign Program Instructions. This proposal would update the existing calculation methodology to align with the redesigned Part D benefit structure implemented under the IRA, which eliminated the initial coverage limit.

The proposed methodology maintains the existing 25 percent minimum and 33 percent maximum coinsurance for specialty tiers. While the underlying calculation has been updated to reflect the redesigned Part D benefit, the range of allowable coinsurance percentages remains unchanged. Part D sponsors must continue to ensure their benefit designs are actuarially equivalent to the defined standard benefit, as required under existing regulations.

When CMS codified the specialty-tier maximum allowable cost-sharing methodology in the CY 2022 Final Rule (86 FR 6078), we concluded in the regulatory impact analysis that the specialty-tier provisions, which also included provisions to allow Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier, were unlikely to have a material impact on Part D costs. Likewise, we do not anticipate that our current proposal to update this methodology to align with the redesigned Part D benefit would have a measurable economic impact on Part D sponsors, beneficiaries, or the Medicare program, as it maintains the same coinsurance ranges that are currently in effect.

3. Effects of the Medicare Coverage Gap Discount Program (§§ 423.100, and 423.2300 Through 423.2345 (Subpart W))

This proposal would codify the sunset of the Coverage Gap Discount Program, which was enacted under the Affordable Care Act and began on January 1, 2011. The Coverage Gap Discount Program sunset was authorized as a part of the Part D benefit redesign under section 11201 of the IRA. Section 11201 of the IRA amended section 1860D–14A of the Act by adding subsection (h) to require that Coverage Gap Discount Program provisions at section 1860D–14A apply before January 1, 2025, and, with respect to applicable drugs dispensed prior to such date, continue to apply on and after January 1, 2025.

The costs and transfers attributable to the Part D Redesign, including sunsetting the Coverage Gap Discount Program, are attributable to the IRA and are not a result of this rule.

4. Effects of the Medicare Part D Manufacturer Discount Program (§§ 423.1, 423.100, 423.505(b), 423.1000, 423.1002, and 423.2700 Through 423.2768 (Subpart AA))

This proposal would codify policies implementing the Manufacturer Discount Program. Section 11201 of the IRA established the Manufacturer Discount Program as a part of the IRA's Part D benefit redesign. Section 11201(f) of the IRA directed CMS to implement the Manufacturer Discount Program using program instruction or other forms of program guidance for 2025 and 2026. The Manufacturer Discount Program began on January 1, 2025, and we are proposing to codify the policies that have been in place since the program's implementation, with refinements.

The costs and transfers attributable to the Part D Redesign, including codifying the Manufacturer Discount Program, are attributable to the IRA and are not a result of this rule.

5. Effects of Third-Party Marketing Organization (TPMO) Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings

This provision proposes to reduce the amount of time that MA Organizations and Part D sponsors are required to retain recordings for sales and marketing calls from 10 to 6 years that was originally established in the May 2022 final rule (87 FR 27704) and subsequently modified in the April 2023 final rule (88 FR 22120) which required an MA organization or a Part D sponsor's contract, written arrangement and/or agreement with the aforementioned entities must ensure that marketing, sales, and enrollment calls with beneficiaries are recorded in their entirety. In addition, CMS has advised that marketing, sales, and enrollment call recordings must comply with the record retention requirements at §§ 422.504(d) and 423.505(d). If finalized, the reduced call retention time from 10 to 6 years will take effect on October 1, 2026, to coincide with the beginning of 2027 plan year marketing, as defined under §§ 422.2263(a) and 423.2263(a).

To determine the cost of the existing requirement and thus the cost savings, CMS reviewed different types of storage costs. The first type is storage in cloud settings where an entity pays per

gigabyte or terabyte and the cost is determined based on the amount of data and how accessible the entity wants the data to be (for example, standard storage, cold line storage, archive storage, etc.). CMS also reviewed other options available for TPMOs, especially individual agents or small agencies, to record and store calls. In this review, CMS found that the industry created and/or marketed different recording tools available to agents and brokers. These tools have a wide range of costs, ranging from free recording services to other tools that are structured around monthly or yearly fees. Moreover, based on information gleaned from previous regulatory work, CMS has also been made aware that field marketing organizations (FMOs) may provide agents and brokers access to call recording technology at a reduced cost or otherwise factor it into agent/broker contractual arrangements. Finally, CMS notes that many of these tools are proprietary and total costs may not be fully transparent until a purchase (or contractual agreement) is made. All told, the variability makes it more difficult to establish the savings associated with this provision.

To estimate the cost savings associated with revising the call recording retention requirement, CMS first estimated the number of licensed and appointed agents to sell Medicare products, including MA plans and PDPs, to be 100,000.[123] CMS acknowledges that there is a range of how each agent accesses call recordings and storage and how much each will pay for these features. CMS also acknowledges that the typical cost to agents combines both the recording and the storage costs into one fee. With these challenges acknowledged, for this proposed rule, CMS is using an average cost of $35 per month, or $420 per year for call recording tools based on the median of the costs that agency was able to identify.[124] [125] [126] [127] Further, CMS is estimating that approximately 60% of the cost is attributed to the recording costs while the other 40% is attributed to the cost of storage ($14 is storage [35*0.4]). Since the proposal requires calls to be retained for 6 years there would be a savings of $5.6 per month ($14*0.4), resulting in a savings of $67.2 per year per agent. Using the $67.2 per year, combined with the estimated 100,000 agents and brokers licensed and appointed to sell Medicare products, CMS estimates that this provision will save an estimated $6.72 million dollars per year ($67.2 [savings per agent per year] * 100,000 [agents]), or 67.2 million dollars over a 10-year period.

Based on the previous noted limitations, CMS is specifically requesting comments on these estimates and welcomes additional data that may help the agency to further quantify the savings associated with this provision. We request comments on our assumptions of savings, taking into account the continued requirement for the recording of a beneficiary's enrollment into a plan.

6. Effects of Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.164, 422.166, 423.184, and 423.186)

We are proposing to add and remove certain measures from the Part C and D Star Ratings program. Historically, measure additions and removals are routine, and such routine changes have had very little or no impact on the highest ratings (that is, overall rating for MA–PD contracts, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). However, given the number of measure removals proposed in this rule, we have estimated the impact of the measure removals on the Medicare Trust Fund in this rule. We are also proposing to not move forward with the implementation of the Health Equity Index (HEI) reward and to continue to include the historical reward factor in the Star Ratings methodology. Beyond the Medicare Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to contract) based on the business strategies and the competitive landscape for each plan and contract.

We simulated the cumulative impact of the proposed changes on MA contracts using the 2025 Star Ratings data. We calculated the net impacts summarized in Table K–3 due to these proposed Star Ratings updates by quantifying the difference in the MA organization's final Star Rating with the proposed changes and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these proposed revisions to the measure set and methodology. Not moving forward with the implementation of the HEI and continuing to include the historical reward factor would be effective for the 2027 Star Ratings and would impact the 2028 plan payments and 2028 Quality Bonus Payments (QBPs). The removal of the Call Center—Foreign Language Interpreter and TTY Availability (Part C), Call Center—Foreign Language Interpreter and TTY Availability (Part D), and Statin Therapy for Patients with Cardiovascular Disease (Part C) measures would be effective also for the 2028 Star Ratings and would impact the 2029 plan payments and 2029 QBPs. The removal of the remaining measures would be effective for the 2029 Star Ratings and would impact the 2030 plan payments and 2030 QBPs.

All impacts are considered transfers, but we request comments on the extent to which provision of goods or services would increase or decrease in association with the payment changes. The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those MA contracts that would have Star Ratings changes under this proposed rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).
- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. We estimated the cumulative impact of the proposed changes to the Star Ratings calculations since there are interactions between the changes. The impacts are shown in Table K3. For the Star Ratings updates, the net impact is estimated to be between $5.02 billion in 2028 and $0.95 billion in 2036, resulting in a 10-year net impact estimate of $13.18 billion, which equates to 0.15 percent of the Medicare payments to private health plans for the years 2027 through 2036.

[123] *https://www.sparkadvisors.com/resource/where-agents-become-pawns-the-dark-side-of-fmo-contracting-and-what-it-means-for-agents.*

[124] *https://www.claap.io/blog/chorus-pricing.*

[125] *https://www.nextiva.com/x20/lpGVDT11_i?utm_source=getvoip&utm_medium=affiliate&utm_campaign=lpgvdt&utm_term=nextiva%20plans.*

[126] *https://www.zoom.us/pricing/zoom-phone.*

[127] CMS recognizes that some of the tools do not include unlimited, 10-year storage. Storage may be an additional cost.

TABLE K3: NET IMPACTS ($ MILLIONS) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Medicare Payments to Private Health Plans
2027	-	0.00%
2028	5,020	0.80%
2029	2,320	0.33%
2030	780	0.10%
2031	700	0.08%
2032	730	0.08%
2033	840	0.09%
2034	940	0.09%
2035	900	0.08%
2036	950	0.08%
Total	**13,180**	**0.15%**

7. Effects of Continuity in Enrollment for Full-Benefit Dually Eligible Individuals in a D–SNP and Medicaid Fee-for-Service (§§ 422.107 and 422.514)

In the April 2024 final rule, we finalized a package of provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) that require that, beginning in contract year 2027, where an MA organization offers a D–SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service areas (even if there is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in contract year 2030, such D–SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D–SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). We also codified at § 422.514(h)(3) two exceptions to the requirements at § 422.514(h)(1) and (2) for exceptions related to instances where (a) the State Medicaid agency contract (SMAC) with the MA organization differentiates enrollment into D–SNPs by age group or to align enrollment in the D–SNP with the eligibility or benefit design used in the State's Medicaid managed care program and (b) the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNPs and PPO D–SNPs.

In the April 2024 final rule at 89 FR 30802 through 30805, we stated that our changes would yield an overall annual estimate of net Part C costs ranging from −$6 million in contract year 2027 to −$207 million in contract year 2034 with total net Part C costs of −$961 million from contract years 2027 through 2034. We estimated an overall annual estimate of net Part D costs would range from −$7 million in contract year 2027 to −$286 million in contract year 2034 with total net Part D costs of −$1,341 million from contract years 2027 through 2034. In the April 2024 final rule (89 FR 30803), we explained that the regulatory change would shift enrollment from less integrated D–SNPs to more integrated D–SNPs over time as more D–SNPs align with Medicaid MCOs. For more context regarding the estimation methodology, see the April 2024 final rule (89 FR 30802 through 30805).

In this proposed rule, we are proposing to add a third exception at § 422.514(h)(3) to allow D–SNPs that serve full-benefit dually eligible individuals in a HIDE SNP or coordination-only D–SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where those individuals are enrolled in Medicaid FFS. These proposed changes would address the challenges of MA organizations complying with the requirements at § 422.514(h) in States where there is no mandatory Medicaid managed care program and avoid the need for MA organizations in those States to cease enrolling full-benefit dually eligible individuals who are in Medicaid FFS starting in 2027 and disenroll those members in 2030 as currently required under § 422.514(h).

We expect that our proposal to establish a third exception at § 422.514(h)(3) would slightly reduce the savings estimates included in the April 2024 final rule since the number of D–SNPs and enrollees impacted by the existing requirement at § 422.514(h) would be reduced, should our proposal be finalized. We note that we are also proposing to add a fourth exception at § 422.514(h)(3) to exempt U.S. Territories that have not adopted Medicare Savings Programs (as defined at § 435.4) from the requirements at § 422.514(h)(1)(i), but we do not expect that this exception would have an impact on savings estimates in the April 2024 final rule. The methodologies and baseline data used in the estimates presented in Table K4 are consistent with those used in the April 2024 final rule estimates, except the Tables K4 and K5 estimates exclude certain HIDE SNPs and coordination-only D–SNPs that

would be exempt under this proposed rule.

For our proposed change to add a third exception at § 422.514(h)(3), as shown in Table K4, we estimate the Part C costs to the Medicare Trust Funds range from $0 million in 2027 to $3 million in 2036, summing to $18 million for the years 2027 through 2036. These estimated costs mean our overall expected Part C savings from implementation of § 422.514(h) would be $943 million (rather than $961 million) over 10 years.

TABLE K4: ESTIMATED PART C COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR EXEMPTING CERTAIN D-SNP ENROLLMENT FROM § 422.514(h)

Calendar Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
BID + REBATE PMPM Difference in Dollars	13.10	13.16	13.02	12.89	12.93	13.04	13.92	14.51	15.10	15.67	
PROJECTED D-SNP Enrollment Exempt from 422.514(h)	517	1,015	1,489	16,228	16,609	16,942	17,239	17,496	17,721	17,904	
Gross Cost ($ millions):	0	0	0	3	3	3	3	3	3	3	21
Net of Part B Premium:	85.1%	85.0%	84.9%	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	
Net Cost ($ millions):	0	0	0	2	2	2	2	3	3	3	18

Table K5 shows the estimated Part D costs of the proposed amendment to § 422.514(h) range from $0 million in 2027 to $4 million in 2036, summing to $24 million for the years 2027 through 2036. These estimated costs mean our overall expected Part D savings from implementation of § 422.514(h) would be $1,317 million (rather than $1,341 million) over 10 years.

TABLE K5: ESTIMATED PART D COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR EXEMPTING CERTAIN D-SNP ENROLLMENT FROM § 422.514(h)

Calendar Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
BID + REINSURANCE PMPM Difference in Dollars	14.09	14.25	14.67	15.00	15.30	15.87	16.47	16.97	17.49	18.03	
Gross Cost ($ millions):	0	0	0	3	3	3	3	4	4	4	24
Net Part D Premium:	-	-	-	-	-	-	-	-	-	-	-
Net Cost ($ millions):	0	0	0	3	3	3	3	4	4	4	24

8. Effects of Rescinding the Mid-Year Supplemental Benefits Notice

This provision proposes rescinding the requirement established in the April 2024 final rule (89 FR 30448) that will require MA organizations to provide annual mid-year notices to enrollees regarding unused supplemental benefits. The requirement will take effect on January 1, 2026, and requires MA organizations to mail a notice between June 30 and July 31 of each plan year to enrollees listing any supplemental benefits they had not utilized during the first 6 months of the plan year. Note that on September 8, 2025, CMS announced its decision to delay enforcement of the requirements under §§ 422.111(l) and 422.2267(e)(42) until further notice. MA organizations are not expected to complete the Mid-Year Supplemental Benefits Notice requirements for the 2026 plan year.

a. Information Collection Requirements

In anticipation of this rescission, CMS removed the associated information collection requirements from PRA package CMS R–267 prior to its submission to OMB for review. Therefore, there are no current information collection requirements associated with this provision that require OMB review or approval for rescission.

The rescission of this requirement would prevent the burden that would have been imposed on MA organizations. Based on updated BLS wage data, this would prevent approximately $498,522 in one-time costs for system updates and policy changes, and approximately $1,355,520 annually in printing and mailing costs.

b. Updated One-Time Cost Prevention

The rescission of this requirement would prevent approximately $499,091 in one-time costs for system updates and policy changes across 774 prepaid contracts. This includes $430,344 (774 prepaid contracts * 4 hours * $139.00/hour) for software system updates performed by software developers, and $68,746.68 (774 prepaid contracts * 1 hour * $88.82/hour) for policy and procedure updates performed by business operations specialists.

c. Annual Cost Prevention

The rescission of this requirement would prevent approximately $1,355,520 per year in printing and mailing costs across 774 prepaid contracts serving 32 million enrollees. This includes $451,840 (32,000,000 notices × $0.01412/page) for single-page mailings, with an estimated average of 3 pages per enrollee resulting in total annual cost prevention of $1,355,520 (32,000,000 notices × 3 pages × $0.01412/page).

Over a 10-year period from 2027 to 2036, we estimate this provision would save approximately $14.1 million (approximately $1.4 million per year), primarily from the elimination of printing and mailing costs that would have been incurred annually, plus the one-time system and policy update costs prevented.

This proposed rescission is consistent with E.O. 14192, ''Unleashing Prosperity through Deregulation,'' which instructs federal agencies to review regulations to alleviate unnecessary regulatory burdens. After reviewing stakeholder feedback and current data on supplemental benefit utilization, CMS determined that the Mid-Year Notice requirement imposes a significant administrative burden on MA organizations that outweighs the intended benefit. Additionally, recent

evidence suggests that enrollees are utilizing supplemental benefits when they need them, with 70 percent of MA enrollees in a recent survey reporting they had used at least one supplemental benefit in the past year.

9. Effects of Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET

This provision adds a new waiver to the list of Part D requirements waived for the LI NET program by exempting the customer call center hours of operation requirements in § 423.128(d)(1)(i)(A). Currently, Part D sponsors are required to maintain toll-free customer call centers open from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. This waiver allows the LI NET program to operate its customer call center Monday through Friday, except holidays, from 8:00 a.m. to 7:00 p.m. Eastern Time.

We estimate that this waiver will result in cost savings of approximately $800,000 to $1,000,000 annually for the LI NET program. These savings result from reduced operational costs associated with maintaining extended customer call center hours.

The reduced hours are appropriate for the LI NET program due to several factors: low call volume after 7:00 p.m. ET historically; automatic enrollment of 90 to 95 percent of LI NET beneficiaries by CMS, reducing the need for prospective enrollee assistance; the transitional nature of the LI NET program; LI NET's open formulary structure; availability of a 24-hour call center serving pharmacists and pharmacies to address the majority of inquiries.

This provision would not adversely impact the LI NET sponsor, individuals' access to prescription drug benefits, or the Medicare Trust Fund. The 24-hour pharmacy call center ensures continued access to necessary support, while the reduced customer call center hours align with actual usage patterns.

D. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this proposed rule would, if finalized, codify existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health.

1. Waiver of Part D Customer Call Center Hours for All Regions Served by LI NET (§ 423.2536)

The first alternative we considered would maintain the current customer call center hours requirement. The LI NET program would comply with the existing customer call center hours requirement in § 423.128(d)(1)(i)(A), maintaining operations from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan. This alternative would result in continued operational costs of approximately $800,000 to $1,000,000 annually compared to the proposed waiver. We reject this alternative because maintaining extended hours is not cost-effective given the historically low call volume after 7:00 p.m. ET. The automatic enrollment process for 90 to 95 percent of LI NET beneficiaries significantly reduces customer service needs, making the extended hours unnecessary. The continued availability of 24-hour pharmacy support ensures adequate access to assistance.

The second alternative we considered would eliminate the customer call center requirements for LI NET. The LI NET program would be completely exempt from maintaining any customer call center, relying solely on the 24-hour pharmacy call center. This alternative would result in maximum cost savings but could potentially impact beneficiary access to customer service. We reject this alternative because it could create access barriers for the 5 to 10 percent of LI NET beneficiaries who are not automatically enrolled and may need customer service assistance. Maintaining customer call center operations during standard business hours (8:00 a.m. to 7:00 p.m. ET) provides an appropriate balance between cost efficiency and beneficiary access to support services.

The proposed provision represents the optimal balance between operational efficiency and beneficiary protection, providing necessary customer service access while eliminating unnecessary costs associated with low-utilization hours.

E. Regulatory Review Costs

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret the proposed rule, then we should estimate the cost associated with regulatory review. We have received approximately 2,000 comments specific to the provisions of our recent proposed rules, and we estimate that a similar number will review this rule upon publication in the **Federal Register**.

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 $132.44 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 10 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $1,324.40 (10 hours × $132.44). Therefore, we estimated that the maximum total cost of reviewing the proposed rule is $2.6 million ($1,324.40 × 2,000 reviewers). However, we expected that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but review just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the proposed rule will be reviewed by an individual reviewer; we therefore estimate the total cost of reviewing to be $0.3 million.

We noted that this analysis assumes one reader per contract. Some alternatives included 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 rationale for this is that a parent organization might have local reviewers assessing potential region-specific effects from the rule.

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://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf,* in Table K6, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this rule over an 11-year period or for contract years 2026 through 2036.

TABLE K6: ACCOUNTING STATEMENT -CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS, CONTRACT YEARS 2026-2036 (MILLIONS)

Category	3% Discount Rate	7% Discount Rate
COSTS		
Annualized monetized costs	-$8.9	-$8.7
TRANSFERS		
Annualized monetized transfers	$1,183.6	$1,156.3
From Federal Government to MA Organizations and PD Sponsors		

G. 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 believe this proposed rule will have a direct economic impact on beneficiaries, health insurance plans, and third-party marketing organizations (TPMOs). Based on the size standards set by the Small Business Administration (SBA) effective March 17, 2023, (for details, see the Small Business Administration's website at *https://www.sba.gov/document/support-table-size-standards*), Direct Health and Medical Insurance Carriers, classified using the NAICS code 524114, have a $47 million threshold for ''small size.'' Many Medicare Advantage organizations (about 30 to 40 percent) are not-for-profit, which allows them to qualify as ''small entities'' so long as they are independently owned and operated and nondominant in their field. We believe all of the not-for-profit organizations qualify as small under the aforementioned criteria. Of the 1,069 businesses using this NAICS code, we believe 799 (or 74.8 percent) are small businesses. Third party marketing organizations, which CMS has usually determined to belong to the category of Insurance Agencies and Brokerages (NAICS code of 524210), have a small size threshold of $15 million. In total, 98.9 percent (119,114 out of 120,434) are considered small.

We are certifying that, if finalized, this rule will not have a significant economic impact on a substantial number of small entities. The analysis in this rule provides descriptions of the statutory provisions, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analysis discussed in this section and throughout the preamble of this proposed rule constitutes our RFA analysis. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The 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 economic impact'' to be 3 to 5 percent or more of the affected entities' costs or revenues, and a ''substantial number'' to mean 5 percent or more of affected small entities within a given industry. To explain our position, we will first note certain operational aspects of the Medicare program.

Each year, MA organizations submit a bid for each plan for furnishing Parts A and B benefits and the entire bid amount is paid to the plan by the government through the Medicare Trust Funds, 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, historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees). 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 contract 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 cost sharing, 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 the government and, in some cases, by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans, and PACE organizations 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.

The preceding analysis shows that meeting the direct cost of the 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 earlier, there 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 MA 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 benefits and/or lower beneficiary cost sharing, 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 the 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 the rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

As indicated in Table K1, the proposals described in this rule are expected to result in cost savings amounting to approximately $9.1 million in 2027 and $9.7 million in subsequent years. Most affected entities are expected to have costs savings as a result of this rule. For example, we anticipate that the 697 MA organizations will experience a net cost savings despite some new costs. The Special Enrollment Period for Provider Terminations provision is expected to result in new costs of $775,064 in 2027 for 697 MA organizations, equal to $1,112 per organization. The provisions on Removing Rules on Time and Manner of Beneficiary Outreach are expected to reduce costs for 697 MA organizations by over $45,000 in 2027, while the provision Rescinding the Annual Health Equity Analysis of Utilization Management Policies and Procedures is expected to lower costs for 697 MA organizations by $813,805 in 2027 and $785,367 annually in subsequent years. Likewise, the provision Rescinding the Mid-Year Supplemental Benefits Notice is estimated to result in $1,854,611 in cost savings for 774 MA organization contracts in 2026 and $1,355,520 annually thereafter, or $2,396 in year one and $1,751 per year after that. For those Medicare Advantage organizations to which all of these provisions apply, expected net cost savings will be $2,396 for 2026, $1,874 for 2027, and $2,878 per year starting in 2028.

Many of the other entities affected by the provisions of this proposed rule are similarly expected to see cost savings, though others will see negligible cost increases. The provision Removing Account-based Medical Plans from Entities Required to Provide Creditable Coverage Disclosures is expected to save 7,049 group health plans about $90,000 collectively every year, or approximately $13 per entity. The provision revising the requirement that TPMOs retain calls for six years is expected to save organizations $6.72 million annually starting in 2027. The passive enrollment provision is expected to result in additional costs of $201,881 annually for an estimated 11 D–SNP contracts, or $18,353 per contract. Any D–SNPs participating in passive enrollment would be approved to do so after consulting with the State Medicaid agency that contracts with the D–SNP and when CMS determines that the passive enrollment will promote continuity of care and integrated care. In most cases, these entities would be expected to benefit from the aforementioned cost savings this rule will produce for MA organizations, and so any D–SNPs approved to participate in passive enrollment would likely incur net costs of $16,479 in 2027, while for 2028 and thereafter the net costs would be $15,475 per contract.

We reiterate our belief that this proposed rule will not have a significant economic impact on a substantial number of small entities. In the case of TPMOs, though we do not know how many are operating in the Medicare space, this rule is expected to produce cost savings for them. The vast majority of MA organizations are likewise expected to see cost savings as a result of this rule. Even among the D–SNPs that are expected to incur new net costs, these costs are not expected to have a significant economic impact. The threshold to qualify as a small business for Direct Health and Medical Insurance Carriers is $47 million of average annual receipts. Presuming some may be very small entities, we may estimate that a few have much smaller annual receipts than the threshold established by the SBA. The 2022 Economic Census indicates that insurance firms with fewer than 10 employees averaged nearly $3.6 million in receipts for that year.[128] Even if receipts have not increased in the years since, the costs incurred by a D–SNP would likely fall well below HHS's 3 to 5 percent threshold for significance. Finally, we also reiterate that Medicare Advantage organizations, including D–SNPs, are expected to include the costs of compliance in their bids. For these reasons, we do not believe these costs result in a significant economic impact on the affected plans. We request comment on the assessment of this rule's impact on small businesses.

[128] US Census Bureau, 2022 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html,* accessed September 22, 2025.

H. Unfunded Mandates Reform Act (UMRA)

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 2025, that threshold is approximately $187 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 $187 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a 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.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a 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.

J. Executive Order (E.O.) 14192, ''Unleashing Prosperity Through Deregulation''

E.O. 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. We estimate that this rule generates $8

million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

K. Conclusion

This proposed rule, if finalized, will result in net annualized cost savings ranging between $8.9 and $8.7 million for calendar years 2026 to 2036, at the 3% and 7% discount rates, respectively. These savings are primarily attributable to the provision revising aspects of TPMO oversight. This proposed rule will also result in net annualized monetized transfers ranging between $1.18 billion and $1.16 billion for calendar years 2026 to 2036, at the 3% and 7% discount rates respectively. These transfers primarily result from changing aspects of the MA and Part D Plan Quality Ratings System.

List of Subjects

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.

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 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 2. Section 422.60 is amended by—
■ a. Revising paragraphs (g)(2)(i) and (2)(ii); and
■ b. In paragraph (g)(2)(vi) removing the phrase ''capacity to passively'' and adding in its place the phrase ''capacity, including care coordinator staffing capacity, to passively''.

The revisions read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as an applicable integrated plan as defined at § 422.561.

(ii) Provide continuity of care for all incoming enrollees that complies with § 422.112(b)(8)(i)(B), with the exception that the minimum transition period is 120 days.

* * * * *

■ 3. Section 422.62 is amended by revising paragraphs (b)(3) introductory text, (b)(5) introductory text, (b)(20) introductory text, (b)(23) introductory text, (b)(23)(ii), (b)(23)(iii), and (b)(27) to read as follows.

§ 422.62 Election of coverage under an MA plan.

(b) * * *

(3) This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. To be eligible, the individual must demonstrate to CMS that—

* * * * *

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction. This SEP requires CMS approval prior to use. The individual must receive a notice, as described in § 422.62(b)(5)(i), to make an election using this SEP.

* * * * *

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

(b) * * *

(23) Individuals affected by a change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per change in the provider network.

* * * * *

(ii) An enrollee is affected by a network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) The MA plan that has changed its network must include in the provider termination notice described at § 422.111(e) information regarding the affected enrollee's eligibility for the SEP and how to use the SEP.

* * * * *

(27) The individual meets such other exceptional conditions as CMS may provide. This SEP requires CMS approval prior to use. The individual must use a CMS-operated mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

■ 4. Section 422.66 is amended by adding paragraph (g) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(d) * * *

* * * * *

(g) *Elections requiring prior CMS approval.*

(1) *CMS approval.* Special Election Periods specified in § 422.66(g)(2) require CMS approval before an individual can use the SEP to make an election.

(i) CMS approval is provided for MA plan elections either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions.

(ii) MA plans may not transmit elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods.* All of the following SEPs require CMS approval prior to use:

(i) SEP for contract violation, § 422.62(b)(3).

(ii) SEP for individuals who disenroll in connection with CMS sanction, § 422.62(b)(5).

(iii) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 422.62(b)(20).

(iv) SEP for other exceptional circumstances, § 422.62(b)(27).

§ 422.101 [Amended]

■ 5. Section 422.101 is amended by—
■ a. In paragraph (f)(3)(iv)(B) removing the phrase ''June 1st and November 30th of each calendar year'' and adding in its place the phrase ''January 1st and March 31st or October 1st and December 31st of each contract year''; and
■ b. In paragraph (f)(3)(iv)(G) removing the phrase ''opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each year.'' and adding in its place the phrase ''opportunity per contract year to submit a corrected off-cycle revision between

January 1st and March 31st or October 1st and December 31st of each contract year.

§ 422.102 [Amended]

■ 6. Section 422.102 is amended by—
■ a. Removing and reserving paragraph (e); and
■ b. In paragraph (f)(1)(iii)(G), removing the phrase ''Cannabis products.'' and adding in its place the phrase ''Cannabis products that are illegal under applicable State or Federal law, including the Federal Food, Drug, and Cosmetic Act.''

■ 7. Section 422.107 is amended by adding paragraph (d)(1)(i) and adding and reserving paragraph (d)(1)(ii) to read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

* * * * *

(d) * * *

(1) * * *

(i) In conjunction with § 422.514(h), to the extent that a State Medicaid agency contract allows a dual eligible special needs plan established through this paragraph (d)(1) to enroll full benefit dually eligible beneficiaries, the contract must stipulate that such full benefit dually eligible beneficiaries cannot be enrolled in a Medicaid managed care organization that is owned and controlled by an entity other than the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization.

(ii) [Reserved]

* * * * *

§ 422.111 [Amended]

■ 8. Section 422.111 is amended by removing paragraph (*l*).

■ 9. Section 422.112 is amended by revising paragraph (a)(8) to read as follows:

§ 422.112 Access to services.

* * * * *

(a) * * *

(8) *Cultural considerations.* 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.

* * * * *

§ 422.137 [Amended]

■ 10. Section 422.137 is amended by removing paragraphs (c)(5), (d)(6), and (d)(7).

§ 422.152 [Amended]

■ 11. Section 422.152 is amended by removing paragraph (a)(5).

■ 12. Section 422.164 is amended by revising paragraph (e)(2) and adding paragraph (e)(3) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(e) * * *

(2) CMS will announce the removal of a measure based upon its application of paragraph (e)(1) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period or will propose and finalize the removal of the measure through rulemaking in advance of the measurement period.

(3) CMS will propose and finalize the removal of a measure for any reason not stated in paragraph (e)(1) of this section through rulemaking in advance of the measurement period.

* * * * *

■ 13. Section 422.166 is amended by—
■ a. In paragraph (f)(1) removing the phrase ''Through the 2026 Star Ratings, this rating-specific'' and adding in its place the phrase ''This rating-specific'';
■ b. Removing paragraph (f)(3); and
■ c. Revising paragraph (h)(2) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(h) * * *

(2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release during which MA organizations can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS.

* * * * *

§ 422.308 [Amended]

■ 14. Section 422.308 is amended in paragraph (c)(1) by removing the word ''gender'' and adding in its place the word ''sex''.

■ 15. Section 422.310 is amended by revising paragraph (f) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) *Use and release of data.* Regarding the data described in paragraphs (a) through (d) of this section, CMS may use and release the minimum data it determines is necessary in accordance with CMS data sharing procedures and applicable Federal laws, subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data, unless authorized by other applicable laws.

* * * * *

■ 16. Section 422.510 is amended by adding paragraphs (a)(4)(xvii), (b)(2)(i)(D), and (c)(2)(iv) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(xvii) Is no longer eligible to offer a dual eligible special needs plan because the MA organization does not hold a contract consistent with § 422.107(b) with the State Medicaid agency.

(b) * * *

(2) * * *

(i) * * *

(D) The contract is being terminated based on § 422.510(a)(4)(xvii).

(c) * * *

(2) * * *

(iv) The contract is being terminated based on paragraph (a)(4)(xvii) of this section.

* * * * *

■ 17. Section 422.514 is amended by adding paragraphs (h)(3)(iii), (iv), and (v) to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(h) * * *

(3) * * *

(iii) If the State Medicaid agency's contract with the MA organization permits full benefit dually eligible beneficiaries to be enrolled in a plan that is not a HIDE SNP or FIDE SNP per § 422.107(d)(1)(i), or a HIDE SNP with the majority of its enrollees in Medicaid fee-for-service, the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D–SNPs for full benefit dual eligible individuals in the same service area.

(iv) MA organizations with D–SNPs subject to paragraph (h)(3)(iii) must comply with responsibilities at § 422.562(a)(5).

(v) If a U.S. Territory has not adopted Medicare Savings Programs, as defined in 42 CFR 435.4, an MA organization operating in such U.S. Territory is exempt from the requirements in paragraph (h)(1)(i) of this section.

§ 422.752 [Amended]

■ 18. Section 422.752 is amended by removing and reserving paragraph (d).

■ 19. Section 422.2261 is amended by adding paragraph (a)(3) to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) * * *

(3)(i) MA organizations offering dual eligible special needs plans with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the MA organization's contract number.

(ii) MA organizations and third-party marketing organizations may not submit materials for the contract under the organization's Multi-Contract Entity number as described in § 422.2262(d)(2)(i).

* * * * *

§ 422.2262 [Amended]

■ 20. Section 422.2262 is amended by removing paragraphs (a)(1)(i) and (a)(1)(ii) and redesignating paragraphs (a)(1)(iii) through (xix) as paragraphs (a)(1)(i) through (xvii), respectively.

* * * * *

■ 21. Section 422.2264 is amended by—

■ a. In paragraph (c)(1)(ii)(D), removing the phrase ''Cards, but not including Scope'' and adding in its place ''Cards and Scope''; and

■ b. Revising paragraphs (c)(2)(i), (c)(3) introductory text, and (c)(3)(i).

The revisions read as follows:

§ 422.2264 Beneficiary contact.

* * * * *

(c) * * *

(2) * * *

(i) If a marketing event directly follows an educational event, the beneficiary must be notified that the educational event is ending and a marketing event will begin shortly and be given a sufficient opportunity to leave the educational event prior to the start of the marketing event.

* * * * *

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics. Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment, the MA plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). The Scope of Appointment must be in writing for in-person personal marketing appointments.

* * * * *

■ 22. Section 422.2267 is amended by—

■ a. Revising paragraphs (e)(5)(ii)(B)(*1*) and (e)(12)(ii)(D);

■ c. Removing and reserving paragraph (e)(31);

■ d. Revising paragraph (e)(41) introductory text and (e)(41)(ii); and

■ e. Removing paragraph (e)(42).

The revisions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(5) * * *

(ii) * * *

(B) * * *

(*1*) Deductible; the initial coverage phase; coverage gap for a year preceding 2025; and catastrophic coverage.

* * * * *

(12) * * *

(ii) * * *

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is affected by the provider termination is eligible for a special election period, as specified in § 422.62(b)(23) (including the start and end dates of that SEP), and Medigap guaranteed issue (GI) rights. The notice must advise individuals who have coverage through an employer or union to contact their benefits administrator before leaving their current MA plan to find out how making such a change may affect their employer or union health benefits.

* * * * *

(31) [Reserved]

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all MA organizations in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.'' If the TPMO sells for all MA organizations in the service area the disclaimer consists of the statement: ''Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov* or 1–800–MEDICARE for help with plan choices.'' The MA organization must ensure that the disclaimer is as follows:

* * * * *

(ii) Verbally conveyed during sales calls prior to the discussion of any benefits.

* * * * *

■ 23. Section 422.2274 is amended by—

■ a. In paragraph (b)(3), removing the phrase ''prior to meeting with potential enrollees'' and adding in its place ''prior to a personal marketing appointment''; and

■ b. Revising paragraphs (c)(9) and (g)(2)(ii).

The revisions read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(9) Establish and maintain a system for confirming all of the following:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all personal marketing appointments (including telephonic and walk-in).

* * * * *

(g) * * *

(2) * * *

(ii) Record and retain for 6 years all marketing and sales calls, including the audio portion of calls via web-based technology, in their entirety.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 24. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 25. Section 423.1 is amended by adding ''1860D–14C. Manufacturer Discount Program.'' in numerical order in paragraph (a)(1) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1860D–14C. Manufacturer Discount Program.

* * * * *

■ 26. Section 423.4 is amended by adding the definitions of ''Geographic area'', ''Outlier prescriber of opioids'', ''Persistent outlier prescriber of opioids'', and ''Specialty'' in alphabetical order to read as follows:

§ 423.4 Definitions

* * * * *

Geographic area means the state in which a prescriber is practicing.

* * * * *

Outlier prescriber of opioids means a prescriber who is a statistical outlier compared to their peers in a specialty and geographic area.

* * * * *

Persistent outlier prescriber of opioids means an outlier prescriber identified by CMS in three consecutive outlier prescriber notifications.

* * * * *

Specialty means the National Plan Provider Enumeration System (NPPES) taxonomy of a prescriber.

* * * * *

■ 27. Section 423.32 is amended by adding paragraph (k) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(k) *Enrollments requiring prior CMS approval—*

(1) *CMS approval.* Special Election Periods specified in § 423.32(k)(2) require CMS approval before an individual can use the SEP to make an enrollment election. CMS approval is provided for Part D enrollments either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. Part D plans may not transmit enrollment elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods.* All of the following SEPs require CMS approval prior to use:

(i) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 423.38(c)(2).

(ii) SEP for contract violation, § 423.38(c)(8).

(iii) SEP for individuals who disenroll in connection with CMS sanction, § 423.38(c)(12).

(iv) SEP for other exceptional circumstances, § 423.38(c)(36).

* * * * *

■ 28. Section 423.36 is amended by adding paragraph (g) to read as follows:

§ 423.36 Disenrollment process.

* * * * *

(g) *Disenrollments requiring prior CMS approval—*

(1) *CMS approval.* Special Election Periods specified in § 423.36(g)(2) require CMS approval before an individual can use the SEP to make a disenrollment election. CMS approval is provided for Part D disenrollments either through the use of a CMS-operated election mechanism or through the individual's receipt of a notice which explains eligibility for the SEP and election instructions. Part D plans may not transmit disenrollment elections to CMS using the specified SEPs without prior CMS approval.

(2) *Special election periods.* All of the following SEPs require CMS approval prior to use:

(i) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 423.38(c)(2).

(ii) SEP for contract violation, § 423.38(c)(8).

(iii) SEP for individuals who disenroll in connection with CMS sanction, § 423.38(c)(12).

(iv) SEP for other exceptional circumstances, § 423.38(c)(36).

* * * * *

■ 29. Section 423.38 is amended by revising paragraphs (c)(2), (c)(8), (c)(12) introductory text, and (c)(36) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

(8) This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. The individual must demonstrate to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

* * * * *

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction. This SEP requires CMS approval prior to use. The individual must receive a notice, as described in paragraph (c)(12)(i) of this section, to make an election using this SEP.

* * * * *

(36) The individual meets other exceptional circumstances as CMS may provide. This SEP requires CMS approval prior to use. The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP.

* * * * *

■ 30. Section 423.56 is amended by revising paragraphs (a) and (b)(3) to read as follows:

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount provided under section 1860D–14C of the Act, and demonstrated through—

(1) The use of generally accepted actuarial principles and in accordance with CMS guidelines; or

(2) For group health plans not receiving a retiree drug subsidy, meeting the following requirements under the simplified creditable coverage determination methodology:

(i) Provision of reasonable coverage for brand name and generic prescription drugs and biological products.

(ii) Provision of reasonable access to retail pharmacies.

(iii) Is designed to pay on average a minimum percent of participants' prescription drug expenses, with the percent value at 73 percent for 2027 and percent values for subsequent years to be updated by CMS in subregulatory guidance in a time and manner determined by CMS to reflect the actuarial value of defined standard prescription drug coverage under Part D.

* * * * *

(b) * * *

(3) Coverage under a group health plan (other than an account-based medical plan as defined at 42 CFR 423.882 (paragraph (4) of the definition of Group health plans)) including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

* * * * *

■ 31. Section 423.100 is amended by—

■ a. Revising and republishing the definition of ''Applicable beneficiary'';

■ b. Adding the definition of ''Applicable discount'' in alphabetical order;

■ c. Revising and republishing the definition of ''Applicable drug'';

■ d. Adding the definition of ''Applicable number of calendar days'' in alphabetical order;

■ e. Revising and republishing the definition of ''Coverage gap'';

■ f. Adding the definition of ''Date of dispensing'' in alphabetical order;

■ g. Revising and republishing the definition of ''Incurred costs'';
■ f. Adding definitions for ''Labeler code'', ''Manufacturer'', ''Manufacturer Discount Program'', ''Manufacturer Discount Program agreement'', ''Medicare Coverage Gap Discount Program'', ''Medicare Coverage Gap Discount Program agreement'', ''National Drug Code (NDC)'', ''Non-applicable drug'', ''Price applicability period'', ''Selected drug'', and ''Third Party Administrator (TPA)'' in alphabetical order.

The additions and revisions read as follows:

§ 423.100 Definitions

* * * * *

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3)(i) For the purposes of the Coverage Gap Discount Program—

(A) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(B) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(C) Has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(D) Has a claim that—

(*1*) Is within the coverage gap;

(*2*) Straddles the initial coverage period and the coverage gap;

(*3*) Straddles the coverage gap and the annual out-of-pocket threshold; or

(*4*) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold; and

(ii) For the purposes of the Manufacturer Discount Program, has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C) of the Act, for covered Part D drugs in the year that exceed the annual deductible specified in section 1860D–2(b)(1) of the Act.

Applicable discount, for purposes of the—

(1) Coverage Gap Discount Program, has the meaning set forth at § 423.2305; and

(2) Manufacturer Discount Program, has the meaning set forth at § 423.2712.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351).

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary; or

(iv) For the purposes of the Manufacturer Discount Program, is provided to a particular applicable beneficiary as a transition fill under § 423.120(b)(3) or as an emergency supply as may be required for an applicable beneficiary who is a long-term care resident.

(3) Not a compounded drug product (as described in § 423.120(d)) that contains an applicable drug; and

(4) For the purposes of the Manufacturer Discount Program, not a selected drug during a price applicability period with respect to such drug.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

* * * * *

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold during the years 2006 through 2024. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

* * * * *

Date of dispensing means the date of service. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

* * * * *

Incurred costs means costs incurred by a Part D enrollee—

(1) For—

(2) * * *

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(3) For 2025 and subsequent years, that are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program under subpart AA of this part.

* * * * *

Labeler code means the first segment of the National Drug Code (NDC) that identifies a particular manufacturer.

* * * * *

Manufacturer means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Coverage Gap Discount Program and the Manufacturer Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Manufacturer Discount Program means the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

Manufacturer Discount Program agreement means the agreement described at section 1860D–14C(b) of the Act.

Medicare Coverage Gap Discount Program (or Coverage Gap Discount Program) means the Medicare Coverage Gap Discount Program established under section 1860D–14A of the Act.

Medicare Coverage Gap Discount Program agreement (or Coverage Gap Discount Program agreement) means the agreement described in section 1860D–14A(b) of the Act.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product's manufacturer, product and package size and type.

* * * * *

Non-applicable drug means any Part D drug that is not an applicable drug and not a selected drug during a price applicability period with respect to such drug.

* * * * *

Price applicability period has the meaning given such term in section 1191(b)(2) of the Act and any applicable regulations and guidance.

* * * * *

Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

* * * * *

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by CMS to carry out sections 1860D–14A and 1860D–14C of the Act.

* * * * *

■ 32. Section 423.104 is amended by—

■ a. Revising paragraphs (d)(1) introductory text, (d)(2) introductory text, (d)(2)(i) introductory text, (d)(2)(iv)(A)(*4*), (d)(2)(iv)(B), and (d)(2)(iv)(D)(*3*);

■ b. Revising and republishing paragraph (d)(3);

■ c. Revising paragraphs (d)(4) introductory text, (d)(4)(iii)(C), and (d)(4)(iv)(E).

■ d. Removing paragraph (d)(4)(iv)(F);

■ e. Adding paragraph (d)(4)(v);

■ f. Revising paragraphs (d)(5)(i) introductory text, (d)(5)(i)(A)(2), and (d)(5)(iii)(F).

■ g. Adding paragraphs (d)(5)(iii)(G) and (H);

■ h. Adding paragraphs (d)(5)(iv)(A), (B), (C) and (D);

■ i. Revising paragraphs (e)(5) introductory text, (e)(5)(i), and (f)(1)(ii)(B)(*3*).

■ j. Adding paragraph (j).

The revisions and additions read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(1) *Deductible.* Subject to § 423.120(g) and (h), an annual deductible equal to—

* * * * *

(2) *Cost-sharing under prescription drug plans.*

(i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and for each year preceding 2025, up to the initial coverage limit under paragraph (d)(3) of this section, and for 2025 and each subsequent year, up to the annual out-of-pocket threshold specified in paragraph (d)(5)(iii) of this section, that is—

* * * * *

(iv) * * *

(A) * * *

(*4*) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section is the specialty-tier cost threshold for the plan year.

* * * * *

(B) * * *

(*1*) CMS modifies the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above or below the specialty tier cost threshold for the prior plan year.

(*2*) If a modification is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

* * * * *

(D) * * *

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, the maximum coinsurance percentage is determined as follows:

(*i*) For years preceding 2025, subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

(*ii*) For 2025 and each subsequent year, dividing the annual out-of-pocket (OOP) threshold, described in paragraph (d)(5)(iii) of this section, by total drug costs (represented by subtracting the plan deductible from the annual OOP threshold then dividing by the intended specialty-tier coinsurance percentage and adding the plan deductible) such that the result is 33 percent. Using the following equation solved for the deductible, each maximum allowable specialty-tier coinsurance percentage point can be inserted to determine the maximum allowable deductible corresponding to that coinsurance.

$$\frac{(\boldsymbol{OOP\ Threshold})}{\left(\frac{(\boldsymbol{OOP\ Threshold} - \boldsymbol{Deductible})}{\boldsymbol{Maximum\ allowable\ specialty\ tier\ coinsurance}} + \boldsymbol{Deductible}\right)} = \mathbf{33\%}$$

(3) *Initial coverage limit.* The initial coverage limit is equal to one of the following:

(i) *For 2006.* $2,250.

(ii) *For years 2007 through 2024.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(iii) *For year 2025 and each subsequent year,* there is no initial coverage limit.

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* For a year preceding 2025, cost-sharing in the coverage gap for applicable beneficiaries is as follows:

* * * * *

(iii) * * *

(C) For 2020 through 2024, 25 percent.

(iv) * * *

(E) For 2019 through 2024, 75 percent.

(v) *For 2025 and each subsequent year,* there is no coverage gap.

(5) * * *

(i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, for 2024 and each subsequent year, cost-sharing equal to $0, and for each year preceding 2024, cost-sharing equal to the greater of—

(A) * * *

(*2*) For subsequent years through 2023, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage

increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

* * * * *

(iii) * * *

(F) *For 2021 through 2024.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

(G) *For 2025.* $2,000.

(H) *For 2026 and each subsequent year.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

* * * * *

(iv) *Annual percentage increase in Part D drug expenditures.*

(A) General. The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(B) *Calculating the annual percentage increase.* The annual percentage increase is the product of the annual percentage trend (as defined in subparagraph (C) of this paragraph) and a multiplicative update (as defined in subparagraph (D) of this paragraph).

(C) *Annual percentage trend.* The annual percentage trend for a given year is the ratio of total Part D drug expenditures in the previous year (numerator) to the total Part D drug expenditures two years prior to the given year (denominator).

(D) *Multiplicative update.* The multiplicative update for a given year is the ratio of the product of the annual percentage trends for all prior recorded years as revised and updated with the most recently available data (numerator) to the product of annual percentage trends in prior recorded years as published in the previous year's rate announcement (denominator).

* * * * *

(e) * * *

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section for a year preceding 2025, or the annual out-of-pocket threshold specified in paragraph (d)(5)(iii) for the year for 2025 and each subsequent year, of an amount equal to at least the product of the following:

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year, for a year preceding 2025, or the annual out-of-pocket threshold described in paragraph (d)(5)(iii) for the year for 2025 and each subsequent year, exceeds the deductible described in paragraph (d)(1) of this section.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(B) * * *

(*3*) For a year preceding 2025, an increase in the initial coverage limit described in paragraph (d)(3) of this section.

* * * * *

(j) *Drugs not subject to the defined standard deductible.*

(1) If a beneficiary has not satisfied their plan deductible but has accumulated sufficient incurred costs, as defined at § 423.100, to satisfy the deductible provided under the Defined Standard benefit, then they will be both an applicable beneficiary under the Manufacturer Discount Program, as defined at § 423.100, and be deemed to have satisfied their plan deductible.

(2) If a plan offers a deductible other than the deductible provided under the Defined Standard benefit and a beneficiary accumulates sufficient incurred costs, as defined at § 423.100, to satisfy the plan deductible but has not accumulated incurred costs across all drugs at or above the deductible provided under the Defined Standard benefit, then applicable discounts, as defined at § 423.2712, under the Manufacturer Discount Program are not available for that beneficiary and the plan must cover the portion of the costs that would be covered by the applicable discount if the beneficiary were an applicable beneficiary until the beneficiary's incurred costs exceed the deductible provided under the Defined Standard benefit and they become an applicable beneficiary.

(3) If a plan offers a deductible other than the deductible provided under the Defined Standard benefit and a beneficiary accumulates sufficient incurred costs, as defined at § 423.100, to satisfy the plan deductible but has not accumulated incurred costs across all drugs at or above the deductible provided under the Defined Standard benefit, then the selected drug subsidy is not available for that beneficiary and the plan must cover the portion of the costs that would be covered by the selected drug subsidy, as described at § 423.329(e), if the beneficiary were an applicable beneficiary until the beneficiary's incurred costs exceed the deductible provided under the Defined Standard benefit and they become an applicable beneficiary.

■ 33. Section 423.128 is amended by revising paragraphs (e)(3)(ii) and (e)(7) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(e) * * *

(3) * * *

(ii) For a year preceding 2025, the initial coverage limit for the current year.

* * * * *

(7) Be provided no later than the end of the month following any month when prescription drug benefits are provided under this part, including, for a year preceding 2025, the covered Part D spending between the initial coverage limit described in *§ 423.104(d)(3)* and the out-of-pocket threshold described in *§ 423.104(d)(5)(iii).*

* * * * *

■ 34. Section 423.184 is amended by revising paragraph (e)(2) and adding paragraph (e)(3) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(e) * * *

(2) CMS will announce the removal of a measure based upon its application of paragraph (e)(1) of this section through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period or will propose and finalize the removal of the measure through rulemaking in advance of the measurement period.

(3) CMS will propose and finalize the removal of a measure for any reason not stated in paragraph (e)(1) of this section through rulemaking in advance of the measurement period.

* * * * *

§ 423.186 [Amended]

■ 35. Section 423.186 is amended by—

■ a. In paragraph (f)(1) removing the phrase ''Through the 2026 Star Ratings, this rating-specific'' and adding in its place the phrase ''This rating-specific'';

■ b. Removing paragraph (f)(3); and

■ c. Revising paragraph (h)(2) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(h) * * *

(2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release

during which Part D plan sponsors can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS.

* * * * *

■ 36. Section 423.265 is amended by adding paragraph (d)(2)(vi) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(d) * * *

(2) * * *

(vi) The assumptions regarding the selected drug subsidy under § 423.329(e) used in calculating the bid.

* * * * *

■ 37. Section 423.286 is amended by revising and republishing paragraph (b) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(b) *Base beneficiary premium percentage.*

(1) The beneficiary premium percentage for any year, except for years 2024 through 2029, is a fraction, the—

(i) Numerator of which is 25.5 percent; and

(ii) Denominator of which is as follows:

(A) 100 percent minus the percentage established in paragraph (b)(1)(ii)(B) of this section

(B) The percentage established in this paragraph equals—

(*1*) The total reinsurance payment that CMS estimates will be paid under § 423.329(c) for the coverage year divided by—

(*2*) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(2) The beneficiary premium percentage for the years 2024 through 2029 is the lesser of the beneficiary premium percentage—

(i) For the immediately preceding year increased by 6 percent; or

(ii) Calculated under the formula computed under paragraph (b)(1)

* * * * *

■ 38. Section 423.308 is amended by—

■ a. Revising the definitions for ''Allowable reinsurance costs'' and ''Gross covered prescription drug costs''; and

■ b. Adding the definition of ''Inflation Reduction Act Subsidy Amount (IRASA)''.

The revisions and addition read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan and the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined at § 423.100 of this part) paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100 of this part). The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

* * * * *

Gross covered prescription drug costs means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of actual costs (as defined at § 423.100) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) with which the Part D sponsor must coordinate benefits, including other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined at § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or, for years prior to 2025, amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or, for years prior to 2025, because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined at § 423.100 and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) All amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100).

* * * * *

Inflation Reduction Act Subsidy Amount (IRASA) means a temporary retrospective subsidy paid to Part D plan sponsors for contract year 2023 for the statutory reduction in cost-sharing and deductible for covered insulin products or for ACIP-recommended adult vaccines, as defined in § 423.100, and is equal to the difference between the following:

(1) The beneficiary cost-sharing for a covered insulin product or an ACIP-recommended adult vaccine under the plan's approved bids submitted under § 423.265 for contract year 2023; and

(2) The applicable statutory maximum cost-sharing for the covered insulin product or for the ACIP-recommended adult vaccine for contract year 2023.

* * * * *

■ 39. Section 423.315 is amended by adding paragraph (h) to read as follows:

§ 423.315 General payment provisions.

* * * * *

(h) *Selected drug subsidy.* CMS provides selected drug subsidy payments described in § 423.329(e) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under

§ 423.329(e)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(e).

■ 40. Section 423.325 is amended by revising paragraph (a)(3) to read as follows:

§ 423.325 PDE submission timeliness requirements.

(a) * * *

(3) Revised PDE records to resolve CMS rejected records at least once every 90 calendar days from receipt of a rejection until the PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record is otherwise found to have been submitted in error.

* * * * *

■ 41. Section 423.329 is amended by revising paragraph (c)(1) and adding paragraph (e) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(c) *Reinsurance payment amount—*

(1) *General rule—*

(i) *General rule for years preceding 2025.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true-out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(ii) *General rule for 2026 and subsequent years.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 20 percent for applicable drugs or 40 percent for drugs that are not applicable drugs of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true-out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

* * * * *

(e) *Selected drug subsidy amount—*

(1) *General rule.* The selected drug subsidy amount is equal to 10 percent of the negotiated price to a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a selected drug during a price applicability period.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the selected drug subsidy amount assumptions submitted with plan bids under § 423.265(d)(2)(vi) of this part and negotiated and approved under § 423.272 of this part, or by an alternative method that CMS determines.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred selected drug subsidy amounts as provided in § 423.343(e).

■ 42. Section 423.336 is amended by revising paragraph (c) to read as follows:

§ 423.336 Risk-sharing arrangements.

* * * * *

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS does not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) Submission of cost data. Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) Lump sum and adjusted monthly payments. CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

* * * * *

■ 43. Section 423.343 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 423.343 Retroactive adjustments and reconciliations.

* * * * *

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section.

(e) *Selected drug subsidy.* CMS makes final payment for selected drug subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim selected drug subsidy payments and total selected drug subsidy costs eligible for subsidy under § 423.329(e) submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the reminder of the coverage year if the interim selected drug subsidy payments exceed the amount payable under § 423.329(e) of if the Part D sponsor does not provide the data in paragraph (e)(1) of this section.

* * * * *

■ 44. Section 423.346 is amended by revising paragraph (a) introductory text to read as follows:

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination, including the following: a determination of the final amount of direct subsidy described at § 423.329(a)(1), final reinsurance payments described at § 423.329(c), final amount of the low income subsidy described at § 423.329(d), final risk corridor payments as described at § 423.336, reconciled Coverage Gap Discount Program payment described at § 423.2320(b), reconciled Inflation Reduction Act Subsidy Amount (IRASA) payment for contract year 2023 described at § 423.308, reconciled Manufacturer Discount Program payment described at § 423.2744(c), and

reconciled selected drug subsidy payment described at § 423.343(e)—

* * * * *

■ 45. Section 423.350 is amended by—

■ a. Adding paragraphs (a)(1)(vi) through (viii); and

■ b. Revising paragraphs (a)(2) and (b)(1).

The additions and revisions read as follows:

§ 423.350 Payment appeals.

(a) * * *

(1) * * *

(vi) The reconciled Inflation Reduction Act Subsidy Amount (IRASA) payment for contract year 2023 described at § 423.308.

(vii) The reconciled Manufacturer Discount Program payment under § 423.2744(c).

(viii) The reconciled selected drug subsidy payment under § 423.343(e).

(2) Payment information not subject to appeal. Payment information submitted to CMS under § 423.322 and reconciled or used in the payment calculations for the reconciled IRASA payment for contract year 2023 described at § 423.308 or under §§ 423.336, 423.343, 423.2320(b), or 423.2744(c) is final and may not be appealed, nor may the appeals process be used to submit new information after the submission of information necessary for CMS to determine retroactive adjustments and reconciliations, including the calculation of risk corridor costs.

(b) * * *

(1) *Time for filing a request.* The request for reconsideration must be filed within 15 calendar days from the date CMS issues the payment reconciliation report for the payment determination that is being appealed under this section by the Part D plan sponsor.

* * * * *

■ 46. Section 423.464 is amended by revising paragraph (f)(2)(i)(C) to read as follows:

* * * * *

(f) * * *

(2) * * *

(i) * * *

(C) Exclude expenditures for covered Part D drugs made by government-funded health programs or the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage or any payments by a manufacturer under the Manufacturer Discount Program.

* * * * *

■ 47. Section 423.504 is amended by adding paragraph (f) to read as follows:

§ 423.504 General provisions.

* * * * *

(f) *Outlier prescribers of opioids.*

(1) CMS will identify and send notifications to outlier prescribers of opioids, which includes information about how the prescriber compares to other specified prescribers and resources on proper prescribing methods.

(2) At least annually, CMS will communicate information about persistent outlier prescribers of opioids to all Part D plan sponsors.

■ 48. Section 423.505 is amended by—

■ a. Revising paragraph (b)(24);

■ b. Adding paragraphs (d)(1)(vi) and (d)(2)(xiii); and

■ c. In paragraph (e)(2), removing the phrase ''under the contract, or'' and adding in its place the phrase ''under the contract, which includes the records containing information identified in paragraph (d) of this section, or ''.

The additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(24) Provide applicable discounts on applicable drugs when dispensed to applicable beneficiaries in accordance with the requirements in subpart W of part 423 for the Coverage Gap Discount Program and the requirements in subpart AA of part 423 for the Manufacturer Discount Program.

* * * * *

(d) * * *

(1) * * *

(vi) Enable CMS to review original format documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon by the Part D plan sponsor to make a coverage determination or otherwise permit a point-of-sale claim adjudication that determine a drug's coverage under the Part D benefit. In instances when a coverage determination is extended, the original coverage determination must be maintained as documentation. The documentation covered by these standards must be made available to CMS during Part D program integrity prescription drug event (PDE) record review audits. Failure to produce this documentation will result in an improper Part D audit determination and will be subject to PDE record deletion in accordance with § 423.325(a)(2).

(2) * * *

(xiii) Documentation or information from all written, electronic, and verbal communications between the pharmacist, prescriber, enrollee, or other relevant stakeholders, in addition to what is included on the pharmacy claim, that is relied upon when Part D plan sponsors make coverage determinations or otherwise permit a point-of-sale claim adjudication that determines coverage of a drug under the Part D benefit, consistent with paragraph (d)(1)(vi). This includes:

(A) Date and time the request for a coverage determination or point-of-sale claim adjudication was received and the identity of the individual who submitted the request.

(B) Name and title (as applicable) of the individual the Part D plan contacted to verify the request (for example, pharmacist, prescriber, enrollee, or enrollee representative).

(C) Information obtained, including the questions asked and responses received, and the final decision rendered.

(D) Diagnosis code for a coverage determination or point-of-sale claim adjudication used to support a medically accepted indication.

(E) Any other information that the Part D plan sponsor utilized to determine the final outcome of the coverage determination or point-of-sale claim adjudication request.

* * * * *

■ 49. Section 423.782 is amended by—

■ a. Revising paragraphs (a)(2) introductory text and (a)(2)(i)(B);

■ b. In paragraph (a)(2)(iii)(A), removing the phrase ''Index, rounded'' and adding in its place the phrase ''Index specified in paragraph (d) of this section, rounded'';

■ c. In paragraph (b)(1), removing the phrase ''Part D drugs, rounded to'' and adding in its place the phrase ''Part D drugs, rounded as specified under § 423.104(d)(5)(iv) to'';

■ d. In paragraph (b)(3), removing the phrase ''in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded'' and adding in its place the phrase ''in § 423.104(d)(5)(i)(A)(2), rounded''; and

■ d. Adding paragraph (d).

The addition reads as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(a) * * *

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA–PD plan below the out-of-pocket limit (under § 423.104), including for years preceding 2025, Part D drugs covered under the PDP or MA–PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) * * *

(B) Those individuals who have income for years prior to 2024 under 135 percent, and for 2024 and subsequent years, under 150 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at *§ 423.773(b)(2).*

* * * * *

(d) *Annual percentage increase in consumer price index (CPI).*

(1) *General.* The annual percentage increase in consumer price index (CPI) for each year is equal to the annual percentage increase in the CPI in the United States for all items per a U.S. city average and is based on data for the 12-month period ending in September of the previous year.

(2) *Calculating the annual percentage increase in CPI.* The annual percentage increase is the product of the annual percentage trend (as defined in subparagraph (d)(3) of this section) and a multiplicative update (as defined in subparagraph (d)(4) of this section).

(3) *Annual percentage trend.* The annual percentage trend for a given year is the ratio of the CPI in the previous year (numerator) to the CPI 2 years prior to the given year (denominator).

(4) *Multiplicative update.* The multiplicative update for a given year is the ratio of the product of the annual percentage trends for all prior recorded years, as revised and updated with the most recent available data (numerator) to the product of the annual percentage trends in prior recorded years as published in the previous year's rate announcement (denominator).

* * * * *

■ 50. Section 423.882 is amended by revising the definition of Gross Covered Retiree Plan-Related Prescription Drug Costs and Allowable Retiree Costs to read as follows:

§ 423.882 Definitions.

* * * * *

Allowable retiree costs means the subset of gross covered retiree plan-related prescription drug costs actually paid by the sponsor of the qualified retiree prescription drug plan or by (or on behalf of) a qualifying covered retiree under the plan and the portion of the negotiated price (as defined in section 1860D–14C(g)(6) of the Act) of an applicable drug (as defined by § 423.100 of this part) paid by manufacturers under the Manufacturer Discount Program (as defined by § 423.100 of this part).

* * * * *

Gross covered retiree plan-related prescription drug costs, or gross retiree costs, means those Part D drug costs incurred under a qualified retiree prescription drug plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

(1) The share of prices paid by the qualified retiree prescription drug plan that is received as reimbursement by the pharmacy or by an intermediary contracting organization, and reimbursement paid to indemnify a qualifying covered retiree when the reimbursement is associated with a qualifying covered retiree obtaining Part D drugs under the qualified retiree prescription drug plan.

(2) All amounts paid under the qualified retiree prescription drug plan by or on behalf of a qualified covered retiree (such as the deductible, coinsurance, cost sharing, or, for years prior to 2025, amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the qualified retiree prescription drug plan.

(3) All amounts paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100 of this part).

* * * * *

§423.884 [Amended]

■ 51. Section 423.884 is amended by—

■ a. In paragraph (c)(2)(v)(D) by removing the word ''Gender'' and adding in its place the word ''Sex.''

■ b. In paragraphs (d), (d)(1)(i), (d)(1)(ii), and (d)(5)(iii)(C) by removing the phrase ''not taking into account the value of any discount or coverage provided during the coverage gap'' and replacing it with the phrase ''for years prior to 2025, not taking into account the value of any discount or coverage provided during the coverage gap and for 2025 and subsequent years, not taking into account the value of any discount provided under the Manufacturer Discount Program.''

■ 52. Section 423.1000 is amended by revising paragraph (a)(3) to read as follows:

§ 423.1000 Basis and scope.

(a) * * *

(3)(i) CMS must impose a civil money penalty on a manufacturer that fails to provide applicable discounts for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with the terms of such manufacturer's—

(A) Coverage Gap Discount Program agreement, in accordance with section 1860D–14A(e)(2) of the Act; and

(B) Manufacturer Discount Program agreement, in accordance with section 1860D–14C(e) of the Act.

(ii) The provisions of section 1128A (other than subsections (a) and (b)) of the Act apply to a civil money penalty under paragraph (a)(3)(i) of this section.

■ 53. Section 423.1002 is amended by

■ a. Revising the definition of ''Affected party''.

The revision reads as follows:

§ 423.1002 Definitions

* * * * *

Affected party means any Part D sponsor or, for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100), or, for purposes of the Manufacturer Discount Program, any manufacturer that is an agreement holder (as defined in § 423.2704), impacted by an initial determination or, if applicable, by a subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate.

* * * * *

■ 54. Section 423.2261 is amended by adding paragraph (a)(3) to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) * * *

(3)(i) Part D sponsors offering dual eligible special needs plans with exclusively aligned enrollment subject to § 422.107(e) must submit all materials for the contract in HPMS under the Part D sponsor's contract number.

(ii) Part D sponsors and third-party marketing organizations may not submit materials for the contract under the organization's Multi-Contract Entity number as described in § 423.2262(d)(2)(i).

* * * * *

§ 423.2262 [Amended]

■ 55. Section 423.2262 is amended by removing paragraphs (a)(1)(i) and (ii) and redesignating paragraphs (a)(1)(iii) through (xviii) as (a)(1)(i) through (xvi), respectively.

■ 56. Section 423.2264 is amended by—

■ a. In paragraph (c)(1)(ii)(D), removing the phrase ''Cards, but not including Scope'' and adding in its place ''Cards and Scope''; and

■ b. Revising paragraphs (c)(2)(i), (c)(3) introductory text, and (c)(3)(i).

The revisions read as follows:

§ 423.2264 Beneficiary contact.

* * * * *

(c) * * *

(2) * * *

(i) If a marketing event directly follows an educational event, the

beneficiary must be notified that the educational event is ending and a marketing event will begin shortly and be given a sufficient opportunity to leave the educational event prior to the start of the marketing event.

* * * * *

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple) for purposes of discussing marketing topics. Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment, the Part D plan (or agent or broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies). The Scope of Appointment must be in writing for in-person personal marketing appointments.

* * * * *

■ 57. Section 423.2267 is amended by—
■ a. Revising paragraph (e)(5)(ii)(A)(2);
■ b. Removing and reserving paragraph (e)(33); and
■ c. Revising paragraphs (e)(41) introductory text and (e)(41)(ii).

The revisions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *
(5) * * *
(ii) * * *
(A) * * *

(*2*) Deductible; the initial coverage phase; coverage gap for a year preceding 2025; and catastrophic coverage.

* * * * *

(33) [Reserved]

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: ''We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov* or 1–800–MEDICARE to get information on all of your options.'' If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: ''Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov* or 1–800–MEDICARE for help with plan choices.'' The Part D sponsor must ensure that the disclaimer is as follows:

* * * * *

(ii) Verbally conveyed during sales calls prior to the discussion of any benefits.

* * * * *

■ 58. Section 423.2274 is amended by—
■ a. In paragraph (b)(3), removing the phrase ''prior to meeting with potential enrollees'' and adding in its place ''prior to a personal marketing appointment''; and
■ b. Revising paragraphs (c)(9) and (g)(2)(ii).

The revisions read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(9) Establish and maintain a system for confirming all of the following:

(i) Beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan.

(ii) Agents and brokers appropriately complete Scope of Appointment records for all personal marketing appointments (including telephonic and walk-in).

* * * * *

(g) * * *
(2) * * *

(ii) Record and retain for 6 years all marketing and sales calls, including the audio portion of calls via web-based technology, in their entirety.

■ 59. Section 423.2300 is amended by revising and republishing the section to read as follows:

§ 423.2300 Scope.

(a) *Scope.* This subpart sets forth the requirements for the Medicare coverage gap discount program based on provisions included in sections 1860D–14A and 1860D–43 of the Act, as follows:

(1) Condition for coverage of applicable drugs under Part D.

(2) The Medicare Coverage Gap Discount Program Agreement.

(3) Coverage gap discount payment processes for Part D sponsors.

(4) Provision of applicable discounts on applicable drugs for applicable beneficiaries.

(5) Manufacturer audit and dispute resolution processes.

(7) Resolution of beneficiary disputes involving coverage gap discounts.

(8) Compliance monitoring and civil money penalties.

(8) The termination of the Medicare Coverage Gap Discount Program Agreement.

(b) *Applicability.* The requirements of this subpart apply before January 1, 2025, and, with respect to applicable drugs dispensed prior to such date, continue to apply on and after January 1, 2025.

■ 60. Section 423.2305 is amended by—
■ a. Revising and republishing the introductory text;
■ b. Revising and republishing the definition of ''Applicable discount' '';
■ c. Revising and republishing the definition of ''Negotiated price''; and
■ d. Removing the definitions of ''Applicable number of calendar days''; ''Date of dispensing''; ''Labeler code''; ''Manufacturer''; ''Medicare Coverage Gap Discount Program''; ''Medicare Coverage Gap Discount Program Agreement''; ''National Drug Code''; and ''Third Party Administrator''.

The revisions read as follows:

§ 423.2305 Definitions.

As used in this subpart and for purposes of the Coverage Gap Discount Program, unless otherwise specified—

Applicable discount means, with respect to a plan year before 2019, 50 percent or, with respect to plan year 2019 through plan year 2024, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

Negotiated price for purposes of the Coverage Gap Discount Program, means the price for a covered Part D drug that—

* * * * *

§ 423.2310 [Amended]

■ 61. Section 423.2310 is amended in paragraph (a)(1) by removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program''.

■ 62. Section 423.2315 is amended by—
■ a. In paragraph (a), removing the phrase ''Program Agreement (or Discount Program Agreement)'' and adding in its place the phrase ''Program Agreement'';
■ b. In paragraphs (b)(5) and (11), removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program'';
■ c. In paragraph (c)(1), removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement'' each time it appears;
■ d. Revising paragraph (c)(2); and
■ e. In paragraph (c)(3), removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement'';

The revision reads as follows:

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

* * * * *

(c) * * *

(2) For 2012 and subsequent years prior to 2025, for a Coverage Gap Discount Program Agreement to be effective for a year, a manufacturer must enter into such Agreement not later than January 30th of the preceding year.

* * * * *

§ 423.2320 [Amended]

■ 63. Section 423.2320 is amended in paragraph (b) by removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program''.

§ 423.2330 [Amended]

■ 64. Section 423.2330 is amended in paragraphs (a)(1) and (b)(3) by removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program''.

§ 423.2335 [Amended]

■ 65. Section 423.2335 is amended by removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program'';

§ 423.2340 [Amended]

■ 66. Section 423.2340 is amended in paragraphs (a), (b), (c) introductory text, and (c)(1) by removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement'';

■ 67. Section 423.2345 is amended by—

■ a. In the section heading, removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement'';

■ b. In paragraph (a)(1)—

(i) Removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement''; and

(ii) Removing the phrase ''Discount Program'' and adding in its place the phrase ''Coverage Gap Discount Program'';

c. In paragraphs (a)(3)(i), (b)(1), (d), and (e) by removing the phrase ''Discount Program Agreement'' and adding in its place the phrase ''Coverage Gap Discount Program Agreement''; and

■ d. Adding paragraph (f).

The addition reads as follows:

§ 423.2345 Termination of Coverage Gap Discount Program Agreement.

* * * * *

(f) Subject to § 423.2300(b) of this subpart, all Coverage Gap Discount Program Agreements under this subpart are terminated as of January 1, 2025.

■ 68. Section 423.2420 is amended by adding paragraphs (b)(4)(iii) through (v) to read as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(4) * * *

(iii) Prospective Manufacturer Discount Program Payments.

(iv) Selected Drug Subsidy Program Payments.

(v) Inflation Reduction Act Subsidy Amounts.

* * * * *

■ 69. Section 423.2536 is amended by adding paragraph (m) to read as follows:

§ 423.2536 Waiver of Part D program requirements.

* * * * *

(m) *Provision of specific information.* Section 423.128(d)(1)(i)(A).

■ 70. The heading for Subpart Z is revised to read as follows:

Subpart Z—Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits

* * * * *

■ 71. Section 423.2600 is revised to read as follows:

§ 423.2600 Payment appeals.

Medicare Part D plan sponsors may appeal program integrity prescription drug event record review audit determinations.

(a) *Issues eligible for appeal.*

(1) CMS's application of Part D policy(ies).

(2) Factual or data errors.

(b) *Issues ineligible for appeal.*

(1) The Part D plan sponsor's failure to submit documentation in the timeframes specified by CMS during the audit.

(2) The program integrity prescription drug event record review audit methodology.

■ 72. Section 423.2605 is amended by—

■ a. In paragraph (a), removing the phrase ''demand letter'' and adding in its place the phrase ''close out letter''; and

■ b. Revising paragraph (e).

The revision reads as follows:

§ 423.2605 Request for reconsideration.

* * * * *

(e) *Notification of decision.* The independent reviewer decides the reconsideration within 60 calendar days after the timeframe for filing a rebuttal has expired, and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

* * * * *

■ 73. Section 423.2610 is amended by—

■ a. In paragraph (d)(2)(i), removing the phrase ''The Part D RAC'' and adding in its place the phrase ''The CMS'';

■ b. In paragraph (d)(3) removing the phrase ''nor CMS may submit'' and adding in its place the phrase ''nor CMS is permitted to submit'';

■ c. In paragraph (e), removing the phrase '' 60 days'' and adding in its place the phrase ''60 calendar days after the timeframe for filing a rebuttal has expired''; and

■ d. Revising paragraph (f).

The revision reads as follows:

§ 423.2610 Hearing official review.

* * * * *

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with § 423.2615.

* * * * *

■ 74. Section 423.2615 is amended by—

■ a. In paragraph (b)(2), removing the phrase ''nor CMS may submit'' and adding in its place the phrase ''nor CMS is permitted to submit'';

■ b. In paragraph (d), removing the phase ''45 days'' and adding in its place ''30 calendar days'';

■ c. Revising paragraph (e).

The revision reads as follows:

§ 423.2615 Review by the Administrator.

* * * * *

(e) *Administrator Review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, after reviewing the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS within 45 calendar days after the timeframe for filing a rebuttal has expired.

■ 75. Part 423 is amended by adding subpart AA to read as follows:

Sec.

423.2700 Basis and scope.
423.2704 Definitions.
423.2708 Conditions for coverage of drugs under Part D.
423.2712 Applicable discounts.
423.2716 Phase-in of applicable discount for certain manufacturers.
423.2720 Determination of phase-in eligibility.
423.2724 Effect of manufacturer acquisition on phase-in eligibility.
423.2728 Recalculation of phase-in eligibility determination.
423.2732 Use of third party administrator.

423.2736 Requirement for point-of-sale discounts.
423.2740 Negative invoice payment process for Part D sponsors.
423.2744 Prospective payments to Part D sponsors.
423.2748 Requirement to use the Health Plan Management System.
423.2752 Manufacturer Discount Program agreement.
423.2756 Manufacturer requirements.
423.2760 Audits.
423.2764 Dispute resolution.
423.2768 Civil money penalties.

Subpart AA—Medicare Part D Manufacturer Discount Program

§ 423.2700 Basis and scope.

(a) *Basis.* This subpart implements section 1860D–14C of the Act and provisions included in section 1860D–43 of the Act.

(b) *Scope.* This subpart sets forth the requirements of the Medicare Part D Manufacturer Discount Program, which requires manufacturers to pay discounts for brand-name drugs and biological products when dispensed to Part D enrollees in the initial and catastrophic coverage phases of the Part D benefit, under the terms of an agreement with CMS, in order for such drugs to be coverable under Part D.

§ 423.2704 Definitions.

As used in this subpart and for purposes of the Manufacturer Discount Program, unless otherwise specified—

Agreement holder means a manufacturer that has executed and has in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

Applicable discount has the meaning set forth at § 423.2712.

Applicable LIS percent has the meaning set forth at § 423.2712(d)(1).

Applicable small manufacturer percent has the meaning set forth at § 423.2712(d)(2).

Covered Part D drug has the meaning set forth at § 423.100.

Dispute submission deadline means the date that is 60 calendar days from the date of the invoice containing the information that is the subject of the agreement holder's dispute.

Negotiated price has the meaning set forth at § 423.100, and with respect to an applicable drug under the Manufacturer Discount Program, such negotiated price includes any dispensing fee and, if applicable, any vaccine administration fee and sales tax.

Network pharmacy has the meaning set forth at § 423.100.

Part D drug has the meaning set forth at § 423.100.

Primary manufacturer has the meaning given such term pursuant to applicable regulations and guidance for the Medicare Drug Price Negotiation Program.

Specified drug means, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified manufacturer.

Specified small manufacturer drug means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the specified small manufacturer.

Total expenditures means with respect to—

(1) Part D, the total gross covered prescription drug costs, as defined in § 423.308; and

(2) Part B, the total Medicare allowed amount (*i.e.,* total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.

§ 423.2708 Conditions for coverage of drugs under Part D.

(a) *General rule.* Except as specified in paragraph (c) of this section, in order for coverage to be available under Part D for a Part D drug of a manufacturer that is an applicable drug or a selected drug during a price applicability period—

(1) The FDA-assigned labeler code of such applicable drug or selected drug must be covered by a Manufacturer Discount Program agreement (described at § 423.2752) that is in effect;

(2) The manufacturer must participate in the Manufacturer Discount Program in accordance with paragraph (b) of this section; and

(3) The manufacturer must have entered into and have in effect a Manufacturer Discount Program agreement in accordance with paragraph (b) of this section.

(b) *Participation in the Manufacturer Discount Program.* A manufacturer is considered to participate in the Manufacturer Discount Program and to have entered into and have in effect a Manufacturer Discount Program agreement for the purposes of paragraph (a) of this section if the manufacturer does either of the following:

(1) Executes and has in effect its own Manufacturer Discount Program agreement.

(2) Participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement that is in effect.

(c) *Exception.* Paragraph (a) of this section does not apply to an applicable drug that is not covered by a Manufacturer Discount Program agreement if CMS has made a determination that the availability of the drug is essential to the health of Part D enrollees. This exception to the general rule in paragraph (a) of this section does not apply to any applicable drug or selected drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to such manufacturer.

(d) *Non-applicable drugs.* Coverage under Part D is available for non-applicable drugs (as defined at § 423.100) of a manufacturer regardless of whether the manufacturer participates in the Manufacturer Discount Program or has a Manufacturer Discount Program agreement in effect.

§ 423.2712 Applicable discounts.

(a) *Defined.* For purposes of the Manufacturer Discount Program, applicable discount means, subject to the requirements of this section, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary who has—

(1) Not incurred costs, as defined at § 423.100, for covered Part D drugs (as defined at § 423.100) in the year that are equal to or exceed the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii) for the year, 10 percent of the negotiated price of such drug; and

(2) Incurred costs, as defined in § 423.100, for covered Part D drugs (as defined at § 423.100) in the year that are equal to or exceed the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii) for the year, 20 percent of the negotiated price of such drug.

(b) *Application of supplemental benefits.* For Part D plans offering supplemental benefits (as defined in § 423.100), the value of any applicable discount under the Manufacturer Discount Program is calculated before the application of supplemental benefits.

(c) *Application of other coverage.* The applicable discount is calculated before any coverage or financial assistance under another health or prescription drug benefit plan or program that provides prescription drug coverage or financial assistance.

(d) *Application of discount phase-in for specified manufacturers and specified small manufacturers.*

(1) *Applicable LIS percent.* For an applicable drug of a specified manufacturer (as described at § 423.2716(a)) that is marketed as of

August 16, 2022 (as described in paragraph (d)(3) of this section) and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3) of the Act), the applicable discount is as follows:

(i) For the individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

(A) For 2025, 1 percent;

(B) For 2026, 2 percent;

(C) For 2027, 5 percent;

(D) For 2028, 8 percent; and

(E) For 2029 and each subsequent year, 10 percent.

(ii) For the individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

(A) For 2025, 1 percent;

(B) For 2026, 2 percent;

(C) For 2027, 5 percent;

(D) For 2028, 8 percent;

(E) For 2029, 10 percent;

(F) For 2030, 15 percent; and

(G) For 2031 and each subsequent year, 20 percent.

(2) *Applicable small manufacturer percent.* For an applicable drug of a specified small manufacturer (as described at § 423.2716(b)) that is marketed as of August 16, 2022 (as described in paragraph (d)(3) of this section) and dispensed for an applicable beneficiary, the applicable discount is as follows:

(i) For the individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

(A) For 2025, 1 percent;

(B) For 2026, 2 percent;

(C) For 2027, 5 percent;

(D) For 2028, 8 percent; and

(E) For 2029 and each subsequent year, 10 percent.

(ii) For the individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—

(A) For 2025, 1 percent;

(B) For 2026, 2 percent;

(C) For 2027, 5 percent;

(D) For 2028, 8 percent;

(E) For 2029, 10 percent;

(F) For 2030, 15 percent; and

(G) For 2031 and each subsequent year, 20 percent.

(3) An applicable drug of a specified manufacturer or a specified small manufacturer, as applicable, is considered to have been marketed as of August 16, 2022 if the applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

(e) *Straddle claims.* In the case of a claim for an applicable drug for an applicable beneficiary that straddles multiple phases of the Part D benefit for claims that do not fall entirely—

(1) Above the annual deductible specified at § 423.104(d)(1), the manufacturer provides the applicable discount on only the portion of the negotiated price that falls above the deductible; and

(2) Below or entirely above the annual out-of-pocket threshold specified at § 423.104(d)(5)(iii), the manufacturer provides the applicable discount on each portion of the negotiated price in accordance with this section based on the benefit phase into which each portion of the negotiated price falls.

(f) *Claims not subject to discount.* The following claims involving an applicable drug are not subject to discounts under the Manufacturer Discount Program:

(1) Medicare Secondary Payer claims.

(2) Medicaid Subrogation claims.

(3) Non-standard format coordination of benefits claims.

(4) Manual claims with a service provider identification qualifier of ''Other''.

(g) *Impact of applicable discount on enrollee cost sharing.*

(1) Except as specified in paragraph (g)(2) of this section, the applicable discount does not affect the application of the standard 25 percent coinsurance under § 423.104(d)(2) or the application of the copayment amount under § 423.104(d)(5).

(2) If, after the applicable discount is applied to the negotiated price of an applicable drug, the enrollee cost sharing specified under the plan would exceed such negotiated price minus the applicable discount, the enrollee cost sharing is the negotiated price minus the applicable discount.

§ 423.2716 Phase-in of applicable discount for certain manufacturers.

(a) *Specified manufacturer.* Subject to the limitation with respect to manufacturer acquisitions described at § 423.2724, a specified manufacturer is a manufacturer of an applicable drug that, in 2021, had—

(1) A Coverage Gap Discount Program agreement, as described at § 423.2315, in effect in accordance with § 423.2720(a)(1);

(2) Total expenditures for all of its specified drugs (as defined in § 423.2704) covered by a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 represented less than 1.0 percent of total expenditures for all Part D drugs in 2021; and

(3) Total expenditures for all of its specified drugs that are single source drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

(b) *Specified small manufacturer.* Subject to the limitation with respect to manufacturer acquisition described at § 423.2724, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021—

(1) Is a specified manufacturer as described in paragraph (a) of this section; and

(2) The total expenditures under Part D for any one of its specified small manufacturer drugs covered under a Coverage Gap Discount Program agreement for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

(c) *Aggregation rule.* All entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section.

§ 423.2720 Determination of phase-in eligibility.

For each manufacturer with one or more FDA-assigned labeler codes covered by a Manufacturer Discount Program agreement, CMS will determine whether the manufacturer is a specified manufacturer or a specified small manufacturer when the manufacturer executes a Manufacturer Discount Program agreement, or, in the case of a manufacturer whose FDA-assigned labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, when such labeler code(s) is first added to such agreement. In applying the aggregation rule at § 423.2716(c), CMS will attribute expenditures for a drug to a manufacturer based on the NDC(s) for the drug, as reported on PDE records. Specifically, CMS will match the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

(a) *Identification of specified manufacturers.*

(1) A manufacturer is considered to have had a Coverage Gap Discount Program agreement in 2021, as specified at § 423.2716(a)(1), if the manufacturer—

(i) Had a Coverage Gap Discount Program agreement in effect during 2021; or

(ii) Participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) was covered by another manufacturer's Coverage Gap Discount Program agreement in effect during 2021.

(2) *Part D total expenditures.* In calculating the Part D total expenditures for 2021, CMS will include the total expenditures, as defined at § 423.2704, reported on all final action, non-delete PDE records submitted as of June 30, 2022 for all Part D drugs with dates of dispensing in benefit year 2021.

(i) For purposes of calculating each manufacturer's Part D total expenditures for applicable drugs and percent share of Part D total expenditures for 2021, CMS will—

(A) Identify the relevant NDCs attributable to the manufacturer as reported on the PDE record based on the manufacturer's FDA-assigned labeler code extracted from the first 5 digits of each NDC;

(B) Calculate the Part D total expenditures for applicable drugs of the manufacturer by summing the 2021 Part D total expenditures for all relevant NDCs attributable to the manufacturer; and

(C) Divide the 2021 Part D total expenditures for all applicable drugs of the manufacturer by the 2021 Part D total expenditures for all Part D drugs, then multiply by 100 to calculate the manufacturer's percent share.

(ii) If the manufacturer's Part D total expenditures for its applicable drugs are less than 1.0 percent of the 2021 Part D total expenditures, CMS will consider the manufacturer to have satisfied the Part D total expenditure criterion for specified manufacturer phase-in eligibility, specified at § 423.2716(a)(2).

(3) *Part B total expenditures.* In calculating the Part B total expenditures for all drugs and biological products for 2021, CMS will include all Part B Carrier, durable medical equipment (DME), and Outpatient Medicare Part B Fee-for-Service claim line items with a drug- or biological product-related Healthcare Common Procedure Coding System (HCPCS) code submitted as of December 31, 2022.

(i) For purposes of calculating each manufacturer's Part B total expenditures for applicable drugs that are single source drugs and biological products and each manufacturer's percent share of Part B total expenditures for 2021, CMS will—

(A) Map all identified HCPCS codes to NDCs;

(B) Identify all mapped HCPCS codes in paragraph (A) of this paragraph that map to NDCs associated with single source drugs or biological products;

(C) Identify all mapped HCPCS codes identified in paragraph (B) of this paragraph that map only to NDCs associated with single source drugs or biological products of the same manufacturer, consistent with the aggregation rule at § 423.2716(c), based on the manufacturer's FDA-assigned labeler code(s) extracted from the first 5 digits of each NDC;

(D) Attribute 2021 Part B total expenditures for all applicable drugs that are single source drugs or biological products identified in paragraph (C) of this section to each manufacturer, consistent with the aggregation rule at § 423.2716(c), based on the manufacturer's FDA-assigned labeler code(s) extracted from the first 5 digits of each NDC; and

(E) Divide the 2021 Part B total expenditures attributed to each manufacturer in paragraph (D) of this paragraph by the 2021 Part B total expenditures for all drugs and biological products, then multiply by 100 to calculate the manufacturer's percent share.

(ii) If the manufacturer's Part B total expenditures for its applicable drugs that are single source drugs and biologicals are less than 1.0 percent of the 2021 Part B total expenditures, CMS will consider the manufacturer to have satisfied the Part B total expenditure criterion for specified manufacturer phase-in eligibility, specified at § 423.2716(a)(3).

(b) *Identification of specified small manufacturers.*

(1) For each specified manufacturer identified in paragraph (a) of this section, CMS will determine if the 2021 total expenditures under Part D for any one of the manufacturer's specified drugs covered under a Coverage Gap Discount Program agreement for 2021, and covered under Part D in 2021, are equal to or greater than 80 percent of the total expenditures for all of its specified drugs covered under Part D in 2021, as required under § 423.2716(b)(2), as follows.

(i) *Identification of specified small manufacturer drugs.*

(A) For purposes of this section, one specified small manufacturer drug includes—

(*1*) For drug products, all dosage forms and strengths of a drug with the same active moiety and the same holder of the new drug application (NDA), as described in section 505(c) of the Federal Food, Drug, and Cosmetic Act, inclusive of products that are marketed under different NDAs.

(*2*) For biological products, all dosage forms and strengths of the biological product with the same active ingredient and the same holder of the biologics license application (BLA), as described in section 351(a) of the Public Health Service Act, inclusive of products that are marketed under different BLAs.

(B) CMS will identify the holder of the NDA or BLA as reported in Drugs@FDA or the FDA Purple Book, respectively.

(C) If a drug is a fixed combination drug, as described in 21 CFR 300.50, with two or more active ingredients or active moieties, the distinct combination of active ingredients or active moieties will be considered one active ingredient or active moiety for the purpose of identifying a specified small manufacturer drug.

(D) CMS will attribute 2021 Part D total expenditures for one specified small manufacturer drug, including authorized generic drugs and repackaged and relabeled drugs, as applicable, to a specified manufacturer based on the NDC(s) for the drug, as reported on PDE records, by matching the labeler code extracted from the first 5 digits of each NDC to the manufacturer to whom the labeler code is assigned by the FDA.

(ii) *Calculation of Part D total expenditures for each drug for 2021.* CMS will calculate the Part D total expenditures for each drug, aggregated in accordance with paragraph (b)(1)(i) of this section, attributable to the manufacturer by summing the Part D total expenditures for all NDCs under each drug as reported on all final action, non-delete PDE records submitted as of June 30, 2022, with dates of dispensing in benefit year 2021.

(iii) *Calculation of each specified drug's percent share of the specified manufacturer's Part D total expenditures for applicable drugs for 2021.* CMS will divide the 2021 Part D total expenditures for each drug, aggregated in accordance with paragraph (b)(1)(i) of this section, by the 2021 Part D total expenditures for all applicable drugs of the manufacturer, as determined under paragraph (a)(2) of this section, then multiply by 100 to determine the percent share.

(iv) If the 2021 Part D total expenditures for one specified drug of the manufacturer are equal to or greater than 80 percent of the manufacturer's 2021 Part D total expenditures for all of its specified drugs, CMS will consider the manufacturer to have satisfied the criterion at § 423.2716(b)(2) for specified small manufacturer phase-in eligibility.

(c) *Written notice of determination.*

(1) CMS will issue a phase-in eligibility determination notice to each manufacturer that has executed and has in effect a Manufacturer Discount Program agreement when such determination is made, delivered by electronic mail, to the primary point of contact as identified by the manufacturer.

(2) In the case of a manufacturer that participates in the Manufacturer Discount Program by means of an arrangement whereby its labeler code(s) is covered by another manufacturer's Manufacturer Discount Program agreement, CMS will issue a phase-in eligibility determination notice to the agreement holder.

§ 423.2724 Effect of manufacturer acquisition on phase-in eligibility.

For purposes of the Manufacturer Discount Program, when a manufacturer acquires another manufacturer after 2021 (that is, the acquired manufacturer becomes part of such acquiring manufacturer under the aggregation rule at § 423.2716(c)), the acquired manufacturer assumes the phase-in status of the acquiring manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

§ 423.2728 Recalculation of phase-in eligibility determination.

(a) *Right to request a recalculation.* A manufacturer that has received a phase-in eligibility determination notice, as described at § 423.2720(c), may request a recalculation of such determination in accordance with the requirements of this section.

(b) *Timeframe and method of filing.* A manufacturer that seeks a recalculation of its phase-in eligibility determination must file the request, in the manner specified by CMS, no later than 30 calendar days from the date the phase-in eligibility determination notice is electronically sent to the manufacturer. In order to receive consideration, the recalculation request must clearly describe the issue(s) forming the basis of the request and include any relevant supporting information.

(c) *Disposition and notification.* After consideration of the issues raised, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer that will include CMS's decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination. The decision is final and binding, subject to the requirements of the Manufacturer Discount Program under section 1860D–14C of the Act, this subpart, and the Manufacturer Discount Program agreement.

(d) *Limitation.* The recalculation process cannot be used to request or be granted an exception to the requirements set forth in statute that determine eligibility for the specified manufacturer or specified small manufacturer phase-in.

§ 423.2732 Use of third party administrator.

(a) CMS will engage a third party administrator (TPA) to assist in the administration of the Manufacturer Discount Program, which may include and is not limited to facilitating—

(1) Manufacturer Discount Program invoicing;

(2) The receipt and distribution of funds of a manufacturer; and

(3) The dispute resolution process described in § 423.2764.

(b) Agreement holders must—

(1) Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA in order to participate in the Manufacturer Discount Program. The TPA agreement will only terminate upon the termination of the Manufacturer Discount Program agreement; and

(2) Establish and maintain electronic connectivity with the TPA for the purpose of timely transmission of data and funds.

§ 423.2736 Requirement for point-of-sale discounts.

(a) *Point-of-sale discounts.* Part D sponsors must provide applicable discounts on applicable drugs at the point of sale on behalf of the manufacturer. As part of this process, plan sponsors must determine—

(1) Whether an enrollee is an applicable beneficiary as described in § 423.100;

(2) Whether a drug is an applicable drug as described in § 423.100; and

(3) The amount of the discount, in accordance with § 423.2712.

(b) *Direct member reimbursement (DMR).* Part D sponsors must provide applicable discounts on claims for applicable drugs submitted by applicable beneficiaries as DMRs, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. While the sponsor must account for the discount in adjudicating the DMR request and the associated PDE submitted to CMS, the point-of-sale requirement does not apply.

(c) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount within the applicable number of calendar days (as defined in § 423.100) of the date of dispensing (as defined in § 423.100) of an applicable drug, consistent with § 423.520.

(d) *Prescription drug event (PDE) requirements.* Part D sponsors must report the applicable discounts made available to their enrollees under the Manufacturer Discount Program on the PDE records associated with such discounts.

(e) *Retroactive adjustments.* Part D sponsors must make retroactive adjustments to applicable discounts as necessary to reflect applicable changes, including changes to the claim, beneficiary eligibility, or benefit phase determined after the date of dispensing.

§ 423.2740 Negative invoice payment process for Part D sponsors.

(a) CMS will invoice negative amounts to Part D sponsors when a PDE(s) which had been previously invoiced is deleted or adjusted such that the reported Manufacturer Discount Program discount amount is less than originally invoiced.

(b) Part D sponsors are required to pay such negative invoice amounts in the manner specified by CMS within 38 calendar days of receipt of the invoice.

§ 423.2744 Prospective payments to Part D sponsors.

(a) *General rule.* CMS will provide monthly prospective Manufacturer Discount Program payments to Part D sponsors for sponsors to advance manufacturer discounts as specified in § 423.2736(a) and reimburse network pharmacies as specified in § 423.2736(c).

(b) *Exception.* CMS will not provide prospective Manufacturer Discount Program payments to employer group waiver plans.

(c) *Reconciliation.* CMS will reconcile prospective Manufacturer Discount Program payments in accordance with subpart G of this part.

(d) *Manufacturer bankruptcy.* In the event that an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of such bankruptcy does not pay the invoiced amounts described in § 423.2756(a), CMS will adjust the Manufacturer Discount Program reconciliation amount for affected Part D sponsors to account for the invoiced amounts owed for the contract year being reconciled. The government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to

attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

§ 423.2748 Requirement to use the Health Plan Management System.

Agreement holders are required to maintain Health Plan Management System (HPMS) access and use the HPMS to—

(a) Provide and maintain required information, as specified by CMS;

(b) Attest to the completeness and accuracy of data necessary for CMS to determine whether the manufacturer qualifies as a specified manufacturer or specified small manufacturer, as described at § 423.2716;

(c) Execute a Manufacturer Discount Program agreement and a TPA agreement; and

(d) As otherwise specified by CMS to administer the program.

§ 423.2752 Manufacturer Discount Program agreement.

Manufacturers that are agreement holders, as defined in § 423.2704, must comply with all requirements of this section.

(a) *Requirements of agreement.* The manufacturer must:

(1) Reimburse, within the required 38-day timeframe, all applicable discounts invoiced to the manufacturer, consistent with the requirements at § 423.2756(b).

(2) Provide CMS with all labeler codes covered by the agreement.

(3) Ensure that the labeler codes provided to CMS under paragraph (a)(2) of this section include, at a minimum, all labeler codes assigned by the FDA to the manufacturer, in accordance with § 423.2756(c)(3).

(4) Comply with the requirements established by CMS for purposes of administering the Manufacturer Discount Program and monitoring compliance with such program, including providing the manufacturer's Employer Identification Number (EIN) and other identifying information to CMS upon request.

(5) Comply with the requirements related to the provision and maintenance of data at § 423.2756(c).

(6) Enter into and have in effect, under the terms and conditions specified by CMS, an agreement with the TPA, as described at § 423.2732(b)(1), and comply with such agreement and all TPA instructions, processes, and requirements.

(7) Provide and attest to information in the manner and form specified by CMS as necessary for CMS to determine eligibility for and implement the specified manufacturer and specified small manufacturer phase-ins described at § 423.2716.

(8) Agree that, no less than 30 days after the date CMS determines that a primary manufacturer of a selected drug has, in accordance with paragraph (c)(1)(ii) of this section, provided notice to CMS of its decision not to enter into or continue its participation in the Medicare Drug Price Negotiation Program and to discontinue its applicable agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, none of the drugs of such primary manufacturer will be covered by the manufacturer's Manufacturer Discount Program agreement.

(9) Comply with all other requirements of the Manufacturer Discount Program.

(b) *Agreement term and renewal.*

(1) A Manufacturer Discount Program agreement described in this section is valid for an initial term of not less than 12 months and automatically renews for a period of 1 year on each subsequent January 1, except as described in paragraph (b)(3) this section, unless terminated in accordance with paragraph (c) of this section.

(2) For calendar year 2025, an agreement holder must enter into such agreement no later than March 1, 2024, and the initial 12-month term of such agreement begins on January 1, 2025 and ends on December 31, 2025.

(3) For calendar year 2026 and subsequent years, a Manufacturer Discount Program agreement will become effective on the first day of a calendar quarter as follows:

(i) An agreement holder must enter into the agreement no later than the last day of the first month of a calendar quarter in order for the agreement to be effective on the first day of the next calendar quarter.

(ii) If an agreement holder enters into the agreement after the last day of the first month of a particular calendar quarter, the agreement becomes effective on the first day of the second calendar quarter after the calendar quarter in which the manufacturer entered into the agreement.

(iii) An initial term that begins on January 1 will end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 will end on December 31 of the following calendar year.

(c) *Termination of Manufacturer Discount Program agreement.*

(1) *Termination by CMS.*

(i) CMS may terminate a Manufacturer Discount Program agreement for a knowing and willful violation of the requirements of such agreement or other good cause shown in relation to a manufacturer's participation in the Manufacturer Discount Program, including good cause as set forth in paragraph (c)(1)(ii) of this section.

(ii) CMS may terminate a Manufacturer Discount Program agreement for good cause, in the case of a primary manufacturer under the Medicare Drug Price Negotiation Program, upon submission of a request from such manufacturer to terminate its applicable agreements under the Manufacturer Discount Program in connection with a notice of the primary manufacturer's decision that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program. If CMS determines such a notice complies with all requirements set forth in applicable regulations and guidance for the Medicare Drug Price Negotiation Program, the primary manufacturer's request will constitute good cause under paragraph (c)(1) of this section to terminate the primary manufacturer's applicable agreements under the Manufacturer Discount Program. The primary manufacturer's applicable agreements include any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, as well as any arrangement under § 423.2708(b)(2) in which FDA-assigned labeler codes of the primary manufacturer are covered under the Manufacturer Discount Program agreement of another manufacturer. If applicable, CMS will effectuate termination of coverage of such FDA-assigned labeler codes of the primary manufacturer that are covered under the Manufacturer Discount Program agreement of another manufacturer in accordance with paragraph (c)(1)(v)(A)(*1*) of this section.

(iii) Any termination by CMS must not be effective earlier than 30 days from the date of the notice to the manufacturer of such termination. If a hearing is timely requested by the manufacturer in accordance with paragraph (c)(1)(iv) of this section, such termination must not be effective prior to resolution of timely appeal requests received in accordance with the requirements of this section.

(iv) CMS will provide, upon written request, a manufacturer a hearing concerning a termination by CMS as follows:

(A) This hearing will take place prior to the effective date of the termination with sufficient time for the termination to be repealed prior to the effective date if CMS determines repeal would be appropriate. If a manufacturer or CMS receives an unfavorable decision from the hearing officer, the manufacturer or CMS may request review by the CMS

Administrator within 30 calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding.

(B) A timely request for a hearing before a hearing officer or review by the CMS Administrator will stay termination until the parties have exhausted their appeal rights under the Manufacturer Discount Program, which means either the timeframes to pursue a hearing before a hearing officer or review by the CMS Administrator have passed or a final decision by the Administrator has been issued and there is no remaining opportunity to request further administrative review.

(C) In the case of a termination by CMS under paragraph (c)(1)(ii) with respect to a primary manufacturer under the Medicare Drug Price Negotiation Program, the hearing will be held solely on the papers. The only question to be decided in such hearing is whether the primary manufacturer has asked to rescind its request to terminate under paragraph (c)(1)(ii) prior to the effective date of the termination. If so, CMS will automatically grant such request from the primary manufacturer to rescind its request to terminate under paragraph (c)(1)(ii).

(v) In addition to the termination under paragraph (c)(1)(ii) of this section of any Manufacturer Discount Program agreement for which the primary manufacturer is the agreement holder, CMS will effectuate the removal of labeler code(s) that are covered under the Manufacturer Discount Program agreement of another manufacturer and termination of coverage of any specific NDC(s) of applicable drugs and selected drugs of a primary manufacturer that are covered under the Manufacturer Discount Program agreement of another manufacturer as follows:

(A) If a primary manufacturer provides notice to CMS that it is unwilling to participate in, or continue its participation in, the Medicare Drug Price Negotiation Program, consistent with paragraph (c)(1)(ii) of this section, no earlier than 30 days from the date CMS sends the notice of termination to the manufacturer in accordance with paragraph (c)(1)(iii) of this section, CMS will effectuate—

(1) The removal of the FDA-assigned labeler code(s) of the primary manufacturer from any Manufacturer Discount Program agreement of another manufacturer whereby such labeler codes of the primary manufacturer are covered in accordance with § 423.2708(b)(2); and

(2) The termination of coverage under any Manufacturer Discount Program agreement specific to NDCs of applicable drugs and selected drugs for which the primary manufacturer is the holder of the new drug application or biologics license application. Such termination of coverage will apply to all applicable drug and selected drug NDCs of the primary manufacturer for which the labeler code is assigned to a manufacturer other than the primary manufacturer and for which the primary manufacturer is the new drug application or biologics license application holder for such drug.

(B) The removal of labeler code(s) in accordance with paragraph (c)(1)(v)(A)(*1*) of this section and the termination of coverage specific to NDCs in accordance with paragraph (c)(1)(v)(A)(*2*) of this section do not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs with such labeler code(s) or such NDCs that were incurred under the agreement before the effective date of removal or termination.

(2) *Termination by the manufacturer.* An agreement holder may terminate its Manufacturer Discount Program agreement for any reason. The effective date of the termination is as follows:

(i) If the agreement holder notifies CMS of its intent to terminate before January 31 of a calendar year, January 1 of the succeeding calendar year.

(ii) If the agreement holder notifies CMS of its intent to terminate on or after January 31 of a calendar year, January 1 of the second succeeding calendar year.

(3) *Post-termination obligations.* Termination of a Manufacturer Discount Program agreement under the requirements of this section does not affect the agreement holder's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with labeler code(s) covered by such agreement that were incurred under the agreement prior to the effective date of the termination.

(4) *Reinstatement.* Reinstatement in the Manufacturer Discount Program subsequent to termination is available to a manufacturer only upon payment of any and all outstanding applicable discounts and penalties incurred under any previous Manufacturer Discount Program agreement or Coverage Gap Discount Program agreement. The timing of the reinstatement must be consistent with the requirements at § 423.2752(b).

(d) *Automatic assignment upon change of ownership.* In the event of a change in ownership of a manufacturer that is an agreement holder, the Manufacturer Discount Program agreement is automatically assigned to the new owner, and all terms and conditions of the agreement remain in effect as to the new owner unless terminated in accordance with requirements at § 423.2752(c). The new agreement holder agrees to be bound by and to perform all the duties and responsibilities under the Manufacturer Discount Program, and assumes all obligations and liabilities of, and all claims incurred against, the prior agreement holder under the Manufacturer Discount Program agreement whether arising before or after the effective date of the change of ownership.

§ 423.2756 Manufacturer requirements.

Manufacturers that are agreement holders, as defined at § 423.2704, must comply with all requirements of this section.

(a) *Manufacturer invoicing.* CMS will—

(1) Calculate the amounts owed for applicable discounts for applicable drugs having NDCs with a labeler code covered by the agreement holder's Manufacturer Discount Program agreement;

(2) Itemize invoices at the NDC level;

(3) Invoice the agreement holder on a quarterly basis, consistent with the published invoicing calendar; and

(4) Invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

(b) *Requirement for timely payment.*

(1) Agreement holders that are invoiced in accordance with paragraph (a) are required to pay invoiced amounts within 38 calendar days of receipt of the invoice, in the manner specified by CMS, except as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) If an invoice deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

(3) Agreement holders are not permitted to withhold payment for any invoiced amount, including a disputed amount while a dispute is pending under § 423.2764, except when the basis for the dispute is that the invoiced amount does not correspond to NDCs of labeler codes covered by the agreement holder's Manufacturer Discount Program agreement. If payment is withheld in such an instance, the agreement holder must notify the TPA within 38 calendar days of the manufacturer's receipt of the applicable invoice that payment is being withheld for this reason.

(c) *Reporting requirements.*

(1) *General.* Agreement holders are required to collect, have available, and maintain appropriate data related to the labeler codes covered by their Manufacturer Discount Program agreement, and maintain such data for a period of not less than 10 years from the date of payment of the invoice.

(2) *Manufacturer ownership.* Agreement holders must—

(i) Provide and attest to ownership and other data, in the form and manner specified by CMS, as necessary for CMS to determine eligibility for and implement the discount phase-ins described at § 423.2716;

(ii) Notify CMS of a change in their ownership no later than 30 calendar days after the agreement holder executes a legal obligation for such an arrangement and no later than 45 calendar days prior to such change in ownership taking effect; and

(iii) If the agreement holder covers the FDA-assigned labeler code(s) of another manufacturer by its Manufacturer Discount Program agreement in accordance with § 423.2708(b)(2), comply with the requirements of paragraphs (c)(2)(i) and (c)(2)(ii) of this section with respect to such other manufacturer.

(3) *Labeler codes.*

(i) An agreement holder is required to cover by its agreement all labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs.

(ii) Consistent with § 423.2708(b)(2), an agreement holder may cover by its Manufacturer Discount Program agreement applicable drugs or selected drugs with labeler code(s) assigned by the FDA to another manufacturer, provided the other manufacturer has not executed and does not have in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

(iii) Agreement holders must provide to CMS:

(A) All labeler codes assigned by the FDA to the agreement holder that contain NDCs for the agreement holder's applicable drugs and selected drugs, consistent with paragraph (c)(3)(iv) of this section.

(B) All labeler codes assigned by the FDA to another manufacturer that the agreement holder covers by its Manufacturer Discount Program agreement and for which the agreement holder agrees to pay discounts.

(iv) Agreement holders must provide labeler code(s) newly assigned by the FDA to the agreement holder to CMS no later than 3 business days after receiving written notification of the labeler code(s) from the FDA, and in advance of providing any NDCs associated with such newly assigned labeler codes to electronic database vendors.

(v) Agreement holders must maintain the list of labeler codes covered by their Manufacturer Discount Program agreement, in the manner specified by CMS. Failure to update labeler codes covered by a Manufacturer Discount Program agreement in accordance with the requirements in this section and applicable CMS guidance does not change an agreement holder's obligation to pay invoiced amounts for applicable drugs.

(4) *FDA and related records.*

(i) Agreement holders must:

(A) Ensure that all of their FDA-assigned labeler codes that contain NDCs for any of their applicable drugs or selected drugs are properly listed on the FDA NDC Directory;

(B) Electronically list all NDCs of their applicable drugs or selected drugs with the FDA in advance of commercial distribution of the product(s);

(C) Maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory; and

(D) Maintain up-to-date listings with electronic database vendors to whom they provide their NDCs for pharmacy claims processing.

(ii) If such agreement holder's Manufacturer Discount Program agreement covers labeler code(s) that are assigned by the FDA to another manufacturer that participates in the Manufacturer Discount Program in accordance with § 423.2708(b)(2), the agreement holder must ensure that the requirements of this section are met with respect to such labeler codes.

(d) Agreement holders are permitted to transfer labeler code(s) from one Manufacturer Discount Program agreement to another provided that the transfer is consistent with the requirements of this subpart and the Manufacturer Discount Program agreement and is approved by CMS.

§ 423.2760 Audits.

(a) *Manufacturer audits of TPA data.*

(1) An agreement holder may conduct periodic audits, no more often than annually, of the TPA data and information used to determine discounts for applicable drugs covered by the agreement holder's Manufacturer Discount Program agreement, directly or through third parties.

(2) The agreement holder must provide the TPA with 60 days' notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The audit is limited as follows:

(i) The data provided to the agreement holder conducting the audit is limited to a statistically significant random sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with labeler codes covered by the agreement holder's Manufacturer Discount Program agreement.

(ii) Manufacturers are not permitted to audit CMS records or the records of Part D sponsors beyond the data provided to the TPA, which includes claim-level information.

(iii) Audits must occur on site at a location specified by the TPA and, with the exception of work papers, such data cannot be removed from the audit site.

(iv) The auditor for the agreement holder may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *CMS audits of manufacturers.*

(1) An agreement holder is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS must provide the agreement holder with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to labeler codes covered by the agreement holder's Manufacturer Discount Program agreement and related NDC last lot expiration dates, utilization, and pricing information relied on by the agreement holder to dispute quarterly invoices, and any other data CMS determines necessary to evaluate compliance with the requirements of the Manufacturer Discount Program.

§ 423.2764 Dispute resolution.

(a) *Initial disputes.* Agreement holders may dispute applicable discounts invoiced to such agreement holder under § 423.2756(a).

(1) *Timeframe and method of filing.* Initial disputes must be filed, in the manner specified by CMS, no later than the dispute submission deadline, as defined at § 423.2704. The agreement holder must explain why it believes the invoiced discount amount is in error and must provide supporting evidence that is material, specific, and related to the dispute.

(2) *Timeframe for making a determination.* CMS will issue a written

determination on an initial dispute no later than 60 calendar days from the dispute submission deadline.

(b) *Independent review.* An agreement holder that receives an unfavorable determination from CMS on its initial dispute or has not received a determination within 60 calendar days from the dispute submission deadline, may request review by the independent review entity (IRE) contracted by CMS.

(1) *Timeframe and method of filing.* A request for review by the IRE must be filed, in the manner specified by CMS, no later than the earlier of the following:

(i) Thirty calendar days from the unfavorable determination on the initial dispute.

(ii) Ninety calendar days from the dispute submission deadline, if no determination was made within 60 calendar days of the dispute submission deadline.

(2) *Information considered.* In addition to the information provided by the agreement holder, the IRE considers information received from CMS, the TPA, the Part D sponsor, or other sources. The IRE may request additional information from the agreement holder for the purpose of considering the appeal. Failure to comply with this request for additional information within the timeframe specified may result in the IRE issuing a denial.

(3) *Timeframe for making a decision.* The IRE issues a written decision to the agreement holder and to CMS no later than 90 calendar days from receipt of the request.

(4) *Notice requirements.* The IRE decision must include all of the following:

(i) A clear statement indicating whether the decision is favorable or unfavorable to the agreement holder.

(ii) An explanation of the rationale for the IRE's decision.

(iii) Instructions on how to request a review by the CMS Administrator.

(5) Effect of IRE decision. A decision by the IRE is binding on all parties unless the agreement holder or CMS files a valid request for review by the CMS Administrator under the process described in paragraph (c) of this section.

(c) *Review by the CMS Administrator.*

(1) CMS or an agreement holder that receives an unfavorable decision by the IRE may request a review of a determination from the IRE by the CMS Administrator.

(2) A request for review by the CMS Administrator must be filed, in the manner specified by CMS, no later than 30 calendar days from the date of the IRE decision.

(3) The CMS Administrator issues a written decision to both parties.

(4) A decision by the CMS Administrator is final and binding.

(d) *Adjustment to invoiced amounts.* CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary) if the dispute is resolved in favor of the agreement holder.

(e) *Limitation.* The dispute resolution process described in this section must not be used to dispute a decision by CMS to terminate an agreement holder's participation in the Manufacturer Discount Program under § 423.2752(c)(1) or a decision by CMS about a manufacturer's eligibility for discount phase-ins described at § 423.2720.

§ 423.2768 Civil money penalties.

(a) *General rule.* An agreement holder that fails to provide, in accordance with the terms of its Manufacturer Discount Program agreement and the requirements of the Manufacturer Discount Program, applicable discounts for applicable drugs covered by the agreement holder's Manufacturer Discount Program agreement and dispensed to applicable beneficiaries is subject to a civil money penalty for each such failure.

(b) *Notice of non-compliance.* When an agreement holder fails to make a timely payment as required under § 423.2756(b), CMS will issue to the agreement holder a notice of non-compliance with information about the violation. The agreement holder has 5 business days from the date of the notice to respond to CMS.

(c) *Determination of the civil money penalty amounts.* CMS must impose a civil money penalty for each failure equal to the sum of:

(1) The amount an agreement holder would have paid with respect to the applicable discount; and

(2) Twenty-five percent of such amount.

(d) *Notice to impose civil money penalties.* If CMS makes a determination to impose a civil money penalty as set forth in paragraph (c) of this section, CMS will send to the agreement holder a written notice of such determination that includes all of the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The agreement holder's right to a hearing as set forth in paragraph (e) of this section.

(6) Information about where to file the request for a hearing.

(e) *Appeal procedures for civil money penalties.* An agreement holder has a right to a hearing following a decision by CMS to impose a civil money penalty according to the administrative appeal process and procedures established in subpart T of this part.

(f) *Collection.*

(1) CMS may not collect a civil money penalty until the affected party (as defined in § 423.1002) has received notice and the opportunity for a hearing under section 1128A(c)(2) of the Act.

(2) An agreement holder that has received from CMS a notice of determination to impose a civil money penalty must pay such civil money penalty in full within 60 calendar days of the date of the CMS notice of determination, except as provided in paragraph (f)(3) of this section.

(3) If the agreement holder requests a hearing to appeal in accordance with 42 CFR part 423, subpart T, the civil money penalty is due, as applicable, once the administrative process as specified in subpart T has concluded.

(4) CMS will initiate the collection of a civil money penalty owed by an agreement holder either following the expiration of 60 days from the date of the CMS notice of determination to impose a civil money penalty, or if later, the conclusion of the administrative process specified in 42 CFR part 423, subpart T, as applicable.

(g) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil money penalties under this section to the same extent that they apply to a civil money penalty or procedures under section 1128A of the Act.

(h) *Bankruptcy.* In the event an agreement holder declares bankruptcy, as described in title 11 of the United States Code, and as a result of such bankruptcy, fails to pay the total sum of the civil money penalties imposed, the government reserves the right to file a proof-of-claim and take any other action under bankruptcy law, as appropriate, to attempt to recover such unpaid amounts and any civil money penalties imposed by CMS under these regulations.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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